



REPUBLIC OF RWANDA

MINISTRY OF HEALTH

RWANDA PHARMACEUTICAL SERVICE ACCREDITATION STANDARDS AND PERFORMANCE ASSESSMENT TOOL KIT

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FOREWORD

The Ministry of Health (MOH) is pleased to publish the first edition of the Rwanda Pharmaceutical Service Accreditation Standards (PSAS). These standards, in part, help fulfill the mission of the Ministry “to provide and continually improve the health services of the Rwandan population through the provision of preventive, curative, and rehabilitative health care, thereby contributing to the reduction of poverty and enhancing the general well-being of the population.”

In 2012, Rwanda initiated a national health care accreditation system. The MOH, with support from USAID, developed and implemented hospital and primary health care standards and trained surveyors and quality improvement (QI) facilitators. With this experience, the MOH proceeded to expand the program and develop standards for pharmaceutical services.

The roles of pharmacists in Rwanda continue to evolve, with the intent to develop clinical pharmacists. Pharmacy professional bodies have also advocated for expansion of the role of community pharmacists, particularly in relation to the provision of services that contribute to disease prevention and health improvement. These new opportunities bring challenges, including the challenge of how to manage the resources necessary to succeed in today's changing environment.

The MOH, in collaboration with its stakeholders, initiated the accreditation program for pharmacies. The PSAS will assist pharmacies to incorporate the essential principles of a QI program into everyday practices. Achieving high-quality services requires leaders to recognize the value of standards and QI and to create an environment where staff are encouraged and supported to identify opportunities to improve.

The PSAS are a key element of the ongoing national QI program. The impact of the standards on the quality and safety of pharmaceutical services will be monitored. Feedback from all stakeholders is welcome to continue to improve the overall quality of the Rwandan health care system and improve outcomes of patient care.

I would like to acknowledge the contributions of institutions, and individuals who contributed to the development of these standards. Special thanks to the US Agency for International Development (USAID) through the Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program for financial support and valuable technical expertise provided throughout the whole process of developing the standards.


Dr. NGAMIJE M. Daniel
Minister of Health



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We also would like to acknowledge the contributions of the Rwanda Food and Drug Authority, Rwanda Pharmacy Council, and all pharmacists, physicians, and nurses for their valuable contributions to developing the first set of PSAS to meet the needs of Rwanda's pharmacy settings.

The standards task force members are congratulated for bringing many suggestions and ideas together to develop these standards.

We would like to especially thank Joy Atwine, a consultant in health care QI, for facilitating and leading the standards development task team and Joanne Ashton for reviewing the document.

ACRONYMS AND ABBREVIATIONS

ADE	adverse drug event
ADR	adverse drug reaction
DTC	drugs and therapeutics committee
EIDSR	Electronic Integrated Disease Surveillance and Response
FIP	International Pharmaceutical Federation
FP	family planning
GPP	Good Pharmacy Practices
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
LMIS	Logistics Management Information System
MOH	Ministry of Health
MSDS	material safety data sheet
MSH	Management Sciences for Health
MTaPS	Medicines, Technologies, and Pharmaceuticals Program
MTM	medication therapy management
N/A	not applicable
OTC	over the counter
PDSA	Plan-Do-Study-Act
PPE	personal protective equipment
PSAS	Pharmaceutical Service Accreditation Standards
PViMS	Pharmacovigilance Information Management System
QI	quality improvement
RLP	reproductive life plan
STG	standard treatment guideline
TOR	terms of reference
USAID	US Agency for International Development
WHO	World Health Organization

GLOSSARY

Administer	Direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or any other means
Adverse event	An injury related to medical management, in contrast to complications of disease; medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care
Clinical privileges	A process to ensure that the medical and surgical care in the facility is provided by practitioners who possess current qualifications (e.g., license, certification) and demonstrated competency for each category of practice
Clinical services	Collection and interpretation of patient data for the purpose of initiating, modifying, and monitoring drug therapy with associated accountability and responsibility for outcomes in a direct patient-care setting
Collaborative medication therapy management	Performance of clinical services by a pharmacist relating to the review, evaluation, and management of drug therapy for a patient who is being treated by a physician for a specific disease or associated disease states, in accordance with a written protocol with a participating physician and in accordance with the policies, procedures, and protocols of the facility
Core standards	Standards that address systems, processes, policies, and procedures that are important for patient care or providing quality services
Credentials	Evidence of competence, current and relevant licensure, education, training, and experience; other criteria may be added by a health care organization
Credentialing	Process of obtaining, verifying, and assessing qualifications of a health care practitioner to provide patient care services in or for a health care organization; the process of periodically checking staff qualifications is called “recredentialing”
Critical standards	Those standards that are required by national laws and regulations or those that, if not met, may cause death or serious harm to patients, visitors, or staff
Effectiveness	Degree to which services, interventions, or actions are provided in accordance with current best practices in order to meet goals and achieve optimal results
Efficiency	Degree to which resources are brought together to achieve desired results most cost effectively, with minimal waste, rework, and effort
Formulary	List of brand name and generic prescription drugs that are approved for prescription by the Government of Rwanda

Hazard	Any threat to safety, e.g., unsafe practices, conduct, equipment, labels, names
Health care-associated infections	Infection originating in a health care facility
High risk	An uncertain event or condition that, if it occurs, potentially results in harm or death
Identifiers	Names or labels associated with a person; the use of two patient identifiers improves the reliability of the patient identification process; examples of acceptable patient identifiers include name, assigned identification number, telephone number, date of birth, social security number, or address
Incident	Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm, which includes errors, preventable adverse events, and hazards
Leadership	In Rwandan hospitals, refers to senior leaders and department heads
Medication reconciliation	Process of comparing a patient's new medication orders with all the medications the patient had been taking prior to changing levels of care
Patient safety	Prevention of errors and adverse effects to patients associated with health care
Pharmacy	Practice of administering, preparing, compounding, preserving, or dispensing drugs, medicines, and therapeutic devices on the basis of prescriptions or other legal authority
Plan of care	A detailed method, formulated beforehand, that identifies needs, lists strategies to meet those needs, and sets goals and objectives; the format of the plan may include narratives, policies and procedures, protocols, treatment guidelines, clinical paths (or care maps), or a combination of these
Policy	Principle or rule to guide decisions and achieve rational outcomes; a policy is a statement of intent and is implemented as a procedure
Procedures	Step-by-step instructions on how to perform a technical skill; this format often involves the use of equipment, medication, or treatment
Protocol	Care management plans that set out specifically what should be done, when, and by whom in providing patient care; they are developed based on from recommendations outlined in STGs
Qualifications	Education, training, experience, competence, registration, certification, or applicable license, law, or regulation of a health care worker

PART I - RWANDA PHARMACEUTICAL SERVICE ACCREDITATION STANDARDS

INTRODUCTION

Improving the quality of health care and services within the health care system is an ongoing quest of the MOH. The commitment of the MOH to quality is evident in the mission of the Rwandan pharmaceutical sector policy:

“to provide and continually improve equitable availability of essential and affordable quality, safe, and effective health commodities and technologies through a sustainable management system and ensuring proper use by health care providers and consumers for improved health of the population.”¹

Since 2006, Rwanda has gained experience in accrediting teaching hospitals by working with the Council of Health Care Service Accreditation of Southern Africa. Through this experience, the MOH identified the need to implement a national accreditation system and create a sustainable process for implementing and measuring achievement of standards. The national accreditation system was initiated in 2012 with hospital standards and surveyor and QI facilitator training.

The commitment to expanding health care services accreditation continues and is focused on improving the quality and safety of pharmacies within health care facilities and the community. The Rwandan PSAS were developed considering *Good Pharmacy Practice: Joint FIP/WHO Guidelines on GPP Standards for Quality of Pharmacy Services and Managing Access to Medicines and Health Technologies*.²

SCOPE AND PURPOSE

This is the first set of Rwandan pharmaceutical service standards. The standards are intended for implementation within the Rwandan hospital and community pharmacies. Although the standards are based on international, evidence-based practices, these standards have been developed to meet the needs of the health care system in Rwanda, and as such, there is no intent for other accrediting organizations to use these standards.

The standards are designed to support the implementation of the pharmacy policyⁱ to meet the national objectives to:

1. Build a quality assurance system to ensure safety, effectiveness, and efficacy of health commodities and technologies from manufacturers to consumers
2. Promote the rational use of health commodities and technologies by both health care providers and consumers
3. Strengthen health product information and pharmacovigilance system

¹ Rwanda Ministry of Health. 2016. National Pharmacy Policy. Kigali, Rwanda.

² Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services https://www.who.int/medicines/services/expertcommittees/pharmprep/CLEAN-RevI-GPP-StandardsQ-PharmacyServices-QAS10-352_July2010.pdf

4. Ensure adequate availability and equitable accessibility of quality essential health commodities and technologies at an affordable cost to individuals and the community in both public and private sectors
5. Promote investment in local manufacturing of health commodities and technologies
6. Strengthen pharmaceutical sector operational capacities to enhance performance and sustainability

STANDARDS DEVELOPMENT

A Pharmaceutical Standards Development Task Force was convened that included participants from the MOH, National Pharmacy Council, Rwanda Food and Drug Authority, health facilities, associations of private pharmacies, MTaPS, and other stakeholders. The group provided initial guidance for standards development by conducting a strength, weaknesses, opportunity, and threat analysis. The group reviewed draft 0 of the standards with the standards performance assessment tool kit against the criteria of “good” standards: valid, reliable, clear, realistic, and measurable. In addition, the group identified standards that they considered were missing and critical.

STANDARDS FRAMEWORK

This document identifies five risk areas on which to focus initial quality and safety improvement efforts. These five areas were developed from an extensive international literature search on health care quality and safety. Levels of effort are identified for each standard to provide a means for evaluating progress in reducing risk and improving quality. An overview of the risk areas is provided in table 1; the highlighted standards have been identified as “critical.”

ORGANIZATION OF STANDARDS

This document covers the following information:

- The five risk areas widely recognized as the major domains toward which risk-reduction strategies should be directed.
- The standard that represents the risk-reduction strategies for that domain.
- The risk link describes the reason that this issue poses a risk to patients.
- The levels of effort that represent progressive achievement in reaching the expectations found in a standard.
 - At level 0, the desired activity is absent, or inconsistent activity related to risk reduction.
 - At level 1, policies, procedures, and plans are in place to address the risk.

- At level 2, processes and mechanisms are in place for consistent and effective risk-reduction activities.
- At level 3, data are available to confirm successful risk-reduction strategies and continued improvement.

CLASSIFICATION OF STANDARDS

Standards are classified as critical or core. The guiding definitions are as follows:

- **Critical:** Critical standards are those standards that are required by national laws and regulations that, if not met, may cause death or serious harm to patients, visitors, or staff. Critical standards are marked gray in this document.
- **Core:** Core standards address systems, processes, policies, and procedures that are important for providing patient care or quality services.

ELIGIBLE ORGANIZATIONS

Licensed pharmacies located in hospitals in the community in Rwanda are eligible for accreditation.

5 RIGHTS

The 5 rights referred to in this document are the right patient, right drug, right dose, right route, and right time³.

³ Little J, Mark S. Pharmacy Patient Bill of Rights: Practice Advancement from the Patient Perspective. *Hosp Pharm.* 2013; 48(5):351–353. doi:10.1310/hpj4805-351

Table 1. Overview of risk areas (highlighted standards are critical)

Risk area ►	1	2	3	4	5
Standard #	Leadership	Competent and capable workforce	Safe environment	Pharmacy services	Improvement of quality and safety
1	Pharmacy leadership and management	Personnel files available, complete, up to date	Regular inspection of environmental safety	Correct patient identification	Quality and patient safety program
2	Pharmacy mission, scope of services, and annual action plan	Credentials of pharmacy staff	Adequate space, equipment and supplies	Medication therapy assessments complete and timely	Client satisfaction
3	Pharmacy policy and procedure manual	Staff members are competent	Management of hazardous materials	Written plans for care	Clinical outcomes monitoring
4	Management of pharmacy health information	Sufficient staff to meet patient needs	Reduction of health care-associated infections through hand hygiene	Clinical protocols and treatment guidelines available and used	Incident reporting system
5	Financial management	Oversight of students/trainees	Proper disposal of sharps and unused pharmaceutical products	Pharmacists role in HIV management	Rational drug use
6	Efficient use of resources	Staff performance management	Management of medical gases	Pharmacists role in FP	Complaint & suggestion management process
7	Compliance with national laws and regulations	Staff education		Safe medication use	Staff satisfaction monitored
8	Commitment to patient and family rights	Staff privileges		Patients educated to participate in their treatment	
9	Patient access to medication therapy			Communication among those caring for patients	
10	Effective inventory management			Preparation of dosage	
11	Current and complete drug formulary, essential, and OTC drug list			Vaccination and cold chain management	
12	Proper functioning of DTCs			Record keeping for patient medication	
13	Procurement of medical products			Drug recall	

RISK AREA #1. LEADERSHIP PROCESS AND ACCOUNTABILITY

The most essential factor in improving quality and patient safety is leadership. Strong leadership is necessary to create and sustain an organizational culture that supports quality, safe pharmaceutical service delivery. Identifying and confirming leaders' commitment to champion a quality organization makes this the first and most essential risk area.

Standard #1. Pharmacy leadership and management
The pharmacy is managed by a professionally competent, legally qualified pharmacist with support from pharmacy technicians and other medical staff.
Risk Link Effective leadership and practice management skills are necessary for delivering pharmacy services in a manner consistent with patients' needs. Management of pharmacy services should focus on the pharmacist's responsibilities as a patient care provider and leader of pharmacy operations by developing organizational structures that support that mission.
Levels of Effort Level 0: The pharmacy leadership structure is unclear or not identified. Level 1: There is a current document that identifies accountable pharmacy staff by name, position, and responsibilities. Level 2: The pharmacy head has a job description and maintains a valid license. Level 3: The performance of the pharmacy head is evaluated, and measures have been taken to continuously improve the results of his/her efforts.

Standard #2. Pharmacy mission, scope of services, & annual action plan
The mission and scope of pharmacy services are defined, and an annual action plan is operationalized to meet the pharmacy's goals and objectives.
Risk Link Safe, high-quality care cannot be provided by an individual—it takes a team—with all staff aligned with the mission and goals. The purpose of the mission and goals is to define how the pharmacy will achieve safety and quality. Leaders need to develop an action (operational) plan to achieve the mission with specific objectives. Leaders need to review progress toward meeting these objectives on a regular basis and adjust the plan as needed to achieve the goals.

Levels of Effort

Level 0: The pharmacy does not have a specific mission, goals, scope of services, or annual action (operational) plan based on community pharmaceutical needs.

Level 1 The pharmacy has a written mission, goals, scope of services, and annual action (operational) plan based on community pharmacy needs.

Level 2: The mission, goals, and plans are communicated to staff and implemented.

Level 3: Progress in achieving the goals and objectives is measured and reviewed in management meetings on at least a quarterly basis.

Standard #3. Pharmacy policy and procedure manual

A policy and procedure manual are present to guide pharmacy practice (administrative and operational).

Risk Link

Well-defined policies, procedures and processes provide a basis for an organization to analyze how to get from their existing state to a target state. By outlining current requirements, operations, risks and controls, they can help identify gaps and improvement opportunities. Only then can organizations intelligently integrate the right controls into the right processes.

Levels of Effort

Level 0: A pharmacy policy and procedure manual is not in place.

Level 1: A pharmacy policy and procedure manual is in place covering administrative and operational practices.

Level 2: The pharmacy staff follow the pharmacy policies and procedures.

Level 3: Compliance with priority policies and procedures is monitored and actions taken to improve, as indicated.

Standard # 4 Management of pharmacy health information

An accurate and complete pharmacy health management information system that supports pharmacists in health care delivery is available for decision making at all levels.

Risk Link

Patients are vulnerable at transitions of care (movements of patients between health care locations, providers, or different levels of care within the same location) as their conditions and care needs change. Pharmacists play an important role in preventing adverse events and medication errors and ensuring the integrity of the medication-use system. Automated systems and software can promote safe, accurate, and efficient medication ordering and preparation, drug distribution, and clinical monitoring.

Levels of Effort

Level 0: There is not an effective pharmacy health management information system.

Level 1: Policies and procedures are in place to guide management of pharmacy health information.

Level 2: Electronic health information is used to support MTM.

Level 3: Pharmacists participate in multidisciplinary meetings that evaluate the pharmacy information system's safety, effectiveness, vulnerabilities, and opportunities for improvement.

Standard # 5 Financial management

Pharmacy managers use accurate and complete financial data to effectively manage resources to achieve strategic objectives.

Risk Link

Poor financial management leads to insufficient operating funds. The primary roles of financial managers are to plan for, acquire, and use funds to maximize the efficiency of the pharmacy and thereby the hospital. Pharmaceutical financing must ensure access to essential medicines for all segments of the population. Inadequate funding of medicines and/or wasted medicines (e.g., expired) impacts the ability to meet patient needs and reduces funds for other necessary resources.

Levels of Effort

Level 0: Policies and procedures are not in place to effectively manage finances.

Level 1: Policies and procedures are in place to guide financial management.

Level 2: Accurate pharmacy financial records are maintained.

Level 3: Pharmacy managers monitor pharmacy finances.

Standard # 6 Efficient use of pharmacy resources

Pharmacy managers and staff are actively involved in efficient use of pharmacy resources.

Risk Link

Using resources wisely is crucial, especially in resource-poor countries. When resources are wasted, there are not sufficient funds to purchase medicines, which ultimately impacts the ability to provide care. Resource management is designed to evaluate the cost and quality of pharmaceutical services. Faced with diminishing resources and escalating costs, the need to use public resources more cost-effectively has never been greater.

Levels of Effort

Level 0: Pharmacy staff are not involved in resource management.

Level 1: Pharmacy staff members have knowledge and skills to manage resources.

Level 2: Actions have been taken to improve pharmacy resource management (e.g., increased efficiency, decreased wastage).

Level 3: Actions taken to improve effective resource management are measured.

Standard # 7 Compliance with national laws and regulations

The standards and regulations of all relevant government bodies (MOH, Rwanda Food and Drug Authority, and Rwanda National Pharmacy Council) are met.

Risk Link

Patients and their families assume that health care organizations comply with national laws and regulations. When organizations ignore such laws and regulations or are not in compliance, patients and staff alike are at risk. Pharmacies need a clear structure to ensure ongoing compliance and reporting to senior leaders and relevant authorities.

Levels of Effort

Level 0: The pharmacy does not maintain copies of national pharmacy laws and regulations.

Level 1: The pharmacy maintains copies of national pharmacy laws and regulations.

<p>Level 2: Pharmacy staff are aware of pharmacy laws and regulations.</p> <p>Level 3: The pharmacy maintains documentation of compliance with requirements, including procurement, distribution, and disposal of drug products.</p>
<p>Standard #8. Commitment to pharmacy patient and family rights</p> <p>Pharmacy managers identify pharmacy patients' and families' rights, and staff respect and protect those rights in the health care process.</p>
<p>Risk Link</p> <p>The World Health Organization (WHO) recognizes that health care is significantly safer when patients exercise their rights to participate in care decisions, receive information in a language and communication method they can understand, and have an advocate present when appropriate. Patients should have the right to medications that are indicated to manage their condition and to safe medication processes that support the 5 rights.</p>
<p>Levels of Effort</p> <p>Level 0: The organization does not have a pharmacy patients' and families' rights document.</p> <p>Level 1: The organization has identified pharmacy patients' and families' rights and communicated them to staff.</p> <p>Level 2: Staff respect and protect the rights of patients and their families.</p> <p>Level 3: The pharmacy asks patients about respect for their rights and uses the information to educate/train staff and improve.</p>

<p>Standard # 9 Access to medication therapy</p> <p>Patients have sustainable access to affordable and effective pharmacy services and treatments.</p>
<p>Risk Link</p> <p>"Most leading causes of discomfort, disability, and premature death can be prevented, treated, or at least alleviated with cost-effective essential medicines . . . Mortality figures across developing regions reflect a huge burden of illness that can be substantially reduced if carefully selected, low-cost pharmaceuticals are available and appropriately used."⁴ Various factors</p>

⁴ Management Sciences for Health. Managing Access to Medicines and Health Technologies MDS-3. 2014. Management Sciences for Health, Arlington, VA.

affect access to medicines: high cost, poor quality, theft, corruption, improper storage, expiration, irrational prescribing, and incorrect use by patients.
<p>Levels of Effort</p> <p>Level 0: Barriers to access to pharmacy services and treatments have not been identified.</p> <p>Level 1: Barriers to access to pharmacy services and treatments have been identified.</p> <p>Level 2: Barriers to access are investigated and actions taken to make improvements.</p> <p>Level 3: Data is used to inform decisions to improve access to services.</p>

<p>Standard # 10. Effective inventory management</p> <p>An efficient and effective supply inventory management system is in place.</p>
<p>Risk Link</p> <p>Adequate numbers of medications and supplies are required to provide care and treatment as well as conduct testing procedures. When these supplies are not available, the patient is at risk of not receiving timely test results and treatments.</p>
<p>Levels of Effort</p> <p>Level 0: Policies and procedures are not in place to manage supplies and equipment in each department.</p> <p>Level 1: Policies and procedures to manage stocked supplies are in place in each department.</p> <p>Level 2: Staff members responsible for inventory management are trained and carry out systematic processes to manage medication inventories.</p> <p>Level 3: Data are collected to determine the effectiveness of inventory management.</p>

Standard #11. DTC⁵ (N/A to community pharmacy) DTC effectively carries out the TOR.
Risk Link The primary responsibilities of the DTC are to ensure high-quality drug therapy for hospital patients and provide liaison between the medical staff and the department of pharmacy services.
Levels of Effort Level 0: A DTC has not been formed or does not have TOR. Level 1: A DTC committee has been formed with TOR. Level 2: The DTC is carrying out its TOR. Level 3: The DTC performance and impact are evaluated.

Standard # 12 Current and complete drug formulary, essential drug list and OTC drugs (z/A to community pharmacy) A well-controlled formulary and lists of essential and OTC drugs are maintained and updated annually by the DTC.
Risk Link DTC committees play a vital role in patient care decisions. One of the committee's goals is to promote the rational, appropriate, and safe use of drugs while fostering cost-effective therapy. The effective implementation of a formulary system can improve the use of health care resources for pharmacies and facilities and can improve patient outcomes.
Levels of Effort Level 0: Written criteria are not developed for drug product selection that addresses the needs of the populations served and requests for specialty medications Level 1: Written criteria are developed and maintained for drug product selection that addresses the needs of the populations served and requests for specialty medications.

⁵ Holloway K, Green T. Drugs and Therapeutic Committee: A Practical Guide. 2003. World Health Organization, Geneva, Switzerland in collaboration with Management Sciences for Health, Arlington, Va.

Level 2: A formulary and lists of essential and OTC drugs are present and readily available to meet the needs of all health care professionals.

Level 3: The impact of and compliance with the formulary and lists of essential and OTC drugs are reviewed in a timely fashion (e.g., through drug-utilization reviews).

Standard # 13 Procurement of pharmaceutical products (N/A to community pharmacy)

Pharmacies implement a value-based procurement system of pharmaceutical products by balancing costs and quality to achieve holistic value in procurement decisions.

Risk Link

As facilities strengthen their procurement systems, financial sustainability is a crucial issue in the context of limited resources. Procurement is one of the areas where major cost reductions can be achieved. Pharmaceutical product spending makes up a considerable part of any health care budget.

Pharmaceutical should aim to ensure that pharmaceutical products are available in enough quantities and affordable for the health system. Product quality is crucial; if quality is compromised, the implications can be serious as this may result in payment for expensive consequences.

Levels of Effort

Level 0: There are no written procurement operational policies and procedures that are in line with Rwanda procurement law to ensure a fair, transparent system.

Level 1: There are written procurement operational policy and procedures that are in line with Rwanda procurement law to ensure a fair, transparent system.

Level 2: The pharmacy management and procurement officer ensures compliance with procurement policies and procedures, including pharmaceutical quality, adheres to the specification in the contract.

Level 3: There is an effective monitoring mechanism to ensure that policies and procedures on procuring quality, safe pharmaceutical products, availability, and affordable pharmaceutical products are complied with.

RISK AREA #2. COMPETENT AND CAPABLE WORKFORCE

Patients assume that the health care professionals providing their care and treatment are competent and capable. It is essential that all pharmacy staff have appropriate and valid credentials and are competent to assist patients with medication management. A primary activity for a competent and capable workforce is appropriate orientation and continuing professional development. These include a general orientation to the organization, such as information on infection control, hazardous materials management, and others. In addition, staff must be oriented to specific department requirements. It is also critical that staff know how to communicate essential patient information from one person to another and from one care unit to another.

Standard #1. Personnel files available, complete and up to date
All pharmacy staff have a personnel file that is complete and up to date according to the policy and procedure.
Risk Link Patients are at risk when health care professionals provide services for which they are not qualified. Thus, job descriptions improve safety by clearly identifying what activities and services the professional is qualified to provide. Job descriptions and job assignments are based on evidence of competence, such as completion of health profession training programs, in-service education, and other work experience.
Levels of Effort Level 0: A policy that outlines the content that is to be included in the personnel file is not written. Level 1: Policies describe the content that is to be included in the personnel file and job descriptions. Level 2: Personnel files are filed in a standardized order and contain all required elements as described in the policy. Level 3: A process is in place to keep personnel files up to date.

Standard #2. Credentials of pharmacy staff
There is a process to gather, verify, evaluate, and authorize pharmacy staff to provide services that are appropriate to their licensure, education, training, and competence.
<p>Risk Link</p> <p>A priority of the Rwandan MOH is to ensure that pharmacy staff possess the knowledge, skills, attitudes, and behaviors necessary to deliver comprehensive medication management in a team-based environment.</p>
<p>Levels of Effort</p> <p>Level 0: There is no process to gather and verify pharmacy staff credentials.</p> <p>Level 1: A policy and procedure describes a uniform process for gathering and verifying pharmacy staff credentials.</p> <p>Level 2: The credentials are gathered and verified according to the policy and procedure.</p> <p>Level 3: Evidence shows that the credentialing process is effective.</p>

Standard #3. Staff orientation and training
All pharmacy personnel possess the education and training to fulfill their job responsibilities.
<p>Risk Link:</p> <p>Professional degree programs cannot provide all the knowledge, skills, and attitudes needed by pharmacists and technicians to practice in a complex and evolving health care system. Ongoing training and education are critical to the success of any safe pharmacy program.</p>
<p>Levels of Effort</p> <p>Level 0: A training plan has not been developed that ensures that staff knowledge and skills are consistent with current pharmacy practice.</p> <p>Level 1: A training plan is in place for orientation and on-going staff development to ensure that staff knowledge and skills are consistent with current pharmacy practice and patient needs.</p> <p>Level 2: The training plan is carried out to meet the educational needs of staff.</p> <p>Level 3: The effectiveness of staff training is monitored.</p>

<p>Standard #4. Pharmacy staff are competent</p> <p>Pharmacy staff possess the knowledge, skills, attitudes, and behaviors necessary to deliver comprehensive medication management in team-based patient care environments.</p>
<p>Risk Link:</p> <p>“Health workforce competencies are considered crucial for attaining high-quality health care.”⁶ To ensure the highest competency of the workforce, proper assessment must occur. Measuring competence is essential for determining the ability and readiness of pharmacy staff to provide quality care services. Therefore, competency measurement can be used to evaluate individuals in terms of their ability to provide services as per the prescribed policies, procedures, and protocols. Methods of validation are used to substantiate the multiple facets of any competency.</p>
<p>Levels of Effort</p> <p>Level 0: High-risk competencies for safe pharmacy practice are not established.</p> <p>Level 1: A checklist of high-risk competencies for safe pharmacy practice is established.</p> <p>Level 2: All pharmacy staff are evaluated on their ability to proficiently carry out high-risk procedures/skills.</p> <p>Level 3: The effectiveness of the competency assessment is evaluated.</p>

<p>Standard # 5 Sufficient pharmacy staff to meet patient needs</p> <p>The pharmacy employs an adequate number of competent, legally qualified pharmacists and support staff (pharmacy technicians) to meet the specific medication-use needs of the patients.</p>
<p>Risk Link</p> <p>Sufficient qualified personnel should be available to ensure the safe and timely delivery of pharmacy services.</p>
<p>Levels of Effort</p> <p>Level 0: A staffing plan has not been developed.</p>

⁶ Santrić Milicevic MM, Bjegovic-Mikanovic VM, Terzic-Supić ZJ, Vasic V. Competencies gap of management teams in primary health care. Eur J Public Health. Vol. 21, Issue 2, April 2011, pp 247–253, <https://doi.org/10.1093/eurpub/ckq010>

Level 1: A staffing plan is written that identifies the number of staff needed per shift, considering the scope of services provided and the workload.

Level 2: The work schedule provides an adequate number of staff (according to the plan) on each shift to meet departmental needs.

Level 3: Staffing plans are evaluated to determine whether adequate staffing is provided; when shortages exist, leaders set priorities and adjust to provide safe services.

Standard #6. Oversight of pharmacy students/trainees

When the organization is a training site for pharmacy students, there is adequate oversight of the students and trainees to ensure that they are known to staff, that their current competence matches any patient care responsibilities they may have, that they have the appropriate level of supervision, and that the training program is integrated into the quality and patient safety program.

Risk Link

Many pharmacies and community pharmacies are training sites for students. It is important that the current competence (level of training) of each trainee is known, and the trainees are appropriately assigned and supervised based on their competency. Trainees can introduce a new level of risk to patients unless the training program is well managed with effective oversight.

Levels of Effort

Level 0: A current policy and procedure on oversight of students/trainees are not present.

Level 1: A current policy and procedure on student oversight are available.

Level 2: The current competence (level of training) of each trainee is known, which is used to make assignments and indicate the level of required supervision.

Level 3: Monitoring is performed to determine whether the oversight of students follows the policy and procedure.

Standard #7. Pharmacy staff performance management

Pharmacy staff performance is evaluated on a regular basis and feedback provided to the employee to improve work performance.

Risk Link

Conducting performance appraisals provides employees with feedback about their work performance based on standards expectations in the job description. When staff are not aware of their performance, they may continue a path that leads to poor patient care, service delivery, or making errors. Therefore, it is important to provide each employee with ongoing feedback on their job performance to provide an opportunity for them to make improvements.

Levels of Effort

Level 0: No policy and procedure exist that describes the performance management process.

Level 1: A policy and procedure describes the performance management process.

Level 2: The performance management process is implemented according to the policy and procedure.

Level 3: The effectiveness of the performance management process is evaluated.

Standard #8. Pharmacy staff privileges

A standardized, objective, evidence-based procedure is used to authorize pharmacy staff to provide clinical services consistent with their qualifications.

Risk Link

Determining current clinical competence and making decisions about which clinical services the pharmacy staff member will be permitted to perform, called “privileging”, is the most critical determination an organization will make to protect the safety of patients and advance the quality of its clinical services.

Levels of Effort

Level 0: There is no process to grant pharmacy privileges nor is it consistently implemented.

Level 1: A policy and procedure describes a standardized process to grant clinical privileges to pharmacists and assign job responsibilities accordingly.

Level 2: The organization uses a standardized procedure to grant privileges on initial appointment and when new skills have been acquired to each type of physician listed in the policy and procedure.

Level 3: Each privileged practitioner provides only those services that have been specifically permitted by the hospital.

RISK AREA #3. SAFE ENVIRONMENT FOR STAFF AND PATIENTS

Health care organizations are very complex places that house a significant amount of equipment, hazardous materials, and many types of patient supplies. These are a few examples of why health care organizations are high-risk places for patients, staff, and visitors. Reducing environmental risks requires leadership's commitment to safety, staff training, regular inspection, maintenance, and monitoring.

Standard #1. Regular inspection of environmental safety

The pharmacy and storage areas are thoroughly and regularly inspected to identify and reduce safety risks.

Risk Link

Patient care areas, which include the pharmacy counter, counseling rooms, and offices, should ensure safe and efficient patient care. Distributive areas should be constructed, arranged, and equipped to promote safe and efficient workflow for staff and patients and to ensure medication integrity. Climate control and fire management systems are needed to provide an environment to protect staff and pharmaceutical products.

Levels of Effort

Level 0: Individual staff members are aware of environmental risks; however, there is no formal inspection or regular process.

Level 1: There is an inspection process to identify and list health care environment risks of all types within the pharmacy and related storage areas.

Level 2: The risks identified during the inspection process are prioritized according to severity and likelihood of occurrence, and a plan is developed to reduce priority risks.

Level 3: The risks identified are systematically reduced or eliminated, and the list is updated through periodic, routine reinspection.

Standard #2. Adequate space, equipment, and supplies

Adequate space, equipment, and supplies shall be available for all professional and administrative functions relating to pharmaceutical services.

Risk Link

Suitable facilities are necessary for compounding, preparing, and labeling sterile and non-sterile products, including hazardous drug products, in accordance with established procedures. The

work environment should promote orderliness and efficiency and minimize the potential for medication errors and contamination of products.
<p>Levels of Effort jj</p> <p>Level 0: The pharmacy is not located for convenient access, staff control, and security. Level 1: The pharmacy is located for convenient access, staff control, and security.</p> <p>Level 2: The facilities enable the receipt, storage, and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety.</p> <p>Level 3: A system is in place to monitor storage conditions, security of pharmaceutical products, and appropriate functional space.</p>

<p>Standard #3. Management of hazardous materials</p> <p>Processes are in place to manage special precautions, equipment, and training for preparation, handling, storage, and disposal of hazardous drug products and products used in their preparation.</p>
<p>Risk Link</p> <p>The first level of risk reduction is identifying the location of hazardous materials and the second level is proper labeling, storage, and handling of the materials. Spilled hazardous materials need to be reported, investigated, and cleared in a manner that does not expose patients and staff to undue risk. One of the most important things that pharmacists can do to prevent exposure to harmful substances is to wear the proper PPE.</p>
<p>Levels of Effort</p> <p>Level 0: Staff members know the location of hazardous materials; however, there is no list available.</p> <p>Level 1: There is an inventory of all locations, types, and volume of hazardous materials and a plan for management, including availability of MSDSs and use of PPE.</p> <p>Level 2: Based on the plan, hazardous materials are safely and properly labeled, stored, disposed, and used.</p> <p>Level 3: Spills and accidents involving hazardous materials are investigated and measures taken to prevent future incidents and/or improve the response to such incidents.</p>

<p>Standard #4. Reduction of health care-associated infections through hand hygiene</p> <p>A hand hygiene program based on accepted guidelines is effective in increasing compliance with hand hygiene guidelines.</p>
<p>Risk Link</p> <p>Transmission of infections most commonly occurs due to the lack of proper hand hygiene. Infections contribute to increased length of stay, cost, morbidity, and mortality. The adoption and consistent use of hand hygiene guidelines from WHO or another authoritative source can dramatically decrease infections.</p>
<p>Levels of Effort</p> <p>Level 0: A hand hygiene program is not in place and hand washing is by individual initiative.</p> <p>Level 1: Hand hygiene is emphasized and guided by evidence-based guidelines.</p> <p>Level 2: A consistent and effective hand hygiene program is in place with adequate equipment and supplies.</p> <p>Level 3: Infection prevention and control data and hand hygiene surveillance data are used to improve the program.</p>

<p>Standard #5. Proper disposal of sharps and expired and unused pharmaceutical products</p> <p>Sharps and expired and unused pharmaceutical products are properly disposed of by staff throughout the organization.</p>
<p>Risk Link</p> <p>Sharps and needles pose a risk for infection and injury to staff, patients, and their families. Proper disposal requires an organized, uniform process that is self-sustaining and not at the discretion of the worker. The regular collection and disposal of collection containers is essential to overall safety in the workplace, and proper disposal is essential for the health and safety of the community.</p>
<p>Levels of Effort</p> <p>Level 0: Disposal of sharps and expired and unused pharmaceutical products is at the discretion of the worker, with little guidance from the organization.</p> <p>Level 1: A policy and procedure provides guidance on proper disposal of sharps and expired and unused pharmaceutical products, which is made known to staff.</p>

Level 2: The disposal of sharps and expired and unused pharmaceutical products is well organized and uniform, with disposable containers collected regularly and disposed of properly.

Level 3: There are data available on injuries and accidents related to sharps and unused pharmaceutical products; these data are then used to continually improve the program.

Standard #6. Management of medical gases

Medical gases are properly installed, tested, operated, and maintained.

Risk Link

There are two types of hazards associated with medical gas equipment: general fire and explosions and mechanical issues, such as physical damage to compressed gas cylinders. Fire and explosions can be caused by incidents involving oxygen, which is the most common gas used in health care facilities, and nitrous oxide, which is used frequently as an inhalation anesthetic.

Compressed gas cylinders that sustain mechanical damage can also be a hazard. Gases inside cylinders are under high pressures, and the cylinders are often heavy. Damage to the regulators or valves attached to a cylinder can allow the escaping gas to propel the cylinder like a torpedo. The pin-index safety system and gas regulators can also suffer physical damage and cause hazards to patients if the wrong gas is delivered.

Levels of Effort

Level 0: Policies, procedures, and qualified staff are not in place for managing medical gases.

Level 1: Policies and procedures are in place for managing medical gases.

Level 2: Medical gases are safely stored and managed according to policy and procedures.

Level 3: Documentation of regular assessments of medical gas management is kept.

RISK AREA #4. PHARMACEUTICAL SERVICES

Pharmacy practice takes place at different levels in the country. A key activity is providing and managing a patient's drug therapy (i.e., pharmaceutical care, including clinical pharmacy services). In community and hospital pharmacies, activities include manufacture, compounding, procurement, and distribution of medicines. Tools used for medicine selection include formularies, STGs, and medicine utilization reviews. The MOH supports expanding pharmacists' responsibilities to include monitoring therapeutic progress, consulting with prescribers, and collaborating with other health care practitioners on behalf of patients.

Standard #1. Correct patient identification
Patients are identified correctly by using two patient identifiers before dispensing medications.
Risk Link Clinical errors are frequently not reversible; thus, the risk of such errors must be reduced. Administering a medication to the wrong patient may have no consequences or may cause morbidity or mortality. Thus, having a method to positively identify each patient is essential.
Levels of Effort Level 0: A policy and procedure that describes when and how patients are to be properly identified is not present or complete. Level 1: A policy and procedure describes when and how patients are to be properly identified, which includes two patient identifiers when providing care, treatment, or services. Level 2: The identification process is observed to be fully implemented and followed. Level 3: Monitoring data are used to continually improve the identification process.

Standard #2. Medication therapy assessments complete and timely (N/A to community pharmacy)
A medication history includes all currently and recently prescribed drugs; previous ADRs, including herbal or alternative medicines; and adherence to therapy.
Risk Link “Medication histories are important in preventing prescription errors and consequent risks to patients. Apart from preventing prescription errors, accurate medication histories are also useful in detecting drug-related pathology or changes in clinical signs that may be the result of drug therapy. A good medication history should encompass all currently and recently

<p>prescribed drugs; previous ADRs, including hypersensitivity reactions; any OTC medications, including herbal or alternative medicines; and adherence to therapy.”⁷ Pharmacists can assist in reducing errors, the risks of ADRs, and prescription costs.</p>
<p>Levels of Effort</p> <p>Level 0: A policy and procedure for conducting medication assessments and reconciliation is not in place.</p> <p>Level 1: A policy and procedure for conducting medication assessments and reconciliation is in place.</p> <p>Level 2: A current medication list and use history for prescription and nonprescription medications, herbal products, and other dietary supplements is documented for each patient.</p> <p>Level 3: A reconciliation review of open and/or closed patient records is done to assess adherence to the process and identify the potential for and any actual harm associated with unreconciled medications.</p>

<p>Standard #3. Written medication therapy plans for care</p> <p>The clinical pharmacist develops and implements, collaboratively with the patient and his/her health care providers, a plan for optimizing medication therapy.</p>
<p>Risk Link</p> <p>Patients are at risk for less-than-optimal outcomes if their care is not planned or if the planned care is provided but not written in the patient’s record to ensure communication of essential information among providers. Effective communication of patient information depends on complete and accurate record entries that are timely and available to all the patient’s care providers.</p>
<p>Levels of Effort</p> <p>Level 0: There is no or an inconsistent process for documenting the planned medication regime.</p> <p>Level 1: A policy and procedure is written to provide guidance on developing a medication therapy plan.</p>

⁷ Fitzgerald RJ. Medication errors: the importance of an accurate drug history. Br J Clin Pharmacol. 2009; 67(6):671–675. doi:10.1111/j.1365-2125.2009.03424

Level 2: Planning patient care is collaborative (with physicians, nurses, and pharmacists) with written care plans that address medication-related problems and optimizes medication therapy.

Level 3: Patients' needs are reassessed and progress toward goals monitored and documented.

Standard #4. Clinical protocols and STGs available and used (N/A to community pharmacy)

Clinical pharmacists work in collaboration with other providers to deliver comprehensive medication management that optimizes patient outcomes through use of clinical protocols and treatment guidelines.

Risk Link

Reducing variation in practice reduces risk of medication errors. Clinical practice protocols and treatment guidelines direct daily management of patient care, thereby reducing the variation among care providers.

Levels of Effort

Level 0: There are no or limited clinical protocols and treatment guidelines.

Level 1: Treatment guidelines and clinical protocols have been adopted for the most common diagnoses/conditions and procedures to guide clinical practice.

Level 2: Treatment guidelines and protocols are used to guide medication management of priority patients and procedures.

Level 3: Compliance by individual clinical pharmacists is monitored.

Standard #5. Pharmacists' role in HIV management

Pharmacists are involved with the health care team in managing HIV/AIDS.

Risk Link

Pharmacists have been recognized as essential members of the HIV patient care team, and their involvement in managing HIV-infected patients has been associated with improved outcomes. Pharmacists need to apply their traditional expertise within an interdisciplinary health care framework in multiple practice settings (inpatient and community), as well as identify and establish new roles in evolving areas of care.⁸

⁸ Schafer JJ, Gill TK, Sherman EM, McNicholl IR, Hawkins B. ASHP Guidelines on Pharmacist Involvement in HIV Care. Am J Health Syst Pharm. Vol 73, Issue 7, 1 April 2016, Pages 468–494, <https://doi.org/10.2146/ajhp150623>

<p>Levels of Effort</p> <p>Level 0: Pharmacists are not involved with the health care team in managing HIV/AIDS.</p> <p>Level 1: Pharmacists are involved with the health care team to test, counsel, and recommend treatment.</p> <p>Level 2: Pharmacists are involved with the health care team in treating complications, preventing HIV, and educating patients on their medication regime.</p> <p>Level 3: Pharmacists provide staff with HIV/AIDS in-service training, monitor adherence to treatment, and assist in providing seamless care transitions.</p>

<p>Standard #6. Pharmacists role in FP</p> <p>Pharmacists are engaged in managing women's contraceptive care.</p>
<p>Risk Link</p> <p>Pharmacists have an evolving role in managing women's contraceptive care.⁹ Women, particularly in rural settings, with low literacy rates and poor economic status may be completely or partially unaware of modern FP techniques. Pharmacists in any practice setting can screen patients for contraceptive needs and those who may benefit from optimizing their contraceptive method. By promoting FP programs, the population growth rate can be reduced, desired family size achieved, and unintended or mistimed pregnancies can be avoided. FP also helps in reducing maternal morbidity and infant and child mortality.</p>
<p>Levels of Effort</p> <p>Level 0: RLPs are not developed.</p> <p>Level 1: Pharmacists help women develop RLPs.</p> <p>Level 2: Pharmacists conduct an FP health history and educate patients about services and contraceptive products.</p> <p>Level 3: Pharmacists monitor adherence to treatment and assist in providing seamless care transitions.</p>

⁹ Riley P, Callahan S, Dalious M. July 2017. Regulation of Drug Shops and Pharmacies Relevant to Family Planning: A Scan of 32 Developing Countries. Bethesda, MD: Sustaining Health Outcomes through the Private Sector Plus Project, Abt Associates Inc.

Standard #7. Safe medication use

Pharmacists take a lead in promoting and implementing measures to ensure safe medication use.

Risk Link

Medication errors represent the most common patient safety error.¹⁰ Medication use is a complex system of processes (selection, storage, prescribing, dispensing, administration, and patient monitoring) that has many risk points. There must be a qualified individual familiar with and responsible for all parts of the medication use system. Check points are also needed to ensure that the right medication in the right dose reaches the right patient at the right time.

Levels of Effort

Level 0: Pharmacists are not actively involved in promoting/implementing safe medication use.

Level 1: Evidence-based measures for reducing medication errors are adopted (e.g., high-alert medications, look-alike/sound-alike drugs).

Level 2: Strategies to reduce the risk of errors in prescribing, dispensing, delivering, storing, administering, and monitoring medications are implemented.

Level 3: Monitoring data include medication errors and adverse events and are used to continually improve medication use.

Standard #8. Patients educated to participate in their medication treatment

Pharmacists ensure that all patients are given adequate information about the medications they receive to help them participate in their own health care decisions and encourage adherence to medication regimens.

Risk Link

Patients are at risk for readmission, poor outcomes, and complications if they and their families are not educated about home medication management. Also, the education needs to include reasons to return for emergency or routine follow-up care.

¹⁰ Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalized patients. JAMA. 1997; 277:307–11. [PubMed]

Levels of Effort

Level 0: Medication education for patients is not standardized or provided.

Level 1: Policies and procedures or protocols describe the types of education that are given to patients.

Level 2: Individualized patient education relevant to their condition is consistently provided and documented regarding medications.

Level 3: There is a process to evaluate the degree to which patients understood the education.

Standard #9. Communication among those caring for patients (N/A to community pharmacy)

Care is coordinated among providers and across systems of care as patients transition in and out of various settings.

Risk Link

Ineffective communication is the most frequently cited category of root causes of sentinel events. Patients often move between areas of diagnosis, treatment, and care on a regular basis and may encounter three shifts of staff each day—introducing a safety risk to the patient at each interval. The hand-over communication between units and between and among care teams might not include all the essential information, or information may be misunderstood. These gaps in communication can cause serious breakdowns in the continuity of care, inappropriate treatment, and potential harm to the patient. Effective communication, which is clear, timely, accurate, complete, and understood by the recipient, reduces error and results in improved patient safety.

Levels of Effort

Level 0: Patient information is not standardized and does not provide enough information to ensure continuity of care.

Level 1: A current policy and procedure are in place that describes a standardized approach to providing information between caregivers that supports patient-centered care.

Level 2: A standardized approach to hand-over communication is used between staff, change of shift, and between different patient care units in the course of a patient transfer.

Level 3: There is a process to assess the effectiveness of hand-over communications.

Standard #10. Preparation of medication dosage
Pharmacy staff correctly prepares and labels prescribed medications.
<p>Risk Link</p> <p>“Preparation of parenteral medications is associated with considerable risk that is medication errors and risk of microbiological contamination.” ¹¹</p>
<p>Levels of Effort</p> <p>Level 0: A policy and procedure are not in place to guide effective preparation of medications.</p> <p>Level 1: A policy and procedure are in place to guide effective preparation and labeling of medications.</p> <p>Level 2: Pharmacy staff effectively carry out policies and procedures.</p> <p>Level 3: Compliance with policies and procedures are monitored, and improvements made as indicated.</p>

Standard #11. Vaccination and cold chain management
Effective and efficient vaccination and cold chain management
<p>Risk Link</p> <p>A widening variety of new vaccines and immunization schedules, a diversity of service delivery strategies, an expanding target population, increased cold chain infrastructure requirements, and insufficient funding are a few of the challenges for maintaining quality vaccination and cold chain management. These challenges can lead “to stock-outs, potential administration of ineffective vaccines, avoidable wastage and inadequate cold-chain capacity, all of which have considerable coverage, performance, and cost implications. These inefficiencies not only hinder the ability to provide much-needed immunizations, they also yield a lower return in health outcomes . . .”¹² It is imperative to provide the right vaccines in the right quantities, in the right condition at the right time in the right place, and at the right supply chain cost.</p>

¹¹ van de Plas A, Smits C, Mens W, et al. Parenteral medication preparation by pharmacy technicians on the ward improves medication safety. *Eur J Hosp Pharm: Science and Practice* 2012; 19:135-136.

¹² WHO. 2014. Immunization supply chain and logistics: A neglected but essential system for national immunization programmes. World Health Organization: Geneva, Switzerland.

<p>Levels of Effort</p> <p>Level 0: Policies and procedures and qualified staff are not present to guide effective vaccination and cold chain management.</p> <p>Level 1: Policies and procedures and qualified staff are present to guide effective vaccination and cold chain management.</p> <p>Level 2: Immunizations are provided using the right vaccines in the right quantities, in the right condition at the right time in the right place, and at the right supply chain cost.</p> <p>Level 3: The program is measured, monitored, and evaluated for availability, quality, and cost and the data are used to improve services.</p>
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<p>Standard #12. Record keeping for patient medications</p> <p>The pharmacy maintains a current, complete, and accurate record for each patient.</p>
<p>Risk Link</p> <p>The lack of accurate and complete patient medication records poses a risk for medication discrepancies, such as duplicating or omitting medications.</p>
<p>Levels of Effort</p> <p>Level 0: A policy and procedure are not present or complete to provide guidance on patient medication record keeping.</p> <p>Level 1: A policy and procedure are present to provide guidance on patient medication record keeping.</p> <p>Level 2: Complete and accurate patient medication profiles and medication treatment records are maintained.</p> <p>Level 3: An audit process is used to monitor the effectiveness of patient medication record keeping.</p>
<p>Standard #13. Drug Recalls</p> <p>Drug recalls are handled properly and promptly, including alerting the public and safely removing the affected product from the market.</p>
<p>Risk Link</p> <p>A drug recall is the most effective way to protect the public from a defective or potentially harmful product. Drugs may be recalled for an assortment of reasons including safety, mislabeling, contamination, and deviations in strength or potency.</p>

Levels of Effort

Level 0: Policies and procedures do not exist for the intervention and dissemination of information on drug recalls.

Level 1: Policies and procedures exist for the intervention and dissemination of information on drug recalls.

Level 2: Recalled drugs are removed from use, and health care professionals and patients who come to fill prescriptions are informed.

Level 3: Drug recall measures are documented, and corrective actions taken if the procedure is not followed.

RISK AREA #5. IMPROVEMENT OF QUALITY AND SAFETY

The pharmacy is an important component of health care organizations, and their patients remain at risk from poor quality and unsafe practices if pharmacy staff do not learn from their good and bad experiences and take actions to continually improve. Efficient pharmaceutical care includes monitoring therapy outcomes and undertaking increased responsibility to increase patient outcomes.

Data are at the core of this learning. Pharmacy staff need to understand and value data collection and analysis in process improvement. Pharmacy staff must gain experience in setting improvement priorities, collecting data, displaying data for better analysis, and finally, planning and implementing improvement strategies. When leaders are committed to QI and value the data that form the basis of evidence-based learning, the organization's culture is focused on quality and safety. This helps create a non-punitive environment and encourages a monitoring and incident-reporting system. It embraces teamwork on all levels and includes patients as important members of their treatment teams and quality efforts. Pharmaceutical system will allow pharmacists to identify, measure, and report what they should be doing, which is fundamental to achieving improvement.

Standard #1. Quality improvement and safety
A pharmacy QI and safety team uses QI techniques to improve pharmacy services.
Risk Link Continuous improvement and constant concern over reducing risks to patients and staff are characteristic of hospitals that are committed to the welfare of their patients. To improve quality and reduce risks, hospitals must constantly evaluate (measure) their performance and use that information to identify ways to improve. This self-evaluation must be planned and ongoing and should focus on systems and processes, not solely on individual performance.
Levels of Effort Level 0: A pharmacy QI team has not been formed. Level 1: A multidisciplinary pharmacy QI team uses QI techniques to identify problems. Level 2: A pharmacy QI plan is developed and implemented. Level 3: Data are accurately collected and used to make sound decisions to improve quality and safety.

Standard #2. Client satisfaction
There is a process to monitor and improve patient satisfaction with pharmacy services.
<p>Risk Link</p> <p>Client satisfaction with pharmacy services and the staff involved in their care is important information that will help identify quality and patient safety issues. This information is useful in identifying priorities for improvement and for understanding if improvements increase patient satisfaction.</p>
<p>Levels of Effort</p> <p>Level 0: There is no systematic process for collecting patient satisfaction information.</p> <p>Level 1: There is a policy, procedure, and tool to monitor patient satisfaction.</p> <p>Level 2: Patient satisfaction is monitored, and the data analyzed according to the policy and procedure.</p> <p>Level 3: Trends in patient satisfaction are used to set priorities for improvement or for further evaluation.</p>

Standard #3. Therapeutics outcomes monitored (N/A to community pharmacy)
Pharmacists monitor therapeutic outcomes for patients with the most prevalent diagnoses and acts to improve them over time.
<p>Risk Link</p> <p>The purposes of caring for patients are to mitigate disease, eliminate or palliate symptoms, and prolong high-quality life. The risk is that, in the absence of monitoring clinical outcomes, less-than-optimal outcomes will be accepted, and patient outcomes will not be improved over time.</p>
<p>Levels of Effort</p> <p>Level 0: Leaders have not identified and/or defined priority therapeutic indicators.</p> <p>Level 1: Leaders have identified and defined priority therapeutic indicators.</p> <p>Level 2: Outcome data are compared to those of previous time periods.</p> <p>Level 3: Data is used by facility staff to make improvements in patient care.</p>

Standard #4. Incident reporting system

There is a system for reporting and analyzing incidents that is fair and non-punitive, based on a clear definition of what is to be reported.

Risk Link

The frequency, magnitude, and impact of incidents can only be known if data are collected and analyzed. Frequently, reviewing data convinces organizations that risk is indeed present and of significant magnitude and impact so that action must be taken to understand and reduce the risk. A difficult challenge is to develop a reporting process that is free of punitive overtones and/or actions.

Levels of Effort

Level 0: Incidents are not reported, verbally reported, or only rarely reported.

Level 1: There is a policy and procedure for the reporting process that clearly defines the incidents to be reported.

Level 2: Reporting includes medication errors, ADRs, and ADEs.

Level 3: Data are analyzed and used to educate staff and to improve processes to avoid similar incidents from reoccurring.

Standard #5. Rational drug use

Rational drug use promotes therapeutically sound and cost-effective use of drugs by health professionals and affordability of drugs for patients and consumers.

Risk Link

WHO estimates that more than half of all medicines are prescribed, dispensed, or sold inappropriately, and that half of all patients fail to take them correctly. The significance of irrational drug use may result in fast development of resistance if adherence is poor and, eventually, treatment failure. The consequences of irrational drug use are poor health outcomes and increased health care costs.¹³

¹³ Chaturvedi VP, Mathur AG, Anand AC. Rational drug use - As common as common sense? Med J Armed Forces India. 2012; 68(3):206–208. doi:10.1016/j.mjafi.2012.04.002

Levels of Effort

Level 0: Policies, procedures, and STGs do not exist to guide practitioners or prescribers on making decisions on appropriate treatments for specific clinical conditions.

Level 1: Policies, procedures, and STGs are available to guide practitioners or prescribers on making decisions about appropriate treatments for specific clinical conditions.

Level 2: All practitioners or prescribers comply with the developed policies, procedures, and STGs.

Level 3: The pharmacy has a system for monitoring rational use of drugs, including compliance to STGs.

Standard #6. Complaint and suggestion management process

There is a process to receive and act on complaints and suggestions from patients, families, and others.

Risk Link

A complaint is often the first indication that a process has failed and that other patients may be at risk for the same or a similar event. Thus, complaints and suggestions are received through an established process so they can be tracked, and actions taken.

Levels of Effort

Level 0: There is no organized complaint and suggestion process.

Level 1. There is a policy or procedure for receiving complaints and suggestions.

Level 2. An effective process for reviewing and resolving complaints is operational. Feedback is given to individuals regarding how the issue was resolved, when possible.

Level 3. Complaints and suggestions are categorized by type and tracked. This information is used to prioritize patient issues and implement solutions. The results of the solutions are monitored for effectiveness.

Standard #7. Staff satisfaction monitored

There is a process to monitor staff satisfaction with the care process, the environment of care, and the education and technical support available to them to support their patient care or other responsibilities

Risk Link

Knowing staff satisfaction with the care process, care environment, education, and technical support will help identify quality and patient safety issues. This information is useful in identifying priorities for improvement and for understanding if improvements already made contribute to staff satisfaction. Satisfied staff members are more likely to provide safe and caring services to patients.

Levels of Effort

Level 0: There is no procedure and/or tool for collecting staff satisfaction information.

Level 1. There is a policy, procedure, and tool to monitor staff satisfaction.

Level 2. Staff satisfaction is monitored according to the policy and procedure, and the data analyzed and reported to staff. An improvement plan is developed and implemented.

Level 3: Trends in staff satisfaction are used to set priorities for improvement or further evaluation.

PART II

Performance Assessment Toolkit

MAY 2020

SECTION I

GUIDANCE ON USING THE TOOLKIT

PURPOSE

The Rwanda PSAS Performance Assessment Tool has been developed based on the Rwandan PSAS which were developed based on Good Pharmacy Practice: Joint FIP/WHO Guidelines on GPP Standards for Quality of Pharmacy Services and Managing Access to Medicines and Health Technologies. These standards will assist pharmacists' surveyors, facility managers, and pharmacy staff to assess the quality of their services. The toolkit can be used to guide the set-up of services and to improve current services. It helps to measure progress toward meeting standards and will be used by external surveyors to accredit pharmacy services.

HOW TO USE THE TOOLKIT

The toolkit is designed to be used in conjunction with the Rwanda PSAS document, and surveyors should also refer to the Rwanda GPP 2019 document to clarify expectations for some of the standards.

WHO CONDUCTS THE ASSESSMENT?

This toolkit can be used by the QI team in the facility to conduct a self-assessment. A team leader needs to be appointed who is responsible for organizing the group, assigning tasks, and coordinating the effort. This person could be the quality focal person or some other individual with the skills to carry out the responsibilities. The best approach is to include assessment team members from all categories of staff, although a subgroup can be designated to carry out most of the work. In addition to pharmacy staff, we recommend that the group include members, such as nurses, physicians, and community members. The effort is to be supported by the central- and district-level health teams.

Part of the learning process occurs through participation. If one person tries to complete the assessment alone the process becomes an audit rather than a learning opportunity for the team. Performing the assessment together increases understanding of the services and fosters team spirit and, ultimately, ownership of the findings. When assignments of team members are being made, it is important to identify individuals who have knowledge of the specific aspect of the service that they will assess. For instance, various members could review the availability of supplies, whereas professional staff would be needed to evaluate the competence of staff in providing services. A community member may be requested to conduct interviews with patients who have used the services.

The toolkit can also be used by a supervisor or other external reviewer to conduct an external assessment. An assessment conducted by someone who is not working in the facility can add

value by offering a fresh view. Regardless of who performs the assessment, it is best carried out with the involvement and participation of all staff.

HOW IS THE TOOLKIT ORGANIZED?

The toolkit is organized into three sections. Section 1 describes the setup of the toolkit and provides guidance on how to use it. Section 2 is the quality assessment tool to assess the quality of services. Section 3 provides other tools, including samples of checklists and forms, that support the use of the quality assessment tool.

The quality assessment tool in section 2 is organized according to **five key risk areas**. **Standards** are listed for each risk area. There is a list of **key documents** that will assist the team in preparing for the assessment, together with suggested **methods** for eliciting the required information. The assessment team needs to be oriented on the data collection tool and the methods that can be used to obtain information.

SECTION 2

The assessment tool is outlined as follows:

- The five risk areas that are the major domains toward which risk-reduction strategies are directed
- The standards that represent the risk-reduction strategies for that domain; standard numbers are highlighted in gray and are considered critical
- The levels of effort that represent progressive achievement in reaching the expectations found in a standard
 - Level 1: STGs, policies, procedures, protocols, and plans have been developed and communicated that describe the expected quality of services to be provided.
 - Level 2: Processes (described in the policies, procedures, protocols, and plans) are implemented in a consistent way.
 - Level 3: There are data to confirm successful risk-reduction strategies and continued improvement.
- The performance findings provide the team with concrete elements to determine whether the standard is met. Four levels of findings are listed for each level of effort (0, 1, 2, and 3).
- The overall score is created by multiplying the weight (level of effort) of the element with the progress (performance findings) toward meeting the standard. For example, if the level of effort is 1 and the performance finding is scored 3, the overall score is $1 \times 3 = 3$. An Excel spreadsheet is available to assist with these calculations.

It is recommended that the team initially assess all standards and associated levels of effort to provide a baseline for future progress toward meeting standards. For easy reference, the five risk areas are outlined in table 1 with the associated standards. The highlighted standards have been identified as critical to providing safe, quality care.

Table 2. OVERVIEW OF RISK AREAS (Standards highlighted are critical.)

Risk area▶	1	2	3	4	5
Standard	Leadership	Competent and capable workforce	Safe environment	Pharmacy services	Improvement of quality and safety
1	Pharmacy leadership and management	Personnel files available, complete, up to date	Regular inspection of environmental safety	Correct patient identification	Quality and patient safety program
2	Pharmacy mission, scope of services & annual action plan	Credentials of pharmacy staff	Adequate space, equipment and supplies	Medication therapy assessments complete and timely	Client satisfaction
3	Pharmacy policy and procedure manual	Staff members are competent	Management of hazardous materials	Written plans for care	Clinical outcomes monitoring
4	Management of pharmacy health information	Sufficient staff to meet patient needs	Reduction of health care-associated infections through hand hygiene	Clinical protocols and treatment guidelines available and used	Incident reporting system
5	Financial management	Oversight of students/trainees	Proper disposal of sharps and unused pharmaceutical products	Pharmacists role in HIV management	Rational drug use
6	Efficient use of resources	Staff performance management	Management of medical gases	Pharmacists role in FP	Complaint and suggestion management process
7	Compliance with national laws and regulations	Staff education		Safe medication use	Staff satisfaction monitored
8	Commitment to patient and family rights	Staff privileges		Patients educated to participate in their treatment	
9	Patient access to medication therapy			Coordinated care	
10	Effective inventory management			Preparation of prescribed medications	
11	Proper functioning of DTCs			Vaccination and cold chain management	
12	Current & complete drug formulary			Recordkeeping for patient medication	
13	Procurement of medical products			Drug recall	

PERFORMANCE ASSESSMENT TOOL

Date:

Name of facility/pharmacy:

Location: (sector, district/province)

Name(s) of assessor(s)

Instructions: Under the title of each risk area, you will find a list of required documents and proposed data collection methods. Score each of the standards starting with level 1. If all performance findings are met for level 1, you may move on to score level 2. In contrast, if level 1 is not fully met, do not move on to level 2, even if you feel some of the elements have been met in level 2. The reason is that this assessment is intended to move the pharmacy through a systematic process for achieving all the standards, building from level 1 to level 2 and, ultimately, to level 3 performance.

After entering all the scores, an overall score can be calculated by multiplying the level of effort by the score of the performance findings. For instance, if all the performance findings in level 1 were met, the score would be 3. The overall score would be level of effort 1 times the assessment finding score 3, thus, $1 \times 3 = 3$.

RISK AREA #I. LEADERSHIP PROCESS AND ACCOUNTABILITY

Required documents	Data collection methods
<ol style="list-style-type: none"> 1. Pharmacy organizational chart 2. Responsibilities of staff members 3. Current professional practice licenses 4. Pharmacy staff job descriptions, including head of pharmacy, and personnel files 5. Pharmacy license 6. Policies and procedures for managing a pharmacy information system 7. Management meeting minutes 8. Pharmacy mission, goals, and scope of services 9. Pharmacy annual action (operational) plan 10. Pharmacy administrative and operational policies and procedures 11. Pharmacy services monitoring indicators, data, and action plans 12. Staff training records 13. Financial controls and reports 	<ol style="list-style-type: none"> A. Leadership interviews B. Staff interviews C. Client/patient interviews D. Document review E. Personnel file review F. Direct observation

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
Standard #I. Pharmacy is managed by a professionally competent, legally qualified pharmacist with support from pharmacy technicians and other medical staff.						
Level I. There is a current document that identifies pharmacy staff by name, position, and responsibilities.	0	There are no documents that describe the organization's current leadership structure.				
	1	A current organizational chart lists the pharmacy positions.				
	2	The current names of persons who are in the positions are listed on the chart and/or observed to be posted on office doors.				

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	3 A document in the administrative manual describes the overall responsibilities of each of the pharmacy positions.					
Level 2. The head of pharmacy has a job description and maintains a valid license.	0 The head of pharmacy does not have a valid license to practice. 1 The head of pharmacy has a current license to practice. 2 A job description outlines the roles and responsibilities of the head of pharmacy. 3 Management meeting minutes (management and department) show evidence that the head of pharmacy is carrying out his/her roles and responsibilities.					
Level 3. The performance of the head of pharmacy is evaluated, and measures have been taken to continuously improve the results of his/her efforts.	0 A personnel file is not kept for the head of pharmacy. 1 A personnel file is kept for the head of pharmacy. 2 The evaluations include objectives, goals or an action plan for improving performance. 3 The personnel file contains quarterly feedback sessions with documentation of progress toward goals.					
Standard #2. The mission and scope of pharmacy services are defined, and an annual action plan is operationalized to meet pharmacy goals and objectives.						
Level 1. The pharmacy has a written mission, goals, scope of services, and annual action (operational) plan based on community	0 Information regarding community needs is not available.					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
pharmaceutical needs.	<ol style="list-style-type: none"> 1 Community needs are assessed to prioritize and assist in the planning of pharmaceutical care provision¹⁴: <ol style="list-style-type: none"> a. Geographic catchment area b. Population demographics c. Types of services and patient volumes d. Disease prevalence/ pharmaceutical needs e. Pharmacological services available f. Communication channels within community g. Use of OTC and traditional medications h. Sources of pharmaceutical public information 2 The pharmacy mission, goals, and scope of services are written. 3 The annual pharmacy action (operational) plan is written. 					
Level 2. The mission, goals, and plans are communicated to staff and implemented.	<ol style="list-style-type: none"> 0 There is no evidence that the mission, goals, or plans have been communicated to the pharmacy staff. 1 The head of pharmacy describes how the mission, goals, and plans are communicated to staff members. 2 Minutes of meetings document that mission, goals, and plans have been communicated to staff members. 					

¹⁴ Williams SE, Bond CM, Menzies C. A pharmaceutical needs assessment in a primary care setting. *Brit J Gen Pract.* 2000; 50(451), 95–99

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	3 Staff interviewed are aware of the mission, goals, and plans.					
Level 3. Progress in achieving the goals and objectives is measured and reviewed in management meetings on at least a quarterly basis.	0 There are no or few minutes that show discussions regarding measures of progress. 1 Pharmacy management meeting minutes include quarterly discussions of the goals and objectives. 2 Data is gathered to measure progress in meeting goals/objectives. 3 Pharmacy management meeting minutes reflect analysis of the data and actions planned to further achieve the goals/objectives.					
Standard #3. A policy and procedure manual is present to guide pharmacy practice (administrative and operational).						
Level 1: A pharmacy policy and procedure manual is in place covering administrative and operational practices.	0 The pharmacy does not have a policy and procedure manual. 1 The following documents are present in the pharmacy administrative manual: <ul style="list-style-type: none"> a. Mission, goals, and annual action plan of the pharmacy department b. Description of pharmacy c. Scope and organization of services d. Communication and collaboration <ul style="list-style-type: none"> ▪ Standing (regular) meetings ▪ Committees 2 Pharmacy operational policies include at least (that are in					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	<p>keeping with the Rwanda GPP 2019):</p> <ul style="list-style-type: none"> a. After-hours access to the pharmacy b. Medication procurement c. Medication management d. Medication reconciliation e. Medication storage and disposal f. Patient education <p>3 The pharmacy policies and procedures are well-written, up to date, complete, and revised and updated (when necessary) at least every two years.</p>					
Level 2: The pharmacy staff follow the pharmacy policies and procedures.	<p>0 Pharmacy staff are not familiar with policies and procedures.</p> <p>1 Priority policies and procedures have been communicated to staff and the communication process has been documented.</p> <p>2 Pharmacy staff interviewed are familiar with the policies and procedures.</p> <p>3 Pharmacy staff were observed to follow selected administrative policies and procedures.</p>					
Level 3: Compliance with priority policies and procedures is monitored and actions taken to improve, as indicated.	<p>0 The pharmacy does not monitor compliance with policies and procedures.</p> <p>1 Data is collected for selected priority administrative policies and procedures to monitor compliance.</p> <p>2 Data is aggregated and analyzed for selected priority operational policies and procedures to monitor compliance.</p>					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	3 The results of the monitoring are reviewed and acted upon to make improvements (PDSA cycle).					
Standard #4. An accurate and complete pharmacy health management information system that supports pharmacists in health care delivery is available for decision making at all levels.						
Level 1. Standard operating procedures are in place to guide management of pharmacy health information.	0 There are no policies and procedures for managing pharmacy health information.					
	1 There are SOPs for managing pharmacy health information that include at least: <ul style="list-style-type: none"> a. Ordering b. Dispensing c. Stock closer d. Approval of requests e. Handover f. How data is recorded and compiled g. Data quality control h. Data reporting/dissemination, analysis, access, use, and confidentiality 					
	2 Staff involved in managing pharmacy health information are trained and have the required skills.					
	3 Electronic data recording tools are available, and the person entering the data has demonstrated that they know how to use them.					
Level 2. Electronic health information is used to support MTM.	0 Management of pharmacy health information is not consistently done according to policies and procedures.					
	1 Management of pharmacy health information is consistent with the existing SOPs.					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	<p>2 Complete and accurate pharmacy data are entered into the LMIS in a timely manner</p> <p>3 Pharmacy data are entered into the PViMS monthly (review past six months).</p>					
<p>Level 3. Pharmacists participate in multidisciplinary meetings that evaluate data for decision making and explore opportunities for improvement.</p>	<p>0 Data are not available or there is no evidence that it is used consistently to make management decisions.</p> <p>1 Health data are available, and there is evidence that it is used consistently to make pharmacy management decisions, e.g., meeting minutes.</p> <p>2 Data are reviewed for quality control (e.g., extreme values, missing data) and documented; the data manager and/or monitoring and evaluation officer communicates results.</p> <p>3 Monthly reports analyzing pharmacy data contain:</p> <ul style="list-style-type: none"> a. Analysis using graphs with trend lines b. Minutes of monthly meetings c. Analysis of pharmacy LMIS and PViMS data 					
Standard #5. Pharmacy managers use accurate and complete financial data to effectively manage resources to achieve strategic objectives.						
<p>Level 1. Policies and procedures are in place to guide financial management.</p>	<p>0 No policies and procedures are in place regarding pharmacy financial management.</p> <p>1 Policies and procedures for financial management include at least:</p>					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	<ul style="list-style-type: none"> a. Authorization and approval of expenditures b. Accounting controls c. Inventory and asset management d. Financial reporting e. Control of financial documents f. Internal and external audit processes g. Management oversight on financial management <p>2 Pharmacy managers are trained in required financial management skills.</p> <p>3 Consolidated budgets are developed and aligned with the pharmacy annual plan.</p>					
Level 2. Accurate pharmacy financial records are maintained.	<p>0 Cash controls and reconciliation of accounts are not consistently done.</p> <p>1 Cash controls and reconciliation of accounts are completed according to financial management policies and procedures.</p> <p>2 Up-to-date price records are maintained to ensure that the most favorable prices are obtained.</p> <p>3 Records of purchases for inventory control and satisfaction of legal and audit requirements are established and maintained.</p>					
Level 3. Pharmacy managers monitor the management of finances.	<ul style="list-style-type: none"> 1. A consistent monthly process for monitoring finances is not evident. 2. Reports/minutes show that managers review pharmacy 					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	budget implementation and adjust accordingly. 3. Reports/minutes show that previous financial internal and external audit recommendations have been implemented. a. Interviewed pharmacy managers can describe how they ensure that proper financial internal and external control procedures are being followed and previous audit recommendations have been implemented.					
Standard #6. Pharmacy managers and staff are actively involved in efficient use of pharmacy resources.						
Level 1. Pharmacy staff members have knowledge and skills regarding resource management.	0 Staff members are not trained in resource management. 1 Pharmacy staff training has occurred within the past year on topics, such as: a. Reducing variations in patient care delivery (use of protocols/ STGs) b. Reducing system inefficiencies and waste 2 Staff training is targeted to resource management issues specific to managing medication. 3 Staff interviewed are aware of actions taken in their department to improve resource management.					
Level 2. Actions have been taken to	0 No actions have been taken based on the training.					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
improve pharmacy resource management, (e.g., increased efficiency, decreased wastage).	<ol style="list-style-type: none"> 1 Documents indicate that opportunities to improve pharmacy resource management have been identified. 2 Plans have been made to improve use of resources (e.g., decrease waste of expired drugs or supplies). 3 Meeting minutes indicate that the plans have been implemented. 					
Level 3. Actions taken to improve effective resource management are measured.	<ol style="list-style-type: none"> 0 Little or no data have been collected to improve use of resources and/or the data is incomplete or inaccurate. 1 Complete and accurate data have been collected for each of the planned improvements. 2 Charts and graphs are used to analyze and interpret data. 3 The plans for resource management are updated based on the results (PDSA cycle). 					
Standard #7. The standards and regulations of all relevant government bodies (MOH, Rwanda Food and Drug Authority, and Rwanda National Pharmacy Council) are met.						
Level 1. The pharmacy maintains copies of national pharmacy laws and regulations, and the head of pharmacy ensures timely communication.	<ol style="list-style-type: none"> 0 Copies of national pharmacy laws and regulations are not kept. 1 Copies of national pharmacy laws and regulations are kept. 2 The documents are observed to be filed in an orderly fashion and easy to locate. 3 The pharmacy head is mandated to communicate any pharmaceutical laws and 					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	regulations within one month of publication.					
Level 2. Pharmacy staff are aware of pharmacy laws and regulations.	<p>0 Pharmacy staff are not knowledgeable about the laws and regulations that apply to their areas.</p> <p>1 When interviewed, pharmacy staff are knowledgeable about the laws and regulations that apply to their areas.</p> <p>2 External pharmacy facility inspection and/or audit reports are present that are dated within the past 12 months.</p> <p>3 There were no deficiencies, or the facility report noted deficiencies and a corrective action plan is being implemented.</p> <p>NOTE: These are inspections/audits conducted by external groups, e.g., MOH, Public Service Commission (human resource policies), or fire brigade.</p>					
Level 3. The pharmacy maintains documentation of compliance with requirements, including procurement, distribution, and disposal of drug products.	<p>0 Pharmacy managers are unaware of whether the organization follows laws and regulations and/or there are observations that the organization is not in compliance.</p> <p>1 When interviewed, pharmacy managers can describe methods used to ensure compliance with laws and regulations.</p> <p>2 Audit data are available demonstrating compliance monitoring.</p>					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	3 There are no problems identified during the facility tour in which laws were not followed (e.g., narcotic management).					
Standard #8. Pharmacy managers identify pharmacy patients' and family rights and staff respect and protect the rights of patients and their families in the health care process.						
Level 1. The organization has identified pharmacy patients' and families' rights and communicated them to staff.	<p>0 No documents are present that describe pharmacy patient and family rights.</p> <p>1 A document is present that describes patient and family rights that covers at least:¹⁵</p> <ul style="list-style-type: none"> • Safe medication process (5 rights) • Education about medications • Knowledgeable and skilled pharmacy staff • Privacy • Confidentiality • Safety and security • Choice <p>2 Patients' and families' rights are posted for public view.</p> <p>3 Staff members interviewed are aware of patient and family rights.</p>					
Level 2. Staff respect and protect the rights of	0 Staff members are unable to describe how they protect patient and family rights.					

¹⁵ Little J, Mark S. Pharmacy Patient Bill of Rights: Practice Advancement from the Patient Perspective. Hosp Pharm. 2013; 48(5):351–353. doi:10.1310/hpj4805-351

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
patients and their families.	<p>1 Staff members can describe how they protect patient and family rights.</p> <p>2 A private area for pharmacist-patient consultations is available.</p> <p>3 Patient and family rights are observed to be respected.</p>					
Level 3. The pharmacy asks patients about respect for their rights and uses the information to educate/train staff and improve.	<p>0 The patient satisfaction survey does not include questions about patients' and families' rights.</p> <p>1 The patient satisfaction survey includes questions regarding respecting patient and family rights (Note: This is not a question like "Does the staff respect your rights?" It would be questions like, "Was your privacy respected?")</p> <p>2 The survey results are documented and show the percentage of patients/families that feel that their rights have been respected.</p> <p>3 Minutes or an action plan shows the analysis of the findings and actions taken (when indicated) to resolve concerns expressed by patients and families.</p>					
Standard #9. Patients have sustainable access to affordable and effective pharmacy services and treatments.						
Level 1. Barriers to accessing pharmacy services and treatments have been identified.	<p>0 A multidisciplinary team has not been organized to reduce barriers to access.</p> <p>1 A multidisciplinary team is organized to reduce barriers to access to pharmacy services and treatments (Note: This may be the QI committee.)</p>					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	<p>2 Barriers to accessing pharmacy services have been identified and documented, e.g., unavailability, financial burden, poor quality, long waiting time, transportation, language, physical weakness, etc.</p> <p>3 Priorities for reducing barriers have been established.</p>					
Level 2. Barriers to access are investigated and actions taken to make improvements.	<p>0 Plans have not been developed to address priority issues.</p> <p>1 Plans have been developed to address priority issues.</p> <p>2 Meeting minutes show that the plans to reduce barriers are being implemented.</p> <p>3 The plans for reducing barriers are updated based on the results (PDSA cycle).</p>					
Level 3. Data is used to inform decisions to improve access to pharmacy services.	<p>0 Data are not effectively used to measure improvement of access to pharmacy services and treatments.</p> <p>1 Data are used to measure improvement to accessing pharmacy services and treatments.</p> <p>2 Actions and results are reported to management.</p> <p>3 Data shows that access to services has improved.</p>					
Standard #10. An efficient and effective supply inventory management system is in place.						
Level 1. Policies and procedures to manage supplies and equipment are in place in each department.	<p>0 Policies and procedures are not in place to manage supplies and equipment in each department.</p> <p>1 Policies and procedures are available for managing supplies and equipment in each department and are in line with national/ international guidelines.</p>					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	<p>2 Each department has a current list of required and existing supplies, equipment, and instruments.</p> <p>3 A staff member in each department is assigned to ensure that adequate levels of (pharmacy) supplies, instruments, and equipment are available.</p>					
Level 2. Staff members responsible for pharmacy inventory management are trained and carry out systematic processes to manage inventories.	<p>0 Inventory management is not consistently carried out.</p> <p>1 Staff interviewed describe a systematic process for reordering supplies and replacing equipment and instruments, e.g., first expired-first out rules.</p> <p>2 Records include maximum/minimum levels, emergency order points, security stock levels, and accurate counting of inventory using stock control cards, an electronic information management system, or a register with stock in and stock out.</p> <p>3 Storage area for supplies, instruments, and equipment is observed to be of sufficient space, well designed, and organized.</p>					
Level 3. Data are collected to determine the effectiveness of pharmacy inventory management.	<p>0 Staff interviewed are unable to describe how QI processes are used to standardize and maintain inventories.</p> <p>1 Staff interviewed describe the use of QI processes (e.g., 5-S) to standardize and maintain inventories.</p> <p>2 An improvement plan is in place for efficient and effective pharmacy stock management.</p>					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	3 Data are used to measure the effectiveness of pharmacy inventory management systems, e.g., monitoring stock-outs.					
Standard #11. DTC effectively carries out the TOR (N/A to community pharmacy)						
Level 1. DTC has been formed with TOR.	0 The TOR for the DTC have not been written or are not up to date.					
	1 The TOR for the DTC have been written and addresses at least: <ol style="list-style-type: none"> Maintaining a hospital formulary of medications approved for routine patient care (see standard #13) Developing and implementing STGs Reviewing drug use and ADRs Establishing procedures for prescribing, dispensing, and administering drugs in the hospital Monitoring and analyzing expenditure on drugs Including a DTC subcommittee on pharmacovigilance 2 Members of the committee should include the following: <ol style="list-style-type: none"> Representative clinician from each major specialty Clinical pharmacist (if available) Nurse (infection control nurse or matron) Head pharmacist Administrator Laboratory technician 					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
	<p>g. Member of the hospital records department</p> <p>3 The members of the committee have nomination letters and have been oriented to the TOR.</p>					
Level 2. The DTC is carrying out its TOR.	<p>0 Regular meetings of the DTC are not held.</p> <p>1 DTC meetings are held at least quarterly or as per the TOR.</p> <p>2 The DTC establishes annual action plans to achieve set goals.</p> <p>3 The meeting minutes are written and include issues identified in meeting the goals and planned actions.</p>					
Level 3. DTC performance and impact are evaluated.	<p>0 Performance of the DTC is not monitored.</p> <p>1 Indicators for monitoring the performance and impact of the DTC are established.</p> <p>2 A self-assessment is completed annually to review committee performance.</p> <p>3 Data on the impact (e.g., reducing costs and improving availability of medications) of the committee are analyzed and actions taken to make improvements (PDSA cycle).</p>					
Standard #12. A current and complete drug formulary, essential drug list, and prescription medicine and OTC drug list are available (N/A to community pharmacy).						
Level 1. Written criteria are developed and maintained for drug product selection that addresses the needs of the	<p>0 Written criteria are not developed for drug product selection that addresses the needs of the populations served and requests for specialty medications.</p> <p>1 Written criteria have been developed; however, evidence is</p>					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
populations served and requests for specialty medications.	<p>not present showing that the criteria were based on identified population needs or specialty medications (if relevant).</p> <p>2 Written criteria are present showing that criteria are based on population needs and requests for specialty medications (if relevant).</p> <p>3 Staff interviewed are familiar with the criteria.</p>					
Level 2. A formulary, essential drug list, and prescription medicine and OTC list are readily available to meet the needs of the population and health care providers.	<p>0 A formulary and essential drug, prescription medicine, and OTC lists are not present.</p> <p>1 An updated formulary is present with the following required elements:</p> <ul style="list-style-type: none"> a. Indications for use b. Effectiveness c. Drug interaction d. Potential for errors and abuse e. ADEs f. Population(s) served (e.g., pediatrics, patients with multi-drug-resistant TB) g. Other risks h. Costs <p>4. Updated essential, prescription medicine, and OTC lists are present and were adopted.</p> <p>5. The staff can readily locate and use the formulary and essential drug, prescription medicine, and OTC lists.</p>					
Level 3. The impact of and compliance with the drug formulary	<p>0 Data are not collected to determine the impact of and compliance with the formulary and</p>					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
and essential drug, prescription medicine, and OTC lists are reviewed in a timely manner (e.g., through drug utilization reviews).	<p>essential drug, prescription medicine, or OTC lists.</p> <ol style="list-style-type: none"> 1 Data are collected to determine the impact of and compliance with the formulary and essential drug, prescription medicine, and OTC lists. 2 Data are analyzed and reviewed at least every two years. 3 Actions are taken to address issues identified during the review (PDSA cycle). 					
Standard #13. Pharmacy implements a value-based procurement system of pharmaceutical products by balancing costs and quality to achieve holistic value in procurement decisions (N/A to community pharmacy).						
Level 1: Written procurement operational policies and procedures are in line with Rwanda procurement law to ensure a fair, transparent system.	<ol style="list-style-type: none"> 0 There are no written procurement operational policies and procedures that are in line with Rwanda procurement law to ensure a fair, transparent system. 1 The policies and procedures are written but not completely in line with the minimum standards for procurement. 2 The policies and procedures are written, complete, and in line with the Rwanda procurement law. 3 Staff interviewed can easily locate the policies and procedures. 					
Level 2: The pharmacy management and procurement officer ensures compliance with procurement policies and procedures,	<ol style="list-style-type: none"> 0 Staff have not been oriented on procurement policies and procedures. 1 Staff have received an orientation on procurement policies and procedures within the past 12 months. 					

Level of effort	Performance findings	Score				
		0	1	2	3	Overall
including pharmaceutical quality, adheres to specifications in the contract.	<p>2 Staff interviewed are familiar with the content of the procurement policies and procedures.</p> <p>3 Procurement of pharmaceutical products complies with existing procurement policies and procedures, and quality adheres to the specifications in the contract.</p>					
Level 3: An effective monitoring mechanism is in place to ensure that policies and procedures on procurement of quality and safe pharmaceutical products, availability, and affordable pharmaceutical products are complied with.	<p>0 Monitoring is not done to evaluate the effectiveness of procurement policies and procedures.</p> <p>1 Indicators have been developed to track the effectiveness of procurement policies and procedures.</p> <p>2 Data on set indicators is collected and analyzed.</p> <p>3 Actions are taken to improve compliance with policies and procedures (PDSA cycle).</p>					

RISK AREA #2. COMPETENT AND CAPABLE WORKFORCE

Required documents	Data collection methods
<ol style="list-style-type: none"> 1. Staff member job descriptions 2. Personnel file management policies and procedures 3. Staff performance management policies and procedures 4. Pharmacy staffing plan 5. Credentialing policies and procedures 6. Privileging policy and procedure 7. Pharmacy staff general orientation program agenda 8. Departmental orientation checklist 9. List of pharmacy trainees and assignments 10. Training records as evidence of meeting various standards 11. Occupational hazard assessment 	<ol style="list-style-type: none"> A. Leader interviews B. Staff interviews C. Document review D. Personnel file review

Look for	Performance findings	Score				
		0	1	2	3	Overall
Standard #1. All pharmacy staff members have a personnel file that is complete and up to date according to the policy and procedure.						
Level 1. Policies describe the content that is to be included in personnel files and job descriptions.	0	A policy describing the contents of personnel files is not written and/or does not contain the required elements.				
	1	A current policy outlines the content of personnel files that includes: a. Current job description b. Curriculum vitae c. Copies of required credentials, including degrees/ diplomas, evidence of registration certificates, and current license (if applicable) d. List of pharmacy staff privileges (if applicable)				

Look for	Performance findings	Score				
		0	1	2	3	Overall
	<p>e. Evidence of completion of resuscitation training (if applicable)</p> <p>f. Annual performance evaluation with annual targets that includes pharmacy service standards compliance</p> <p>g. Training certificates</p> <p>h. Evidence of participation in orientation (new personnel only)</p> <p>2 A current policy indicates that the job description contains at least:</p> <p>a. Education, training, and experience required</p> <p>b. Reporting relationship (who they report to)</p> <p>c. Roles and responsibilities</p> <p>d. Job contract</p> <p>3 A policy describes the content of volunteer and contracted personnel files</p> <p>a. Copy of contract</p> <p>b. Qualifications (education, training, and experience)</p> <p>c. Current professional license (if indicated)</p> <p>d. Proof of orientation</p> <p>e. Required health assessments/ vaccinations</p> <p>Notes:</p> <ul style="list-style-type: none"> Orientation records are only expected for personnel that have been hired within the past six months. 					

Look for	Performance findings	Score				
		0	1	2	3	Overall
	<ul style="list-style-type: none"> Other forms of documentation would be acceptable, e.g., computerized list of staff that participated in an activity with dates of the activity and the providers. This would include training activities and lists of vaccinations. 					
Level 2. Personnel files are filed in a standardized order and contain all required elements as described in the policy.	<p>0 Personnel files were not arranged in an organized standard format.</p> <p>1 Personnel files were arranged in an organized standard format.</p> <p>2 All personnel files reviewed had evidence of a current license/credentials.</p> <p>3 Most personnel, volunteer, and contractor worker files contained the required items.</p>					
Level 3. A process is in place to keep personnel files up to date.	<p>0 There is no or an inconsistent process for maintaining the personnel files up to date.</p> <p>1 A policy and procedure describe the process for maintaining personnel files up to date.</p> <p>2 Personnel files are observed to be managed and maintained up to date as provided in the policy and procedure.</p> <p>3 There is a system to monitor non-compliance gaps and an improvement plan is developed and implemented to close the gap.</p>					
Standard #2. There is a process to gather, verify, evaluate, and authorize pharmacy staff to provide services that are appropriate to their licensure, education, training, and competence.						

Look for	Performance findings	Score				
		0	1	2	3	Overall
Level 1. A policy and procedure describe the process for gathering and verifying credentials of pharmacy staff and assigning staff job responsibilities accordingly.	<p>0 There is no pharmacy staff credentialing and assignment policy and procedure.</p> <p>1 A current policy and procedure lists credentials required, including registration and certification with the National Pharmacy Council, licensure, education, training, and competence.</p> <p>2 A current policy and procedure describe verification of credentials through the National Pharmacy Council.</p> <p>3 A current policy and procedure describe how pharmacy staff credentials are used to assign job responsibilities and when to extend their scope of services (task shifting).</p>					
Level 2. The credentials are gathered and verified according to the policy and procedure, and pharmacy staff are assigned roles and responsibilities based on the credentials.	<p>0 A complete set of required credentials is not maintained for each pharmacy staff member.</p> <p>1 All credentials required are copied by the facility and maintained for each pharmacy staff member in their personnel files.</p> <p>2 Pharmacy staff members that are extending their scope of services (task-shifting) have associated competency levels defined and assessed, which are documented in their personnel files.</p> <p>3 Pharmacy staff do not provide direct patient care until at least licensure/registration are verified.</p>					
Level 3. Evidence shows that the	<p>0 There is no data that shows that the verification process is carried</p>					

Look for	Performance findings	Score				
		0	1	2	3	Overall
credentialing process is effective.	<p>out according to the policy and procedure.</p> <ol style="list-style-type: none"> 1 A dated and signed document indicating that credential verification has been done for each pharmacy staff member is present. 2 A document is present showing that the facility verifies that the third party (allied health professional council) implements the verification process described in the policy and procedure. 3 Audits are conducted to ensure that pharmacy staff appointments are made according to hospital policy. 					
Standard #3. All pharmacy personnel possess the education and training to fulfill their job responsibilities.						
Level I. A training plan is in place for orientation and on-going staff development to ensure that staff knowledge and skills are consistent with current pharmacy practice and patient needs.	<ol style="list-style-type: none"> 0 There is no training policy and procedure, or it does not address orientation and ongoing training. 1 A training policy and procedure describes the process for assessing, planning, implementing, and evaluating the pharmacy training program. 2 An assessment of education/ training needs of all pharmacy staff is conducted annually (e.g., results of QI monitoring, performance gaps, new procedures, and accreditation surveys), and training needs are identified. 3 The pharmacy has an annual, written pharmacy staff training 					

Look for	Performance findings	Score				
		0	1	2	3	Overall
	plan based on assessed training needs.					
Level 2. The training plan is carried out to meet the educational needs of staff.	<p>0 A training record and/or attendance is not kept.</p> <p>1 Complete records of training activities and attendance are kept for each training activity.</p> <p>2 The majority (80%) of pharmacy training activities have been conducted as planned.</p> <p>3 Pharmacy staff present quarterly to the clinical staff meeting to share what they have learned.</p>					
Level 3. The effectiveness of staff training is monitored.	<p>0 Minutes of staff meetings do not show that staff share learning.</p> <p>1 Minutes of staff meetings show that staff that received training outside the facility share the learning with other pharmacy staff (e.g., content outline, handouts used).</p> <p>2 The majority (80%) of pharmacy staff training activities are monitored for training effectiveness.</p> <p>3 The monitoring data is analyzed and used to improve training effectiveness.</p> <p>Note: Effectiveness can be measured by return demonstration of skills or linked with quality monitoring, e.g., improved documentation and adherence to policies/procedures or protocols. Staff satisfaction with the training activity is not the intended measure of effectiveness for this standard.</p>					

Look for	Performance findings	Score				
		0	1	2	3	Overall
Standard #4. Pharmacy staff possess the knowledge, skills, attitudes, and behaviors necessary to deliver comprehensive medication management in team-based patient care environments.						
Level 1: A checklist of high-risk competencies for safe pharmacy practice is established.	0	High risk competencies for safe pharmacy practice have not been established.				
	1	A list of high-risk competencies for safe pharmacy practice has been established for the pharmacist.				
	2	A list of high-risk competencies for safe pharmacy practice has been established for pharmacy technicians.				
	3	The list includes at least: a. Common drug interactions b. Common and severe side or adverse effects, allergies, and therapeutic contraindications associated with medications c. Pharmacy laws and regulations d. Sterile and non-sterile compounding (as relevant) e. Medication safety f. Medication storage				
Level 2: All pharmacy staff are evaluated on their ability to proficiently carry out high-risk procedures/skills.	0	A competency assessment procedure is not developed.				
	1	A competency assessment procedure is developed.				
	2	The competency assessment is carried out for all pharmacy staff members annually.				
	3	Documentation of competency verification is maintained in each staff member's personnel file.				
Level 3: The effectiveness of the competency	0	Indicators are not established to monitor the effectiveness of the competency assessment.				

Look for	Performance findings	Score				
		0	1	2	3	Overall
assessment is evaluated.	<ol style="list-style-type: none"> 1 Indicators are established to monitor the effectiveness of the competency assessment. 2 Indicator data are analyzed to determine the effectiveness of the competency assessment. 3 The competency assessment process is improved based on the findings (PDSA cycle). 					
Standard #5. The pharmacy employs an adequate number of competent, legally qualified pharmacists and support staff (pharmacy technicians) to meet the specific medication-use needs of patients.						
Level 1. A staffing plan is written that identifies the number of staff needed per shift, considering the scope of services provided and the workload.	<ol style="list-style-type: none"> 0 A pharmacy staffing plan has not been developed. 1 The pharmacy has a staffing plan, which includes the number and categories of staff needed per shift. 2 When staffing levels do not meet needs, policies and procedures are in place that describe actions to be taken, e.g., reassign staff, on-call staff. 3 Most staffing plans are based on workload, e.g., workload indicators for staffing needs. 					
Level 2. The work schedule provides an adequate number of staff (according to the plan) on each shift to meet the departmental needs.	<ol style="list-style-type: none"> 0 An interview with the head of pharmacy indicates that schedules are not developed based on the staffing plan. 1 Staffing schedules are filled out according to the plans; however, the number of staff that worked in the past month was consistently less than planned (e.g., a staff shortage occurred 10 times in 30 days). 2 Staffing schedules are filled out according to the plan, and much of the time, staffing is consistent with 					

Look for	Performance findings	Score				
		0	1	2	3	Overall
	<p>the plan (e.g., a staff shortage occurred 5 times or less in 30 days).</p> <p>3 When interviewed, the head of pharmacy can describe how they effectively manage situations in which staffing needs are not met that is consistent with the policy and procedure.</p>					
Level 3. Staffing plans are evaluated to determine whether adequate staffing is provided; when shortages exist, leaders set priorities and adjust to provide safe services.	<p>0 There is no evaluation of staffing plans.</p> <p>1 Reviewing planned staffing data in relation to the staff that worked is done in the department monthly.</p> <p>2 The data is used to identify gaps and take action to meet staffing needs.</p> <p>3 Workload studies are done to evaluate staffing needs.</p>					
Standard #6. Oversight of students/trainees						
Level 1. A current policy and procedure are available on student/trainee oversight.	<p>0 A current policy and procedure on student/trainee oversight are not present.</p> <p>1 A current policy and procedure are available on student/trainee oversight.</p> <p>2 A current list of students/trainees and their objectives and assignments is present for the pharmacy service.</p> <p>3 A list of students/trainees and their assignments are posted.</p>					
Level 2. The current competence (level of training) of each student/trainee is known and forms the basis for assignments and	<p>0 There is no information available on the competency levels of students/trainees.</p> <p>1 Information about competency levels and training objectives is available for some students/ trainees but not others.</p>					

Look for	Performance findings	Score				
		0	1	2	3	Overall
level of required supervision.	<p>2 Information is available on the competence level and objectives of each type of student/trainee.</p> <p>3 An interview with the head of pharmacy demonstrates that students/trainees are assigned functions consistent with their competency level and objectives, and they are supervised as required.</p>					
Level 3. Monitoring is performed to determine whether the oversight of students/trainees complies with the policy and procedure.	<p>0 There is no evidence that students/trainees are supervised according to the policy and procedure.</p> <p>1 The student/trainee assignment form indicates that all students/ trainees are supervised according to policy and procedure and met their objectives</p> <p>2 Orientation records show that all trainees are oriented to the pharmacy's quality and safety policies and procedures.</p> <p>3 Department records show that student oversight is routinely performed.</p>					
Standard #7. Pharmacy staff performance is evaluated on a regular basis and feedback provided to the employee to improve work performance.						
Level 1. A policy and procedure describe the performance management process.	<p>0 There is no policy and procedure for performance management.</p> <p>1 A current policy and procedure are in place that describes the performance management process.</p> <p>2 Each category of employee has a job-specific evaluation/ performance targets related to assigned tasks in the job description.</p>					

Look for	Performance findings	Score				
		0	1	2	3	Overall
	3 Staff interviewed are aware of the performance management process.					
Level 2. The performance management process is implemented according to the policy and procedure.	<p>0 Annual evaluations are not done and/or not consistently performed according to the policy and procedure.</p> <p>1 Personnel files for most staff contain individual, annual performance evaluations conducted within the past 12 months.</p> <p>2 At least two performance targets are set with each employee with a plan to achieve these targets that are linked to the goals of the organization (e.g., achieving targets).</p> <p>3 Performance evaluation feedback is provided to each staff member and progress toward the goals/objectives is documented.</p>					
Level 3. The effectiveness of the performance management process is evaluated.	<p>0 The effectiveness of pharmacy performance management has not been evaluated within the past 15 months.</p> <p>1 Performance management process is reviewed using at least the following questions:</p> <ul style="list-style-type: none"> a. Were evaluations done on time? b. Did everyone who was supposed to receive an evaluation get one? c. Were employee performance goals written and progress noted? d. Did staff receive performance evaluation feedback? <p>2 An evaluation of the performance management</p>					

Look for	Performance findings	Score				
		0	1	2	3	Overall
	<p>process has been conducted within the past 15 months.</p> <p>3 The results of the evaluation were analyzed, and actions taken to make improvements.</p>					
Standard # 8 Pharmacy staff privileges: A standardized, objective, evidence-based procedure is used to authorize pharmacists and technicians to provide clinical services consistent with their qualifications.						
Level 1. A policy and procedure describe a standardized process to grant privileges to pharmacists and pharmacy staff and to assign job responsibilities accordingly.	<p>0 There is no professional staff privileging policy and procedure.</p> <p>1 A policy and procedure describe a standardized process for approving pharmacy staff privileges, including approving special and temporary privileges and the training and experience required for new procedures.</p> <p>2 A core set of privileges is defined for categories of practitioners, e.g., pharmacists and pharmacy technicians, including task-shifting.</p> <p>3 A current policy and procedure describe how the credentials are used to assign job responsibilities.</p>					
Level 2. The organization uses a standardized procedure to approve privileges on initial appointment and when new skills have been acquired to each type of practitioner listed in	<p>0 A process for approving privileges is not in place or is inconsistently applied.</p> <p>1 Each pharmacy practitioner has defined core privileges and special privileges (e.g., task-shifting (e.g., compounding medications, FP counseling), with evidence of training/experience to perform the special procedure, documented in the personnel file, which has been</p>					

Look for	Performance findings	Score				
		0	1	2	3	Overall
the policy and procedure.	<p>updated within the past 24 months.</p> <p>2 Privileges are communicated to relevant departments through a written document.</p> <p>3 A personnel file is kept for practitioners given temporary privileges (e.g., visiting foreign pharmacists) that includes:</p> <ul style="list-style-type: none"> a. Licensure status b. Written request c. Verified information supports a favorable determination regarding the request d. Practitioner's qualifications and ability to exercise the requested privileges 					
Level 3. Each privileged practitioner provides only those services that have been specifically permitted by the hospital.	<p>0 There is no or inconsistent evidence of monitoring professional practice.</p> <p>1 All pharmacists are included in the monitoring and evaluation of professional practice. These may be included in the performance appraisal process. Indicators may include medication error rates and compliance with STGs.</p> <p>2 Areas of achievement and potential improvement related to behaviors and clinical results are documented in the personnel file.</p> <p>3 Findings are used for determining privileges and are reflected in the list of privileges.</p>					

RISK AREA #3. SAFE ENVIRONMENT FOR STAFF AND PATIENTS

Required documents	Data collection methods
<ol style="list-style-type: none"> 1. List of pharmacy environmental risks 2. Pharmacy facility inspection report (see risk area #1, standard #8) 3. Pharmacy facility improvement plan 4. Hazardous materials inventory, policies, and procedures 5. MSDSs 6. Environmental safety plans, policies, and procedures 7. Reports of staff attendance for required training 8. Reports for monthly safety rounds 9. Infection prevention and control policies and procedures 	<ol style="list-style-type: none"> A. Leader interviews B. Staff interviews C. Document review D. Personnel file review E. Inspection F. Observation

Look for:	Performance findings	Score				Overall
		0	1	2	3	
Standard #1. The pharmacy and related storage areas are thoroughly and regularly inspected to identify and reduce safety risks.						
Level 1. There is an inspection process to identify and list health care environment risks of all types within the pharmacy.	0	There is no checklist of environmental risks.				
	1	A safety team uses a checklist to identify risks in the pharmacy.				
	2	There is a comprehensive list of all types of environmental risks in the pharmacy, including those relating to safety, security, hazardous materials, fire safety, biomedical equipment, utilities (power and water), and infection control (e.g., waste management).				
	3	The risks are assessed at least quarterly in the pharmacy.				
	Note: The safety team may be members of the QI committee.					
Level 2. The risks identified during the	0	A pharmacy team has not been organized to review the risks.				

Look for:	Performance findings	Score				Overall
		0	1	2	3	
inspection process are prioritized according to severity and likelihood of occurrence, and a plan is developed to reduce priority risks.	<ol style="list-style-type: none"> 1 A pharmacy team has been organized to review the risks. 2 The pharmacy risks have been prioritized using a set of criteria (see note below). 3 The pharmacy facility improvement plan includes actions to reduce priority risks. <p>Note: The risk criteria should include at least 1) the potential severity of an event, injury, or failure and 2) likelihood of the event, injury, or failure occurring.</p>					
Level 3. The risks identified are systematically reduced or eliminated, and the list is updated through periodic, routine reinspection	<ol style="list-style-type: none"> 0 There is no evidence that the plan has been initiated. 1 Minutes or reports indicate that the pharmacy facility improvement plan has been implemented. 2 Implementation of the pharmacy facility improvement plan is monitored at least quarterly as evidenced in meeting minutes. 3 The improvement activities and results are reported to both management and the QI officer. 					
Standard #2. Adequate space, equipment, and supplies shall be available for all professional and administrative functions related to pharmacy services.						
Level 1. The pharmacy is located for convenient access, staff control, and security.	<ol style="list-style-type: none"> 0 Medications are not available after working hours through a licensed professional. 1 In the absence of 24-hour pharmacy services, access to a limited supply of medications is available (observed) to 					

Look for:	Performance findings	Score				Overall
		0	1	2	3	
	<p>authorized, licensed health care professionals to fill urgent medication orders.</p> <p>2 Drug financing options are available through some form of drug benefits as part of health insurance.</p> <p>3 A high level of security is provided to avoid counterfeit pharmaceuticals:</p> <ul style="list-style-type: none"> a. Health care professionals are educated to become vigilant. b. Patient/community awareness is increased concerning the risks of counterfeit drugs. 					
<p>Level 2. The facilities enable the receipt, storage, and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety.</p>	<p>0 A separate office space is not available or is insufficient.</p> <p>1 A separate room or area is available for office functions, including a desk, filing, communications, and references.</p> <p>2 The dispensing area includes:</p> <ul style="list-style-type: none"> a. A pickup and receiving area b. Work counters and space for automated and manual dispensing activities c. Temporary storage, exchange, and restocking of trolleys d. Security provisions for drugs and personnel e. A clean work area with a laminar flow workstation designed for compounding sterile solutions 					

Look for:	Performance findings	Score				Overall
		0	1	2	3	
	<p>3 Cabinets, shelves, and/or separate rooms or closets for:</p> <ul style="list-style-type: none"> a. Bulk storage b. Active storage c. Refrigerated storage d. Secure storage for narcotics and controlled drugs e. Storage for general supplies, records, and equipment not in use 					
Level 3. There is a system in place to monitor storage conditions, security of pharmaceutical products, and appropriate functional space.	<p>0 There is no system for monitoring storage and security of pharmaceutical products.</p> <p>1 Documents reviewed show that a system for monitoring storage and security of pharmaceutical products is in place.</p> <p>2 Data on the storage and security of pharmaceuticals is collected and analyzed.</p> <p>3 Actions are taken to improve pharmaceutical storage and security (PDSA cycle).</p>					
Standard #3. Processes are in place to manage special precautions, equipment, and training for preparation, handling, storage, and disposal of hazardous drug products and products used in their preparation.						
Level 1. There is an inventory of all the locations, types, and volumes of hazardous materials.	<p>0 There is no list of hazardous materials.</p> <p>1 There is a list of hazardous materials in the pharmacy.</p> <ul style="list-style-type: none"> a. Name and description (e.g., composition of a mixture) of the hazardous product 					

Look for:	Performance findings	Score				Overall
		0	1	2	3	
	b. Classification (e.g., code, class, or division) c. Quantity of hazardous product d. MSDS 2 The list is updated annually. 3 A plan for managing the materials is in place (refer to Rwanda GPP 2019).					
Level 2. There are policies and procedures for managing hazardous materials.	0 There are no policies and procedures for safe and proper handling, labeling, storage, and use of hazardous materials. 1 There are policies and procedures for safe and proper handling, labeling, storage, and use of hazardous materials, including MSDS available for staff reference for each hazardous material. 2 Staff is observed using appropriate PPE when handling and disposing of hazardous materials. 3 Monthly safety rounds to check that hazardous materials are labeled, stored, and used properly are documented.					
Level 3. Spills and accidents involving hazardous materials are investigated, and measures taken to prevent future incidents and/or improve the response to such incidents.	0 There are no policies/procedures for managing spills or accidents. 1 Policies and procedures are in place for managing spills or accidents involving hazardous materials. 2 Staff have been instructed on and can describe how to manage spills or accidents (may be included in orientation training or staff meetings). 3 Data are collected and analyzed (e.g., results of monthly safety					

Look for:	Performance findings	Score				Overall
		0	1	2	3	
	rounds and incident reports) and actions taken to improve hazardous material management.					
Standard #4. Reduction of health care-associated infections through hand hygiene						
Level 1. Hand hygiene is emphasized and guided by evidence-based guidelines.	<p>0 There are no hand hygiene policies/procedures.</p> <p>1 There are hand hygiene policies/ procedures based on current practices (e.g., WHO).</p> <p>2 Policies and procedures have been communicated to staff (e.g., in-service training, posters above sinks).</p> <p>3 Staff interviewed are aware of hand hygiene policies and procedures.</p>					
Level 2. A consistent and effective hand hygiene program is in place with adequate equipment and supplies.	<p>0 Adequate hand washing/hygiene facilities and supplies (including water, soap, disposable towels, and/or alcohol hand gel) are not consistently available.</p> <p>1 Adequate hand washing/hygiene facilities and supplies are conveniently located for staff use.</p> <p>2 The head of pharmacy describes a systematic process for ensuring availability of adequate supplies, e.g., use of a daily checklist.</p> <p>3 Most staff are observed performing hand hygiene according to policies/procedures.</p>					

Look for:	Performance findings	Score				Overall
		0	1	2	3	
Level 3. Infection prevention and control data and hand hygiene surveillance data are used to improve the program.	<p>0 No data or incomplete data are collected on hand hygiene practices.</p> <p>1 A standardized hygiene observation tool and method is used to collect data.</p> <p>2 Data are collected on a scheduled basis.</p> <p>3 The data are aggregated and used to identify gaps and develop improvement plans (PDSA cycle).</p>					
Standard #5. Sharps and unused pharmaceutical products are properly disposed of by staff throughout the organization.						
Level 1. A policy and procedure provide guidance on proper disposal of sharps and unused pharmaceutical products and is made known to staff.	<p>0 There are no policies and procedures on disposal of sharps and unused pharmaceutical products.</p> <p>1 Policies and procedures on the disposal of sharps and unused pharmaceutical products are based on current practice.</p> <p>2 Staff interviewed are aware of proper disposal of sharps and unused pharmaceutical products.</p> <p>3 Sufficient supplies of sharps containers are available in all relevant locations.</p>					
Level 2. The disposal of sharps and unused pharmaceutical products is well organized and uniform, with disposable containers collected regularly and disposed of properly.	<p>0 The disposal of sharps and unused pharmaceutical products is not well organized and uniform.</p> <p>1 Puncture-proof sharps containers are properly located in all relevant areas.</p> <p>2 Sharps containers are observed to be no more than 3/4 full, sealed, and disposed of according to policy/procedure.</p> <p>3 Documentation shows that pharmaceutical waste (narcotics</p>					

Look for:	Performance findings	Score				Overall
		0	1	2	3	
	and dangerous drugs) are disposed of according to policy and procedure.					
Level 3. Data on injuries and accidents related to sharps and unused pharmaceutical products are available; these data are used to continually improve the program.	0 No data are collected related to needle sticks or sharps injuries. 1 Data are collected related to needle sticks and sharps injuries. 2 Results of data are communicated at least quarterly to the Infection Prevention and Control Committee and DTC. 3 Data are used to develop and implement plans to improve practice.					
Standard # 6 Medical gases are properly installed, tested, operated and maintained.						
Level 1. Policies and procedures and qualified staff are in place for managing medical gases.	0 Current policies and procedures on managing medical gases are not in place. 1 Current policies and procedures on managing medical gases are in place. 2 A maintenance program with inventories, inspections, and maintenance schedules is developed (name, type, serial number, and location of each regulator are recorded and held in the pharmacy). 3 Qualified individuals inspect and maintain medical gas systems (documented training certification program).					
Level 2. Medical gases are safely stored and managed.	0 Gas cylinders are not stored properly. 1 Only gas cylinders and cylinder accessories are stored in rooms containing gas cylinders.					

Look for:	Performance findings	Score				Overall
		0	1	2	3	
	<p>2 Storage locations are locked or otherwise secured, have electrical devices protected from physical damage, and are provided with racks, chains, or other fastenings to secure cylinders from falling.</p> <p>3 Documentation shows that each patient and appropriate member of the patient's family or caregiver receive full and proper instruction from a pharmacist or suitably trained person in the safe care and handling of cylinders and associated equipment (Rwanda GPP 2019).</p>					
<p>Level 3. Documentation of regular weekly assessments of medical gas management is kept.</p>	<p>0 Verifying gas cylinder content is not carried out according to policy and procedure.</p> <p>1 Verifying gas cylinder content is observed to be carried out according to policy and procedure.</p> <p>2 A comprehensive maintenance, inspection, and testing program for existing medical gas systems is documented.</p> <p>3 Actions are taken to follow up on gaps identified during inspections of medical gases.</p>					

RISK AREA #4. PHARMACY SERVICES

Required documents	Data collection methods
<ol style="list-style-type: none"> 1. Policy and procedure describe the content of medication management assessments 2. Policies and procedures on planning patient care and discharge 3. Policy and procedure for adopting treatment guidelines and clinical protocols 4. FP protocols and guidelines/policies and procedures for safe medication use 5. Policy and procedure for developing patient medication therapy plans of care 6. Policies and procedures on patient medication education 7. Policies and procedures on communication among caregivers 8. Policy and procedure for preparation and labeling prescribed medications 9. Policies and procedures for cold chain management and/or immunizations 10. Policy and procedure for medication record keeping 11. Policy and procedure for controlled medicines 12. Medication management assessment form 13. Policies and procedures for removing drugs or devices subjected to a recall from shelves, storage, and inventory 	<ol style="list-style-type: none"> A. Leader interviews B. Staff interviews C. Document review D. Medical record review E. Personnel file review

Look for	Performance findings	Score				Overall
		0	1	2	3	
Standard #1. Patients are identified correctly by using two patient identifiers before dispensing medications.						
Level 1. A policy and procedure describe when and how patients are to be properly identified, which includes two	0	There is no policy and procedure on identifying patients.				
	1	A policy and procedure describe when patient identification is required by the pharmacy staff.				
	2	A policy and procedure that requires using two patient identifiers (e.g., full name, date of				

Look for	Performance findings	Score				Overall
		0	1	2	3	
patient identifiers when providing care, treatment, or services.	<p>birth, medical ID number, or address); the patient's room number does not qualify as a form of identification.</p> <p>3 The policy and procedure have been approved and are dated within the past 24 months.</p>					
Level 2. The identification process is fully implemented and followed.	<p>0 None of the staff members can state any two identifiers that are in the policy and procedure.</p> <p>1 All staff members interviewed can describe when patient identification is required.</p> <p>2 All staff members interviewed can state how to correctly identify patients.</p> <p>3 Pharmacy staff members are observed to identify patients according to policy and procedure.</p>					
Level 3. Monitoring data are used to continually improve the identification process.	<p>0 No data for monitoring patient identification are found.</p> <p>1 Accurate and complete data are collected to determine if the staff are following the procedure.</p> <p>2 Data on patient identification are aggregated, displayed, and analyzed.</p> <p>3 Reports or other documents show that actions were taken to improve patient identification.</p>					
Standard #2. A medication history/assessment includes all current and recently prescribed drugs, previous ADRs, herbal or alternative medicines, and adherence to therapy (N/A to community pharmacy).						
Level 1. A policy and procedure for conducting medication	<p>0 There are no policies and procedures on performing medicine management assessments.</p>					

Look for	Performance findings	Score				Overall
		0	1	2	3	
assessments and reconciliation are in place.	<ol style="list-style-type: none"> 1 A policy and procedure describe the content of medication management assessments conducted by pharmacy staff. 2 Staff interviewed are aware of how to conduct a medication management assessment. 3 The assessment forms are designed to collect the information required. 					
Level 2. A current medication list and use history for prescription and nonprescription medications, herbal products, and other dietary supplements is documented for each patient.	<ol style="list-style-type: none"> 0 A current medication list and use history has not been completed. 1 A current medication list and use history has been completed for each patient record reviewed. 2 Pharmacy staff are observed to inspect patient medication containers for name and dosage. 3 Pharmacy staff are observed to compare the medication history with the physician's medication record. 					
Level 3. Open and/or closed patient records are reconciled to assess adherence to the process and identify any actual harm associated with unreconciled medications.	<ol style="list-style-type: none"> 0 No data were found on monitoring documentation of assessments. 1 Accurate and complete data are collected to determine if the staff are following the policy. 2 Data regarding medication assessments, including reconciliation, are aggregated, displayed, and analyzed. 3 Minutes or other documents show that actions were taken to improve documentation (PDSA cycle). 					
Standard #3. The clinical pharmacist develops and implements, collaboratively with the patient and his/her health care providers, a plan for optimizing medication therapy.						

Look for	Performance findings	Score				Overall
		0	1	2	3	
Level 1. A policy and procedure are written to guide development of a medication therapy plan.	<p>0 Policies and procedures regarding the process for developing patient medication therapy plans are incomplete.</p> <p>1 A current policy and procedure describe the process for developing patient medication therapy plans.</p> <p>2 Forms are readily available to staff for writing the plan of care.</p> <p>3 Clinical staff receives training/ mentoring in writing and implementing effective medication therapy plans.</p>					
Level 2. Planning patient care is collaborative (e.g., physicians and nurses) with written care plans, including discharge planning, that are relevant to the patient's current condition.	<p>0 Most medical records do not have medication therapy plans.</p> <p>1 Medication therapy plans are written according to the policy and procedure.</p> <p>2 Medication therapy plans are consistent with current treatment guidelines.</p> <p>3 Discharge planning needs are identified in the medication therapy plan.</p>					
Level 3. Patients' needs are reassessed and progress toward goals monitored and documented.	<p>0 Medication therapy plans are not updated based on changing needs.</p> <p>1 Patients' needs are reassessed, and the medication therapy plan is revised according to reassessment results.</p> <p>2 Patients' progress in achieving goals or desired results of treatment, care, or service is monitored and documented.</p> <p>3 A collaborative team meeting (including physicians, nurses, patient/ family, and other care</p>					

Look for	Performance findings	Score				Overall
		0	1	2	3	
	givers) is conducted for patients with complex therapeutic needs.					
Standard #4. Clinical pharmacists work in collaboration with other providers to deliver comprehensive medication management that optimizes patient outcomes by using clinical protocols and treatment guidelines (N/A to community pharmacy).						
Level 1. Treatment guidelines and clinical protocols are adopted for the most common diagnoses/ conditions and procedures to guide clinical practice.	<p>0 A policy and procedure for adopting clinical protocols are not available.</p> <p>1 A policy and procedure for adopting clinical protocols are available.</p> <p>2 Treatment guidelines, protocols, and/or algorithms have been adopted for common diagnoses/ conditions, including at least:</p> <ul style="list-style-type: none"> a. Malaria b. HIV/AIDs c. FP d. Diabetes mellitus e. Hypertension f. Congestive heart failure g. Tuberculosis <p>3 Treatment guidelines/protocols are based on current evidence, referenced, and approved by the pharmacy staff.</p>					
Level 2. Treatment guidelines and protocols are used to manage priority patients and procedures.	<p>0 Treatment guidelines and protocols are not consistently used to guide practice.</p> <p>1 Treatment guidelines and protocols are observed to be readily available to pharmacy staff.</p> <p>2 All relevant staff interviewed are familiar with treatment guidelines and protocols.</p> <p>3 Documentation in most reviewed medical records indicates that</p>					

Look for	Performance findings	Score				Overall
		0	1	2	3	
	treatment guidelines and protocols are implemented.					
Level 3. Compliance by individual health care providers (nurses, physicians or others) is monitored.	<p>0 Compliance with treatment guidelines and/or protocols is not monitored.</p> <p>1 Data on using medication treatment guidelines and/or protocols are collected, aggregated, and analyzed.</p> <p>2 The data are tracked by individual pharmacy staff members.</p> <p>3 The results are included as part of the staff members' performance improvement evaluation.</p>					
Standard #5. Pharmacists are involved with the health care team in managing HIV/AIDS.						
Level 1. Pharmacists are involved with the health care team to test, counsel, and recommend treatment.	<p>0 Pharmacists are not involved with the health care team managing HIV/AIDS.</p> <p>1 An interview with pharmacists shows that they are involved with HIV testing initiatives by recommending testing, providing and/or counseling on tests, and assisting health care providers with test interpretation.</p> <p>2 Pharmacists recommend appropriate treatment or additional testing when necessary, in collaboration with the patient care team.</p> <p>3 Pharmacists contribute to assessing a patient's willingness to initiate ART and document a readiness assessment (e.g., barriers to adherence to therapy).</p>					
Level 2. Pharmacists are involved with the health care team	<p>0 Pharmacists are not involved in HIV prevention.</p> <p>1 Documentation shows that pharmacists play a role in HIV</p>					

Look for	Performance findings	Score				Overall
		0	1	2	3	
in treating complications, preventing HIV, and educating patients on their medication regime.	<p>prevention through both pharmacologic and behavioral interventions.</p> <p>2 Documentation shows that pharmacists play a role in identifying and treating emerging complications.</p> <p>3 During observation, education about medication indication, dose, route, frequency, potential adverse effects, and the importance of adherence occurs at every patient encounter.</p>					
Level 3. Pharmacists provide staff in-service training, monitor adherence to treatment, and assist in providing seamless care transitions.	<p>0 Pharmacists are not involved in in-service training of health care staff.</p> <p>1 Pharmacists practicing in HIV medicine provide in-service training to health care staff and conduct community seminars for patients, caregivers, and the public on HIV, ART, drug interactions, ADR/ADE, and adherence.</p> <p>2 An interview with pharmacists indicates that they monitor refills for availability and timelines and notify the prescriber of any concerns.</p> <p>3 Documentation shows that pharmacists assist other health care providers in providing seamless care transitions (from outpatient care to institutional care, during hospitalization, and at the time of discharge) to prevent medication errors.</p>					
Standard #6. Pharmacists are engaged in managing women's contraceptive care.						
Level 1. Pharmacists help	0 FP protocols and guidelines are not available.					

Look for	Performance findings	Score				Overall
		0	1	2	3	
women develop RLPs.	<ol style="list-style-type: none"> 1 FP protocols and guidelines are readily available to pharmacy staff. 2 Pharmacists are trained to develop RLPs. 3 Pharmacists help couples develop an RLP, including goals patients make about having or not having children, and encourages intentional pregnancy planning.¹⁶ 					
Level 2. Pharmacists conduct a health history and educate patients about services and contraceptive products.	<ol style="list-style-type: none"> 0 A health history is not obtained, and/or the patient's blood pressure is not measured. 1 A health history is obtained, and the patient's blood pressure measured and documented. 2 Documentation shows that pharmacists educate patients about products to ensure appropriate use, assess adherence, address possible drug interactions, and monitor adverse effects. 3 An interview with pharmacy staff indicates that "youth-friendly" services are promoted to foster an atmosphere where adolescents feel comfortable seeking information on reproductive health needs, including pregnancy prevention. 					
Level 3. Pharmacists monitor adherence to treatment and	<ol style="list-style-type: none"> 0 Indicators are not measured to determine the effectiveness of FP. 1 Indicators are measured to determine the effectiveness of FP. 					

¹⁶ ¹⁶ Family Planning National Training Centers. Asking clients about their reproductive life plan. [updated 2015 April] <http://fpntc.org/sites/default/files/resource-libraryfiles/Asking%20Clients%20about%20their%20RLP%20%20Handout.pdf>.

Look for	Performance findings	Score				Overall
		0	1	2	3	
assist in providing seamless care transitions.	<p>2 A team reviews the data and develops plans to make improvements.</p> <p>3 Data shows that the rate of unintended pregnancies is reduced.</p>					
Standard #7. Pharmacists take a lead in promoting and implementing measures to ensure safe medication use.						
Level I. Evidence-based measures for reducing medication errors are adopted (e.g., high-alert medications, look-alike/sound-alike drugs).	<p>0 Policies and procedures for safe medication use are not in place and/or are incomplete.</p> <p>I Policies and procedures that describe management processes for safe medication use are consistent with WHO guidelines, which include at least:</p> <ul style="list-style-type: none"> a. Look-alike sound-alike drugs b. Use of abbreviations c. When making telephone orders d. During transcription of medication orders e. Medication accuracy at transitions of care f. Avoiding IV tubing disconnections g. How medications are verified before administration h. How to manage high-alert medications, including concentrated electrolytes i. Narcotics and psychotropic drugs j. Mode of transportation of temperature of controlled medicines 					

Look for	Performance findings	Score				Overall
		0	1	2	3	
	<p>k. Authorized staff to prescribe and administer medications</p> <p>2 All staff involved in medication management receive in-service training on safe medication use.</p> <p>3 Relevant staff interviewed are aware of policies and procedures (refer to Rwanda GPP 2019).</p>					
<p>Level 2. Strategies for prescribing, dispensing, delivering, storing, administering, and monitoring medications to reduce risks of errors are implemented.</p>	<p>0 Safe medication use policies and procedures are not consistently carried out.</p> <p>1 Observation in the clinical areas demonstrates adherence to safe medication use:</p> <p>a. Avoiding use of abbreviations</p> <p>b. Using a read-back process for telephone orders</p> <p>c. Performing medication reconciliation</p> <p>d. Using the 5 rights</p> <p>e. Managing narcotics according to procedures</p> <p>2 Containers are observed to be appropriate for the medication dispensed and protected from contamination.</p> <p>3 Every prescription dispensed in a pharmacy is reviewed by a pharmacist, who decides what action is necessary.</p>					
<p>Level 3. Monitoring data, which includes medication errors and adverse events, are used to</p>	<p>0 There are no data on medication errors.</p> <p>1 Adverse events and medication errors are identified and reported.</p> <p>2 Data on medication errors and adverse events are collected, aggregated, and analyzed.</p>					

Look for	Performance findings	Score				Overall
		0	1	2	3	
continually improve medication use.	3 Progress is evident toward implementing the DTC's pharmaco-vigilance action plan, which contains interventions for reducing medication errors.					
Standard #8. Pharmacists ensure that all patients are given adequate information about the medications they receive to help them participate in their own health care decisions and encourage adherence to medication regimens.						
Level 1. Policies and procedures describe the importance of patient education and the types of education that are given to patients.	0 There are no policies and procedures on patient medication education. 1 The patient and family education policy and procedure include: a. Assessing patient and family educational needs b. Providing education for patient and family management of medications c. Ways to evaluate the effectiveness of the education 2 The policy and procedure describe using effective educational approaches, e.g., groups, 1:1, use of verbal and written instructions, and return demonstration. 3 Staff interviewed are aware of the policies and procedures.					
Level 2. Individualized patient education is consistently provided and documented regarding medications.	0 There is no evidence that pharmacy staff participate in patient and family education. 1 Pharmacy staff are observed providing patient and family education. 2 Documentation indicates that patients and families participate in medication management educational sessions.					

Look for	Performance findings	Score				Overall
		0	1	2	3	
	3 Medical records show individualized education is consistently provided that includes at least (as needed): <ol style="list-style-type: none"> Safe use of medications Potential interactions between medications and food Nutritional guidance Pain management Home medication self-management 					
Level 3. There is a process to evaluate the degree to which patients understood the education.	0 There is no evidence that patient and family education was effective. 1 Staff members interviewed describe their approaches to evaluating the effectiveness of patient and family education. 2 Most medical records have documentation that the patient and family understood the instructions. 3 The effectiveness of patient and family medication education approaches are evaluated and documented, e.g., adherence rates.					
Standard #9. Care is coordinated among providers and across systems of care as patients transition in and out of various settings (N/A to community pharmacy).						
Level 1. A current policy and procedure are in place that describe a standardized approach to providing information between caregivers that	0 There are no policies and procedures on communication among caregivers. 1 A policy and procedure describe a standardized approach to hand-over communication between staff, change of shift, and between different patient care units during a patient transfer (e.g., situation, background, assessment, recommendation technique).					

Look for	Performance findings	Score				Overall
		0	1	2	3	
supports patient-centered care.	<p>2 Write-down and read-back steps are included in the policy and procedure.</p> <p>3 Staff interviewed indicate that all pharmacists are involved in change-of-shift reporting.</p>					
Level 2. A standardized approach to hand-over communication is used between staff, change of shift, and between different patient care units during a patient transfer.	<p>0 Staff are unaware of the hand-over technique.</p> <p>1 Staff interviewed are knowledgeable about the techniques.</p> <p>2 Pre-prepared hand-over report templates are provided to staff coming in for the next shift, e.g., daily report summary of staff meetings (refer to the reporting template).</p> <p>3 Prepared reports are consistently completed based on the policy and procedure.</p>					
Level 3. There is a process to assess the effectiveness of hand-over communications.	<p>0 There is no process for assessing the effectiveness of hand-over communications.</p> <p>1 Data are collected on the effectiveness of the hand-over process.</p> <p>2 Data are aggregated and analyzed.</p> <p>3 The results are used to improve the hand-over communication process.</p>					
Standard #10. Pharmacy staff correctly prepare and label prescribed medications.						
Level 1. A policy and procedure are in place that guides effective preparation and	<p>0 There is no policy and procedure for preparing and labeling prescribed medications.</p> <p>1 There is a policy and procedure for preparing and labeling prescribed medications.</p>					

Look for	Performance findings	Score				Overall
		0	1	2	3	
labeling of medications.	<p>2 The policy and procedure address the following:</p> <ul style="list-style-type: none"> a. Labeling, which must be checked for name, dose, and route and compared with the medication administration record b. Medication containers are labeled whenever medications are prepared but not immediately administered. c. Clarifying orders or procedures that are unclear d. Planning medication administration to avoid disruption: e. Prepare medications for one patient at a time. f. Follow the 5 rights of medication preparation. g. Check that the medication has not expired. h. If a patient questions or expresses concern about a medication, stop and do not administer. i. Never document that a medication has been given until it has been administered. <p>3 Staff interviewed are aware of how to implement the policy and procedure.</p>					
Level 2. Pharmacy staff effectively carry	<p>0 Some medication products are not clearly labeled.</p> <p>1 All medication products are observed to be clearly labeled,</p>					

Look for	Performance findings	Score				Overall
		0	1	2	3	
out the policies and procedures.	<p>which will remain permanently attached to the containers under all storage conditions.</p> <p>2 Medication administration is documented in accordance with policies and procedures.</p> <p>3 Pharmacy staff are observed following the 5 rights when preparing medications.</p>					
Level 3. Compliance with policies and procedures is monitored, and improvements made as indicated.	<p>0 Indicators to monitor preparation and labeling of medications have not been established.</p> <p>1 Indicators are established to monitor preparing and labeling medications.</p> <p>2 Data are collected, aggregated, and analyzed.</p> <p>3 Documentation shows that actions are taken to improve these processes (PDSA cycle).</p>					
Standard #11. Effective and efficient vaccination and cold chain management						
Level 1. Policies and procedures and qualified staff are present to guide effective vaccination and cold chain management.	<p>0 There are no policies and procedures for cold chain management and/or immunizations.</p> <p>1 There are policies and procedures for cold chain management (refer to Rwanda GPP 2019) and immunizations, including:</p> <ol style="list-style-type: none"> Refrigerator breakdown Loss of electricity supply Defrosting or other disruptions to the cold chain <p>2 Documentation shows that staff procuring, storing, distributing, or transporting thermolabile pharmaceuticals have been trained.</p>					

Look for	Performance findings	Score				Overall
		0	1	2	3	
	3 Documentation shows that staff administering vaccinations are competent.					
Level 2: Immunizations are provided using the right vaccines in the right quantities, in the right conditions, at the right time, in the right place, and at the right supply chain cost.	<p>0 Interviews with staff and observations indicate that the cold chain is not managed effectively.</p> <p>1 Interviews with staff and observations indicate that the cold chain is managed effectively.</p> <ol style="list-style-type: none"> No cold chain interruptions during the past three months Cold chain guaranteed in case of power failure (kerosene fridge with a kerosene stock of at least 5 liters, or a functioning generator) Temperature of the fridge within limits (2-8 °C) checked and recorded twice daily <p>2. A review of documents and observation shows that transportation of products is secure, and the temperature is maintained to specifications using approved transportation, such as refrigerated vehicles and containers.</p> <p>3. Staff interviewed describe that vaccinations are administered according to procedure.</p>					
Level 3: The program is measured, monitored, and evaluated for availability, quality, and cost, and the data is	<p>0 A delivery document is not used and/or is not consistently or correctly documented.</p> <p>1 A delivery document shows evidence that transport requirements have been met including: (refer to Rwanda GPP 2019)</p> <ol style="list-style-type: none"> Product security 					

Look for	Performance findings	Score				Overall
		0	1	2	3	
used to improve services.	<ul style="list-style-type: none"> b. Product has not been tampered with and product containers are not damaged c. Protection from weather d. No risk of contamination <p>2 Cold chain management and immunization indicators are monitored.</p> <p>3 Data is analyzed and used to improve cold chain management and immunization (PDSA cycle).</p>					
Standard #12. The pharmacy maintains a current, complete, and accurate record for each patient.						
Level 1. A policy and procedure guide patient medication record keeping.	<p>0 There is no policy and procedure for medication record keeping.</p> <p>1 A policy and procedure describe expectations for medication record keeping (refer to Rwanda GPP 2019).</p> <p>2 The policy defines:</p> <ul style="list-style-type: none"> a. Who is authorized to make entries in medication record b. How to make corrections in the record c. Legibility d. Dating and timing entries e. Signatures and use of stamps f. Using approved abbreviations <p>3 The policy indicates that any warning or precaution issued by professional institutions or authorized officials regarding medicines or pharmaceutical</p>					

Look for	Performance findings	Score				Overall
		0	1	2	3	
	legislation is recorded and complied with immediately.					
Level 2. Complete and accurate patient medication profiles and medication treatment records are maintained.	<p>0 Individual patient medication records are not kept or are incomplete.</p> <p>1 A patient medication record is kept in the pharmacy that includes:</p> <ul style="list-style-type: none"> a. Full names of the patient b. Address and telephone number of the patient c. Patient's date of birth d. Patient's gender e. Patient's current weight f. Name of the prescriber and date of consultation g. A list of all medicines obtained (prescription and non-prescription) by the patient at the point of supply during the 12-month period immediately preceding the date of dispensing h. Number allocated to each prescription dispensed and the date thereof i. Any known allergies, adverse reactions, and idiosyncrasies the patient has toward pharmaceutical products and technologies j. Family history of the patient, where applicable k. Presence of other factors, e.g., smoking l. Medical history of the patient m. Any other pharmaceutical products and technologies 					

Look for	Performance findings	Score				Overall
		0	1	2	3	
	<p>currently being used by the patient, and any related information indicated by care providers</p> <p>2 Pharmacist records all professional actions that might require confirmation in the future.</p> <p>3 Up-to-date records of prescriptions are kept.</p>					
Level 3. An audit process is used to monitor the effectiveness of patient medication record keeping.	<p>0 Medication record reviews are not performed quarterly.</p> <p>1 Staff interviewed describe the medication record review process, which includes the following:</p> <ul style="list-style-type: none"> a. Review of the completeness (content) and legibility of entries b. A representative sample size c. Representative samples of all disciplines that make entries in the medication record <p>2 A multidisciplinary approach is followed regarding monitoring prescriptions (refer to Rwanda GPP 2019).</p> <p>3 Data are aggregated and analyzed, and actions are taken to make improvements.</p>					
Standard #13. Drug recalls are handled properly and promptly, including alerting the public and safely removing the affected product from the market.						
Level 1: Policies and procedures exist for the intervention and dissemination of	<p>0 Policies and procedures are not written for the effective batch recall of medicines.</p> <p>1 Policies and procedures are written for removing from use any drugs or devices subjected to a recall.</p>					

Look for	Performance findings	Score				Overall
		0	1	2	3	
information on drug recalls.	<p>2 Meeting or training records show that facility staff are informed of the policies and procedures.</p> <p>3 Staff interviewed can describe their role when medicines or medical gases are recalled.</p>					
Level 2: Recalled drugs are removed from use and health care professionals and patients who come to fill prescriptions are informed.	<p>0 The head of pharmacy cannot accurately describe the procedure for informing professionals and patients regarding a recall of medications.</p> <p>1 The head of pharmacy describes the procedure for informing professionals and patients regarding a recall of medications.</p> <p>2 Pharmacists describe how they ensure that patient care is not interrupted or compromised because of drug recalls.</p> <p>3 Recalls of faulty medical gases document the sets, names, types, serial numbers, and locations of each regulator and are held in the pharmacy.</p>					
Level 3: Drug recall measures are documented, and corrective actions taken if the procedure is not followed.	<p>0 Documentation shows that recalled drugs are not identified and disposed of properly.</p> <p>1 Documentation shows that recalled drugs are identified and disposed of properly.</p> <p>2 The efficiency of a recall to appropriately warn customers and remove the defective product is monitored.</p> <p>3 Actions are taken when issues are identified.</p>					

RISK AREA #5. IMPROVEMENT OF QUALITY AND SAFETY

Required documents	Data collection methods
<ol style="list-style-type: none"> 1. Tool to monitor client satisfaction, data, and actions for improvement 2. List of indicators for key clinical outcomes 3. Incident reporting policy and procedure 4. Policies and procedures for recall of pharmaceuticals 5. Policies, procedures, and STGs for rational drug use 6. Policy and procedure for managing complaints and suggestions 7. Policy and procedure for monitoring staff satisfaction 	<ol style="list-style-type: none"> A. Leader interviews B. Staff interviews C. Document review D. Medical record review E. Personnel file review

Levels of Effort	Performance findings	Score				Overall
		0	1	2	3	
Standard #1. A pharmacy QI and safety team uses QI techniques to improve pharmacy services.						
Level 1. A multidisciplinary pharmacy QI team uses QI techniques to identify problems	<ol style="list-style-type: none">1. A pharmacy QI team has not been formed.2. A multidisciplinary team, including doctors, nurses, and other key stakeholders, meet to improve medication management.3. The pharmacy team receives QI in-service training and guidance to apply QI methods.4. The multidisciplinary team is functional, e.g., members attend at least 9 meetings a year.					
Level 2. A pharmacy QI plan is developed and implemented.	<ol style="list-style-type: none">0 There are no meeting minutes that show that the QI plan has been effectively implemented.1 A pharmacy QI and patient safety plan is developed.2 Meeting minutes show that the goals/objectives of the quality plan are being tracked on a quarterly					

Levels of Effort	Performance findings	Score				Overall
		0	1	2	3	
	<p>basis, and indicators are reported and acted upon according to the plan.</p> <p>3 Each quality indicator has a clear definition, formula, data collection method, person responsible for data collection, frequency of data collection, and target.</p>					
Level 3. Data is accurately collected and used to make sound decisions to improve quality and safety.	<p>0 Data is not accurately collected to measure indicators.</p> <p>1 Data is accurately collected to measure indicators.</p> <p>2 Data is presented in appropriate graphs/charts to demonstrate the results.</p> <p>3 An action plan is developed, and the PDSA cycle implemented.</p>					
Standard #2. There is a process to monitor the client satisfaction with pharmacy services.						
Level 1. There is a policy, procedure, and a tool to monitor client satisfaction.	<p>0 There is no policy, procedure, or tool to monitor client satisfaction.</p> <p>1 A policy and procedure for monitoring patient satisfaction has been developed.</p> <p>2 A tool has been developed and tested.</p> <p>3 A sufficient sample size has been obtained for the targeted populations.</p>					
Level 2. Client satisfaction is monitored, and the data analyzed according to the policy and procedure.	<p>0 Leaders do not describe an effective client satisfaction process.</p> <p>1 Leaders describe an effective patient satisfaction survey process.</p> <p>2 Data have been collected accurately (without missing data or mistakes in calculations).</p> <p>3 Data have been aggregated, analyzed, and displayed.</p>					

Levels of Effort	Performance findings	Score				Overall
		0	1	2	3	
Level 3. Trends in patient satisfaction are used to set priorities for improvement or for further evaluation.	0 The data have not been used to make improvements. 1 An action plan has been developed to address priority issues identified. 2 Staff interviewed are aware of patient satisfaction results and the actions being taken. 3 Minutes of meetings show that progress is being tracked.					
Standard #3. Pharmacists monitor the therapeutic outcomes for patients with the most prevalent diagnoses and act to improve them over time (N/A to community pharmacy).						
Level 1. Leadership identifies and defines priority therapeutic indicators.	0 Indicators have not been established for key clinical outcomes. 1 Indicators have been established for key clinical outcomes (including Electronic Integrated Disease Surveillance and Response EIDSR , malaria, and maternal, neonatal, and child death indicators) as established by hospital leadership. 2 Each indicator has a clear definition, formula, data collection method, person responsible for data collection, frequency of data collection, and target. 3 Data are collected accurately and completely for each of the key clinical outcome indicators, including verbal autopsy for maternal and neonatal death.					
Level 2. Outcome data are compared to those of previous time periods.	0 Most data for clinical outcome indicators are not aggregated and analyzed. 1 Clinical outcome data are aggregated and analyzed for each indicator.					

Levels of Effort	Performance findings	Score				Overall
		0	1	2	3	
	<p>2 The data are effectively displayed in graphs and charts.</p> <p>3 The data are compared to established targets and trends over time.</p>					
Level 3. Data are used by the facility staff to make improvements in patient care.	<p>0 An improvement plan has not been developed.</p> <p>1 The data are used to develop an improvement plan.</p> <p>2 The improvement plan is implemented.</p> <p>3 The data and results are presented to the QI and DTCs.</p>					
Standard #4. There is a system for reporting and analyzing incidents that is fair, non-punitive, and based on a clear definition of what is to be reported.						
Level 1. There is a policy and procedure for the reporting process that clearly defines the incidents to be reported.	<p>0 There is no incident reporting policy and procedure.</p> <p>1 An incident reporting policy and procedure identifies the events to be reported and how individuals affected are informed of the situation.</p> <p>2 Sentinel events are defined, and a process is in place for analyzing each sentinel event identified (root cause analysis).</p> <p>3 Staff interviewed are aware of how to implement the policy and procedure.</p>					
Level 2. The reporting process is implemented, and data are collected for incidents.	<p>0 Few or no incidents have been reported.</p> <p>1 Incident reports are submitted for all events that relate to medication management.</p> <p>2 The incidents are categorized into types and severity of events, persons involved, and locations.</p>					

Levels of Effort	Performance findings	Score				Overall
		0	1	2	3	
	3 The report indicates that individuals affected by the incident are informed of the situation.					
Level 3. The data are analyzed and used to educate staff and improve processes to avoid similar incidents from occurring.	0 The data are not aggregated, analyzed, and displayed. 1 Data related to incident reporting are aggregated, analyzed, and displayed. 2 Plans are made to reduce the potential for these events recurring. 3 The results of the interventions are tracked, and actions taken accordingly (PDSA cycle).					
Standard #5. Rational drug use						
Level 1: Policies, procedures, and STGs are available to guide practitioners and prescribers to make decisions about appropriate treatments for specific clinical conditions.	0 Policies and procedures for rational drug use are not developed. 1 Policies, procedures, essential drug lists, and STGs for rational drug use are developed. 2 An antibiotic policy is developed. 3 Prescribing physicians are sensitized to the policies and procedures.					
Level 2: All practitioners or prescribers comply with the developed policies, procedures, and STGs.	0 Meeting minutes show that the DTC is not actively involved in guiding and monitoring drug use. 1 Meeting minutes show that the DTC is actively involved in guiding and monitoring drug use. 2 All pharmacy staff interviewed understand the policy and procedure for rational drug use. 3 Documentation shows that pharmacy staff are involved with educating the public about rational use of					

Levels of Effort	Performance findings	Score				Overall
		0	1	2	3	
	medications, e.g., proper use of antibiotics.					
Level 3: The facility has a system for monitoring rational use of drugs, including compliance with STGs.	<p>0 The pharmacy does not monitor compliance with STGs.</p> <p>1 Data is collected for selected priority STGs to monitor for compliance.</p> <p>2 Data is aggregated and analyzed.</p> <p>3 The results of the monitoring are reviewed and acted upon to make improvements.</p>					
Standard #6. Complaint and suggestion management process						
Level 1. There is a policy or procedure for receiving complaints and suggestions.	<p>0 There is no policy and procedure regarding oral or written complaints and suggestions, or the process is not systematic at the pharmacy.</p> <p>1 There is a policy and procedure regarding oral or written complaints and suggestions.</p> <p>2 Pharmacy staff describe a process for reviewing complaints.</p> <p>3 The process is easily accessible to the public, e.g., pencils and paper available.</p>					
Level 2. An effective process for reviewing and resolving complaints is operational. Feedback is given to individuals regarding how the issue was resolved, when possible.	<p>0 Pharmacy staff cannot describe how they advise patients regarding the complaint process.</p> <p>1 Staff members describe steps that they take to resolve patient complaints.</p> <p>2 Pharmacy staff can advise the patient and the family about the complaint management process.</p> <p>3 Staff members refer patients/families according to the policy when they are unable to resolve patient/family issues.</p>					

Levels of Effort	Performance findings	Score				Overall
		0	1	2	3	
Level 3. Complaints and suggestions are categorized by type and tracked. This information is used to prioritize patient issues and implement solutions. The results of the solutions are monitored for effectiveness	0 Complaint data are not categorized and trended. 1 Data is aggregated, analyzed, and trends identified. 2 Minutes show that complaints and suggestions are systematically reviewed at pharmacy weekly meetings. 3 Action plans are developed and implemented to correct recurring problems.					
Standard #7. Staff satisfaction monitored						
Level 1. There is a policy, procedure, and tool to monitor staff satisfaction.	0 There is no policy, procedure, or tool to monitor staff satisfaction. 1 A policy and procedure for monitoring staff satisfaction has been developed. 2 A tool has been developed and tested. 3 A sufficient sample size has been obtained (at least 80% of all staff).					
Level 2. Staff satisfaction is monitored according to the policy and procedure, and the data analyzed and reported to staff. An improvement plan is developed and implemented.	0 Patient satisfaction data have not been collected. 1 An annual pharmacy staff satisfaction survey is conducted. 2 Data have been collected accurately. 3 Data have been aggregated, analyzed, and displayed accordingly.					

Levels of Effort	Performance findings	Score				Overall
		0	1	2	3	
Level 3: Trends in staff satisfaction are used to set priorities for improvement or for further evaluation.	<p>0 The results of the staff satisfaction survey have not been shared with the staff.</p> <p>1 Staff meeting minutes show that the outcomes of the survey are made known to staff.</p> <p>2 An action plan has been developed to address priority issues identified.</p> <p>3 The action plan has been implemented, progress is being tracked and the impact is measured.</p>					