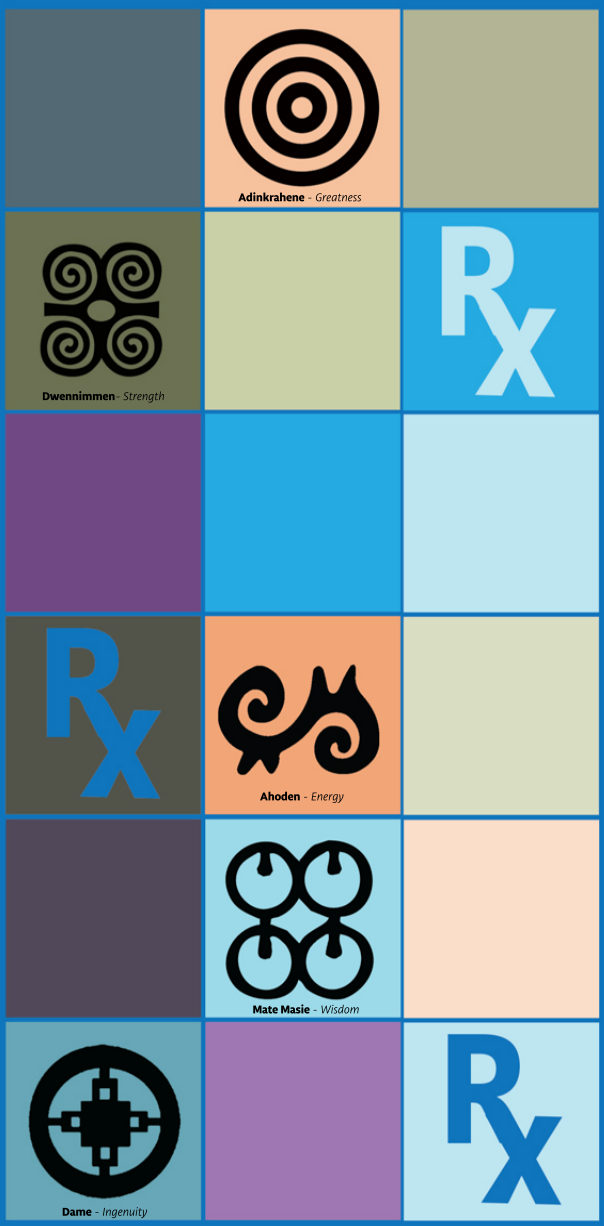

Republic of Ghana

Ministry of Health

Standards and Practice Guidelines for Pharmaceutical Services

2nd Edition, 2018

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PREFACE

The need for harmonisation and standardisation of pharmaceutical activities for efficiency and improved quality of service is important for service provision. Pharmaceutical care is a patient-centred outcome oriented pharmacy practice. This requires collaboration among the pharmacist, the patient and other health care providers to ensure that pharmacotherapy is safe and effective.

The purpose of this document is to define standards, roles, activities, responsibilities and procedures in providing pharmaceutical services in all health institutions in Ghana. This edition is a product of the incorporation of the guidelines and standard operating procedures (which was captured as a separate document in the previous edition) and job descriptions for the various grades of pharmacists on various aspects of pharmaceutical services. It is also intended to enhance uniformity in pharmacy practice and improve the quality of health care in the country.

Appropriate manuals will be developed from these guidelines and operating procedures to further facilitate pharmaceutical service delivery. It is hoped that the content of this document when appropriately used will assist pharmacists and support staff to provide quality services.

This guide has been reviewed as part of the efforts to strengthen the role of pharmacists in the achievement of the health sector's strategic objectives of improving access, efficiency and quality of health services in Ghana. The first edition of this document was written in 2002 and has been used by pharmacists and other staff working in public health pharmacies. It was necessary to review the document with the changing trends in pharmacy practice.

The review of the document was through a wide consultative process including workshops and meetings involving stakeholders from the health sector.

It is expected that this guide will be used practically on the job to assist users in the following areas:

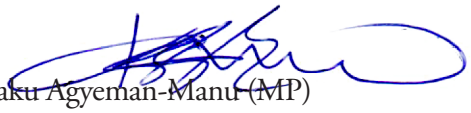
- Improve quality standards for pharmaceutical service delivery and serve as a means for monitoring and evaluation of those standards
- Provide basis for job assignment, assessment and evaluation
- Serve as a guide that outlines the steps necessary for the provision of quality pharmaceutical services
- Serve as a tool for orientation and training of interns and other trainees

This document must be seen as a dynamic document, which captures the minimum requirements for pharmaceutical service delivery.

It is expected that pharmacists in the public and private sectors will find this guide useful in their daily work.

Any other relevant emerging information that will go to improve the quality and relevance of this guide should be communicated to the office of the Director of Pharmaceutical Services, Ministry of Health.

We hope all users shall find the guide useful.



Kwaku Agyeman-Manu (MP)

Hon. Minister of Health

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This document was prepared in collaboration with the persons and institutions listed below whose contributions are hereby acknowledged.

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About this book

The document consists of thirteen chapters. It begins with a chapter on ethics, professional competency and quality assurance practice standards to guide the professional activities of the pharmacist. It also points out the need for organisation of structures and processes to ensure optimum outcomes.

The next chapter focuses on the fundamental concepts and skills that is a basic acceptable standard for every pharmacist. The document further describes standard procedures for safe and secure handling of medicines. The concept of clinical pharmacy is introduced in one of the chapters as a discipline that enables the application of pharmaceutical knowledge and skills to help maximise drug therapy. Clear and explicit guidelines and standard operating procedures are provided to encourage the concept of team work.

Subsequent chapters provide operating procedures on small-scale manufacturing, central intravenous additive services, record keeping, research methodology, leadership and governance structures as well as procurement activities. The final chapter provides job description and specification of pharmacy grades.

Each operating procedure is accompanied by job tools to help guide in the performance of tasks in the outlined procedures. Some of the job tools are provided in the appendix; others can be downloaded at

www.ghndp.org/standards

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ABBREVIATIONS

ADR	Adverse Drug Reaction
AIDS	Acquired Immune Deficiency Syndrome
BMR	Batch Manufacturing Record
BNF	British National Formulary
CEO	Chief Executive Officer
CHPS	Community-based Health Planning Services
CIVAS	Centralized Intravenous Additive Services
CMS	Central Medical Stores
CPD	Continuous Professional Development
CSIR	Centre for Scientific and Industrial Research
DANIDA	Danish International Development Agency
DPS	Director of Pharmaceutical Services
DOT	Directly Observed Therapy
DTC	Drugs and Therapeutics Committee
EML	Essential Medicines List
EMR	Electronic Medical Records
EPA	Environmental Protection Agency
FDA	Food and Drugs Authority
GCNet	Ghana Community Network
GCP	Ghana College of Pharmacy
GDP	Good Dispensing Practice
GHS	Ghana Health Service
GMP	Good Manufacturing Practices
GSP	Good Storage Practices
HIV	Human Immuno-deficeiency Virus
ICB	International Competitive Bidding
ICT	Information and Communication Technology
IMC	Interim Management Committee
IP	Investigational Product
KNUST	Kwame Nkrumah University of Science & Technology
KPI	Key Performance Indicator
LMIS	Logistics Management Information System
LPO	Local Purchase Order
MDG	Millennium Development Goals
MFM	Master Formulary and Methods
MHT	Management Health Team
MIS	Management Information System
MMDA	Municipal Metropolitan & District Assemblies

MOH	Ministry of Health
MSQ	Maximum Stock Quantity
NACP	National AIDS Control Programme
NCB	National Competitive Bidding
NDIRC	National Drug Information Resource Centre
NDP	National Drug Policy
NHIS	National Health Insurance Scheme
NMIMR	Noguchi Memorial Institute for Medical Research
OTC	Over-the-Counter
PPM	Planned Preventive Maintenance
PRC	Packing Records Control
QA	Quality Assurance
QC	Quality Control
RIRV	Requisition, Issue and Receipt Voucher
RMS	Regional Medical Stores
ROQ	Re-order Quantity
RIRV	Requisition Issues Receipt Voucher
RUM	Rational Use of Medicines
SDG	Sustainable Development Goals
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
SRA	Stores Receipt Advice
STG	Standard Treatment Guidelines
TB	Tuberculosis
TPN	Total Parenteral Nutrition
UNDP	United Nations Development Programme
USAID	United States Agency for International Development
WAPCP	West African Post-graduate College of Pharmacists
WHO	World Health Organisation
WISN	Workload of Staffing Needs

Chapter 1

Ethics of practice, professional competence and quality assurance

Pharmaceutical services represent a set of professional activities of the pharmacist oriented to securing human and veterinary pharmaceutical products and health care products and to optimising effective, safe and quality pharmacotherapy.

The practice of pharmacy has the primary obligation of rendering pharmaceutical services to the public such that the preparation, compounding, dispensing and storage of medicines and other medical products among others is safeguarded. To meet such obligation, principles of professional conduct for pharmacists are necessary.

The practice of pharmacy requires knowledge, skills and integrity; therefore, the laws of the nation restrict the practice of pharmacy to registered persons with special training and qualification in line with the Health Professions Regulatory Bodies Act, 2013 (Act 857) and Public Health Act, 2012 (Act 851).

1.1. Ethics guiding the practice of pharmacy in Ghana

The ethics of pharmacy practice outlined is extracted from the constitution of the Pharmaceutical Society of Ghana (2016).

In order to protect and maintain the trust and well-being of the public, pharmacists are required to observe the code of ethics throughout their career to ensure high standards of personal and professional conduct and continuing competence relevant to their area of practice.

Article 1:

The pharmacist shall at all times, as a first priority, recognize the rights, health and well-being of the client

Article 2:

The pharmacist shall encourage clients to participate in decisions about their health and shall respect their preferences

Article 3:

The pharmacist purchases, compounds and dispense only medicines of good quality

Article 4:

The appearance of the premises should reflect the professional character of pharmacy, that is to say, the pharmacist keeps his pharmacy and immediate surroundings well sanitized and equipped with reference books, accurate weighing and measuring devices and other apparatus suitable for the proper performance of his professional duties

Article 5:

The pharmacist is a good citizen and upholds and defends the laws of the nation; he keeps himself informed on pharmacy and laws of medicine, and other relevant laws pertaining to sanitation, health and safety. They co-operate with the enforcement authorities. They shall not engage in any activity that will bring the profession into disrepute and shall expose, without fear or favour, illegal or unethical conduct in the profession

Article 6:

The dispensing of medicines or professional services of a pharmacist shall not be advertised directly or indirectly, except that:

a. the terms "Dispensing Chemist"; "Pharmacist"; "Pharmaceutical Chemist"; or "Druggist" may be used simply as personal description on the facia or other appropriate position on a pharmacy, on labels or on business stationery, and in telephone or other directories

b. a discreet announcement in the local press may be made of the opening of a new pharmacy to a new address, or change in opening hours

Article 7:

An announcement may be made as to dispensing services available in a locality in accordance with established laws and conventions

Article 8:

Methods of sales promotion designed to encourage the general public to purchase or obtain more of a medicinal product than they may reasonably require shall not be used. Display of material for the sale to the public of medicinal products or medicinal appliances which is undignified in style shall not be used

Article 9:

Promotion of a medicine must be in accordance with the terms of its registration, and must not be inconsistent with the particulars listed in its package insert

Article 10:

A pharmacist shall not allow others to use his name, qualifications, address or photograph in connection with the distribution of any medicinal product to the public

Article 11:

A pharmacist shall render a reasonably comprehensive pharmaceutical service and care to the public at all times by ensuring that the client receives sufficient information and advice to enable the safe and effective use of medicines

Article 12:

A pharmacist shall not refuse a reasonable request to supply pharmaceutical products or provide services in an emergency

Article 13:

A pharmacist shall not supply to any member of the public any substance, medicinal product or medical appliance, which he knows or has reason to believe is intended to be used in a manner which would be detrimental to health, or whose quality he has reason to doubt

Article 14:

The pharmacist shall willingly make available his expert knowledge of medicines to other health professions

Article 15:

The therapeutic efficacy of prescriptions shall not be discussed with patients or others in such a manner as to impair confidence in the prescriber

Article 16:

A pharmacist who has accepted a prescription for dispensing shall dispense the prescription in accordance with the established national drug policies in force

Article 17:

A pharmacist must respect the confidentiality of information acquired in the course of professional practice relating to a patient and the patient's family. Such information must not be disclosed to anyone without the consent of the patient or appropriate guardian unless the interest of the patient requires such disclosure

Article 18:

A pharmacist may recommend a medical practitioner or medical practice to a member of the public seeking medical services in the best interest of the patient

Article 19:

A pharmacist shall at all times be ready to help other pharmacists in providing an efficient pharmaceutical service

Article 20:

Pharmacists shall avoid unacceptable descriptions which are either inaccurate or inimical to the relationship amongst pharmacists

Article 21:

The pharmacist keeps himself informed regarding professional matters by reading current pharmaceutical, scientific and medical literature, attending seminars and by other means

Article 22:

The pharmacist adheres to fair business practices, meets his obligations promptly and fulfils his agreements and contracts

Article 23:

The pharmacist must boldly display in his establishment his own name and the names of other pharmacists working with him

Article 24:

A pharmacist is encouraged to join organizations which promote the advancement of pharmacy

Article 25:

A pharmacist assuming responsibility for any pharmacy function, whether as an employee, locum, adviser or otherwise, is professionally accountable for all decisions to supply a medicine or provide care

Article 26:

A pharmacist must only accept work where he has the requisite skills and fitness for the tasks to be performed

Article 27:

A pharmacist must ensure that all delegated tasks are assigned to competent persons

Article 28:

Pharmacists must ensure that all relevant SOPs, policies and guidelines relating to pharmacy practice are adhered to

1.2. Professional competency of a pharmacist

Competency is a set of context-bound but transferrable attributes essential for effective performance, which draws on knowledge, skills, attitudes, values and professional judgment to perform in specific situation. Pharmaceutical care therefore requires critical skills, which must be given the necessary recognition and premium to assure the quality of care.

The pharmacist therefore:

1. Takes personal responsibility for learning and developing a foundation for subsequent continuing professional development
2. Communicates in a credible and effective way, orally and in writing
3. Undertakes structured problem-solving
4. Appreciates and has an understanding of main sources of medicines; ways in which medicines are purified, characterized and analysed; their physico-chemical properties; and properties medicines display as biologically active molecules in living systems
5. Has an understanding of the design, manufacture and performance of medicine dosage forms and is able to critically appreciate the inter-relationship between formulation, drug delivery and therapeutic effectiveness
6. Understands the medicine development process, market authorization and pharmacovigilance
7. Has capability of performing pharmaceutical calculations accurately
8. Has capability of preparing extemporaneous products including preparations by aseptic techniques
9. Interprets data for quality, safety and efficacy in health care
10. Interprets and evaluates prescription and other medicines and advice patients and other health care professionals about medicines and their use
11. Is aware of and understands quality assurance systems for pharmaceutical products and services
12. Develops and improves standard operating procedures for assigned duties and responsibilities
13. Is conversant with professional, legal and ethical responsibilities of the pharmacy profession
14. Has capacity to undertake critical appraisal of information in all forms of presentation
15. Has capacity to apply appropriate research approaches and methods to address scientific and practice problems
16. Has knowledge, understanding and skills for promoting good health
17. Understands and can explain concepts of medicines management and pharmaceutical care

1.3. Quality assurance

Quality assurance (QA) comprises all activities including administrative or procedural that are implemented during the course of production of medicinal products or delivery of services to achieve their intended purpose. QA includes all plans, processes, and procedures that are put in place to ensure that pharmaceutical care/services that are available are consistent in quality and safety and in addition, the medicinal products possess proven parameters of quality, efficacy, safety and conform to all requirements as stipulated by regulation. It involves systematic measurement, comparison with a standard, monitoring of processes and a feedback mechanism that confers error prevention at all times. In this context two principles must guide the understanding of QA and these are:

a. "Fit for purpose" - the medication should be suitable for the intended purpose; and
b. "Right first time" – mistakes or errors should be eliminated in all the processes of care delivery

For QA to have its impact, a quality system embracing the organizational structure, roles and responsibilities, processes, procedures and resources for implementing quality management of pharmaceutical care must be mandatorily put in place. The pharmaceutical quality system must therefore be embedded in the overall pharmaceutical management function that determines and implements pharmaceutical services at all levels.

It shall be the responsibility of the director or head of the pharmacy unit to instigate the development of a quality assurance policy document to guide the delivery of quality pharmaceutical care and services. In addition, the director or head of pharmacy shall ensure management's commitment and active involvement in the implementation of the QA policy in all activities, processes and procedures of the pharmacy department.

An experienced and qualified pharmacist, designated as a QA coordinator, shall monitor and ensure adherence to all the critical quality system parameters and provide feedback for continuing quality improvements of service/ care provision.

The Pharmacy Council and Food and Drugs Authority (FDA) by their mandates shall provide statutory leadership, regulatory guidelines, standards and compliance tools to ensure that delivery of pharmaceutical services/ care and mixing, compounding, preparation, storage, supply or use of medicinal products are in accordance with the Health Professions Regulatory Bodies Act, 2013 (Act 857) and Public Health Act, 2012 (Act 851).

Chapter 2

Fundamental Concepts and Skills

This chapter discusses the fundamental concepts, which will equip pharmacists with the knowledge and skills to help them practise confidently and professionally.

2.1 Client-centred health care

Pharmacists are committed to meeting the pharmaceutical care needs of patients in Ghana in order to optimise the benefits of drug therapy and minimise its risks. To meet this commitment, the practice of pharmacy is evolving to embrace the concept of pharmaceutical care.

Pharmaceutical care is defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improves or maintains the patient's quality of life" (Hepler and Strand, 1990)

The patient is the centre of health care as stated in the Public Health Act, 2012 (Act 851) section 167 (6th schedule). The Public Health Act aims at ensuring that health care providers including pharmacists as well as patients/clients and their families understand their rights and responsibilities.

The Act among other things addresses the under listed:

- The right of the individual to an easily accessible, equitable and comprehensive health care of the highest quality within the resources of the country
- Respect for the patient as an individual with right of choice in the decision of his/her health care plans
- Right to protection from discrimination based on culture, ethnicity, language, religion, gender, age and type of illness or disability
- The responsibility of the patient/client for personal and communal health through preventive, promotive and simple creative strategies
- The right to quality basic health care irrespective of his/her geographical location

In all health care activities, the patient's dignity and interest are paramount.

2.2 Professionalism and professional judgement

Pharmacy is practiced with the highest standards of professionalism and professional judgement. They are bound by the Health Professions Regulatory Bodies Act, 2013 (Act 857) and guided by the pharmacy practice code.

Pharmacists are encouraged to conduct themselves in the highest standards of professionalism. This implies that high professional standards must be demonstrated in a set of values, behaviours and relationships; and should be attained in the following areas:

- Excellence and continuous professional development

- Professional appearance and deportment
- Confidence
- Reliability - responds to patients needs promptly and in a professional manner
- Competence - an expert in area of practice
- Empathy
- Legal and ethical behaviour - adhere strictly to the professions code of ethics and any legal requirement
- Accountability - accountable for one's actions at all times
- Good (clear and unambiguous) communication - communicate effectively and share knowledge

It is necessary for the pharmacist to employ the use of accumulated knowledge and experience, as well as critical reasoning, to make an informed professional decision often to solve or ameliorate a problem presented by, or in relation to, a patient; or policies and procedures affecting patients. He/she should take into account the law, ethical considerations, relevant standards and all other relevant factors related to the surrounding circumstances. Furthermore, his/her judgement should resonate with the core values, attitudes and behavioural indicators of professionalism.

2.3 Clinical check/assessment

The role of the pharmacist in patient care has changed over the years. Once more focused on the management and dispensing of medicines (products), pharmacists now are increasingly providing direct care to patients (expanded role of the pharmacist, which is patient focused). They work with other health care professionals and patients to improve medicines and ultimately patient safety.

When supplying medicines to a patient, one of the key skills a pharmacist has to perform is clinical checks and/or assessment of the medicines that are being supplied.

This skill is fundamental to the provision of pharmaceutical care. It aims at identifying and resolving or preventing drug - related problems.

Performing a clinical check involves identifying potential pharmaco-therapeutic problems by evaluating all relevant information such as:

- Patient characteristics e.g. drug allergies, weight, total body surface area, medical history
- Disease state or diagnosis
- Medicines prescribed or treatment summary i.e. total course prescribed, maximum daily dose, medicine interactions, cautions and counselling required
- Biomedical or laboratory results e.g. hepatic and renal function

It is important to note that, clinical checks and assessments go beyond dose accuracy and medicines interaction. It is a multifaceted skill, which often involves interaction with patients and other health care professionals.

To perform clinical checks, the pharmacist draws on knowledge acquired on human physiology as well as medicines and clinical experience together with professional judgement. A proper clinical check and assessment improve medicines safety and effectiveness and contributes vastly to patient safety and public health.

A clinical check is performed using a structured and logical approach. The three core areas that must be assessed are:

1. Patient characteristics
2. Medication regimen
3. Administering and monitoring treatment

2.3.1 Patient characteristics

Patient characteristics that should be assessed include:

- Who the patient is - the pharmacist must establish whether the patient falls into a group where the treatment is contraindicated or a specific caution is required. Patient groups who must be specially cared for include children, pregnant or breastfeeding women, and the elderly. Certain medicines are gender specific such as oral contraceptive medicines for females and benign prostatic hyperplasia medicines for males
- Other disease states the patient has - co-morbidities such as renal and hepatic impairment or cardiac failure can exclude the use of particular treatments or necessitate dose adjustments
- Patient intolerance - some patients are allergic to certain medicines and non-medicines e.g. peanuts or lactose

2.3.2 Medication regimen

In performing clinical checks, the aspects of the prescribed medicines that should be considered are:

- The indication for the medicines - it is important to check whether the medicine is appropriate for the indication and in line with clinical guidelines
- Changes in regular treatment - during treatment, there can be changes in the regular therapy e.g. in the dose or strength or the duration of therapy. The pharmacist must confirm that these changes are intentional
- Dose, strength and frequency - during clinical checks, pharmacists should check that the dose, strength and frequency of prescribed medicines are appropriate for the patient and the disease. For appropriateness, the pharmacist must consider patients age, weight, hepatic and renal function, co-morbidities, concomitant drug therapies and lifestyle pattern
- Dosing of the formulation - the pharmacist must check that for the formulation prescribed, the dose and frequency are appropriate.
- Medicine compatibility and interactions: new and regular therapies should be evaluated for clinically significant interactions, duplications and antagonistic activities
- Monitoring requirements - certain medicines require monitoring and for these, pharmacists should check for the latest test results and determine whether any dose adjustments must be made

2.3.3 Administering and monitoring treatment

Medication related errors can be prevented when medicines are administered appropriately and monitored effectively. Factors relating to administration and monitoring of a medicine should be considered in a clinical check and must include:

- The route of administration - the pharmacist must check to ensure that the prescribed route of administration is appropriate for the patient and whether the preparation is available for the route
- Compatibility - The pharmacist must check compatibility of drugs with food, other drugs, and patient characteristics must be assessed

A pharmacist upon completion of clinical assessment must endorse the prescription with indelible ink to indicate its readiness to be dispensed.

2.3.4 Record keeping

To ensure continuity of care, pharmacists must keep records of all activities undertaken during patient care. All significant clinical checks and interventions must be recorded; including details of discussions and agreed decisions reached with other health care professionals. Such records can be made on the prescriptions, patient medical records or in the interventions record book.

2.4 Taking medication history

Medication histories are useful in preventing prescription errors and in detecting drug-related pathology or changes in clinical signs that may be the result of drug therapy. A good medication history should include all currently and recently prescribed drugs, previous adverse drug reactions, hypersensitivity reactions, any over-the-counter medications, herbal or alternative medicines, and adherence to therapy.

An accurate medication history provides a basis for assessing the appropriateness of a patient's current medicines and directing future treatment choices. Accurate medication history ensures safe and effective therapy.

Sources of information that may be used when taking a medication history include:

- Patient or patient's representative
- Patient's medicines
- Repeat prescriptions
- Referral letters
- The patient's folder
- Health facility discharge summaries or outpatient appointment notes
- Community pharmacy patient medication records
- Other health facility records
- Other health care professionals

2.5 Counselling patients/clients

An important key role of the pharmacist is to be able to counsel patients ensuring that they understand their medicines, the role that their medicines play in maintaining their wellbeing and empower patients to use them safely and effectively. Counselling involves being able to build a rapport with the patient, having good communication skills, empathy, being able to put the patient at ease and confer an understanding and belief that the health of the patient is important to the pharmacist. Involving and engaging the patient in the counselling process will help to ensure that the pharmacist- patient relationship is concordant.

NOTE: Document the process of counselling e.g. the number of patients counselled, areas of counselling, disease conditions etc.

2.6 Documentation of pharmacist's interventions

Pharmacist's intervention is targeted at preventing medication errors thereby improving on the quality of service. A medication error is any preventable event that may lead to or cause inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer.

Medication errors may occur at any time from the medication order to consumption by the patient. It is important to manage medication errors because it helps to strengthen the "no blame" culture in response to adverse health care events, it facilitates organisational learning through the findings of thorough and careful instigations at local level, it provides a framework for practitioners to improve practice and it ensures appropriate actions are taken and applied by managers at all levels for service delivery. (See Appendix 1 and 2 for patient intervention form and medication error reporting form respectively).

2.7 Professional empowerment/development

Professional empowerment is about enabling professionalism. For pharmacists and pharmacy interns, it is about the development of knowledge, skills, experience, confidence and credibility as well as the cultivation of professional values, attitudes and behaviours, which collectively empower the pharmacist with authority and enables professionalism. It is also about creating an enabling environment.

Professional training involves:

- Pharmacy qualification from a recognised institution
- Pre-registration training
- Continuing professional development (CPD)
- Further education

2.8 Research involvement

Pharmacists, regardless of their workplace setting, are becoming increasingly involved in research activities. It is important that pharmacists have a good understanding of the ethical implications and requirements for research and how these impact on their work practices. This applies whether they are leading the research themselves or being asked to participate in research led by others. For both of these types of involvement pharmacists can seek advice from a range of sources e.g. the ethical review committees of various institutions including Ghana Health Service, teaching hospitals, tertiary institutions. [Refer to Chapter 10 on Pharmacy Practice Research].

2.9 Professional regulation and legal requirements

Pharmacy practice is regulated by the Health Professions Regulatory Bodies Act, 2013 (Act 857) and other laws such as the Public Health Act, 2012 (Act 851), the Public Procurement Act, 2003 (Act 663), the Public Procurement (Amendment) Act, 2016 (Act 914), Specialist Health Training and Plant Medicine Act, 2011 (Act 833), Ghana Labour Act, 2003 (Act 651), National Pensions (Amendment) Act, 2014 (Act 883) among others. Pharmacists are therefore required to be conversant with the relevant laws governing the practice.

Chapter 3

Good Dispensing Practice

Preamble

Good dispensing practice ensures that an effective form of the correct medicine is delivered to the right patient. The standards and practice guidelines for pharmaceutical services seek to spell out the operational standards as well as the step-by-step activities that should be carried out by the pharmacist or dispenser to ensure that a client/patient visiting a Pharmacy receives the most appropriate care.

The dispensing person

The pharmacist assesses the prescription or medication request for appropriateness, selects and retrieves the product or device from its storage point and dispenses. To ensure that medicines delivered to patients/clients meet the desired and intended purpose, it is essential that:

- An appropriate form of the right drug is delivered to the right patient/client
- The prescribed dosage and quantity is given
- The drug is appropriately packaged so as to maintain its potency
- Clear instructions (verbal and non-verbal) are provided
- Feedback

The dispensing environment

The dispensing process should be carried out in a client-friendly environment, which ensures:

- Efficient flow of work
- Efficient communication and supervision
- Private and confidential counselling
- The premises, fixtures and equipment should conform to agreed standard specifications

The dispensing process

In dispensing, accuracy is more important than speed. In order to prevent error as well as reduce dispensing time, the following strategies may be adopted:

- Organize patient flow such as establishing systems to receive payment and treatment and issuing medicines
- Issuing numbers linked to the order in which treatment will be dispensed
- To improve safety, pre-package and label commonly used medicines
- Organizing work so that more than one individual involved in the dispensing process for each prescription. This also introduces a system of counter checks

Operational flow diagram

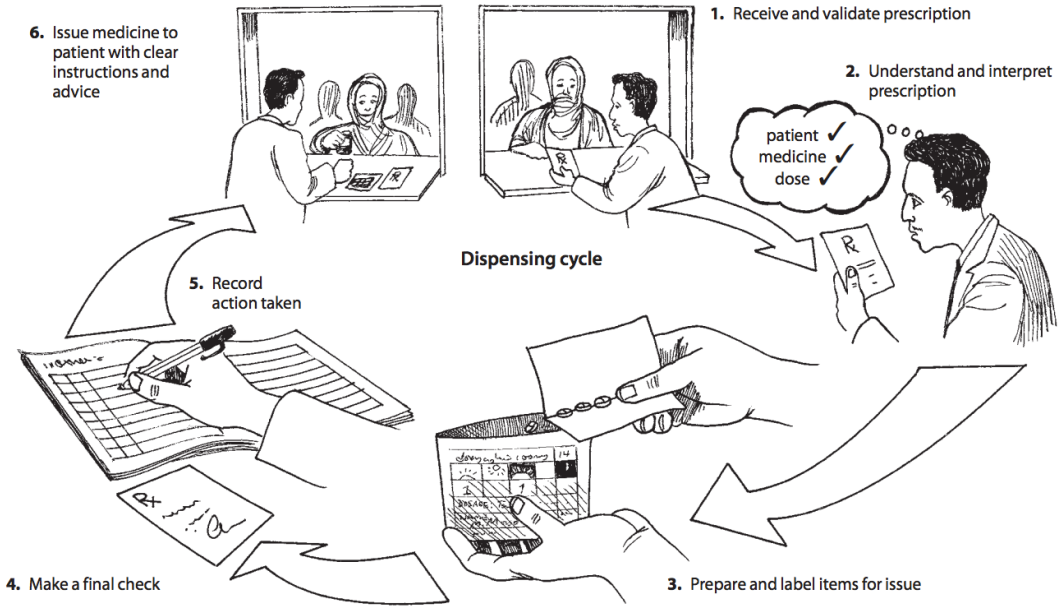

Fig 1: The dispensing cycle

http://apps.who.int/medicinedocs/documents/s19607en/s19607en.pdf

Aspects of operations

3.1 Receipt, validation, evaluation, assessment of prescriptions and/or request for medications and pharmaceutical products

Standard statement

All prescriptions must be received and evaluated by a Pharmacist to ensure their validity and their therapeutic appropriateness.

Operating procedures

Procedure 3.1: SOP for the receipt, validation, evaluation, assessment of prescriptions and/or request for medications and pharmaceutical products
1. Receive client/patient (and the prescription) warmly maintaining confidentiality at all times and throughout the encounter
2. Verify the identity of the client/patient presenting the prescription or medication request and ensure that he/she is the right person a. Ask for the name of the client/patient b. Probe further into his/her particulars (e.g. address, age, etc.) c. Discretely interact with/question the patient during identity verification

Procedure 3.1: SOP for the receipt, validation, evaluation, assessment of prescriptions and/or request for medications and pharmaceutical products

3. Read the entire prescription carefully to determine the prescriber's intent
   - **a.** Determine the patient's disease or condition requiring treatment
   - **b.** Determine the reason the prescription is indicated relative to the diagnosis or the patient's clinical conditions (e.g. an antibacterial for an infection)
   - **c.** Interpret all terminologies including units of measure and Latin abbreviations

4. Determine the medicine availability, fees, paying status of the patient, exemptions, waiting and collection time of the products and inform the client/patient in line with good customer care

5. Validate the prescription or medication request for accuracy and completeness as well as in terms of legal requirements

   Check for the following information on the prescription

   - **a.** Patient information
     - ⊙ Name
     - ⊙ Age
     - ⊙ Home address
     - ⊙ Telephone number
     - ⊙ Patient's hospital identification number
     - ⊙ Diagnosis/agreed NHIS diagnostic code where applicable
     - ⊙ Known allergies
     - ⊙ NHIS number of the patient where possible
     - ⊙ Date the prescription was written
   - **b.** Prescriber information
     - ⊙ Name
     - ⊙ Medical and dental council registration number
     - ⊙ Name and address of health facility
     - ⊙ Telephone number
     - ⊙ Signature
   - **c.** Pharmaceutical product/medication information
     - ⊙ Name of the product (this should be generic [non-proprietary], with the brand [proprietary] name in brackets if desired)
     - ⊙ Product strength
     - ⊙ Dose and frequency
     - ⊙ Route of administration
   - **d.** Any other legal instructions required by
     - ⊙ Food and Drugs Authority
     - ⊙ Pharmacy Council
     - ⊙ Medical and Dental Council
     - ⊙ Nurses and Midwives Council

6. Check for any other directions for the pharmacist

   May be relevant for:

   - **a.** Compounding
   - **b.** Labelling (i.e. information to be put on the prescription label)
   - **c.** Guidance on drug administration including schedule and duration of use
   - **d.** Patient care (e.g. radiological procedures, laboratory tests and diet)
   - **e.** Prescription refill

Procedure 3.1: SOP for the receipt, validation, evaluation, assessment of prescriptions and/or request for medications and pharmaceutical products

7. Perform routine assessment for therapeutic appropriateness.
   Check for:
   a. Dose appropriateness for age and medical condition of the patient
   b. Medication interaction (consider clinically significant drug-drug, drug food interactions, drug biochemistry interactions etc.)
   c. Medication error
   d. Incompatibility (consider pharmacological, physicochemical, chemical incompatibilities etc.)
8. Clarify any inaccurate, incomplete or illegible prescription with your supervisor or the prescriber.
   a. Contact the prescriber if necessary to ascertain any ambiguity on the prescription; if in doubt, ask
   b. Verify and take the necessary steps to correct prescription errors

   Note: Ambiguous and illegible prescriptions are main causes of medication errors and misinterpretation.
9. Determine the quantity to be dispensed (prescribed) and instructions for use
10. Document all activities and interventions made on prescriptions.

Note: The procedure of receipt, evaluation and validation of a prescription shall be performed or supervised by a qualified pharmacist. The pharmacist must be alert in correctly interpreting all prescriptions. The patient or patient's representative, or other health care officer should be informed of the availability of medicines, fees, exemptions, waiting and collection time. This is necessary for good customer care services.

Job tools

1. The pharmacists activity record book
2. The pharmacists intervention form (Appendix 1)
3. Medication error reporting form (Appendix 2)

3.2 Selection, packaging and labelling of medications and pharmaceutical products

Standard statement

Medicines shall be packaged and labelled to ensure that the right information is provided and the product is safe, efficacious and the right quality is maintained for the appropriate use.

Operating procedures

Procedure 3.2: SOP for the selection, packaging and labelling of medications and pharmaceutical products

1. Select the appropriate medication in accordance with the route of administration
   a. Order or recommend or select the medical device or medication administration device (e.g. syringe of appropriate size or vaginal applicator etc.)
   b. Select a bioequivalent multi-source generic pharmaceutical product for a prescribed brand product in accordance with organizational practice regulations/guidelines [Drugs and Therapeutic Committee (DTC) regulations]

   Note: To aid in correct selection, it is good practice to physically separate or clearly highlight containers of medicines of similar brand names or products of different strengths with similar packaging.
2. Communicate generic substitution or therapeutic interchange to the prescriber and the patient

Procedure 3.2: SOP for the selection, packaging and labelling of medications and pharmaceutical products

3. Package products in containers and packaging materials which comply with official monographs or manufacturing specification

Note: Separate and well-equipped pre-packaging areas shall be created.

4. Choose the appropriate label (manual or electronic) and label dispensed medicines to contain the following information:
   - a. The generic name, dosage forms, strength and quantity of the medicine. If necessary, the proprietary name of a drug can be written in brackets after the generic name
   - b. The dosage instructions
   - c. Name of the patient
   - d. Out/In-patient number
   - e. Age of the patient
   - f. Date of supply
   - g. Name and contact address of facility where medication is dispensed
   - h. Residential address
   - i. Direction for correct storage of the medicine
   - j. Relevant cautionary instruction
   - k. Name of dispenser
   - l. Any other legal instruction required by the FDA and the Pharmacy Council
5. Select and affix cautionary labels such as:
   - a. Store in a refrigerator
   - b. Keep away from children

Note: Labelling should be legible, clear and unambiguous in a manner the patient can understand.

6. Document all actions and medicines (including all packaging materials and labels) selected in the appropriate record book (electronic storage device)

Perform Final Checks

A final check of all products, doses, etc. should be done to ensure accuracy in the above procedures prior to the issue of medicines to clients or patients.

- a. Get another person, preferably your supervisor, to cross check the label
- b. Match the prescription with the medicine(s) and label(s)
- c. Verify the content of each package by visual examination
- d. Document all actions and interventions made

Re-packaging of medications:

Select appropriate re-packaging materials for the various dosage forms:

- e. Plastic envelopes for tablets/capsules
- f. Plastic bottles with screw caps for liquid preparations
- g. Use appropriate equipment to repackage products from bulk packs

Avoid contamination and spillage by:

- h. Using tablet counters for solid oral dosage forms.
- i. Using manual or electronic liquid dispensers for liquid dosage forms
- j. Wearing protective clothing during re-packaging and avoid using bare hands

Note: Repacking must be in a clean environment in accordance with GMP/good dispensing practice (GDP) requirements.

Job tools

1. The pharmacists activity record book

2. Packaging materials for medicines dispensing (http://apps.who.int/medicinedocs/documents/s19607en/s19607en.pdf)

3.3 Issuing and delivery of medications and pharmaceutical products with provision of information/counselling

Standard statement

The right medicines together with the relevant information shall be issued to the right patient or client.

Operating procedures

Procedure 3.3: SOP for the issuing and delivery of medication and pharmaceutical products including vaccines and sera with provision of information/counselling

The pharmacist must

1. See every prescription and make judgement as to what action is necessary
2. Confirm the identity of the client
3. Give information, advice and counselling on the medications to the client/patient This includes:
   a. Name of the medication
   b. How to use or administer the medicine (e.g. chewed or swallowed whole with water or any other instruction). Careful explanations/advice should be given on how to use or administer the medicine and should include:
      i. Dose to be taken
      ii. Frequency of administration
      iii. Duration of treatment
      iv. Route of administration and any other relevant medicine administration instructions
      v. Advice on food and use of other medicines
      vi. Possible side-effects as well as what to do when they occur
      vii. When to use the medicine
      viii. When to stop using the medication
      ix. When to seek advice
      x. What to do when you miss a dose
      xi. Proper storage of the medicine etc.

Note: Verbal advice and non-verbal is important, since inadequate interpretation of labelling may pose problems.

4. Provide written information, preferably patient information leaflet/insert from manufacturer
5. Deliver medications to the client/patient with the appropriate information to ensure their proper use
6. Ensure that a patient or carer understands the information and/or advice provided to ensure safe and effective use of the medicine. Use symbols where necessary. The pharmacist must also ensure that the directions on the labels of dispensed products are understood and secure feedback
7. Supply an adherence reminder aid to accompany the prescription container as appropriate
8. Demonstrate medical device use to client/patient
9. Maintain confidentiality and privacy, and accord respect at all times
10. Refer to clinical pharmacist for extended counselling activity (See Chapter 4 on Clinical Pharmacy, Refer to SOP for the provision of Pharmaceutical Care)

In-patient dispensing

Refer to in-patient medicine supply sheet

Administration of Directly Observed Therapies (DOT)

Administer and directly supervise the administration of medicines to the patient on DOT

Provision of Information on Vaccines and Sera

1. Prepare and submit service or billing documents to appropriate authorities
2. Fill claim forms from patients/client
3. Submit returns to RMS, CMS as appropriate
4. Document and keep copies of all returns/issues

Job tools

1. In-patient medicine supply sheet
2. MOH/GHS monthly/quarterly vaccines return form (Appendices 3, 4 & 5)
3. Requisition issue receipt voucher (RIRV)

3.4 Documentation

Standard statement

All transactions and interventions shall be accurately documented.

Operating procedures

Procedure 3.4: SOP for documentation

1. Document any form of intervention on the prescription, in the patient folder as well as in an intervention book created at the pharmacy. Details of the recording should include the following:
   a. The name and department of the prescriber involved
   b. Reasons for intervention
   c. The outcome
   d. Time and date of the intervention
   e. Name and signature of pharmacy staff who did the intervention

   Note: Document all non-available medicines prescribed
2. Keep records of all prescriptions and interventions in the pharmacy for a minimum of two (2) years and archive
3. Resolve and document all errors (prescribing, dispensing, and medicines administration errors). When complex doses are prescribed, calculate the dose for the administering nurse or patient
4. Record the cost of the available/dispensed medication on the prescription form as backup and ideally systemized for compliance and firewalled to prevent interference due to E-fraud
   a. Keep all useful data in the pharmacy dispensing point to enable management collate operational and management information
   b. Collate data at the close of each day and provide forms for the purpose. Details shall include the following:
      i. Quantities of each medicine consumed
      ii. Number of patients/clients served
      iii. Total medicines dispensed for the day, by volume and by value (insured and non-insured)
      iv. Prescription and dispensing errors detected
      v. Dispensing interventions
      vi. Adverse medicine events reported
5. Ensure that every intervention is documented

NOTE THAT AT THE END OF EACH ACTIVITY YOU ARE TO DOCUMENT ALL ACTIONS TAKEN.

Job tools

1. Pharmacist intervention form (Appendix 1)
2. Medication error reporting form (Appendix 2)
3. Pharmacist activity record book
4. Pharmacist dispensary register

3.5 Management of premises, fixtures and equipment

Standard statement

Premises shall be suitably designed to be client-friendly and also ensure efficient flow of work. Fixtures and equipment shall be suitable and adequate for the operations to be performed.

Operating procedures

Procedure 3.5: SOP for the management of premises, fixtures and equipment

1. Premises
   - **a.** The pharmacy dispensary area should allow for:
     - ⊙ Efficient flow of work
     - ⊙ Efficient communication and supervision
     - ⊙ Private and confidential counselling
   - **b.** Working surfaces, cupboards and shelves should be made of smooth, impervious and washable material, and be well maintained at all times
   - **c.** All cupboards for storing narcotic and psychotropic medicines should conform to regulatory requirements
   - **d.** Adequate toilet facilities must be available and must be kept clean and in good order. A vented lobby must be provided for entrance to a toilet. Toilets must not in any case open directly into the pharmacy dispensary
   - **e.** Hand-washing facilities must be provided in the toilet area or the lobby together with a conspicuous notice requesting users to wash their hands. Facilities must include soap and clean towels or hand dryer
   - **f.** Toilet areas must not be used for storage or as a source of water for dispensing
   - **g.** A suitable and adequate means of waste disposal must be available and in use. Waste material should not be allowed to accumulate and must be collected in suitable, covered receptacles for removal to collection points
   - **h.** Care should be taken to segregate any special waste
   - **i.** Pharmacy should have security system that minimizes theft and pilferage
   - **j.** The building housing the pharmacy should be immovable
2. Equipment

   Equipment inventory shall include:
   - **a.** A fitted sink in the dispensary with an adequate supply of potable water
   - **b.** A preparation bench (of a size not less than 1.8m x 1.0m) with an impervious working surface. Use of the bench should be solely for dispensing, compounding and other related processes
   - **c.** Electronic weighing scales, tablet counters, and weights. These must be validated regularly to maintain accuracy
   - **d.** A refrigerator unit capable of storing products within a temperature range of 0-8 degrees Celsius. Efficiency regularly monitored. Storage exclusive for medicine
   - **e.** A range of graduated, stamped glass measures, spatulas, mortar and pestles
   - **f.** A homogeniser
   - **g.** Computers and label printers
   - **h.** Photocopier
   - **i.** Air Conditioner to ensure optimum temperature is maintained
3. Equipment cleaning and maintenance
   - **a.** Equipment must be kept clean and checked for cleanliness before use
   - **b.** There should be a record of equipment and their maintenance schedules
   - **c.** Each pharmacy unit manager should submit a regular (at least half-yearly) planned preventive maintenance report to the head of pharmacy

Job tools

1. Premises inspection checklist
2. Fixtures equipment inspection checklist

Chapter 4

Clinical Pharmacy Practice

Preamble

Clinical pharmacy practice is defined as a health care discipline in which pharmacists provide direct patient care services that optimizes medication therapy; promotes health; wellness and improves quality of life of patients.

The principal objective of the practice is to maximize the outcomes of medicine therapy, minimize possible toxicities and to generally improve the quality of patient care.

Main activities of clinical pharmacy

1. Maximizing clinical effect of medicines using the most effective treatment for each type of patient
2. Minimizing the risk of treatment induced adverse events
3. Monitoring therapy, cost-effectiveness and patient compliance with therapy

Clinical pharmacy services include the following:

- Individualization of therapy (Pharmaceutical care)
- Provision of drug information services to health professionals and the general public (Drug information services)
- Development of clinical competencies in pharmacists and education of other health care professionals (Continuous Professional Development)
- Patient education and counselling on medicines use (Concordance)
- Preventing, detecting and reporting medication error, possible drug interactions, adverse drug reactions and inappropriate medicine use (Pharmacovigilance)
- Operational research activities, clinical trials and clinical audits to ensure the safety and efficacy of all medicines in use (Research and clinical governance)

Operational flow diagram

Fig 2: Components of clincal pharmacy practice

Aspects of Operations

4.1 Individualisation and Optimisation of Therapy

Standard Statement

Subjective and objective parameters shall be used in individualizing and optimising patients' drug therapy.

Operating Procedures

Procedure 4.1: SOP for individualisation and optimisation of therapy

Planning patient selection and targeting

1. Select/screen clients/patients who require particular services
2. Target your services to those patients who need them most through an initial plan
3. Prioritize, plan care, implement plan to those patients who need them most
4. Update your plan accordingly

For specific cases:

1. Verify the diagnosis
2. Identify therapeutic goals
3. Identify client/patient factors and care issues systematically through assessment of:
   - a. Patient characteristics
   - b. Disease factors (presenting complaints, history, past-medical history, family history, diagnosis, differential diagnosis, stage of disease, laboratory findings, etc.)
   - c. Functional and cognitive factors (mobility, balance, hygiene, dexterity, sight, memory, attention, orientation, etc.)
4. Identify medication risk factors systematically through assessment of:
   - a. Response to current and previous medicine treatment (onset, efficacy)
   - b. Medicine disposition factors (e.g. hepatotoxicity, nephrotoxicity, cardiotoxicity, respiratory toxicity etc.)
   - c. Toxicity factors (e.g. allergy, contra-indications, ADRs, interactions)
   - d. Availability of medicine(s) (legal status, formulary status, prescribing policy, source of supply, cost implication)
   - e. Medicine administration (administration protocols, formulation, route of administration etc.)
   - f. Delivery devices
   - g. Complexity of regimen
   - h. Compliance/Adherence
   - i. Duration of therapy
5. Check for pharmaceutical care issues such as drug-drug interactions, duplication of therapy, over-dosage, allergies and sub-standard medicines etc. Pharmacists should collaborate with physicians, nurses and biomedical scientists who will be involved in the provision of the service, for example medications with narrow therapeutic indexes, medications with several drug-drug interactions, drug-food interactions, etc. Pharmacists should liaise with
   - a. Laboratory services and agree on:
     - ⊙ Blood sampling and collection details (techniques, times, volume of blood and type of tube)
     - ⊙ Processing and reporting method for results
     - ⊙ A request form with details on how the results will be reported to the physician
   - b. Nurses for appropriate timing of drug administration
   - c. Physicians for interpretation of serum drug levels

Procedure 4.1: SOP for individualisation and optimisation of therapy

6. Determine and implement patient monitoring plan
   a. Monitor specific parameters e.g. blood drug levels (or their metabolites where necessary). This is important:
      - For drugs with narrow therapeutic index
      - For drugs with established therapeutic plasma concentration range
      - When the pharmacological effect is proportional to serum drug concentration
      - When the correlation between plasma drug concentration and clinical effect is better than that between the drug dose and its effect
      - When monitoring the drug level: enhances the ability of the clinician to maximize the clinical effect and minimize toxicity of the drug
      - When drug toxicity and disease presentations are difficult to distinguish
   b. Monitor patients' response to therapy (using objective and subjective parameters)
      - Efficacy (i.e. patient's recovery)
      - Toxicity (side effect)
      - Biochemistry
      - Haematology
      - Microbiology
      - Others (example, availability and accessibility of medicines)
   c. Assess the response to therapy based on above
7. Liaise with prescriber and alter the therapeutic regimen if necessary then repeat steps 4 to 6

Note: Conditions for patient counselling

- Patients on new medicines should be counselled
- All newly diagnosed non-communicable diseases should be counselled by pharmacists. Identify, document and monitor medicines likely to cause adverse drug events
- Identify and list patient problems that may compromise the efficacy of the medications
- Consult and interact with medical staff and patients to ensure both objective and subjective assessment of the patient's condition
- Encourage 24-hour coverage of patient therapy monitoring

Job tools

1. SOP manual for the provision of pharmaceutical care (individualisation and optimisation of therapy)

4.2 Provision of information on medicinal products and devices, training and education and counselling (drug information services)

Standard statement

Clinical pharmacy practice shall provide the necessary information, training and education to ensure the appropriate use of medicines and devices by health care professionals, clients and patients

Operating procedures

Procedure 4.2: SOP for the provision of information on medicinal products and devices, training and education and counselling

General drug information services

8. Identify patients with a peculiar need for special education and counselling, and address such needs. (See Chapter 3 on good dispensing practices)
9. Educate clients, health care professionals and the public on the safe and effective use of medicines and devices
10. Train health care staff involved in the education and counselling of patients/carers on the use of medicines and devices
11. Organise and provide drug information services to health care professionals and patients/clients
12. Follow a systematic approach in providing drug information services

PART ONE

Responses to drug information requests (Passive)

1. Receive the following demographic information on caller
   - a. Name
   - b. All relevant contact telephone numbers
   - c. Profession
   - d. Origin/Department
   - e. Type/Class of enquiry
2. If necessary, request for background information on the patient or case. This may include:
   - a. Clinical diagnosis
   - b. Name, age, sex, weight and identity number
   - c. Pregnancy status if applicable
   - d. Relevant laboratory values /results
   - e. Co-morbid conditions and/or allergies
   - f. Medications for co-morbid conditions
   - g. Concurrent medications
3. Establish the ultimate question and classify request/query
   - a. Verify the appropriateness of query
   - b. Take note of when answer to query is needed
   - c. Assess query to determine urgency of response
4. Negotiate acceptable response time with the enquirer
5. Conduct a systematic search based on the ultimate question and the classification of the query. Identify and search relevant reference sources.
6. Document the summarized response in the logbook and attach or print out any detailed (typed out) response
   - a. Check the response with the drug information unit supervisor
7. Formulate, package and deliver appropriate answer taking into consideration who the enquirer is
   - a. Take note that the enquirer may require further information
   - b. Prepare properly to address further queries on the subject
8. Record time and date of response provided to Enquirer

PART TWO

Generating information of interest to health professionals (Active)

Preparing Medication use policies and procedures (with support of DTC)

Improving adverse drug reporting systems and medication use evaluation programmes

Creating and distributing newsletters and drug bulletins containing pertinent medication use information

Formulary management

Job tools

1. Drug information data base
2. Drug information log book
3. Primary, secondary and tertiary sources of drug information
4. ICT support with 24 hours internet connectivity
5. Query log form

4.3 Medicines use evaluation

Standard statement

Medicines use evaluation process (including prescription monitoring and evaluation of the cost and cost effectiveness of pharmaceuticals) shall be carried out regularly to ensure that all patients receive rational (safe, affordable and effective) drug therapy.

Operating procedures

Procedure 4.3: SOP for medicines use evaluation (prescription monitoring, evaluation of the cost and cost effectiveness of pharmaceuticals)

Medicines use evaluation

1. The DTC takes the responsibility for medicines use evaluation. The pharmacist plays a leading role in this activity
2. The DTC establishes priorities for evaluation. For example, medicines with
   a. High use
   b. High risk
   c. High cost
   d. Evidence of inappropriate use etc.
3. Develop or adapt measuring tools (e.g. WHO indicators on medicines use evaluation)
4. Obtain approval for the medicines use evaluation process
5. Proceed with data collection and analysis
6. Identify any significant opportunity for improvement of services and recommend interventions
7. Obtain approval for corrective action and review periodically

Prescription monitoring

1. Find out more about patients from nursing, medical and pharmacy notes/records
2. Provide appropriate advice based on prescription monitoring (inpatient and outpatient)
3. Check that:
   a. The medication prescribed is appropriate to the patient's diagnosis
   b. The dosage form, dose, route, frequency and timing are appropriate
   c. The prescription is complete, unambiguous and legible
   d. A new prescription is written when current treatment is altered
   e. The duration of treatment is appropriate
   f. The treatment is not duplicated by pharmacologically similar medicines
   g. There are no incompatibilities
   h. Medicine-medicine and medicine–food interactions are considered
   i. Allergy, hypersensitivity and tolerance are considered
   j. The medication is administered as prescribed
   k. The prescription adheres to the Essential Medicines List (EML), Standard Treatment Guidelines (STG) or hospital protocols

Procedure 4.3: SOP for medicines use evaluation (prescription monitoring, evaluation of the cost and cost effectiveness of pharmaceuticals)

4. Use a checklist to determine for each medicine prescribed:
   - a. If the prescription is legal and valid
   - b. What it is used for generally
   - c. What it is used for in this client/patient
   - d. What the usual dose is
   - e. If the dose is appropriate
   - f. If the client's/patient's age affects the dose or choice of medicine
   - g. If the client/patient is allergic to the medicine(s)
   - h. If the medicine(s) interact with any other medicines prescribed for this client/patient
   - i. If the medicine(s) cause side effects for which other medicines may have been prescribed
   - j. How the medicine(s) should be administered e.g. what volume of diluents and over which period for intravenous therapy
   - k. The route of administration
   - l. The duration of therapy
   - m. If there are any additional instructions which should be added
5. Check if the medicine being administered is in accordance with the prescription
6. Consult appropriate reference material e.g. STG, EML, British National Formulary (BNF), data Sheet

Evaluating the cost and cost-effectiveness of pharmaceuticals

1. Define and understand the different cost analysis methods relevant to choosing medicines for the health facility's formulary list
2. Understand how to read and assess journal articles concerning an economic study

Job tools

1. Prescription monitoring check list
2. Guide to drug utilization studies (http://apps.who.int/medicinedocs/en/d/Js21868en/)

4.4 Preventing, detecting, and reporting adverse drug reactions (pharmacovigilance)

Standard statement

Patients shall be continuously monitored for drug-induced morbidity and mortality.

Operating procedures

Procedure 4.4: SOP for preventing, detecting and reporting adverse medicines reactions (pharmacovigilance)

1. Prescriptions and other relevant patient data shall be monitored to identify problems or opportunities for intervention necessary for optimising treatment. The following shall be ensured:
   - a. Medicine administration charts shall be monitored
   - b. The medication prescribed is appropriate to the patient's diagnosis
   - c. A new prescription is written when current treatment is altered
   - d. Pharmacologically-similar drugs do not duplicate treatment
   - e. There are no incompatibilities
   - f. Drug-drug and food-drug interactions are considered

Procedure 4.4: SOP for preventing, detecting and reporting adverse medicines reactions (pharmacovigilance)

- **g.** Allergy, hypersensitivity and intolerance are considered
- **h.** The medication is administered as prescribed
- **i.** All processes, interventions and outcomes must be documented

2. Take the Patient's medication history as follows:

- **a.** Obtain consent from person providing the information
- **b.** Consider the patient and /or the carers as the primary source of information
- **c.** Obtain additional information from health care professionals, medical and nursing notes
- **d.** Document all details of previous and current medications. The details required include:
  - ⊙ Drug name
  - ⊙ Indication
  - ⊙ Formulation
  - ⊙ Strength
  - ⊙ Dosage regimen
  - ⊙ Duration of treatment
  - ⊙ Supplier or source
  - ⊙ Prescriber
- **e.** Evaluate patient's perceptions of their disease and therapy, compliance with previously prescribed regimens, drug therapy failures, adverse drug reactions (including drug allergies and hypersensitivities) and current medical problems
- **f.** Assess current and future treatment options in relation to previous medicine use and make appropriate recommendations
- **g.** Document interventions and recommendations. It may include a written report in the patient's medical notes. The information should be recorded in a clear and concise format, signed and dated by the pharmacist who took the medication history and should include recommendations
- **h.** Standard intervention forms to capture pharmaceutical care issues in pharmacies and wards (See Appendix 1)

3. Monitor and report adverse drug reactions

- **a.** Identify those drugs known to produce predictable dose-related adverse effects. Take steps to ensure their appropriate use, and avoid their use if an equally effective and safer alternative is available
- **b.** Identify those patients who will require close monitoring as a result of compromised ability to take or use medicines
- **c.** Check that patients are not exposed to risk through unnecessary drug use, disregard for stated warnings, special precautions or contra-indications, or through drug interactions with prescribed medicines, over the-counter medicines, food or drink
- **d.** Identify those patients with a history of intolerance or hypersensitivity to a particular drug or class of drugs and avoid the use of that drug (or class of drugs) if possible
- **e.** Ensure that patients receive cautionary and advisory labels counselling on the correct use, storage and disposal of their medicines
- **f.** Educate pharmacy staff and other health care staff on the prevention, detection and reporting adverse drug reactions
- **g.** Monitor patients on newer drugs for any adverse reactions or any unexpected events
- **h.** Monitor patients for delayed drug effects with both established and newer drugs

JOB TOOLS

1. Patient medication profile forms (Refer SOP manual for provision of pharmaceutical care)
2. Adverse drug reaction (ADR) forms (http://www.fdaghana.gov.gh)
3. Pharmacist intervention report form (Appendix 1)

4.5 Participation in operational research and clinical trials

Refer to Chapter 10 on Pharmacy Practice Research

4.6 Medication history taking

Standard statement

Patient medication history should be assessed by a pharmacist as a baseline requirement for targeted patients or carer

Operating procedures

Procedure 4.6: SOP for medication history taking
1. Consider the following important areas during the process of medication history taking: a. Determine whether the client/patient actually takes all the medicines prescribed b. Determine whether the doses/frequencies are correct c. Determine whether the correct formulation has been used d. Determine how compliant/adherent the client/patient is e. Determine whether the client/patient uses any over-the-counter (OTC) medicines (e.g. antacids) or herbal medicines f. Obtain an in-depth medication history. Patients who may benefit from an in-depth medication history include the following: ⊙ Those with an extensive range of allergies ⊙ Those with conditions for which there is a wide range of medication available, which may have been tried in the past ⊙ Those with multiple medical problems, which may interact with each other ⊙ Those with problems, which may be affected by OTC medicines
2. Extract information from the case notes before going to see the client/patient
3. Ask for client's/patient's own medicines
4. Interview close relatives for additional information
5. Organize the data to relate the medicines to medical problems, the responses, efficacy and toxicity
6. Check to see if this serves the purpose of optimizing current and future medicine therapy for the Client/Patient

Job tools

1. Patient medicine history form (Refer to SOP manual for pharmaceutical care)

4.7 Data management on medicines and other health technologies

Refer to Chapter 7 for more information

4.8 Prioritising patient care

Standard statement

Patients with newly diagnosed non-communicable chronic diseases, problem drugs, special needs, the elderly, critical conditions should be targeted.

Operating procedures

Procedure 4.8: SOP for prioritising patient care
1. Base prioritization on assessment of the needs of different client/patient groups
2. Conduct prioritization in accordance with selected disease state, medication therapy, and the elderly clients/patients on poly-pharmacy prescriptions
3. Do targeting as a process of selecting client/patient groups to receive particular pharmacy services
4. Conduct screening by quickly assessing individual clients/patients within a targeted group
5. Identify those clients/patients who do require the Pharmacist's immediate attention
6. Document the outcomes of the screening process
7. Formulate a pharmaceutical care plan

Job tools

1. Patient medication profile forms (Refer to SOP manual for pharmaceutical care)
2. Pharmaceutical care plan checklist (Refer to SOP manual for pharmaceutical care)

Chapter 5

Local Small-Scale Manufacturing

Preamble

Good manufacturing practice (GMP) plays a key role in ensuring that the products of the establishment meet the laid down standards at all times and that all steps necessary to achieve and maintain such standards are rigorously monitored.

When products are manufactured or pre-packed in our health institutions, the standards for these processes should conform to the requisite good manufacturing practices to assure safe, quality and efficacious products.

Products manufactured for local consumption (small-scale manufacturing) should have an acceptable range and depth of pre-manufacturing, in-process and post-manufacturing testing procedures. Indeed, standard licensing and inspection processes need to be in place to ensure the required confidence in the products. In view of the above, there may be the need for the re-designing of existing structures to accommodate small-scale manufacturing in public and private settings. In manufacturing and pre-packing, arrangements should be made to meet requirements for GMP, which should include:

- Premises
- Equipment
- Personnel
- Raw and packaging materials
- Quality control measures
- Documentation
- Storage
- Waste disposal
- Monitoring (clinical usage and feedback)

The manufacturing premise should have the following:

- Adequate space
- Clean and dust-free environment
- Easy to clean walls, floors and working surfaces that are free from cracks
- Supply of clean air
- Easily accessible and well located changing rooms and washroom facilities
- Separate manufacturing premises and separate dispensing areas

- Separate locations for different operations (e.g. aseptic rooms for clean manufacturing)
- Fire-fighting equipment and a fire exit.
- Adequate lighting
- Well-labelled sections
- Good drainage systems

The establishment and maintenance of a satisfactory system of quality assurance and the correct manufacture and control of pharmaceutical products and active ingredients is dependent on the calibre of personnel. For this reason, there must be adequately qualified personnel to carry out all the tasks for which the manufacturer is responsible.

At all levels of pharmaceutical care delivery, capacity must be built for preparations of patient-specific extemporaneous products.

Packaging, labelling and storage of finished pharmaceutical products are important facets of quality assurance. Adequate specifications for containers, proper packaging and effective storage are indispensable to prevent or diminish the loss of quality caused by handling or movement in the distribution chain. It is important to ensure that the procedures for the procurement, handling and control of primary and printed packaging materials should be the same for t raw materials.

A complete list of all the packaging materials is required for a standard batch size, including quantities, sizes and types with the code or reference number relating to the specifications for each packaging material. The packaging control procedures for dosage forms should be as rigorous as manufacturing control procedures.

Packaging records control (PRC) starts with the receipt of packaging materials from the vendor/stores as with the receipt of raw materials.

In spite of all the precautions taken, occasional slips may occur, hence the need for recall of finished products.

Apart from the control of the production processes, it is also important that waste products are well disposed of and the environment in which medicines are produced is such that it does not in itself create an avenue for contamination of the product. Potential sources of contamination should be controlled through an integrated comprehensive programme of sanitation and hygiene.

Operational flow diagram

Fig 3: Operational requirements for GMP

Aspects of Operations

5.1 Premises

Standard statement

Premises must be adapted to suit the operation being carried out. It should be laid out in such a way as to allow production to take place in areas connected in a logical order, corresponding to the sequence of the operations and to the highest level of sanitation.

Operating procedures

Procedure 5.1: SOP for manufacturing premises

Physical structure

1. Locate, design, construct and maintain structure to suit the operation being carried out
2. Minimize the risk of errors and permit effective cleaning through appropriate design and layout
3. Clean premises carefully and regularly
4. Carry out planned preventive maintenance (PPM)
5. Equip premises with netting, burglar proofing etc. to guarantee maximum protection against the entry of insects and other animals

Storage areas

1. Install dust extractors at areas meant for manufacturing, weighing and storage
2. Have adequate storage space to allow for orderly storage of the various categories of materials and products such as:
   a. Starting raw materials
   b. Packaging materials
   c. Intermediate products
   d. Bulk and finished products
   e. Products in quarantine and on release
   f. Rejected, returned and recalled products
3. Design or adapt storage areas to ensure good storage conditions
   a. Keep storage areas clean, dry and within acceptable temperature limits
   b. Monitor special storage conditions such as temperature and humidity where required
   c. Check that receiving and dispatch bays protect materials and products from the weather
   d. Design and equip reception areas to allow containers of incoming materials to be cleaned before storage
   e. Restrict access to all areas reserved for the quarantine of materials and products
   f. Separate sampling area for starting raw materials
   g. Segregate the storage of rejected, recalled and returned materials or products
   h. Store all highly active materials, narcotics, dangerous medicines and substances presenting special risks of abuse, fire or explosion in secure areas
   i. Store in secure places, printed materials considered critical for the labelling of pharmaceutical products

Weighing areas

Carry out the weighing of materials in separate areas specially designed for that purpose. Install dust extractors at areas meant for manufacturing, weighing and storage

Procedure 5.1: SOP for manufacturing premises

Manufacturing areas

1. Adequately space, design, equip and maintain small scale manufacturing areas to a standard approved by the Foods and Drugs Authority (FDA)
2. Thoroughly clean manufacturing areas, after each production to prevent cross contamination between products
3. Install dust extractors at areas meant for manufacturing, weighing and storage
4. Use white tiles for the walls for easy cleaning and identification of particles and cracks as well as for preventing microbial growth on the surface
5. For the floors, use materials that can be easily cleaned and which will prevent accidental slipping
6. Provide adequate lighting, effective ventilation with air-control facilities to ensure temperature and humidity control
7. Provide changing rooms and toilet facilities that are easily accessible to the workers, but not too close to manufacturing area(s)
8. Place fire-fighting equipment (e.g. bucket of sand, fire extinguishers) within easy reach and at vantage points. Educate workers on how to use and maintain them
9. Install smoke detectors for early warning signals
10. Provide two or more fire exit points and educate staff on fire escape drills

Aseptic areas

1. Designate the following areas for aseptic activities:
   a. Raw materials store
   b. Weighing and measuring rooms
   c. Preparation and packaging/filling areas
   d. Quarantine store/area
   e. Area for washing and cleaning of bottles
   f. Changing room for staff
2. Check that the environment is free from dust and microbial contamination
3. Test the environment for microbial count every week
4. Provide a system to ensure an outward flow of air

Quality control areas

1. Separate quality control (QC) Laboratories from production areas to prevent cross contamination
2. Separate areas where microbiological and chemical tests are carried out
3. Design QC laboratories to suit the operations to be carried out in them
4. Provide adequate storage space for samples, reference standards and records
5. Provide fume chambers
6. Provide a separate instrument area to protect instruments against electrical interference, vibration and contact with excessive moisture

Job tools

1. Basic equipment needed for local small-scale manufacturing (Appendix 6)

5.2 Equipment

Standard statement

The equipment design should be suitable for the manufacturing process. There should be a system of planned preventive maintenance (PPM) including a system of inspecting and repairing all equipment on a regular basis. This must be documented.

Operating procedures

Procedure 5.2: SOP for manufacturing equipment
1. Ensure the availability of basic equipment, accessories and spare parts (Refer to Appendix 6)
2. Locate, design, construct and maintain equipment to suit the operation to be carried out
3. Select and install equipment that would minimize the risk of errors. Select and install production equipment that can be easily and thoroughly cleaned on a scheduled basis to avoid cross contamination
4. Check that equipment is protected from the build-up of dust, dirt and anything that would adversely affect the quality of products
5. Label fixed pipe works and devices clearly to indicate the contents and where applicable, the direction of flow
6. Pay special attention to the provision of non-interchangeable connections or adopters for dangerous gases and liquids
7. Calibrate and service equipment and instruments regularly. Institute a system of planned preventive maintenance
8. Keep records of such maintenance and calibrations
9. All specialised equipment should have written instructions on their use nearby for reference purposes
10. Make available balances and other measuring equipment of an appropriate range and specifications for production and control operation
11. The types of equipment used should be appropriate for the prevailing temperature, humidity and voltage
12. Check water daily for pH, particulate matter and cleanliness
13. Arrange equipment and cabinets appropriately to prevent unnecessary obstructions
14. Use suitable control-laboratory equipment and instruments for the testing procedures undertaken
15. Choose carefully and use appropriate washing and cleaning equipment to avoid any contamination
16. Remove any defective equipment from the production and quality control areas
17. Clearly label all defective equipment as such
18. Cleaning of equipment should be carried out by qualified personnel
19. A supervisor must carry out inspection and certification of cleaned equipment
20. Use protective clothing (white overall, hair gear, facial mask, boots, gloves and goggles) where volatile substances are in use
21. Properly document all processes and procedures done on equipment

Job tools

1. The basic equipment needed for local small-scale manufacturing (Appendix 6)
2. Log books and manuals for planned preventative maintenance

5.3 Personnel

Standard statement

Every member of the production team must be qualified and duly trained in the principles of the current codes of good manufacturing practice (GMP). Training on the job should be provided at a local manufacturing plant for a specified duration for all pharmacists.

Operating procedures

Procedure 5.3: SOP for personnel

Organizational structure

1. Make sure individual responsibilities are clearly understood by the personnel concerned and recorded as job descriptions (See Appendix 7)
2. Key personnel include the heads of production, quality assurance (QA) and QC
3. The heads of production and QC are independent of each other
4. Key personnel responsible for supervising the manufacture and quality control of pharmaceutical products should possess the requisite qualification and practical experience required
5. Make all personnel aware of the principles of GMP that affect them directly
6. All personnel must receive orientation, continuing technical training and hygiene instructions
7. Adequate numbers of personnel with the requisite qualifications and practical experience should be employed
8. The responsibilities placed on any individual must not be so extensive as to present any risk to quality
9. Draw up an organizational chart comprising all responsible staff and their specific duties recorded in written descriptions
10. There should be no gaps or unexplained overlaps in the responsibilities of personnel concerned with the production process
11. Motivate all personnel to support the establishment and maintenance of high-quality standards
12. Prevent unauthorized persons from entering the production, storage and QC areas

Training

1. Organize training and retraining programmes for all personnel whose duties take them into production and QC laboratories. The target persons should include the technical, maintenance and cleaning personnel
2. Organize basic induction training on theory and GMP and provide appropriate training for duties assigned to newly recruited personnel
3. Periodically conduct assessment of the continuing training programme and its practical effectiveness
4. Validate all training programmes
5. Keep records of all training programmes for all personnel
6. Give specific training to personnel working in areas where highly active, toxic, infectious or sensitive materials are handled
7. Discuss fully, the concept of QA and all other measures capable of improving its understanding and implementation, during training sessions

Personal hygiene and health of personnel

1. All personnel must undergo health examination prior to employment/attachment and regular checks during employment/attachments
2. Periodic eye examination should be provided to personnel conducting visual inspections of products
3. Ensure that all staff observe high level of personal hygiene

Procedure 5.3: SOP for personnel

4. Instructions for washing of hands should be conspicuously posted together with other precautionary measures to be taken before entering the production areas
5. Any person shown to have an apparent illness or open lesions should not be allowed in the production area
6. Personnel must wear clean, disinfected protective clothes and hair coverings
7. Personnel must not wear jewellery, make-ups or any material that could fall off and contaminate a product
8. Do not permit smoking, eating, drinking and chewing in production and QC areas
9. Do not allow plants, food, drinks and personal medicines to be kept in all areas of production and QC

Job tools

1. Personnel qualified to be part of the local small-scale manufacturing team (Appendix 7)
2. Training materials

5.4 Acquisition of raw and packaging materials

Standard statement

Raw and packaging materials should be adequately safe and be of the right quality and stability.

Operating procedures

Procedure 5.4: SOP for acquisition of raw and packaging materials

Procurement of raw materials

1. The procurement of the starting raw materials must involve the heads of QA, QC and production
2. Purchase materials from pre-qualified suppliers only in accordance with Public Procurement Act, 2003 (Act 663), Public Procurement (Amendment) Act, 2016 (Act 914) and other Acts affecting purchase of pharmaceutical inputs and raw materials or the Ministry of Health (MOH) procurement manual (See Chapter12)
3. Check the containers of each consignment for integrity of package, label, delivery notes and supplier's labels
4. Check all consignments to make sure that they correspond to the order
5. Consider each batch as separate for sampling, testing and release if one delivery of material is made up of different batches
6. Quarantine raw material brought to warehouse/store immediately after receipt until all necessary tests are performed i.e. identity, purity, strength, other specification
7. Use the raw materials only after the QC section has released it
8. Store all materials under the appropriate conditions recommended by the manufacturer
9. Keep records/information of the acquisition of all materials. The batch numbers of the raw material should be put on the batch manufacturing record (BMR)

Manufacturer's label

1. The stock record card must specify the following:
   a. Designated name of the product
   b. Internal code reference
   c. Batch number(s) given by the supplier/vendor on receipt by the manufacturer
   d. Expiration date or maximum period of storage before re-examination

Procedure 5.4: SOP for acquisition of raw and packaging materials

Packaging materials

These include amber/coloured bottles for light sensitivity liquid preparations and glass bottles for products that are incompatible with plastics.

Packaging materials like bottles, caps, inserts, labels and cartons should have specifications, which QC department should ensure are met from batch to batch.

Job tools

1. Procurement manual
2. Manufacture-related records (e.g. batch manufacturing records, stock records cards etc.)

5.5 Quality control measures

Standard statement

The manufacturing operation shall follow well-documented and validated procedures and instructions.

Operating procedures

Procedure 5.5: SOP for quality control procedures and instructions

1. For each production batch, the production manager should copy what is in the master formulary and methods (MFM) and use it to produce the batch manufacturing record
2. Take samples from top, middle and the bottom layer of the batch to get a representative sample
3. Develop, adopt and document procedure for product recall for each unit (See Appendix 8 and procedure 5.11)
4. Quarantine the final product until QC releases it after checking for quality
5. Retain records for manufacturing including distribution, which enable the complete history of a batch to be traced, in a comprehensible and accessible form
6. Establish written instructions for self-inspection to provide a minimum and maximum standard of requirement (World Health Organisation requirement). These may include questionnaire (GMP requirements) covering the following areas:
   a. Calibration of instruments or measuring systems
   b. Validation
   c. Complaints management
   d. Documentation
   e. Equipment
   f. Labels control
   g. Maintenance of building and equipment
   h. Personnel
   i. Premises including personnel facilities
   j. Production and in-process control
   k. Quality control
   l. Recall procedures
   m. Results of previous self-inspection
   n. Sanitation and hygiene
   o. Storage of starting material and finished products

Job tools

1. Generic complaints form for dealing with warnings and defective products (Appendix 8)

2. Master formulary and methods (MFM)
3. Manufacture-related records (including records on product distribution, product batches etc.)
4. Good manufacturing practice (GMP) requirements checklist

5.6 Sampling raw materials

Standard statement

The sampling of raw materials must follow validated procedures and instructions to ensure that quality, stability and safety of the product is maintained and must be documented accordingly

Operating procedures

Procedure 5.6: SOP for sampling raw materials

1. Sample all raw materials procured for manufacturing purposes for quality testing by QC department/unit
2. Enter the following information into the sampling record book:
   a. Name of product
   b. Batch number
   c. Date of expiry
   d. Date of receipt
   e. Supplier's name
   f. Total quantity or weight of consignment
   g. Number of containers received
   h. Date of sampling
3. The QC department should indicate the methods of sampling and sampling plan
4. Sampling instructions must be clear
5. Use and store sterilized equipment separately from others
6. Observe all other necessary precautions to avoid cross contamination of the material
7. Mark containers to be sampled and carefully reseal them after sampling
8. Place on each container a label indicating the following:
   a. Name of the sampled material
   b. Batch number
   c. Identity number of the container from which the sample has been taken
   d. The signature of the person who collected the sample
   e. Date of sampling
   f. Specify the amount(s) by weight/volume of sample(s)
9. Conduct sampling in such a way as to prevent contamination or cross-contamination if it is performed in the storage area

Job tools

1. Sampling instructions manual
2. Sampling record book

5.7 Quality control documentation

Standard statement

Every stage of quality control shall be documented to provide the recorded evidence of conformity with specifications for identity, strength, purity, shelf life and other quality parameters.

Operating procedures

Procedure 5.7: SOP for quality control documentation
1. The warehouse/store manager should raise a "GOODS RECEIVED NOTE" to QC manager
2. Enter name of raw material in sample book.
3. Allocate QC number to material to serve as batch identification number on each consignment of the batch
4. Raise a QC raw material record card and maintain a raw material laboratory book
5. Issue a quarantine label for each container of material
6. Attach in-house label on the same side as supplier's label
7. Test the raw materials to ascertain conformity with specifications for identity, strength, purity, shelf life and other quality parameters before releasing them for use by the production unit

Job tools

1. Sampling record book
2. Quality control raw material record card
3. Raw material laboratory book
4. Quarantine label

5.8 Quality assurance at different stages of production

Standard statement

The concept of quality assurance shall be built into the operations of production with the sole objective of ensuring that finished products are safe and of the right quality required for use.

Operating procedures

Procedure 5.8: SOP for quality assurance at different stages of production
In-process control
1. Test all raw materials procured for manufacturing purpose by both physical and chemical methods to ensure conformity to official standards
Assessment of manufacturer's certificate of analysis
2. Obtain the original certificate of analysis from the supplier/vendor.

Procedure 5.8: SOP for quality assurance at different stages of production

3. Verify if the certificate consists of the following:
   a. Name of the material or product
   b. State dosage forms of materials
   c. Batch number of product or material
   d. References to the relevant specifications and testing procedures
   e. Test results, including observations, analytical data and references to any specifications (limits)
   f. Date(s) of testing
   g. Initials/signature(s) of the person(s) who performed the test
   h. Initial(s)/signature(s) of the person(s) who verified the testing and calculations
   i. Clear statement of release
   j. Signature of designated responsible person and date
4. Check whether materials were dispensed by QC personnel, following a written procedure
5. Verify if the right materials were accurately weighed or measured and the right procedures adhered to
6. Check if each dispensed material and its weight or volume was independently checked by a supervisor and the check recorded

In-house testing of raw materials

1. Check that raw materials are of the right stability, purity, safety and quality
2. Follow all tests instructions given in the relevant written test procedure for each material or product
3. The supervisor should check the results before the material or product is released or rejected
4. The QC manager should see to it that materials whose standards are in the official compendia be tested for conformity with specification for:
   a. Physical attributes
   b. Identity
   c. Purity
   d. Strength
   e. Safety
   f. Quality
5. Verify if the above specifications were checked before full analysis was done on any batch
6. Bulk and mix together all samples from the same consignment thoroughly
7. All the information obtained on the material should be properly documented in the QC report book and validated by the head of the QC department
8. Quarantine all materials till all tests are completed
9. Release raw materials from quarantine and affix to each container **"pass"** label when results obtained from samples tested comply with standards
10. Repeat test for samples that have failed
11. Label "**reject**" and store away in a separate section of warehouse/store if the material still failed
12. Assign QC or batch number for each batch that has passed the QC test, to serve as reference number on the label
13. Document reference numbers in batch manufacturing record (BMR)

In-house testing of intermediate products

1. Test intermediate products such as liquids, solid mixtures, granules and creams for uniformity of distribution and moisture content prior to finishing

Procedure 5.8: SOP for quality assurance at different stages of production

2. Take samples of intermediate products at appropriate intervals and run these tests at various stages:
   a. Liquid mixtures – temperature, pH, colour consistency, viscosity, homogeneity
   b. Semi-solid – viscosity, pH, colour
   c. Dry powder mixtures – uniformity of content, granules of active ingredient, moisture content
   d. Tablets and capsules (pre-packing) – hardness, friability, disintegration time, thickness, dissolution rate, content assay of active ingredients
3. QC should analyze these products physically and chemically, before pre-packing is done, since they are purchased from the open market
4. Tests are done at each stage of production by a QC inspector who issues a "**stop"** card on each batch container before samples are taken
5. A "**go"** card is issued and production continued to the next stage when results comply with appropriate standards
6. The production manager should copy, for each batch, what is in the master formulary methods (MFM) and use it to produce the BMR

In-house testing of finished products

A finished product is one that has undergone all stages of production including packaging and is in its final container and is appropriately labelled.

1. Hold them in quarantine until their final release
2. Store them under conditions established by official compendia
3. Do an appropriate laboratory determination to ascertain satisfactory conformity with standard for each batch of products to its finished product prior to release
4. Reject products that fail to meet the established specifications
5. Perform reprocessing if feasible
6. Ensure that the reprocessed product meets all specifications and other qualities prior to its acceptance and release

Validation of testing procedures

1. Validate all test procedures periodically (at least once a year)
2. Make available appropriately authorized and dated specifications including tests on identity, content, purity and quality for starting and packaging materials, intermediate or bulk and finished products
3. Document specifications for water, solvents and chemicals used in production
4. Ensure that each specification is approved by QC department
5. Conduct periodic revisions of the specifications to comply with new editions of the official compendia
6. Make available pharmacopoeia, reference standards, reference spectra and other reference materials in the QC laboratory

Job tools

1. Official compendia
2. Quality control report book
3. Master formulary methods (MFM)
4. Batch manufacturing record (BMR)

5.9 Handling packaging and labelling

Standard statement

There shall be the procedures for the handling of primary and printed packaging materials to maintain quality.

Operating procedures

Procedure 5.9: SOP for handling packaging and labelling

Packaging

1. Store printed packaging materials in secure places so as to exclude the possibility of unauthorized access and also to avoid mix-up
2. Ensure that all issues have approval and that documentation in packaging control record book is rigorously carried out
3. Give a specific reference number or identification mark to each delivery or batch
4. Destroy and record the disposal of outdated or obsolete materials
5. Check packaging materials for identity, quality, and conformity with the packaging instructions
6. Thoroughly wash and clean containers and closures in water before use
7. Ensure that containers should be impervious to moisture

Labelling

1. Control the labels' sources and supply
2. Ensure that two persons check the labels to establish that the words, strengths and batch numbers are correct and clear
3. Check the issues from stores are strictly in accordance with existing stores regulations
4. Carry out label reconciliation. Make sure the number used plus the number remaining equal the number issued from the stores
5. Attach specimen label to the batch manufacturing record to ensure security
6. Build security into the labels by using different colours to distinguish between different medicines, dosage forms and strengths
7. Ensure that the supervisor checks on the label more than once against the specification or against what is on batch manufacturing record (BMR)
8. Ensure that the labels contain the following information:
   a. The name, form, strength and volume/weight of the product and batch number
   b. Instructions for use
   c. Date of manufacture
   d. Date of expiry (Caution: pre-packed products may not retain original expiry date)
   e. Name and address of the facility
   f. Any auxiliary label e.g. cautions

   The labelling must be legible, clear, unambiguous and be in English language.

Job tools

1. Packaging control record book
2. Batch manufacturing record (BMR)

5.10 Bulk packaging

Standard statement

The packaging of bulk material should be done following laid down procedures and in accordance with quality control requirements

Operating procedures

Procedure 5.10: SOP for bulk packaging

Packaging records control (PRC) and procedures

1. Affix appropriate labels on bulk products, making reference to:
   a. Name of product
   b. Description of pharmaceutical form, strength and method of application
   c. Pack size expressed in terms of the number and weight/volume of product in final container
   d. Indication of batch number
   e. Expiration date
   f. Write or document details of in-process controls with instructions for sampling and acceptance limits
2. Ensure that the correct container, closures and inserts are used at all times
3. Ensure that no cross contamination occurs during packaging of products
4. Ensure that packaging lines are certified clean and free of previous packaged materials before other products are brought in
5. Do a complete reconciliation of packaging materials and units of products packed after each packaging operation
6. Ensure that laid down standard relevant control procedures are set in motion for sampling and for thorough inspection
7. Apply a quarantine label till QC releases product after due inspection
8. Ensure that all necessary documentation is completed by production personnel and countersigned by QC manager after physical inspection of packaging line
9. Check records of previously packaged product to ensure that on final release of product, no trace of contamination from previously packed product is recorded
10. Ensure the reconciliation of all packaging units with the total number of packaging components supplied
11. Ensure that excess containers, caps, inserts, etc. are not left behind after the specific packaging operation

Job tools

1. Quarantine label
2. Quality control bulk packaging record book

5.11 Product recall

Standard statement

As part of quality control and safety measures, defective products shall be recalled from the distribution chain promptly and where not possible its use shall be suspended until such a time that the defect is corrected.

Operating procedures

Procedure 5.11: SOP for product recall

Generic complaints and recall procedures

1. Respond promptly to any warning or recall of defective medicines
2. Receive complaints about product defect
3. Conduct prompt preliminary investigation to verify the truth or otherwise of the information received
4. Document both the complaint and the results of the preliminary investigation
5. Suspend the use of the product if the result of the preliminary investigations indicates a problem
6. Initiate thorough investigations
7. Involve the QC department or the production unit in the investigations
8. Follow administrative procedures to inform the suppliers if it is a procured product
9. Order for a recall or withdrawal, if the outcome of the investigation indicates that there is a problem
10. Reconcile stock records and quarantine the product
11. Inform and reassure the complainant and interested stakeholders if the result indicates that the problem does not originate from the product
12. Disseminate the outcome of the initial query and the outcome of the investigations to all stakeholders
13. Ensure that defective product complaint form is filled
14. State the type of complaint, name of complainant, date and time of complaint
15. State the source, identity, name, dosage form, batch number, and manufacturing and expiry dates of product
16. Verify the problem
17. Describe the effect(s) on client(s)/patient(s)
18. State how product was used, when last administered, duration of use and other medications
19. State the indication for which product is used
20. State any known allergies/idiosyncrasies
21. Describe product defect
22. State any colour changes, deformities on product, inconsistencies and failure to meet other physical properties (e.g. dissolution)
23. Report on any preliminary investigation
24. State the date, time and action taken after preliminary investigation
25. Decide whether to continue or suspend use
26. Recommend alternatives and investigate
27. Inform management
28. Prepare a final investigation report
29. State the action taken after final investigation
30. Recall product or continue use depending on outcome of investigations
31. Ensure that the distribution records are readily available to the person(s) responsible for recalls
32. Ensure that the distribution records contain sufficient information

Job tools

1. Stock records
2. Defective product complaint form (Appendix 8b)

5.12 Waste disposal and environmental contamination control

Standard statement

Waste products (liquid and solid) obtained through the process of manufacturing shall be disposed according to the environmental protection agency (EPA) specifications.

Operating procedures

Procedure 5.12: SOP for waste disposal

1. All pharmacists engaged in small-scale manufacturing should obtain copies of the EPA specifications on waste disposal
2. Supervisors should ensure that all members of the production team are trained to dispose waste (obtained through the process of manufacturing) according to the EPA specifications for correct waste disposal

Waste disposal control

1. Store toxic waste and inflammable materials in suitably designed separate and enclosed containers
2. Make provision for proper and safe storage of waste material awaiting disposal
3. Do not allow waste materials to accumulate
4. Collect waste materials in suitable receptacles for removal to collection points
5. Dispose of waste materials safely and in a sanitary manner at regular but frequent intervals
6. Dispose of waste products (gases, liquids and solids) obtained through the process of manufacturing according to the environmental protection agency's (EPA) guidelines or regulations

Environmental and contamination control

1. Ensure that technical measures are taken to control contamination
2. Segregate the production lines and ensure appropriate cleaning after each batch
3. Provide appropriate pressure differentials, air extraction, and appropriate airlocks
4. Use a "closed system" of production
5. Test products for residues of contaminants during production
6. Use filtered air to minimize re-circulation or re-entry of untreated air
7. Wear protective clothing in areas where products with special risk of cross-contamination are processed
8. Clean equipment after every production
9. Monitor and keep adequate record of the environment in the QC department
10. Include swab tests on the floor, walls, dust, drains and surfaces of the equipment in the sampling of the environment
11. Carry out microbiological sampling of the various production and aseptic areas periodically and routinely
12. Ensure that environmental control records conform to the number, types and limits of micro-organisms
13. Monitor the extent of dust in the production and aseptic areas

Job tools

1. Environmental protection agency (EPA) guidelines
2. Personal protective equipment
3. Environmental control records

Chapter 6

Centralized Intravenous Additives Services (CIVAS)

Preamble

Centralized Intravenous Additives Services (CIVAS) is a hospital pharmacy-based unit whose main function is the provision of prepared intravenous doses for direct administration to patients via the parenteral route. It is concerned with the provision of selected intravenously administered medicines such as ready to use injections or small volume infusions. It aims at reducing the work of health care providers on the wards on one hand, and minimizing the risk of errors in patient care on the other.

The pharmacist is responsible for the CIVAS unit and shall ensure accuracy, and promote efficiency. The pharmacist shall continuously update his/her knowledge.

The determination of the range of products is institution-specific and must be done by the drugs and therapeutics committee (DTC) in consultation with the various stakeholders (i.e. clinicians, pharmacists and nurses).

These preparations are made in controlled, aseptic conditions according to defined procedures.

CIVAS is to ensure that locally prepared intravenous doses for patients are:

1. Prescribed according to guidelines
2. Safe and efficacious
3. Contain required ingredients in the correct amounts
4. Sterile and contamination-free
5. Stable for the shelf life stated
6. Packed, labelled and stored appropriately to maintain sterility
7. Administered to the right patient correctly
8. Unused preparations are disposed of appropriately

The pharmacist shall accept CIVAS prescriptions that are valid and written on a special order or requisition form and identify CIVAS products in relation to dose, flow of fluid, strength/concentration.

Standard statements and guidelines are presented to cover the following areas in CIVAS:

1. Selection of range of products for CIVAS
2. Prescribing for CIVAS products
3. Receipt of CIVAS requests
4. Processing of requests
5. Preparation of products
6. Labelling and checking CIVAS products

7. Distribution and storage
8. Administration of CIVAS products
9. Returned CIVAS preparations
10. Documentation
11. Environment for preparation of CIVAS products
12. Personnel
13. Quality assurance
14. Quality control

These standards are to guide the operations of CIVAS within health facilities.

Operational flow diagram

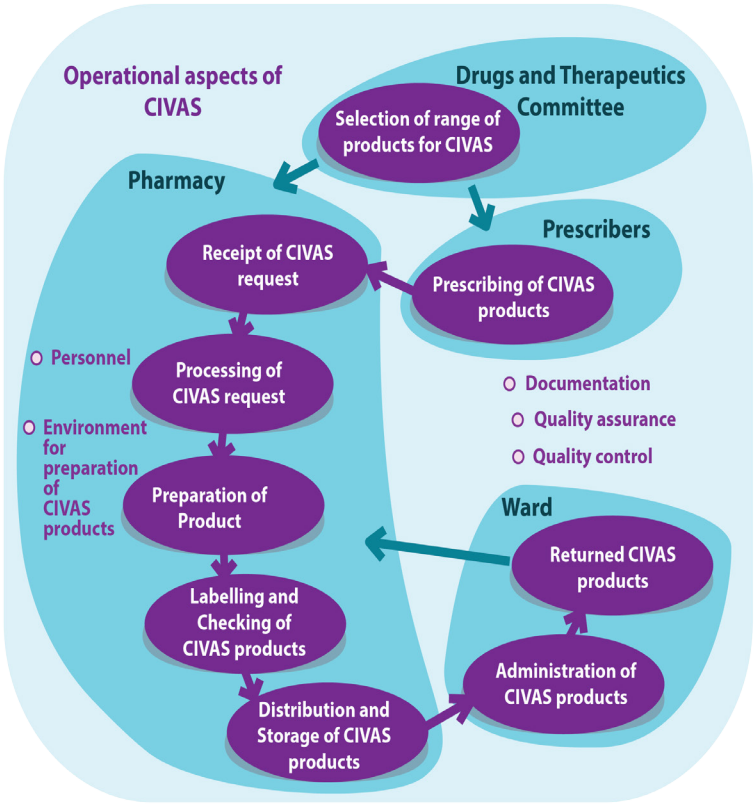

Fig 4: Operational aspects of CIVAS

Aspects of operations

6.1 Selection of range of CIVAS products

Standard statement

The hospital drugs and therapeutics committee (DTC) shall determine the type and list of preparations to be provided by the CIVAS.

Operating procedures

Procedure 6.1: SOP for selection of range of CIVAS products
1. The DTC in consultation with stakeholders in the hospital shall develop criteria for selecting intravenous preparations for CIVAS
2. The DTC shall then select list of preparations to be provided by CIVAS and the defined areas in the hospital to receive CIVAS supplies
3. The list shall be agreed upon by the stakeholders and reviewed periodically to meet the needs of patients requiring particular preparations

Job tools

1. Facility drug bulletin

6.2 Prescribing for CIVAS

Standard statement

Prescribers with requisite training and experience shall prescribe CIVAS products.

Operating procedures

Procedure 6.2a: SOP for prescribing for CIVAS
1. Prescribe CIVAS products on a special-order form
2. Medical officers with the requisite training and experience will prescribe CIVAS products
3. The prescriber must state the indication for which a CIVAS product is required explicitly on the order form
4. The prescription for CIVAS product shall contain the following information: a. How the product will be administered b. The required dose(s) of the product required c. Frequency of administration d. Signature, rank and clinical team of the prescribing officer e. The name, age, weight and ward of the patient f. The date for the prescription and the time product is required
5. Define areas in the hospital to receive CIVAS products
6. Accept CIVAS prescriptions that are written on a special order or requisition form
7. Issue appropriate receipts to accompany the patient's medication records or folder

Procedure 6.2b: SOP for request for CIVAS on a special-order form
8. The special order must have the following attributes: a. Date written b. Date for initiation of therapy c. Frequency of administration d. Period of administration e. Method of administration f. Indication for use g. Dose(s) h. Unit volume i. Rate of infusion

Procedure 6.2b: SOP for request for CIVAS on a special-order form
j. Name of patient k. Age of patient l. Ward of patient m. Name of prescriber n. Designation of prescriber o. Signature of prescriber

Job tools

1. CIVAS product requisition form (Appendix 9)

6.3 Receipt of CIVAS requests

Standard statement

Every CIVAS request shall be presented in written form and received by a pharmacist working in the CIVAS unit. Oral requests shall not be accepted. The nurse in charge of the ward shall submit the request to the CIVAS unit in time with the patient medication records and/or the folder.

Operating procedures

Procedure 6.3: SOP for receipt of CIVAS request and the processing of the request
1. Receive the prescription, document and process the CIVAS request a. Accept the prescription from the bearer and screen b. Document the name of the patient, the prescriber, the bearer, the ward of the patient, and the time of receipt c. Assess the order for clinical effectiveness d. Contact prescriber immediately in case of any doubts e. Authorize the preparation of CIVAS when satisfied with order f. Issue appropriate receipts to accompany the patient's medication records or folder 2. Perform clinical checks and authorize the preparation of the CIVAS product a. Check for appropriate indications, drug interactions, appropriateness of doses, any incompatibilities and method of administration b. Identify CIVAS products in relation to dose, flow of fluid, strength/concentration c. Contact the prescriber for more information or clarification before processing the request when the need arises d. Authorize the preparation of a CIVAS product by filling the appropriate forms, and sign your name on the form and stamp '*APPROVED*' on the order form when the request meets all the requirements

Job tools

1. CIVAS receipt record book

6.4 Preparation and labelling of CIVAS products

Standard statement

Preparation of dosage units shall be carried out by or under the supervision of a pharmacist. It must follow clearly defined procedures in accordance with the principles of good manufacturing practice.

Operating procedures

Procedure 6.4: SOP for the preparation and labelling of CIVAS products

1. Develop and continuously update standard operating procedures, protocols and formulae for CIVAS products
   a. Develop standard operating procedures with qualified staff
   b. Keep and maintain up to date standard operating procedures for all manufacturing operations in a well labelled display file kept in a secure and accessible place
2. Prepare CIVAS products in the approved premises (aseptic laboratory)
   a. Produce CIVAS products in closed systems to prevent cross contamination
   b. Prepare formally authorized master formulae and batch size to be manufactured
   c. Write out formally authorized packaging instructions for each product, pack size and type
   d. Wear appropriate protective clothing in the production area
   e. Clean the working area and equipment before preparations are started
   f. Clean containers for filling preparations before filling
   g. Access to production areas shall be restricted to authorized personnel only
   h. Define areas in the hospital to receive CIVAS products
3. Identify the active and inactive ingredient(s) required and the various strengths requested
   a. Assemble all ingredients required
   b. Select the appropriate dissolution agent
   c. Using aseptic methods, skilfully prepare the prescribed product
   d. Prepare, package and store the product in appropriate containers (e.g. syringe, bag, and/or bottle)
   e. Place the prepared product in the "*OUT*" window
4. Clearly label every CIVAS product according to the requirements developed by the FDA.
   a. Inspect and check every finished CIVAS thoroughly for any quality defects
   b. Check the label on the container for the following information:
      - The name of the product
      - The list of active ingredients and the amount of each present
      - The CIVAS unit assigned batch number
      - The date of manufacture
      - The date of expiry
      - The recommended storage conditions or handling precautions that may be necessary
      - Directions for use, warnings and precautions
      - The name and address of CIVAS unit that prepared the product
      - The name and signature of the person who prepared the product
      - The name and signature of the person who checked for accuracy and completion
   c. A final check on the finished product shall be carried out to ensure that all the labelling requirements are met
5. Make records for the batch produced according to guidelines
   a. Use the products master formulae to record in the batch processing record
   b. Keep the batch processing records for each batch processed
   c. Keep the batch packaging records for each batch processed
6. Only authorized persons (e.g. QC pharmacist or an authorized pharmacist) should release finished products

   Note: The patient, ward and the prescriber should be identified when dispensing aseptic products.

Job tools

1. CIVAS preparation protocols
2. Master formulae
3. Batch records book
4. CIVAS product dispatch form (Appendix 10)

6.5 Distribution and Storage

Standard statement

Distribution and storage of finished CIVAS products shall be in accordance with laid down procedures and guidelines.

Operating procedures

Procedure 6.5: SOP for distribution and storage

1. Keep all Storage areas clean, dry and maintained within acceptable temperature limits
   a. Storage areas shall be of sufficient capacity
   b. Provide a refrigerator for the storage of thermolabile products
   c. Replicate the storage conditions of CIVAS products in clinical areas (wards) as that of the production area
   d. Where special storage conditions are required, clearly state these, check and monitor adherence to the required conditions
   e. Specify storage conditions of finished products in the pharmacy and in defined clinical areas for each product
   f. Maintain products delivered from the pharmacy to defined clinical areas within the temperature limits appropriate for the integrity of the products
2. Train personnel involved in the transportation of finished products in appropriate handling of these products
3. Appropriately document every delivery and receipt of finished products in designated log books
4. Deliver all finished products within agreed times
5. The nurse in-charge of the ward or responsible for using CIVAS products shall receive and store the products
6. Trained personnel must document all aspects of handling the product
7. Determine the shelf life of un-used returned products and assess for re-use. This should be done by a suitably qualified person
8. Supply CIVAS products to a named patient for a 24 hour period, provide refills for a maximum of three days. For further supplies to the named patient, make on a new order
9. Only trained personnel must handle and distribute CIVAS product

Job tools

1. CIVAS product dispatch form (Appendix 10)

6.6 Administration of CIVAS products

Standard statement

Only trained and qualified staff shall carry out the administration of CIVAS products to patients in accordance with laid down protocols and procedures.

Operating procedures

Procedure 6.6: SOP for administration of CIVAS preparations

1. Provide a guide to the choice of needles and catheter gauges needed for administration and make it available to defined clinical areas where CIVAS products are used

Procedure 6.6: SOP for administration of CIVAS preparations
2. Document every procedure carried out in the administration of a CIVAS product in the appropriate forms and books
3. Provide guidelines on flushing solutions for CIVAS products to defined clinical areas
4. Provide guidelines on incompatibilities and drug interactions for CIVAS products to defined clinical areas
5. Provide guidelines on the administration of total parenteral nutrition (TPN) to defined clinical areas
6. Only trained and authorized personnel in oncology shall reconstitute or administer cytotoxic drugs per intravenous route
7. Provide guidelines on uncomplicated mixing of drugs with infusions to all defined clinical areas
8. Provide guidelines on aseptic procedures for intravenous administration of CIVAS products to all defined clinical areas
9. Provide guidelines on protocols for checking the hazards of intravenous administration to all defined clinical areas

Job tools

1. Guidelines and administration protocols for CIVAS products

6.7 Returned CIVAS preparations

Standard statement

All unused CIVAS products after issue, whether opened or unopened, shall be returned to the CIVAS unit for appropriate storage or disposal.

Operating procedures

Procedure 6.7: SOP for return of CIVAS preparations after issuing
1. All returned CIVAS preparations shall be assessed by qualified personnel with the appropriate skills
a. Investigate further those CIVAS preparations with problems
b. Identify all problems and possible causes
c. Reuse those CIVAS preparations without problems after vigorous assessment by a qualified officer
d. Maintain the appropriate conditions for the supply of CIVAS products to wards, even when the products are being returned (e.g. if a cold chain was used to supply CIVAS products to ward, this must be maintained)
e. Appropriately dispose of returned CIVAS products that are not reusable in compliance with the FDA procedure for disposal
f. Procedure for disposal must comply with the requirements of the FDA

Job tools

1. FDA disposal manual for CIVAS

6.8 Documentation

Standard statement

Every stage of CIVAS activity shall be documented to provide recorded evidence of the safety and quality of the product.

Operating procedures

Procedure 6.8: SOP for documentation of CIVAS preparations

1. Design the appropriate forms for recording data
   a. Appropriate forms include data sheets, reporting forms, batch processing records, equipment logbooks etc.
2. Design the appropriate numbering systems for procedures, processes and materials in a way that can be traced throughout the data records
3. Prepare standard operating procedures, protocols and master formulae for each CIVAS preparation and state the specification for each product
   a. Provide specific details that define the quality of materials, production environment, production and control processes and the quality of the final product
4. Keep separate records for preparations for individual Patient and drug records

Job tools

1. CIVAS preparation protocols
2. Master formulae
3. Records for CIVAS preparations

6.9 Personnel

Standard statement

An adequate number of suitably qualified staff with job descriptions shall be available to carry out all the tasks for which the CIVAS unit is responsible.

Operating procedures

Procedure 6.9: SOP for personnel handling CIVAS products

1. The head of the CIVAS unit shall be a qualified QC pharmacist
2. The production area for CIVAS is restricted to authorized staff only
3. Wear protective clothes at all times before entering production area
4. Define an effective organizational structure with clearly stated responsibilities
5. The workload on any one individual shall be such that it does not compromise his/her efficiency and thus the quality of the product
6. Staff shall be conversant with the principles of good manufacturing practices (GMP) especially as relates to aseptic manufacturing. There shall be initial and continuing training relevant to their job requirements
7. Personal hygiene procedures including the use of protective clothing should apply to all persons entering production areas, whether they are temporary or full-time employees or non-employee e.g. visitors, senior managers, and inspectors

Job tools

1. Training manual

6.10 Environment for preparation of CIVAS products

Standard statement

The location, construction or adaptation, layout and design of a CIVAS unit shall aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt and, in general, any adverse effect on the quality of products.

Operating procedures

Procedure 6.10: SOP for maintenance of a CIVAS unit

1. Premises shall be situated in an environment that presents minimum risk of contamination to the manufacturing process
   - **a.** Design and construct the premises of the facility in a suitable way to facilitate good sanitation and protection against the entry of pests
   - **b.** Develop and implement a protocol for regular maintenance and cleaning of premises and equipment
   - **c.** Control electrical supply, lighting, temperature, humidity, and ventilation so that they do not adversely affect, directly or indirectly, either the pharmaceutical products during their manufacture and storage, or the accurate functioning of equipment
   - **d.** Separate the production area from other areas such as the rest room, canteen etc. to prevent contamination
   - **e.** Changing rooms, storerooms and toilets shall be easily accessible and appropriate for the number of users
   - **f.** The layout of the production area shall facilitate the logical sequence of the manufacturing process
2. Build the concept of QA and QC into the operations of the CIVAS unit with the sole object of ensuring products are of the quality standard required for their intended use
   - **a.** Observe requirements for GMP and GDP
   - **b.** Specify clearly in a written form all the production and quality control operations
   - **c.** Double check all measurements and weights
   - **d.** Double check all packaging and labelling operations
   - **e.** Check all the finished products in accordance with the defined procedures
   - **f.** Only authorized persons (e.g. QC pharmacist or an authorized pharmacist) shall release finished products
   - **g.** Put in place and implement a quality audit system
   - **h.** Ensure that finished products conform to the specifications of the said products

Job tools

1. Maintenance protocols

6.11 Quality assurance and quality control

Standard statement

The concept of quality assurance shall be built into the operations of CIVAS units with the sole object of ensuring that CIVAS products are safe and of the right quality required for their intended use. A CIVAS product shall not be released until its quality has been certified.

Operating procedures

Procedure 6.11: SOP for quality assurance and quality control

Quality assurance

3. CIVAS products shall conform to the requirements of GMP
4. Clearly specify production and quality control operations in a written form
5. Clearly specify managerial responsibilities in job descriptions
6. Validate all equipment and controls on starting materials and methods
7. Check the finished product according to the defined procedures
8. Certify each CIVAS product after each production in accordance with laid-down procedures before releasing the product
9. Make satisfactory arrangements to ensure that the CIVAS products are stored, distributed and properly handled so that quality is maintained
10. Put in place and implement a quality audit system

Quality Control

Adequate resources shall be available to ensure that all the quality control arrangements are effectively and reliably carried out

1. Make available adequate facilities, trained personnel and approved procedures for sampling, inspection, and testing of materials, and where appropriate for monitoring environmental conditions for quality control purposes
2. Build the concept of QA and QC into the operations of the CIVAS unit with the sole object of ensuring products are of the quality standard required for their intended use
3. Observe requirements for GMP, GDP as well as good storage practice (GSP)
4. Specify clearly in a written form all the production and quality control operations
5. Double check all measurements and weights
6. Double check all packaging and labelling
7. Check all the finished products in accordance with the defined procedures
8. Ensure that finished products conform to the specifications of the product
9. Carry out sampling, inspection and testing procedures. Record and investigate any deviations detected

Job tools

1. Quality control manual

Chapter 7

Record Keeping and Data Management

Preamble

Pharmacy record keeping and data management are necessary requirements in ensuring an effective management information system (MIS) to improve the provision of pharmaceutical services. Records shall be kept for a minimum of 2 years at the pharmacy.

The following records shall be kept:

- Records on selection, procurement, storage, and distribution of medicines
- Records on utilization of medicines
- Records on equipment and personnel
- Records on small-scale manufacturing
- Records on clinical and public health programmes
- Records on vaccine and immunoglobulin safety

Operational flow diagram

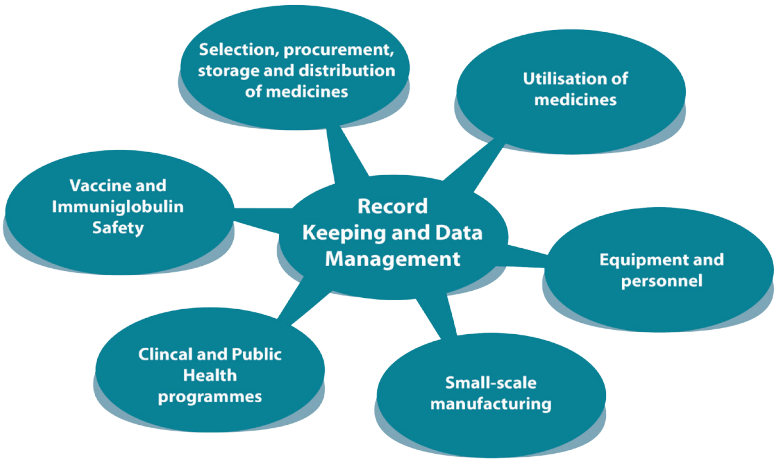

Fig 5: The scope of records keeping and data management

Aspects of Operations

7.1 Records on selection, procurement, storage, and distribution of medicines

Standard statement

Relevant data on the processes of selection, procurement, storage, and distribution of medicines shall be captured in order to generate the needed management information to support effective planning of pharmaceutical services.

Operating procedures

Procedure 7.1: SOP for keeping records on selection, procurement, storage and distribution of medicines

1. Maintain records on the following for two years to aid the medicines selection process
   - **a.** Records of medicines consumed
   - **b.** Statistics on morbidity and data on disease patterns
   - **c.** Reviewed records *[A list of required items reviewed by the drugs and therapeutics committees (DTC)/ institutional management committee (IMC)]*
2. Comply with the all procedures in the procurement manual and maintain records on the following to aid the process of medicines procurement
   - **a.** The procurement plan
   - **b.** The bid document where applicable
   - **c.** The minutes of the meeting of the entity tender committee
   - **d.** Pro-forma invoices
   - **e.** Local purchase order books (LPO)
   - **f.** Stores receipt advice books (SRA)
   - **g.** Procurement register
   - **h.** Award letters
3. Maintain records on the following to ensure a more efficient and effective process of medicines storage and distribution for two years
   - **a.** Invoices
   - **b.** Ledgers
   - **c.** Tally cards/computer records
   - **d.** Requisition and issue vouchers
   - **e.** Temperature and humidity charts
   - **f.** Register of unserviceable items
   - **g.** Manufacturing dates
   - **h.** Expiry dates
   - **i.** Batch numbers
   - **j.** Donations/free items
   - **k.** Ward stock
   - **l.** Dangerous drugs
   - **m.** Pricing
   - **n.** Drug revenue

Procedure 7.1: SOP for keeping records on selection, procurement, storage and distribution of medicines
o. ABC value analysis or VEN system analysis p. Tracer drug availability q. Poisons r. Any other relevant records

Job tools

1. Record-keeping software
2. Dangerous drug record (Appendix 11)
3. Other data recording tools

7.2 Records on utilization of medicines

Standard statement

Data on the quantitative and qualitative use of medicines shall be recorded to enable the generation of management information, in support of rational drug use and pharmaceutical care provision.

Operating procedures

Procedure 7.2: SOP on the records on utilization of medicines
1. Maintain the following records to aid the process of rationalizing medicines utilization in the pharmacy department for a period of two years a. Drug supply to patients b. Exemptions categories must be specified c. Drug revenue d. Prescription analysis e. Issues from stores to the various dispensing outlets f. Interventions g. Drug bulletins h. Adverse drug reactions (ADR) [www.fdaghana.gov.gh] i. Drug information services j. Patient medication profiles k. Counselling (include client's impressions as part of client satisfaction survey) l. Databases m. Information sources n. Any other relevant documents

Job tools

1. ADR forms (www.fdaghana.gov.gh)
2. Drug information database
3. Record-keeping software
4. Other data recording tools

7.3 Records on equipment and personnel

Standard statement

Records on equipment and personnel shall be kept and updated to ensure efficiency of operation.

Operating procedures

Procedure 7.3: SOP on records on equipment
1. Maintain the following records on equipment and personnel to ensure the efficiency of operations. a. Equipment i. Equipment specifications ii. Inventory of equipment iii. Equipment manuals iv. Records of unserviceable equipment v. Planned preventive maintenance (PPM) schedules including contract records b. Personnel vi. Recruitment and deployment vii. Duty roster viii. Leave schedule ix. Training x. Appraisal reports xi. Supportive supervision records

Job tools

1. Equipment register
2. Record-keeping software
3. Other data recording tools

7.4 Records on Small-scale manufacturing

Standard statement

Records shall be kept of both the small-scale manufacturing processes and products to facilitate audit and planning.

Operating procedures

Procedure 7.4: SOP on records on small scale manufacturing
1. The under listed records of small scale manufacture shall be kept to comply with the requirement of good manufacturing practices (GMP) a. Batch manufacturing record b. Complaints and recall procedures c. Equipment inventory d. Master formulary and methods (MFM) e. Packaging materials and labels f. Product inventory

Procedure 7.4: SOP on records on small scale manufacturing

g. Quality control (in-process and end-product)
h. Raw material inventory
i. Release procedures
j. Standard cleaning procedures
k. Training
l. Certificate of analysis of the raw materials

Job tools

1. Record-keeping software
2. Other data recording tools

7.5 Records on programme (clinical and public health)

Standard statement

Records of relevant programmes shall be kept to support planning and research and to improve quality and efficiency of services.

Operating procedures

Procedure 7.5: SOP on clinical and public health records

1. To maximize the benefits derived from programme, the pharmacy department shall keep the following records:
   a. Programme documents/manuals – (initial, interim, final, progress)
   b. Programme evaluation
   c. Technical reports on programme activities carried out

Job tools

1. Technical reports on programme activities
2. Programme-specific guidelines

7.6 Records on vaccine and immunoglobulin safety

Standard statement

Records on vaccine and immunoglobulin safety shall be kept to support planning and research and to improve quality and efficiency of services.

Operating procedures

Procedure 7.6: SOP on record on vaccine safety

1. To maximize the benefits derived from vaccination, the pharmacy department shall keep the following records:

Procedure 7.6: SOP on record on vaccine safety
a. Programme documents/manuals – (initial, interim, final, progress) **b.** Programme evaluation **c.** Technical reports on programme activities carried out **d.** Safety information

Job tools

1. Programme-specific guidelines
2. Technical reports on vaccination activities
3. Drug information databases

Chapter 8

Safe and Secure Handling of Medicines

Preamble

Medicines are powerful tools for modern therapeutics. They are potentially dangerous if misused and abused. There is the need to give interpretation to the existing policies on secure handling of medicines outlined in the national medicines policy through specific guidelines. It is hoped that these together with other policy guidelines on professional standards of practice will ensure the safe and secure handling of all medicines.

The main task in ensuring safe and secure handling of medicines is to be able to account for a medicine from the time of ordering through to the time of administration to the patient (along the 'medicine audit trail').

This task requires the application of what is often referred to as the principle of "three Rs" - responsibility, record-keeping, and reconciliation. At each step where medicines are issued, there shall be clearly laid-down procedures.

Responsibility

- Follow laid down procedures when medicines change hands
- State clearly who is responsible for the medicines
- Determine whether the responsibility is delegated and how far the delegation extends

Record-keeping

- Determine what should be recorded, where, by whom and for how long records should be kept
- Pre-print data recording tools (e.g. books, forms) and use them for training purposes
- Reconciliation
- Determine how often reconciliation should be done and who should do it

The following are activities along the 'medicine audit trail' where the safe and secure handling principles above shall apply:

1. Procurement, transportation and storage
2. Dispensing
3. Administration to/by patients
4. Disposal of medicines
5. Education and training
6. Use of controlled stationery
7. Clinical trials

Operational flow diagram

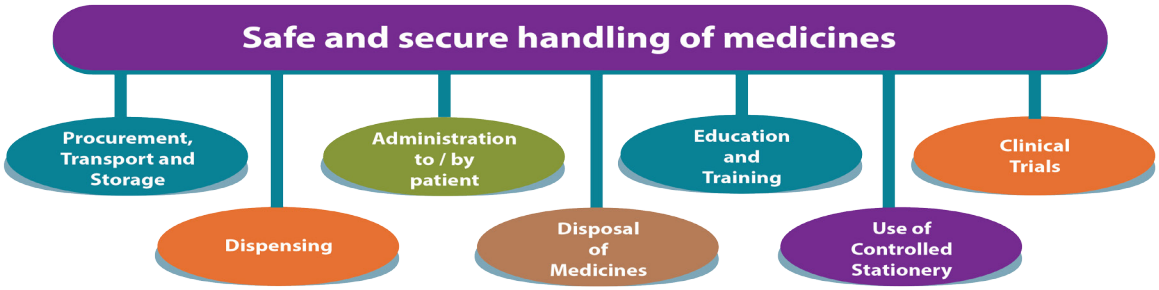

Fig 6: Activities requiring the principles of safe and secure handing of medicines

Aspects of operations

8.1 Safe and secure handling of medicines in procurement, transportation and storage

Standard statement

The pharmacist shall ensure that the safe, secure handling of medicines is not compromised during procurement, transportation and storage.

Operating procedures

Procedure 8.1: SOP for the safe and secure handling of medicines in procurement, transportation and storage

Procurement

The pharmacist shall take responsibility for initiating and monitoring all procurement processes in relation to medicines and associated commodities

1. Make available all documents, data recording forms/books and other record keeping materials needed for the procurement process (e.g. tender documents, minutes of procurement committee meetings, invoices etc.)
2. Procure only medicines that are in conformity with institutional formulary and in accordance with guidelines on selection, quality, quantity and delivery (i.e. the procurement manual, essential medicines list etc.)
3. Maintain accurate records with regard to all medicines procured (e.g. store received vouchers, local purchase orders, bin cards, way bills etc.)
4. Store all medicines in accordance with the manufacturer's storage recommendations
5. Store medicines securely on the ward/department in such a way as to be accessible to only authorized ward staff (in line with the SOPs for storage of pharmaceuticals)
6. Use lockable, immobilized cabinets, wall-mounted cupboards or similar arrangements assessed as suitable by the pharmacist

Distribution of medicines

The pharmacist in-charge shall hold himself accountable for the distribution of medicines from the pharmacy. The distribution list may include a number of outlets such as other public hospitals, clinics, wards, departments and agencies. Medicines may also be distributed to health professionals in the community, hospital teams and other health care professionals in other practices

Procedure 8.1: SOP for the safe and secure handling of medicines in procurement, transportation and storage

1. Subject all medicines to good storage practices
2. Prepare a list of medicines to be stocked in the wards/units/departments in consultation with the medical staff and the ward managers
3. Carry out weekly inspections of wards/units/departments stocks with reconciliation where necessary
4. Notify the head of pharmacy of all discrepancies detected by the pharmacy or other staff
5. Investigate and report all discrepancies to the next highest authority
6. Check and recheck all controlled medicines on wards/units/departments whenever there are changes in the personnel responsible on the wards/units/departments
7. Reconcile all medicine stocks with records at locally determined intervals
8. Keep records of all checks made, including the identities of the staff members carrying out those checks

Transport of medicines within the hospital

The security of all medicines is the responsibility of the persons involved from the point of issue to receipt

1. Give clear instructions to the person transporting the medicines as to whom they should make delivery to
2. Make those transporting the medicines responsible for the maintenance of security until they are delivered to an authorized person and the delivery acknowledged
3. Convey medicines from one point to the other in sealed boxes through authorized persons along with order books and other controlled stationery
4. Transport controlled medicines and prescription-only-medicines in locked cabinet or receptacle

Transport of medicines to other hospitals and clinics

1. Transport medicines to other hospitals in containers, which are sealed and tamper-evident
2. Keep these containers under surveillance whilst awaiting collection, during transportation and at receipt

   Note: All facilities must have pharmacists or else the units be graded as dispensaries
3. Ensure that the person transporting the medicine (e.g. porter etc.) is clear as to the destination and to whom they should make delivery
4. For medicines such as vaccines, delivery should be done within the shortest possible time. At no time should the cold chain be broken. Vaccines should be carried in accordance with the manufacturer's specification
5. The pharmacist shall be responsible for the transport of medicines to other hospitals and clinics
   a. Ensure that transport of medicines to other hospitals is done in containers, which are sealed and tamper-evident
   b. Keep containers under surveillance whilst awaiting collection, during transportation, and at receipt
6. All medicines shall be stored according to the manufacturer's specifications
   a. The pharmacist takes responsibility for the safekeeping of the medicines
   b. Ensure that medicines trolley is locked and immobilized when not in use
   c. In each unit/department, there shall be separate compartments for storage as follows:
      i. Narcotic and psychotropic substances, lockable
      ii. Medicines for internal use
      iii. Medicines for external use
      iv. Refrigerator/freezer for medicines
      v. Diagnostic reagents
      vi. Intravenous fluids and sterile topical fluids
      vii. Inflammable fluids and gases
7. Temporary closure of department/unit
   a. When the department/unit is to be closed temporarily (e.g. weekends), the pharmacist shall make adequate arrangements to ensure the safe and secure custody of the medicines held in the department/unit

Job tools

1. Dangerous drug record (Appendix 11)
2. Requisition books
3. Store ledger
4. Invoices
5. Way bill
6. RIRV
7. Expired drug ledger
8. Record-keeping software

8.2 Safe and secure handling of medicines in dispensing

Standard statement

Dispensing and supply of medicines shall conform to good dispensing practices.

Operating procedures

Procedure 8.2: SOP for safe and secure handling of medicines in dispensing

The pharmacist takes full control of all medicines supplied and used in the hospital, including programme medicines

1. Issue at point of use for an in-patient in accordance with local practices/procedures on ward stocks
2. Dispense medicines individually from the pharmacy for individual in-patients
3. Distribute via institutional transport system to the appropriate ward, clinic or hospital
4. Dispense individually from the pharmacy for discharged patients or for out-patient use

Note

1. The drug and therapeutics committee of the health facilities determine which drugs are stocked by each department/ward. This policy is reviewed from time to time
2. The pharmacist at each clinical unit decides, in consultation with medical staff and the nurse in charge, the amounts and the range of medicines to be supplied to and stocked in wards/units/departments
3. Medicines can be ordered in three ways:
   a. Medicine ordered by the pharmacist as part of their duties in stocking the institution with the required needs
   b. Medicines supplied as part of a regular top-up service by the pharmacy
   c. Medicines ordered by the nurse in-charge of the ward/department. Only medicines on the agreed stock list for the ward may be ordered in this way
4. Pharmacy staff check the security of ward/unit/department stocks, including narcotic and psychotropic drugs periodically, at least every week. They carry out inspections of ward/department stocks with reconciliation where necessary, and report the findings to the head of the pharmacy
5. The head of the pharmacy is notified of all discrepancies whether detected by pharmacists or other staff, and ensures the appropriate investigation and report in accordance with the laid down procedures for handling of such incidents
6. At locally determined intervals, reconciliation of pharmacy stocks with records takes place. Discrepancies are investigated with the help of other departments where appropriate
7. A record is kept of all checks made, including the identities of the staff carrying out those checks

Procedure 8.2: SOP for safe and secure handling of medicines in dispensing

8. The authorization of a qualified prescriber is obtained before medicines can be administered to patients. This authorization is given in one of two ways:
   a. A prescription written by a qualified practitioner on an official medicines administration chart form
   b. In accordance with locally agreed standing orders assessed by a qualified practitioner as appropriate for that patient
9. A record of administration is made, and the administering nurse(s) identified
10. Medication refused or wasted is recorded and returned to the pharmacy
11. Two nurses shall be involved in administering medicines to children or in the administration of narcotic and psychotropic substances
12. Where a second nurse checks the administration of a medicine, the identity of that nurse shall also be recorded

Job tools

1. Requisition books
2. Stock records
3. Other relevant data recording tools
4. Record keeping software

8.3 Education and training in safe and secure handling of medicines

Standard statement

The head of pharmacy shall ensure that all staff involved in the handling of medicines shall be regularly and appropriately trained in the safe and secure handling of medicines.

Operating procedures

Procedure 8.3: SOP for education and training in safe and secure handling of medicines

1. Train all staff involved in the handling of medicines appropriately with regard to safety and security of medicines
2. Educate staff on medicine handling and any identified gaps in knowledge with regards to the above
3. Address the above within ward-based induction programme with the support of mentors
4. Educate all members of the ward-based team, both clinical and non-clinical, in the safe and secure handling of medicines
5. Include "discrepancies" in the education programme (breaches of security and evidence of tampering)
6. Address issues on reporting, documentation and resultant action, within the educational programmes

   Note

   The training programme shall include the following areas of dealing with untoward occurrence, for example:
   a. Incident reporting
   b. Breaches of security
   c. Evidence of tampering
   d. Documentation
   e. Resultant action

   Document all training activities carried out

Job tools

1. Training manual on safe and secure handling of medicines

8.4 Safe and secure handling of medicines in administration

Standard statement

The pharmacist shall ensure that the safe, secure handling of medicines is not compromised during administration by ensuring that the requisite instructions and precautions are adhered to by setting in motion monitoring parameters for optimum drug administration.

Operating procedures

Procedure 8.4: SOP for safe and secure handling of medicines in administration

1. Monitor the administration of medicines to an individual patient through:
   a. A qualified nurse in accordance with a written prescription by an authorized practitioner
   b. A suitably qualified practitioner
   c. Self-administration by a patient
2. A mechanism is to be put in place to illicit response from patients about their current medication history to enable the pharmacist and prescriber identify what treatment regimen the patient is following
3. Unlike medicines supplied by the pharmacy department within the hospital, there is no continuous control of the quality of the medicines brought in by patients. Therefore their quality cannot be assured and patients' own medicines may be used only where their quality has been assessed and approved by the pharmacist in-charge
   a. Handle these medicines in the wards/units/departments considering the following:
      i. they are the property of the patient
      ii. they should not be destroyed or otherwise be disposed of without the consent of the patient
      iii. they shall be used in the treatment of that patient only where their identity is known and that they are of the appropriate quality and are approved for use by the pharmacist in-charge
      iv. they may not be used in the treatment of any other patient
   b. Handle individual patient's medication with the same precautions as the wards/units/departments stocks and return medication to the patient if not used
   c. Return the medicines to the client/patient via an identified adult if not taken away by him/her
   d. Take note that responsibility for security is transferred to that adult
   e. Send the medicines to the pharmacy for destruction if the patient or his or her agent agrees
   f. Note that responsibility and security is the same as for wards/units/departments stocks of medicines
   g. Note that where patient's own medicines are to be used for his or her continued treatment in the wards/units/departments, the responsibility for them and their security are the same as for wards/units/departments stocks of medicines

Self-administration of medicines by patients

Using self-administration systems is seen as a practical method of improving patient involvement and control of medicines when in hospital. Patients gain a better understanding of their medication(s) while retaining their independence and achieving a greater degree of satisfaction.

The adoption of a self-administration system does not diminish the responsibility of all staff to ensure the safe and secure handling of medicines and the duty of care for either the self-administrating patient or other patients of the hospital.

Procedure 8.4: SOP for safe and secure handling of medicines in administration

The main aims of the system are:

i. To encourage patients to be more independent and take responsibility for their own medicines
ii. To assess patients' adherence and where necessary to improve it through education and agreement
iii. To equip patients with the skills and knowledge appropriate for the safe and effective management of medicine therapy on discharge
iv. To develop patients' understanding and respect for modern medicines

Levels of patients' dependency will vary between wards/units/departments, between patients and also during a single episode. The requirements of each clinical area may vary and therefore self-administration systems shall be determined for each clinical area by the pharmacist responsible for it in close co-operation with the nursing and medical staff.

Patient assessment for self-administration

While the overall philosophy is that all patients should self-administer their medicines, not all patients will be able or be appropriate for the self-administration system. Careful assessment of patients is therefore essential to identify those who cannot or should not self-administer medicines.

Note that responsibility for the assessment of the patient lies with the nurse or manager in-charge. Keep a record of the assessment together with the patient's informed and/or written consent as part of the patient's case record.

Criteria for exclusion:

i. Exclude patients who did not take their own medicines prior to admission and will not do so after discharge
ii. Exclude patients physically or mentally incapable of managing their medicines (some patients, on improvement of their condition, may prove suitable for self-administration at a later date)
iii. Exclude patients who do not wish to self-administer medicines
iv. Exclude patients for whom the nature of the medicine prevents self-administration by them

Supply of medicines to patients for self-administration

i. Determine the needs of the patient based on the prescription
ii. Dispense medication individually to patients participating in a self-administration system
iii. Do not allow wards/units/departments stock of medicines to be used for self-administration
iv. Supply each medicine in a container appropriate to the individual needs of the patient and possibly be a 'child resistant' one as well
v. Label the containers individually for the patient, together with the name and strength of the medicine and directions for dosing

Job tools

1. Relevant data recording tool
2. Record-keeping software

8.5 Safe and secure handling of controlled stationery

Standard statement

Stationery specification designed for use in drug management shall be strictly controlled to ensure that they do not get into wrong hands, to prevent them from being used to obtain medicines fraudulently.

Operating procedures

Procedure 8.5: SOP for safe and secure handling of controlled stationery

Controlled stationery is any stationery, which, if left in the wrong hands, could be used to obtain medicines fraudulently

Procedure 8.5: SOP for safe and secure handling of controlled stationery

1. Receive, hold, secure and distribute all stocks of controlled stationery
2. Designate a person within the pharmacy to be responsible for the issue of controlled stationery
3. Supply only one book/pad of forms to each ward/unit/department at any given time
4. Seal every completed register, using sticky tape with signature of officer in-charge across the tape, and store on the wards/units/departments so as to prevent further use or alteration

Note

1. Stocks of controlled stationery are to be received, held securely and distributed only by authorized health personnel. These controlled stationeries shall include the following:
   a. Treatment sheets
   b. Requisition and issue books
   c. Prescription forms
   d. Controlled drug books
   e. Any other ledger books determined by managements

Job tools

1. Record book for the receipt, issue and distribution of controlled stationery
2. Record-keeping software

8.6 Safe and secure disposal of medicines

Standard statement

All out-of-date medicines and any stock no longer required shall be clearly marked as unserviceable stock and shall be retrieved and returned to the pharmacy with appropriate security precautions.

Operating procedures

Procedure 8.6: SOP for safe and secure disposal of medicines

Dispose medicines no longer to be administered, for whatever reasons, under the direction of the pharmacist in-charge

Note

1. Narcotic and psychotropic substances
   a. Individual doses of narcotic and psychotropic substances, which are prepared, but not administered, are to be destroyed by the department/unit in the presence of a second person who may be a registered nurse, a pharmacist or a doctor
   b. The pharmacist(s) witnesses the destruction of all other narcotic and psychotropic substances no longer suitable for use
   c. In both cases, an entry is to be made in the ward narcotic and psychotropic substances register, including the names of those involved in the destruction
2. Other medicines liable to misuse
   a. Individual doses of other medicines, which are no longer needed and are liable to misuse, are to be destroyed in the department/unit in the presence of a witness. A record of the destruction shall be made, and those involved identified
   b. Sealed unit doses need not be destroyed and may be returned to the department/unit stocks ensuring that the name, strength, and batch number of the medicine match the container to which it is returned. A qualified medical staff preferably a pharmacist shall check this action

Job tools

1. Disposal records book
2. Narcotics and psychotropic substances register

8.7 Safe and secure handling of medicines in clinical trials

Standard statement

Special handling procedures shall be put in place for medicines used in clinical trial to ensure they are safe and secure.

Operating procedures

Procedure 8.7: SOP for safe and secure handling of medicines in clinical trials
Only a pharmacist shall receive samples and clinical trial materials from the manufacturer or his representatives
1. The researcher shall make appropriate arrangements with a designated pharmacist for the management of the trial medicines
2. The pharmacy department shall keep a copy of all trial protocols, including codes, for studies being undertaken in the hospital
3. Extra precautions need to be taken with these medicines to ensure safety and security in their use, since the medicines under investigation are generally unfamiliar to the staff handling them and/or are coded to prevent ready identification by either the investigator or the patient
4. The procurement, distribution and storage of clinical trial products shall be in accordance with the provisions of the clinical trial protocols of the FDA
5. Record of drugs in clinical trial shall be kept in coded form. Dispensing, issue, administration, and disposal of all medicines shall be in accordance with the clinical trial protocols

Job tools

1. Clinical trials evaluation forms
2. Clinical trial protocols

Chapter 9

Formulary Management

Preamble

The effective implementation of drug policies and the efficient utilization of drugs in health institutions are subject to challenges which include the multiplicity of drugs, the wide range of professional opinion within a health system, the pressures of powerful external market forces and limited drug budgets.

Formulary management is to encourage rational procurement and prescribing of safe, effective and affordable drugs by selecting drugs recommended by the local health-care providers working as a team.

The scope shall include the following:

- Provision of guidelines for the selection of the drugs, which reflects the institution needs
- Ensuring the availability of these drugs
- Ensuring compliance to agreed therapeutic protocols
- Conducting regular reviews of the formulary

Operational flow diagram

Fig 7: The scope of formulary management

Aspects of operations

9.1 Medicines selection guidelines

Standard statement

Institutional formularies shall be developed through evidence-based selection of medicines that meet its requirements. These shall guide prescribing and medicine supply and shall be subject to regular review.

Operating procedures

Procedure 9.1: SOP for provision of medicines selection guidelines
1. Ensure that all medicines in the formulary are duly registered with the FDA
2. Develop local formulary according to the national formulary classifications system. The formulary shall be based on the level of care and reflect the local needs of the health institution based on the epidemiological profile of its catchment area
3. Ensure that inclusion of drugs outside the national medicines formulary conforms to the procedures prescribed in the essential medicines list/national medicines policy
4. Ensure that drugs selected have empirical and adequate data on efficacy and safety from clinical studies and is available in a form in which adequate quality, bioavailability, stability under storage conditions and use is established
5. The drug and therapeutics committee (DTC) or institution shall ensure the development of treatment protocols for specific disease conditions according to national guidelines for the various clinical units for adoption by the facility

Job Tools

1. Standard treatment guidelines
2. Essential medicines list
3. National health insurance medicines list
4. National medicines policy

9.2 Availability of selected medicines

Standard statement

Selected medicines shall be available at all times. Institutional procurement and stock management shall be guided by the formulary list.

Operating procedures

Procedure 9.2: SOP for ensuring availability of selected medicines
1. The DTC in all public health institutions shall be responsible for the management of the formulary
2. The management of the health facility shall put in place a drug procurement evaluation committee comprising all relevant members from pharmacy, medical, nursing, procurement etc. [in line with Public Procurement Act, 2003 (Act 663) and Public Procurement (Amendment) Act, 2016 (Act 914)]. Local situation may be brought to bear on the composition of the committee
3. The pharmacy shall ensure regular and timely distribution of drug bulletins
4. The DTC shall ensure regular and timely distribution of drug formularies and treatment protocols. Process shall involve extensive consultation with all stakeholders within institution
5. The DTC shall ensure that only drugs on the formulary are procured and made available at all times

Job Tools

1. Institutional formulary
2. Institutional drug bulletins

9.3 Conducting regular review of the formulary guidelines

Standard statement

The formulary guidelines shall be regularly reviewed and this will include evaluation and selection of medicines for inclusion or deletion in the formulary.

Operating procedures

Procedure 9.3: SOP for conducting regular review of the formulary guidelines
1. Conduct regular programme of evaluation for inclusion or deletion on medicines in the formulary under the ambit of the DTC with clear guidelines on procedure
2. Apply the tool developed by the committee for formulary monitoring and evaluation to ensure its effective implementation. The rationale is to ensure implementation, accountability and enforcement of the use of listed medicines, which shall be available most times in the facility. Sanctions could be recommended by the DTC
3. Consider requests for addition of new drugs from only health-care personnel and these are to be justified with documented evidence on efficacy, relative efficacy, safety and comparative cost-effectiveness and a declaration of no conflict of interest
4. Establish procedures for adding medicines for clinical trials to non-formulary medicines under the ambit of the DTC
5. Educate all staff of the health institution about the formulary list and a list of non-listed drugs prescribed by clinicians within the facility should be kept by the pharmacy. The name of the prescriber, the name and quantity and the indication for use of the drug recorded
6. If a new drug is added to the list for reasons of improved efficacy, safety or lower price, give serious consideration to deleting the drug which was previously on the formulary list for the same indication

Job Tools

1. Formulary monitoring and evaluation tool
2. Formulary review guidelines

Chapter 10

Pharmacy Practice Research and Clinical Trials

Preamble

Pharmacy practice research aims to improve patient care through the collection of data and testing of hypothesis to generate appropriate information to support decisions regarding the nature, extent and quality of pharmaceutical care.

Pharmacists should build capacity in research and be encouraged to undertake research studies that promote safe, effective and efficient use of drugs, which will enhance provision of good quality pharmaceutical services.

The scope of practice research shall include:

- Preparations towards the study
- Performing the study
- Disseminating the results
- Implementation of recommendations

Operational flow diagram

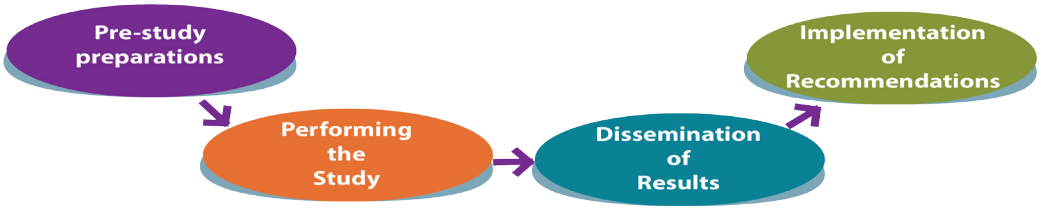

Fig 8: The scope of practice research

Aspects of the operations

10.1 Pre-study preparations

Standard statement

Preparations towards pharmacy practice research shall follow systematic procedures.

Operating procedures

Procedure 1: SOP for pre-study preparations
1. Identify area(s) of study with possible benefits for pharmaceutical services
2. Set research question or hypothesis that is to be tested
3. Formulate objectives and aims of the study
4. Set the title of the study
5. Set up the research team
6. Identify source(s) of funding
7. Conduct background study on the issue under investigation
8. Define the methodology:
a. Indicate overall study design and duration
b. Location of study
c. Sample size, type of subjects, and selection of subjects
d. Method of data collection
e. Type of analysis
f. Person to perform the analysis
g. Decide on what constitutes a significant result or a null result
9. Draw up research proposal and submit for approval
10. Submit proposal for ethical committee's review
11. The proposal developed shall be duly endorsed by the relevant authorities

Job Tools

1. Pre-study preparation protocols

10.2 Performing the study

Standard statement

The research shall conform to the specification in the proposal.

Operating procedures

Procedure 10.2: SOP for Performing the Study
1. Obtain ethical clearance from the appropriate ethics review committee and consent of subjects
2. Conduct a pre-test to study the feasibility, reliability and validity of variables
3. Collect data systematically and objectively
4. Ensure unbiased data collections
5. Ensure confidentiality of data throughout the study
6. Analyse data
7. Draw conclusions and state limitations of study
8. State how the results could be incorporated into practice and the possible benefits

Job Tools

1. Study protocols
2. Ghana health service ethical clearance guidelines

10.3 Dissemination of results

Standard statement

Research findings shall be effectively disseminated and implemented.

Operating procedures

Procedure 10.3: SOP for disseminating results
1. Publish articles by following standards for publication of scientific papers
2. Disseminate publications as widely as possible
3. Acknowledge funding and any support
4. Declare conflict of interest (if any)

10.4 Implementation of recommendations

Standard statement

Recommendations from the study shall be implemented where feasible.

Operating procedures

Procedure 10.4: SOP for Implementation of Recommendations
1. Review the recommendations and select the feasible ones
2. Develop strategies for implementation of the feasible recommendations
3. Support incorporation of the tested results of the study into practice and pursue its implementation

10.5 Clinical Trials

Standard statement

Clinical trials are specially designed research studies of drugs undergoing development or in use and other health devices or technologies. A clinical trial is a highly controlled study, which requires optimum protection of participants whilst ensuring that accurate and credible data is collected to support scientific and medical decisions.

A pharmacist shall conduct activities related to a clinical trial as required by the FDA, Ghana.

Clinical trials shall be conducted in accordance with the Public Health Act, 2012 (Act 851), regulatory requirements and international standards, and shall require the involvement and cooperation of a multidisciplinary team to ensure efficiency and professionalism.

Operating procedures

Procedure 10.5: SOP for conducting clinical trials
1. Obtain approval from the MOH for all clinical investigations before conducting studies. Where there is an ethical review committee and a DTC in an institution, obtain approval from these bodies
2. Obtain the consent of volunteers or patients enrolled in a clinical trial
3. Pharmacists handle all clinical trial medicines
4. Administer clinical trial medicines in accordance with procedures set out in clinical trial protocols
5. Dispense, issue, administer, and dispose of all medicines in accordance with the clinical trial protocols

Procedure 10.5: SOP for conducting clinical trials

6. Clinical trials with unlicensed medicines. A special permit is obtained from FDA for medicines that do not have a product license to be included in clinical trials. Such unlicensed products carry additional risks in terms of patient safety; take great care to ensure the safety of the patient during the clinical trial.
7. Electronic medical records (EMR) and claims data can be employed for research work and drug utilization studies
8. The sponsor of a clinical trial appoints a study pharmacist(s) in consultation with the principal investigator of the study
9. The appointed pharmacist(s) is responsible for the management of pharmaceutical investigational products (IP) only in respect to the trial for which he/she has been appointed
10. No person is appointed a study pharmacist unless he/she qualifies as per requirements of the FDA's guidelines for authorization of clinical trials in Ghana
11. Appropriate documentation regarding the appointment e.g. contracts and delegation log is to be duly signed by the sponsor, principal investigator and pharmacist respectively before the start of the study
12. The pharmacist, during consultations and negotiations for the signing of the documents in (*11*) above, ensures that his/her role is consistent with responsibilities outlined below that apply to the respective study under consideration
13. The person to be appointed as a study pharmacist ensures that his/her role in the study does not present any conflict with other clinical trials and/or local regulatory requirements
14. The person delegated as a study pharmacist may perform the under listed duties as agreed on with the Sponsor and Principal Investigator:

Development of trial documentation on IPs

a. Contribute to the development and continuous update of the under listed documents to ensure adequate provision of optimum pharmaceutical care to participants throughout the conduct of the trial:
   i. Protocol
   ii. Investigator's brochure
   iii. Pharmacy manual
   iv. Summary of product characteristics
   v. Packaging insert or user manual
   vi. Product label
   vii. Standard operating procedures for all protocol activities related to management of pharmaceutical products used for the trial

Importation or procurement of IPs

b. On receipt of a consignment of the IP on site, the pharmacist ensures that the shipping and delivery records include:
   i. Dates of shipment/delivery
   ii. Quantities/doses of the respective products received
   iii. Batch/lot numbers of the respective products received
   iv. Manufacture and expiry dates of the product(s)
   v. Unique code numbers assigned to the product and the trial subjects
   vi. Certificate of analysis or lot release certificate for the respective products and/or batches received

c. On receipt of a consignment of the IP on site, the pharmacist ensures that condition and quality of the product is adequate with the availability of temperature/humidity monitoring records if applicable

d. Discrepancies noted in points (*b*) and (*c*) above is to be recorded and communicated as required by the study protocol and/or SOPs

Procedure 10.5: SOP for conducting clinical trials

e. The under listed documents covering importation shall also be kept as part of product accountability records:
   i. Copy of application letter/e-mail requesting for regulatory approval for the importation/purchase of the products(s)
   ii. Copy of Ghana Community Network (GCNet) form indicating clearance by FDA

Storage of IPs

f. The pharmacist ensures and maintains adequate storage conditions for the IP as required by the approved protocol, investigator's brochure, pharmacy manual or summary of product characteristics (SmPC) for the clinical trial.

g. Storage conditions for the products include:
   i. Appropriate temperature and humidity conditions
   ii. Adequate security to the storage area
   iii. Availability of systems that ensure access control to the storage area
   iv. Availability of systems that will prevent mix-up of IPs and other non-study related products

h. The following records are to be suitably filed regarding the storage of IPs:
   i. Temperature/humidity monitoring charts
   ii. Cold chain records
   iii. Other special instructions such as handling of radioactive materials
   iv. Deviations and corrective actions where applicable

Dispensing of IPs

The pharmacist ensures that:

i. IPs are strictly prepared, and dispensed as per the approved protocol and other related study documents

j. Current good manufacturing and dispensing practices are adhered to taking into consideration the design (e.g. randomization scheme, blinding strategy) of the trial

k. Records kept at the pharmacy clearly indicate:
   i. Use by individual study participants
   ii. Quantity dispensed to the participant
   iii. The date the respective quantity was dispensed
   iv. Quantity returned by the participant (if applicable)
   v. The procedures recorded in such a manner as to facilitate product accountability to every individual to whom a product was dispensed

l. Products intended for clinical trial shall under no circumstance be dispensed to patients outside the trial unless explicit approvals have been received from both the sponsor of the trial and the FDA

m. There are systems in place to provide appropriate and required counselling on use of the product to each individual to whom the investigational product is administered

n. Records of correct usage and compliance accurately captured in source documents

Disposal of IPs

o. The pharmacist ensures that adequate records on returned, unused or destroyed IPs are available at the pharmacy

p. Documentation regarding the basis of returned, un-used or destroyed products are to be kept. It is essential that per subject information on this is duly kept

q. IPs shall be disposed of in accordance with the sponsor's instructions or according to the approved protocol

r. Without prejudice to *(q)* above, IPs shall only be disposed of in accordance with the FDA's regulatory requirements

s. The following shall apply for the destruction of IPs:
   i. Prior approval from the FDA before destruction
   ii. Adequate stock taking and accountability before destruction
   iii. Involvement of other relevant stakeholders
   iv. Issuance of FDA certificate of destruction

Procedure 10.5: SOP for conducting clinical trials

Good clinical practice (GCP) audits/inspections

t. During GCP inspections or audits the pharmacist is to ensure that appropriate logs and documentation that will allow accounting for every single unit of product received are available. The documentation is to show consistency and accuracy of information from shipment to use/return/destruction

u. Presence of the pharmacist during product accountability is considered critical to successful accountability of IPs in a clinical trial

Others

v. The delegated study pharmacist on whom the main responsibility of adequate management of IPs lie ensures adequate qualification (by training and experience) of all persons that are required to perform any activity related to the management of the IPs

w. The delegation log is to appropriately reflect any such delegation

x. The study pharmacist ensures calibration and validation of all equipment used in handling and or dispensing IP e.g. freezers, temperature monitors, weighing scales etc.

15. The pharmacist considering his/her training and level within the health system of Ghana may alternatively play roles in clinical trials that are not specific to the pharmacy profession

The pharmacist in this case based on additional training and experience may serve as;

a. A member of the technical advisory committee on clinical trials if the pharmacist qualifies as an expert as specified in section 153, Part 8 of the Public Health Act, 2012 (Act 851) and is invited by the FDA to serve on the committee

b. A member of an ethics review committee to assess the ethical validity of proposed clinical trials

c. A member of a data and safety monitoring board who continuously monitor accruing data from ongoing trials to advise the sponsor on whether or not to proceed with a trial as intended

d. A trial monitor/coordinator or manager where he/she shall assist the investigation team to comply with the trial requirements

e. Data manager, archiving clerk, procurement officer or any other role for which he/she is qualified

Job Tools

1. Clinical trial protocols

Chapter 11

Pharmaceutical Workforce, Leadership, Governance & Financial Management

Preamble

Emerging demands in global health care delivery impose the need for specialisation in pharmaceutical care. This challenge is met by training and subsequently appointing qualified pharmacists into the identified areas of specialty. As a manager, the onus lies in the pharmacist to effectively put the combined efforts of all team members together for the benefit of the patients/clients.

11.1 Leadership

Pharmacy has strong professional leadership, clear strategic vision, governance and controls necessary to ensure patient safety and provide optimum medication therapy.

Professional Leadership

The pharmacy team recognises that they have a duty of care to patients and therefore always act in the interest of the patient. The pharmacy team is open, candid and transparent. In the public sector, the director of pharmaceutical services (DPS) leads through commitment, encouragement, compassion and continuous learning approach whilst the superintendent pharmacist leads in the private sector. However, professional leadership at all levels is encouraged and developed.

Strategic Leadership

The heads of the various units of pharmacy ensure that the organization maintains a clear vision for pharmaceutical services and optimal use of medicines at all times. The unit heads are held accountable for the standards of pharmaceutical services and quality of medicines used in the organization. The heads provide assurance to their respective management or boards about the safe and secure handling of medicines within the organization.

Operational Leadership

The heads of the various units of pharmacy ensures that pharmaceutical services are safe and in consonance with organizational priorities and puts the patient first. The type and level of resources required to deliver safe

and effective pharmaceutical services and to support the rational use of medicines are identified and must be provided for by management. There are key performance indicators to enable internal and external assessment of the operational and financial performance of pharmaceutical services. The service structure has clear lines of professional and organizational responsibility and is reviewed regularly. Additionally, feedback from patients, service users and colleagues inform the development of pharmaceutical services.

Clinical Leadership

The pharmacy team is recognised as experts on medicine-related issues in the organization at all levels. The team provides the leadership, advice, support and education to other health care professionals and support staff about safe and effective use of medicines. They also support the development of integrated care pathways that involve medicines as a treatment option.

11.2 Governance & financial management

Governance is a strategic framework that combines effective oversight, coalition building and regulation effective to system design, accountability and transparency.

11.2.1 Governance Structure

Teaching Hospitals

- Director of Pharmacy (Teaching Hospital)/Consultant
- Deputy Director of Pharmacy/Senior Specialist
- Chief Pharmacist/Specialist
- Deputy Chief Pharmacist
- Principal Pharmacist
- Senior Pharmacist
- Pharmacist
- Pharmacy House Officer
- Pharmacy support staff

Regional Hospitals

- Deputy Director of Pharmacy/Senior Specialist/Consultant
- Chief Pharmacist/Specialist
- Deputy Chief Pharmacist
- Principal Pharmacist
- Senior Pharmacist
- Pharmacist
- Pharmacy House Officer
- Pharmacy support staff

District Hospitals

- Chief Pharmacist/Specialist
- Deputy Chief Pharmacist
- Principal Pharmacist
- Senior Pharmacist

- Pharmacist
- Pharmacy House Officer
- Pharmacy support staff

Private Hospitals

- Deputy Director of Pharmacy/Senior Specialist/Consultant
- Chief Pharmacist/Specialist
- Deputy Chief Pharmacist
- Principal Pharmacist
- Senior Pharmacist
- Pharmacist
- Pharmacy House Officer
- Pharmacy support staff

System Governance

Systems of work are established that are safe, productive, support continuous quality improvement, regularly audited and comply with all relevant regulations. Pharmaceutical care interventions are documented and audited to demonstrate the impact of the service on patient outcomes and to help target resources.

Controlled medicines are managed in line with relevant legislation and governance requirements. There are effective complaints systems for patients and staff to encourage patient safety, continuous learning and service improvements. Standard operating procedures guide the delivery of pharmaceutical services across the organization.

Financial Governance

Robust organizational planning, financial planning and reporting are periodically undertaken. Medicines utilization reports are produced that support budget management and monitoring of clinical practice.

11.3 Workforce

The pharmacy team has requisite skill specialisation, capacity and capability to develop and provide safe and quality services to patients.

11.3.1 Workforce Planning

The pharmacy workforce is planned and resourced to support productivity, safety, and service quality. Where workforce shortfalls are identified corrective measures are put in place to guarantee the safety of patients. Succession planning arrangements are in place and are linked to workforce training and personnel development plans.

Workload in the facility (service statistics) = Staffing requirement divided by standard workload (for one staff)

11.3.2 Workforce Development

The pharmacy workforce has an effective performance management and personal development planning process. The pharmacy team has roles and responsibilities clearly defined in their job descriptions and their performance appraised yearly. There are systems in place to ensure that competency is maintained and developed to meet changing service needs, patient expectation and the introduction of new technologies. All members of the pharmacy team are aware of their own level of competency and how these competencies can be further developed in their roles and careers.

11.3.3 Education and Training

Continuous professional development (CPD) is provided for all members of the pharmacy team. The Pharmacy Council is mandated by section 80(b) of the Health Professions Regulatory Bodies Act, 2013 (Act 857) Part 4 to set standards for continuous professional development of pharmacists and other pharmacy support staff by accrediting the programme(s) of relevant training institutions, agencies and firms to implement the CPDs in line with the required competencies as well as ensure a collective continuing education for the various grades of professional practice.

11.4 Skill specialisation for various pharmacy functions

Skill specialisation is the group of occupational categories required for the effective and efficient performance of the functions of an organization. It is determined by the range of services to be provided and the skills required.

To determine the skill specialisation, it is necessary to identify the job contents and job specifications of all the services to be performed by the pharmacist. The following outlines the job descriptions associated with the performance of these pharmacy functions and the categories of personnel who by their training are best suited for the performance of these duties. It is hoped that this will serve as a guide to recruitment and deployment of pharmacy human resource.

The main service areas are as follows:

- Medicine supply management
- Dispensing and patient counselling
- Specialist pharmacy services
- Local small-scale manufacture of medicines
- Education and counselling of patients
- Training of other health care professionals
- Management of institutional formularies and treatment protocols
- Research
- Pharmacovigilance and drug safety
- Immunoglobulins and vaccines management
- Management of family planning commodities
- Health Technology assessment
- Health promotion programmes
- Policy and management
- Regulation
- Drug information services
- Community Pharmacy Practice

Competency Matrix

Table: Competency matrix for pharmacy practice

Grade	Role Purpose *(acknowledged)	Competencies
Pharmacist Work station i/c	Provide pharmaceutical care, manufacture medicines and ensure patient safety by reviewing, dispensing prescriptions and counselling patients in line with approved policies/guidelines.	Prescription management; Patient education; Records and data management; Basic communication management; Basic computer skills; Basic report writing; Basic quality assurance
Senior Pharmacist Unit head (dispensary of medicines, stores, production, drug information, ward pharmacy Etc.)	Supervise and/or manage pharmacy operations in assigned location and provide pharmaceutical care, manufacture medicines and ensure patient safety by reviewing, dispensing prescriptions and counselling patients in line with approved policies/guidelines.	Complex computer skills; Communication management; Forecasting & quantification; Education for complex patients; RUM; Clinical case management; NHIS management; Procurement processes; Passive drug information management.
Principal Pharmacist Pharmacy manager (Drug Information, stores, production, dispensary)	Responsible for monitoring the implementation of approved pharmaceutical service policies, guidelines and procedures to ensure effective therapeutic outcomes in the use of medicines. Scope of work includes participating in the management of the day to day activities of the assigned Health Facility.	Pharmacy resource management; Complex report writing; Data analysis; Research methods; Stores management; Basic accounting principles; Pharmaco-economics; Active drug info management; Project development and implementation; Critical evaluation of biomedical literature; Service delivery assessment; Procurement and Supply management
Deputy Chief Pharmacist Deputy director/Senior manager	Manage and monitor the implementation of approved policies, guidelines/procedures of the pharmaceutical services within assigned location to ensure effective administration/dispensing of medications to patients as well as provide advice and counselling on the proper use/storage of drugs. Scope of work includes participating in the management of the day to day activities of the assigned Health Facility to ensure effective therapeutic outcomes.	Pharmaco-epidemiology; Health policy development, monitoring and evaluation; Financial administration; Public administration; Problem-solving and decision-making; arbitration skills; people management; Delegation and responsibility assessment/job appraisal
Chief Pharmacist Director	Responsible for the management and monitoring the implementation of approved policies, guidelines/procedures of the pharmaceutical services to ensure effective administration/ dispensing of medications to patients as well as provide advice and counselling on the proper use/ storage of medicines. Scope of work includes the day to day management and administration of the activities of designated health facility to ensure effective medical/ therapeutic outcomes.	
Specialist Pharmacist	Provide specialist advice in the development and implementation of strategies, policies, guidelines/ procedures for the pharmaceutical /health services including expert practice in all aspects of specialised health services to achieve optimum quality outcomes.	Clinical problem-solving; Leadership; Ward and patient etiquette; Drug information management; Communication skills; Interpretation of patient clinical data including investigations; Drug therapy evaluation and review; Complex patient education; Drug selection; Drug formulary development; Clinical pharmacokinetics; Pharmaco-economics; Pharmacy resource management; Complex report writing; Data analysis; Research methods; Project development and implementation; Critical evaluation of biomedical literature; Service delivery assessment
Senior Specialist Pharmacist		

Grade	Role Purpose *(acknowledged)	Competencies
Consultant	Direct and provide specialist advice in the development/ implementation of strategies, policies, guidelines/procedures for the pharmaceutical/health services including expert practice in all aspects of specialised health services and advance pharmacy services to achieve optimum quality outcomes.	Strategy and policy development; People development and management; Service and job appraisal; Financial administration; Public administration; Problem-solving and expert decision-making; Arbitration skills; Delegation and responsibility assessment/job appraisal

Note: As personnel progress through the grades, additional skills and competencies are built and added onto existing skills and competencies acquired in previous grades

11.4.1 Medicine supply management

Job content

- **a.** Selection
- **b.** Forecasting and quantification for medicines and other related items
- **c.** Procurement
- **d.** Receipt
- **e.** Storage
- **f.** Distribution
- **g.** Inventory management
- **h.** Use

11.4.2 Dispensing and patient counselling

Job content

- **a.** Prescription evaluation and validation
- **b.** Packaging and labelling
- **c.** Issuing of medicines and patient counselling
- **d.** Providing drug information
- **e.** Documentation

11.4.3 Specialist pharmacy services

11.4.3.1 Clinical pharmacy services

Job content

- **a.** Medication history taking and identification of pharmaceutical care issues
- **b.** Education and counselling of patients
- **c.** Prescription and medication monitoring
- **d.** Identification of patient and medication risk factors
- **e.** Prevention, detection and reporting adverse drug reactions
- **f.** Individualization of drug dosage requirements
- **g.** Evaluation of medicines use
- **h.** Provision of drug information to clients and other health workers
- **i.** Participation in health promotion activities
- **j.** Discharge counselling, adherence counselling and counselling to ensure medication compliance

11.4.3.2 Other specialist pharmacy services

The job content and categories of personnel who provide these services are specific and are to be defined. The specialist positions are clinical pharmacist, public health pharmacist, social and administrative pharmacist, research pharmacist, industrial pharmacist, pharmacist in academia and community pharmacist among others according to the West Africa post graduate college of pharmacist (WAPCP), Ghana college of pharmacists (Refer to the Ghana college of pharmacists for details) and the Ghana health service (GHS).

Note: See the Specialist Health Training and Plant Medicine Act, 2011 (Act 833) for the procedure or pathways for career progression within the profession.

11.4.4 Local small-scale manufacture of medicines

Job content

a. Quality assessment of raw materials
b. Compounding
c. Packaging and labelling
d. Documentation
e. Quality control

11.4.5 Education and counselling of patients

Job content

Educate patients and facilitate in the training of patients/community members on the appropriate use of medicines and pharmaceutical appliances.

11.4.6 Training of other health care professionals

Job content

Facilitate in the training of other health care professionals on the appropriate use of medicines and pharmaceutical appliances.

11.4.7 Management of institutional formularies and treatment protocols

Job content

a. Playing a leading role in the formation and functioning of interdisciplinary standing committee (e.g. DTC, and QA Team) to develop formularies and treatment protocols
b. Ensuring the compilation, publication and use of the formularies and protocols
c. Ensuring that medicines stocked conform to the formulary as much as possible
d. Ensuring periodic review of the formulary and treatment protocols
e. Actively participating in clinical and mortality meetings

11.4.8 Research

Job content

a. Operational research for service improvement
b. Research in any relevant pharmaceutical and health discipline including clinical trials

11.4.9 Health promotion programmes

Job content

a. Develop or contribute to the development of health education materials
b. Organize and implement health education programmes to promote the rational use of medicines
c. Participate in other public health promotion programmes

11.4.10 Policy and management

Job content

a. Formulate, implement and review relevant health and pharmacy policies
b. Apply managerial skills for the realization of the institutional goal
c. Apply appropriate managerial skills in the running of the pharmacy unit/directorate of the institution to ensure efficiency of operations and realization of institutional goals

11.4.11 Drug information services

Job content

a. Establish and operate a system for the generation, collation, storage, and maintenance of relevant data on medicines and their use
b. Develop and operate a system for the dissemination of drug information to all enquirers
c. Develop indicators and guidelines for data management
d. Apply the most convenient and modern technology/methods for the operation of the drug information unit

11.5 Pharmacy staff utilization

Preamble

The pharmaceutical care team is made up of the pharmacist, pharmacy technicians, and other support staff, with the pharmacists being the leader of the team. For the provision of quality pharmaceutical care, the level of competence of the team members has to be high and regularly upgraded.

Staff utilization refers to the most efficient way of deploying staff in terms of numbers and skills specialisation in a facility to ensure efficient performance. In determining the staff utilization of pharmacy departments at the various facilities the following should be considered:

1. Range of services provided
2. Workload. (E.g. bed occupancy and out-patient attendance)
3. Working hours and shift system. (The current policy of the
4. Ministry of Health is that all static curative health facilities should provide 24 hours service)
5. Vacation/leave
6. An in-depth study of the factors above should be undertaken to determine the staff skill specialisation and the right numbers required at each facility.

Standard statement

The management authority in charge of any health care institution shall ensure that the right numbers of relevant categories of pharmacy staff are recruited for the efficient performance of the pharmaceutical care functions of the institution.

Operating procedures

Procedure 11.5: SOP for determining staff utilization

The procedure involves the use of the workload indicator of staffing needs (WISN) tool which is used to estimate staffing needs based on workload. The following steps are used to determine this:

Step 1: Determine WISN priorities

Step 2: Estimate available working time

Step 3: Define components of daily work

Step 4: Set activity standards

Step 5: Establish standard workloads

Step 6: Calculate allowance factors

Step 7: Determine required staff

Step 8: Analyse WISN results

Note

WISN ratio = 1 means staff sufficient for workload

WISN ratio < 1 means staff not sufficient for workload

WISN ratio > 1 means more than enough staff for work load

Note:

Ensure that the categories of pharmacy staff include:

a. Pharmacists

b. Pharmacy technicians

Job Tools

1. Workload indicator of staffing needs (WISN) model (www.who.int/hrh/resources/wisn_user_manual/en/)

Chapter 12

Procurement and Stock Management

Preamble

Procurement is defined in the procurement procedure manual (PPM) to include the planning and use of funds available to the budget management centre (BMC) to acquire goods and services amongst others.

From the perspective of the pharmaceutical services, procurement is concerned mostly with the acquisition of commodities required for the provision of pharmaceutical care as per the procurement Act. This chapter therefore focuses on the various steps in the procurement of pharmaceutical goods.

Aspects of operations

12.1 Procurement from central or regional medical stores

Standard statement

The process of procurement from central and regional medical stores shall follow the established standard procedure.

Operating procedures

Procedure 12.1: SOP for procuring from central or regional medical stores
1. Prepare the list of medicines, non-medicine medical consumables and other goods that may be determined from time to time by the institutional DTC for procurement by the BMC
2. Source first, requirements from the regional medical stores (RMS) or central medical stores (CMS) as appropriate
3. Buy the said items only from the open market when such items are not available at the RMS or CMS
4. Confirm the non-availability of the requirements with the issuance of a "**Certificate of Non-availability**" from the RMS or CMS

Job Tools

1. Procurement procedure manual
2. Logistics management information system (LMIS) manual
3. Quantification guidelines

12.2 Procurement process and procedures

Standard statement

The process of procurement shall follow the established standard procedure.

Operating procedures

Procedure 12.2: SOP for procurement process

Product selection

1. Selection must be based on a formulary prepared by the DTC of the institution
2. Review from time to time to continuously meet the desired needs of the facility
3. At the health centre and clinic levels, requisition for re-supply is based on the routinely used medicines at those levels
4. Support for and cross-checking of requisitions are carried out by the district pharmacist or the district health management team (DHMT) in the case of the district level and by the director of pharmacy in the case of the regional hospital

Forecasting medicines requirements

1. Use the combination of consumption and morbidity methods, which use data on past medicines consumption and also the pattern of common diseases within the catchment area to get the most accurate prediction of future needs
2. Prepare and circulate procurement plans for the ensuring year by the last quarter of current year

Inventory control

1. Maximum stock and re-order quantities

The maximum stock quantity (MSQ) is the highest quantity of a product or drug entity a facility should have on hand at any point in time. The re-order quantity (ROQ) is the quantity that is needed to replenish a particular drug entity to the required or most economic level.

   a. Set and maintain MSQ in order to ensure health facilities have enough commodities on hand to meet their clients'/patients' needs and to simplify the process of calculating order quantities
   b. Base the MSQ and ROQ on consumption at any time
   c. Consult section II of logistics management of public sector health commodities in Ghana for details on how these quantities are calculated

Job Tools

1. Logistics management of public sector health commodities in Ghana
2. Procurement manual
3. Consumption and morbidity records
4. LMIS manual
5. Quantification guidelines

12.3 Commodities management responsibilities by levels

Standard statement

Commodities management responsibilities by levels shall follow the established standard procedure.

Operating procedures

Procedure 12.3: SOP for commodities management responsibilities by levels

Health facility level

1. Request the products that are needed to treat clients/patients
2. Provide to the RMS, the information it needs to fill the orders it receives

District level

1. Provide support to the health facilities through monitoring and advocacy
2. Review health facility requisition quantities
3. Transmit requisitions to RMS
4. Assist health facilities to process their payment cheques
5. Follow up to ensure that payments are made to the RMS
6. Assist health facilities in case of discrepancies or other problems with commodities received

Regional medical stores

1. Be responsible for filling health commodity requisitions and delivering products to the health facilities within the region
2. Provide price lists to health facilities
3. Set the schedules for commodity deliveries and related activities
4. Deliver health commodities to the health facilities
5. Work with the health facilities and the districts to resolve all discrepancies
6. Collect, collate and distribute the health commodity data that is needed for decision making by stores managers and programme personnel at various levels of the system
7. Collate the requisitions from the districts or health facilities
8. Determine the quantities of the various items required
9. Complete the requisition portion of the combined requisition, issue and receipt voucher (RIRV)
10. Submit the requisition voucher to the supply source, CMS or private supplier
11. Obtain a minimum of three invoices or quotations from different sources for price comparison as is required by regulation in the case of private supplier

All levels

Some commodity management tasks are performed at more than one level, as is the case in the health facilities and at the regional level

1. Receive, check and record all commodities from suppliers
2. Use the existing inventory control methods for the effective management of stocks
3. Constantly monitor the conditions of all commodities in the stores

Job Tools

1. Procurement procedure manual
2. Requisitions books
3. LMIS manual
4. Quantification guidelines

12.4 Procurement methods for goods from outside the CMS and RMS

Standard statement

The method for procurement of goods from outside the CMS and RMS shall follow the established standard procedure.

Operating procedures

Procedure 12.4: SOP for procuring goods from outside the CMS and RMS

1. Follow the under-listed procurement methods as appropriate
   a. International competitive bidding (ICB)
   b. National competitive bidding (NCB)
   c. Limited international bidding
   d. Local or international shopping
   e. Direct contracting
2. Refer to chapter 4 of the procurement procedure manual for details

Job Tools

1. Procurement procedure manual
2. LMIS manual
3. Quantification guidelines

12.5 Summary of activities for commodity re-supply

Standard statement

Commodity re-supply activities shall follow the established standard procedures.

Operating procedures

Procedure 12.5: SOP for summarised activities for commodity re-supply

A major component of re-supply activities includes the submission of the requisition, issue and receipt voucher (RIRV) to the appropriate source of supply

1. Use local purchase order (LPO) for private sector purchases
2. Determine the requisition quantities
3. Review the requisition quantity with district staff (health facilities only)
4. Complete the requisition portion of the RIRV
5. Submit the voucher to the supply source - RMS for health facilities and CMS or private supplier for RMS.

Receipt of products from supplier

1. Check the quantity and quality of the products received
2. Complete the receiving portion of the RIRV
3. Store and maintain the products in the facility store room

Process for making payment

For detailed description of re-supply activities at health facility to regional level refer to section II and job aids in section III of the logistic management of public sector Health commodities in Ghana and SOPs

Obtaining products through the LPO

The primary goal at the RMS level is to have sufficient quantity of stock on hand to meet all health facility needs. Normally, RMS will obtain its re-supplies from the CMS through the requisition system.

Procedure 12.5: SOP for summarised activities for commodity re-supply

Sometimes, products may not be available at the CMS, or the RMS may receive a shipment of commodities from CMS in which the quantity issued is less than requisition quantity. In both of these cases the RMS is automatically authorized to make a local procurement/purchase using an LPO.

1. Follow the procedures that are provided for in the current MOH procurement procedure manual to obtain commodities through LPO
2. Follow the normal procedures for receiving commodities including quality assurance, storage and up-dating the store keeping records, once the products are received

Receiving commodities

This is the final step in the re-supply process

1. Verify the number of boxes received
2. Sign the way bill
3. Give documents to the driver
4. Open and unpack boxes
5. Write quantities received and sign RIRV
6. Arrange the commodities in stores
7. Update stock keeping records
8. Distribute the RIRV
9. Follow-up to district or region if necessary

Issuing commodities in health facilities

Once the commodities have been received and stored in the facility stores, they are ready for issue to the pharmacy/dispensary staff that will dispense them to the clients/patients.

1. Establish own specific internal issuing process, following the general guidelines in the MOH
2. Use the forms listed below and others to collect and document dispensed-to-user data:
   a. Prescription register
   b. Family planning daily summary and monthly totals/form
   c. Vaccines return form
   d. Other programme specific forms
3. Refer to relevant documents and SOPs for details on how to document some of these data

Inventory Management

Inventory management at the health facility level includes two main activities. These include monitoring the quantities of stock on hand and maintaining product quality.

4. Monitor quantities of stock on hand by doing stock-taking on a regular basis.

Monitor the quality of the products by conducting regular visual inspection of the products, periodically sending samples of products for laboratory assessment of quality and by maintaining the stores in good order

Job Tools

1. Procurement procedure manual
2. LMIS manual
3. Quantification guidelines
4. Local purchase order (LPO) form
5. Requisition issues receipt voucher (RIRV)

Chapter 13

Job Descriptions

This chapter outlines the professional grades and job descriptions of pharmacy staff in the Ministry of Health and Ghana Health Services (MOH/GHS).

Pharmacists

1. Consultant pharmacist
2. Senior specialist pharmacist
3. Specialist pharmacist
4. Chief pharmacist
5. Deputy chief pharmacist
6. Principal pharmacist
7. Senior pharmacist
8. Pharmacist

Technicians

9. Chief dispensing technician
10. Assistant chief dispensing technician
11. Principal dispensing technician
12. Senior dispensing technician
13. Dispensing technician

Detailed job description/specification

1. Pharmacist

Job Title	Pharmacist
Grade	Pharmacist
Responsible to	Head of Unit/Senior Pharmacist
Accountable to	Head of Department/Head of Facility
Job Purpose	Provide pharmaceutical information to ensure patient safety in line with approved policies/guidelines.

Main Duties & Responsibilities

1. Implement approved pharmaceutical service policies, standard operating procedures (SOPs), and work plan to ensure the achievement of objectives.
2. Interpret/review medical prescriptions to ensure therapeutic compatibilities and prepare the required medications in line with approved guidelines/standards.
3. Update medicines reconciliation processes to enhance patient safety at ward level.
4. Participate in clinical ward rounds and collaborate with the medical team to ensure all medication issues are resolved accordingly.
5. Provide medicine and pharmacological information to multidisciplinary health care team within approved limit of authority.
6. Monitor the effects of medications by reviewing clinical signs and symptoms including blood pressure monitoring, pulse monitoring, spirometry from patients' chart.
7. Compound sterile and non-sterile pharmaceuticals in accordance with recognised protocols /guidelines as directed by superior officer.
8. Dispense prescribed medications to patients by compounding, reconstituting, packing and labelling pharmaceutical products.
9. Counsel patients appropriately on adherence safety to optimize therapeutic outcome
10. Ensure a safe and clean working environment by complying with procedures, guidelines and regulations on drug storage/dispensary and adherence to infection prevention and control protocols.
11. Keep comprehensive database on pharmaceutical products to ensure efficient stocking, stock control and for other compliance purposes.
12. Report adverse drug reactions/events.
13. Recommend safe combinations of medicines or solutions to specific patient problems within prescribed limits of authority.
14. Replenish and monitor emergency medicine tray to ensure adequate supply of quality emergency medicines at the wards.

15. Provide discharge/exit counselling services in relationship to drug therapy for all patients to ensure optimisation of treatment.
16. Maintain and update records on financial and accounting transactions related to the operations of assigned location.
17. Prepare and submit periodic reports relating to job function to head of unit.
18. Support preparation of plans and budget for the facility.
19. Participate in the procurement, storage and distribution of safe, effective medicines within assigned facility
20. Lead and actively participate in the activity of drug and therapeutic committees within assigned location
21. Provide input in the preparation of the annual operating budget to support pharmaceutical operations in assigned location and implement same.
22. Conduct performance appraisal and provide input for career development and recommend performance incentives for subordinate staff.
23. Supervise subordinates in the discharge of assigned responsibilities.
24. Perform any other official duties that are incidental in relation to your job.

Communication and Working Relationships

– Maintain effective communication with other team members in the facility.
– Maintain good relationship with pharmaceutical organizations and relevant regulatory bodies.
– Participate actively in clinical meetings.
– Attend performance review meetings and participate actively on issues related to pharmaceutical service.
– Participate in multi-professional meetings and scientific conferences as required in the facility.

Personal and People Development

– Develop and maintain continuing personal and professional development to meet the changing demands in the area of pharmaceutical services.
– Monitor own performance against agreed objectives and targets.
– Promote an enabling environment for staff development and training to meet required standards.

Management

– Contribute to the maintenance of an accurate database on pharmaceutical services in the Hospital.
– Identify and undertake any cost improvement measures as required.
– Promote a positive image for GHS.
– Provide leadership and mentorship to inspire junior colleagues for future development.

Research

– Undertake/Participate in operational research and development activities on pharmacy practice within the facility.

Health Safety Responsibilities

– Take care of own safety and ensure the safety of other staff working within the unit.

– Promote adherence to health and safety policies, guidelines and protocols in the assigned location.

Quality Assurance

– Promote the establishment and monitoring of quality improvement systems for pharmaceutical services in the facility.

Further Information

The post holder must at all times:

– Work in accordance with the Code of Conduct and Disciplinary Procedures of the GHS.

– Strictly adhere to the provisions of the Patient's Charter.

– Adhere to GHS administrative policies and procedures.

This job description is intended as a guide to the principal duties and responsibilities for the post and should not be considered an exhaustive list. It is subject to change in line with future development of the service.

PERSON SPECIFICATION

1. Pharmacist

Criteria	Essential	Desirable
Educational Qualification and Experience	Bachelor of pharmacy from a recognized university plus one (1) year national service or internship in a recognized health facility	Doctor of Pharmacy
Knowledge	– Knowledge and understanding of laws, rules, Acts and regulations in health care operations and clinical practices. – Stay abreast with legislations, rules/regulations, laws etc. on medicines acquisition, dispensing etc. as prescribed by regulatory authorities (Pharmacy Council, Food and Drugs Authority, Ghana Standards Authority, etc.) – Knowledge in the use of research methodologies and tools relative to health care practices. – Knowledge and application of ethical requirements of the practice. – Experience in medicine regimen and patients case reviews. – Knowledge and experience in conducting therapeutic reviews of prescriptions	
Skills & Abilities	– Ability to identify and manage medications risk/safety issues. – Ability to deal sensitively with patients' emotions/concerns and maintain patient's confidentiality. – Technical skill in compounding and manufacturing medicines. – Good numerical ability/quantitative skills. – Ability to work under pressure and multi-task in a fast paced environment. – Ability to negotiate, persuade and manage conflicts. – Good communication, presentation and report writing skills. – Knowledge and experience in case management. – Knowledge in the use of Microsoft office, Internet and other Software/tools in dispensary practice. – Supervisory, counselling and interpersonal skills in a team setting. – Exhibit high sense of professionalism	
Personal Attributes	High level of Integrity, flexibility, enthusiasm, motivation, courteousness, trustworthiness, assertiveness, empathy.	

2. Senior Pharmacist

Job Title	Pharmacist
Grade	Senior Pharmacist
Responsible to	Head of Department/Principal Pharmacist
Accountable to	Head of Facility/Head of Department/Director of Pharmacy
Job Purpose	Provide pharmaceutical information to ensure patient safety in line with approved policies/guidelines.

Main Duties & Responsibilities

1. Implement approved pharmaceutical service policies, standard operating procedures (SOPs), and work plan to ensure the achievement of objectives.
2. Evaluate/Interpret medical prescriptions/requests and liaise with prescribers and/or superior officer on dosages, medication to ensure therapeutic compatibilities and optimized outcomes in line with approved guidelines/standards.
3. Update medicines reconciliation processes to enhance patient safety at ward level.
4. Participate in clinical ward rounds and collaborate with the medical team to ensure all medication issues are resolved accordingly.
5. Provide medicine and pharmacological information to multidisciplinary health care team within approved limit of authority.
6. Monitor the effects of medications by reviewing clinical signs and symptoms including blood pressure monitoring, pulse monitoring, spirometry from patients' chart.
7. Compound sterile and non-sterile pharmaceuticals in accordance with recognised protocols /guidelines as directed by superior officer.
8. Dispense prescribed medications to patients by compounding, reconstituting, packing and labelling pharmaceutical products.
9. Counsel patients appropriately on adherence safety to optimize therapeutic outcome
10. Ensure a safe and clean working environment by complying with procedures, guidelines and regulations on drug storage/dispensary and adherence to infection prevention and control protocols.
11. Keep comprehensive database on pharmaceutical products to ensure efficient stocking, stock control and for other compliance purposes.
12. Keep records on adverse drug reactions/events and submit such reports to the National Drug Information Resource Centre and the Pharmacovigilance Unit of the FDA
13. Recommend safe combinations of medicines or solutions to specific patient problems within prescribed limits of authority.
14. Replenish and monitor emergency medicine tray to ensure adequate supply of quality emergency medicines at the wards.

15. Provide discharge/exit counselling services in relationship to drug therapy for all patients to ensure optimisation of treatment.
16. Maintain and update records on financial and accounting transactions related to the operations of assigned location.
17. Prepare and submit periodic reports relating to job function to head of unit.
18. Conduct performance appraisal and provide input for career development and recommend performance incentives for subordinate staff.
19. Support preparation of plans and budget for the facility.
20. Participate in the procurement, storage and distribution of safe, effective medicines within assigned facility
21. Lead and actively participate in the activity of drug and therapeutic committees within assigned location
22. Perform any other official duties that are incidental in relation to your job.
23. Analyse prescribing trends to inform decisions and enhance rational use of medicines.
24. Identify untreated health problems and liaise with physician for appropriate treatment.
25. Provide information to nursing and other medical staff in relation to new medications.
26. Provide input in the preparation of the annual operating budget to support pharmaceutical operations in assigned location and implement same.
27. Supervise subordinates in the discharge of assigned responsibilities.
28. Participate in the vetting of NHIS claims in the assigned facility.
29. Maintain and update data/records on financial transactions relating to the Pharmacy department.
30. Facilitate the training of Pharmacists, Pharmacy Technicians, Interns and support continuing professional development of pharmacists on current and new developments in pharmacy services.

Communication and Working Relationships

- Maintain effective communication with other team members in the facility.
- Maintain good relationship with pharmaceutical organizations and relevant regulatory bodies.
- Participate actively in clinical meetings.
- Attend performance review meetings and participate actively on issues related to pharmaceutical service.
- Participate in multi-professional meetings and scientific conferences as required in the facility.

Personal and People Development

- Develop and maintain continuing personal and professional development to meet the changing demands in the area of pharmaceutical services.
- Monitor own performance against agreed objectives and targets.
- Promote an enabling environment for staff development and training to meet required standards.

Management

- Contribute to the maintenance of an accurate database on pharmaceutical services in the Hospital.
- Identify and undertake any cost improvement measures as required.
- Promote a positive image for GHS.
- Provide leadership and mentorship to inspire junior colleagues for future development.

Research

- Participate in research and development activities on pharmacy practice within the facility.

Health Safety Responsibilities

- Take care of own safety and ensure the safety of other staff working within the unit.
- Promote adherence to health and safety policies, guidelines and protocols in the assigned location.

Quality Assurance

- Promote the establishment and monitoring of quality improvement systems for pharmaceutical services in the facility.

Further Information

- The post holder must at all times:
    - Work in accordance with the Code of Conduct and Disciplinary Procedures of the GHS.
    - Strictly adhere to the provisions of the Patient's Charter.
    - Adhere to GHS administrative policies and procedures.

This job description is intended as a guide to the principal duties and responsibilities for the post and should not be considered an exhaustive list. It is subject to change in line with future development of the service.

PERSON SPECIFICATION

3. Senior Pharmacist

Criteria	Essential	Desirable
Educational Qualification and Experience	Bachelor of Pharmacy from a recognized university plus at least three (3) years relevant working experience.	Doctor of Pharmacy
Knowledge	– Good understanding of pharmaceutical therapy and direct patient care. – Good knowledge of drug administration and health & safety guidelines. – Good knowledge and understanding of laws, rules, acts and regulations in health care operations and clinical practices. – Good knowledge in the use of research methodologies and tools relative to health care practices. – Good knowledge and application of ethical requirements of the practice. – Adequate experience in drug regimen and patients case reviews. – Proven knowledge and experience in conducting therapeutic reviews of prescriptions.	
Skills & Abilities	– Ability to identify and manage medications risk/safety issues. – Ability to deal sensitively with patients' emotions/concerns and maintain patient's confidentiality. – Good technical skill in compounding and manufacturing medicines. – Good numerical ability/quantitative skills. – Ability to work under pressure and multi-task in a fast paced environment. – Good ability to work under pressure and multi-task in a fast paced environment. – Ability to negotiate, persuade and manage conflicts. – Good communication, presentation and report writing skills. – Good Knowledge and experience in case management. – Good Knowledge in the use of Microsoft office, Internet and other Software/tools in dispensary practice. – Good supervisory, coaching, counselling and interpersonal skills in a team setting. – Exhibit high sense of professionalism	
Personal Attributes	High level of Integrity, flexibility, enthusiasm, motivation, courteousness, trustworthiness, assertiveness, empathy.	

3. Principal Pharmacist

Title	Pharmacist
Grade	Principal Pharmacist
Responsible to	Head of Department
Accountable to	Head of Department/ Director of Pharmacy/ Head of Facility
Job Purpose	Provide Pharmaceutical and medicine information to the medical team, patients and caregivers on medication contents, utilization, therapeutic actions, adverse reactions or interactions of drugs to ensure safe and effective therapeutic outcomes.

Main Duties & Responsibilities

1. Implement approved pharmaceutical service policies, standard operating procedures (SOPs), and work plan to ensure the achievement of objectives.
2. Evaluate/Interpret medical prescriptions/requests and liaise with prescribers and/or superior officer on dosages, medication to ensure therapeutic compatibilities and optimized outcomes in line with approved guidelines/standards.
3. Update medicines reconciliation processes to enhance patient safety at ward level.
4. Participate in clinical ward rounds and collaborate with the medical team to ensure all medication issues are resolved accordingly.
5. Provide medicine and pharmacological information to multidisciplinary health care team within approved limit of authority.
6. Monitor the effects of medications by reviewing clinical signs and symptoms including blood pressure monitoring, pulse monitoring, spirometry from patients' chart.
7. Compound sterile and non-sterile pharmaceuticals in accordance with recognised protocols /guidelines as directed by superior officer.
8. Dispense prescribed medications to patients by compounding, reconstituting, packing and labelling pharmaceutical products.
9. Counsel patients appropriately on adherence safety to optimize therapeutic outcome
10. Ensure a safe and clean working environment by complying with procedures, guidelines and regulations on drug storage/dispensary and adherence to infection prevention and control protocols.
11. Keep comprehensive database on pharmaceutical products to ensure efficient stocking, stock control and for other compliance purposes.
12. Keep records on adverse drug reactions/events and submit such reports to the National Drug Information Resource Centre and the Pharmacovigilance Unit of the FDA
13. Recommend safe combinations of medicines or solutions to specific patient problems within prescribed limits of authority.

14. Replenish and monitor emergency medicine tray to ensure adequate supply of quality emergency medicines at the wards.
15. Provide discharge/exit counselling services in relationship to drug therapy for all patients to ensure optimisation of treatment.
16. Maintain and update records on financial and accounting transactions related to the operations of assigned location.
17. Prepare and submit periodic reports relating to job function to head of unit.
18. Conduct performance appraisal and provide input for career development and recommend performance incentives for subordinate staff.
19. Support preparation of plans and budget for the facility.
20. Participate in the procurement, storage and distribution of safe, effective medicines within assigned facility
21. Lead and actively participate in the activity of drug and therapeutic committees within assigned location
22. Analyse prescribing trends to inform decisions and enhance rational use of medicines.
23. Identify untreated health problems and liaise with physician for appropriate treatment.
24. Provide information to nursing and other medical staff in relation to new medications.
25. Provide input in the preparation of the annual operating budget to support pharmaceutical operations in assigned location and implement same.
26. Supervise subordinates in the discharge of assigned responsibilities.
27. Participate in the vetting of NHIS claims in the assigned facility.
28. Maintain and update data/records on financial transactions relating to the Pharmacy department.
29. Facilitate the training of Pharmacists, Pharmacy Technicians, Interns and support continuing professional development of pharmacists on current and new developments in pharmacy services. Provide input into the development of policies, standard operating procedures (SOPs), work plans and other support systems for the operations of Pharmaceutical Services.
30. Educate physicians, nursing staff and patients (inpatient and outpatient) about prescribed medication regimes with the aim of improving compliance.
31. Participate in clinical trial when the opportunity avails itself.
32. Participate in the review and update of Hospital's Medicines formulary and promote its adherence.
33. Prepare individualized patient-based pharmaceutical care plan.
34. Monitor and report on Narcotic and Psychotropic substances, sera, ARVs, TB medicines, etc. used in assigned hospital/facility.
35. Supervise the preparation, reconstitution and compounding of medicines for dispensing.
36. Monitor to ensure the efficient collection, storage, processing and utilisation of data in the pharmacy to inform Management and for Clinical Care decisions.
37. Conduct regular audit of prescriptions to minimise adverse reactions and drug-disease interactions.
38. Provide input into the development of the annual procurement plan to facilitate the procurement of pharmaceutical products.

39. Conduct operational research and disseminate findings to improve on pharmaceutical services and therapeutic outcomes.
40. Perform any other official duties that are incidental in relation to your job.

Communication and Working Relationships

- Maintain effective communication with other team members in the facility.
- Maintain good relationship with pharmaceutical organizations and relevant regulatory bodies.
- Participate actively in clinical meetings.
- Attend performance review meetings and participate actively on issues related to pharmaceutical service.
- Participate in multi-professional meetings and scientific conferences as required in the facility.

Personal and People Development

- Develop and maintain continuing personal and professional development to meet the changing demands in the area of pharmaceutical services.
- Monitor own performance against agreed objectives and targets.
- Promote an enabling environment for staff development and training to meet required standards.

Management

- Contribute to the maintenance of an accurate database on pharmaceutical services in the Hospital.
- Identify and undertake any cost improvement measures as required.
- Promote a positive image for GHS.
- Provide leadership and mentorship to inspire junior colleagues for future development.

Research

- Participate in research and development activities on pharmacy practice within the facility.

Health Safety Responsibilities

- Take care of own safety and ensure the safety of other staff working within the unit.
- Promote adherence to health and safety policies, guidelines and protocols in the assigned location.

Quality Assurance

- Promote the establishment and monitoring of quality improvement systems for pharmaceutical services in the facility.

Further Information

- The post holder must at all times:
    - Work in accordance with the Code of Conduct and Disciplinary Procedures of the GHS.
    - Strictly adhere to the provisions of the Patient's Charter.
    - Adhere to GHS administrative policies and procedures.

This job description is intended as a guide to the principal duties and responsibilities for the post and should not be considered an exhaustive list. It is subject to change in line with future development of the service.

PERSON SPECIFICATION

3. Principal Pharmacist

Criteria	Essential	Desirable
Educational Qualification and Experience	Bachelor of Pharmacy from a recognized university plus five (5) experience on the grade of Senior Pharmacist or a total of eight (8) years continuous working experience as a Pharmacist.	Doctor of Pharmacy
Knowledge	– Demonstrated knowledge and understanding of pharmaceutical therapy and direct patient care. – Solid knowledge of drug administration and health & safety guidelines. – Adequate knowledge and understanding of laws, rules, Acts and regulations in health care operations and clinical practices. – Good technical knowledge in the use of research methodologies and tools relative to health care practices. – In-depth knowledge and application of ethical requirements of the practice. – Proven experience in drug regimen and patients case reviews. – Proven knowledge and experience in conducting therapeutic reviews of prescriptions.	
Skills & Abilities	– High ability to identify and manage medications risk/safety issues. – Good ability to deal sensitively with patients' emotions/concerns and maintain patient's confidentiality. – Adequate technical skills in compounding and manufacturing medicines. – Good numerical ability/quantitative skills. – High ability to work under pressure and multi-task in a fast paced environment. – Good negotiation, persuasion and conflicts management skills. – Excellent communication, presentation and report writing skills. – Demonstrated knowledge and experience in case management. – Very good knowledge in the use of Microsoft office, Internet and other Software/tools in dispensary practice. – Excellent supervisory, coaching, counselling and interpersonal skills in a team setting. – Good Knowledge in the use of Microsoft office, Internet and other Software/tools in dispensary practice. – Good supervisory, coaching, counselling and interpersonal skills in a team setting. – Ability to educate/train subordinates – Exhibit high sense of professionalism	

Personal Attributes	High level of Integrity, flexibility, enthusiasm, motivation, courteousness, trustworthiness, assertiveness, empathy.	

4. Deputy Chief Pharmacist

Title	Pharmacist
Grade	Deputy Chief Pharmacist
Responsible to	Head of Department
Accountable to	Head of Facility
Job Purpose	Provide Pharmaceutical and medicine information to the medical team, patients and caregivers on medication contents, utilization, therapeutic actions, adverse reactions or interactions of drugs to ensure safe and effective therapeutic outcomes.

Main Duties and Responsibilities

1. Lead in the development of operational plans of the Pharmacy department and participate in the preparation of the overall strategic plan of the facility.
2. Support the implementation of plans and budgets to ensure the achievement of objectives.
3. Play active role in the development of pharmaceutical services policies, standard operating procedures (SOPs), procedural manuals, protocols in managing pharmacy operations in the facility to ensure optimal services and evaluate their impact.
4. Keep comprehensive database on pharmaceutical products to ensure efficient stocking, stock control and for other compliance purposes.
5. Collaborate with various clinical teams to develop optimum treatment plan to ensure safe, efficacious and cost-effective therapy to patients.
6. Assess prescriber's medication orders with respect to overall patient therapy to evaluate potential adverse drug reactions, improper drug selection, over dosage, medication use without indication etc.
7. Identify and resolve drug therapy problems and provide evidence-based patient-centered medication therapy recommendations as part of the interdisciplinary team.
8. Determine cost-effective and appropriate formulary alternatives for non-formulary drugs within assigned location.
9. Liaise with physicians in creating and managing the drug regimens of patients with chronic disease states (e.g. diabetes, asthma, etc.).
10. Provide advice on the pharmaceutical and pharmacodynamics properties of drugs including alterations of these parameters in 'special groups' of patients.
11. Initiate innovations to improve the quality of pharmaceutical/medical care in assigned location in accordance with approved standards.

12. Manage the pharmacy staff to ensure the availability of adequate numbers, quality and continuous development to meet the needs of the assigned area of operations.
13. Initiate investigations into challenges arising from the use of pharmaceutical products and submit findings/recommendation for improvements.
14. Ensure the formation and monitor the effective functioning of Medicines and Therapeutic Committee in all Health facilities.
15. Monitor and evaluate quality of pharmaceutical services/public health activities to ensure adherence to policies/guidelines and address any noncompliance issues where appropriate.
16. Ensure that emergency treatment/management protocols and guidelines are available and posted at vantage points within assigned area of operations.
17. Provide training on clinical and ward pharmacy to pharmacists and other health professionals on how to identify, resolve and/or prevent medicine related problems to achieve therapeutic objectives.
18. Prepare and submit periodic reports on the state of pharmaceutical services within assigned location.
19. Develop the annual operating budget of assigned unit/facility as an input into the preparation of the overall annual operating budget for pharmaceutical services.
20. Review and recommend for approval proposals to facilitate funding opportunities to support research works, education, outreach programmes and training activities.
21. Recommend payments for Approval for medicines supplied and for pharmaceutical services rendered within assigned location.
22. Review and analyse pharmacy related audit queries submitted by the Audit Implementation Committee and provide responses and solutions to prevent future occurrences.
23. Collaborate with External Auditors to ensure that all pharmacy-related audit issues are resolved.
24. Participate in the activities of the entity tender committee for the procurement of medicines to ensure that safe, efficacious and cost effective medicines are procured.
25. Develop Key Performance Indicators (KPIs), conduct performance appraisal for subordinate staff and provide input for career development and recommend performance incentives.
26. Perform any other official duties that are incidental in relation to your job.

Research & Development

– Facilitate and conduct operational research and clinical audits in assigned location and disseminate results for Management decision making.
– Conduct periodic surveys on the rational use of medicines and analyse the results to determine trends and adherence to the Standard Treatment Guidelines and propose solutions to irrational medicine use.
– Participate in research and development activities on pharmacy practice within the facility.

Communication and Working Relationships

– Maintain effective communication with other team members in the facility.
– Maintain good relationship with pharmaceutical organizations and relevant regulatory bodies.
– Participate actively in clinical meetings.

- Attend performance review meetings and participate actively on issues related to pharmaceutical service.
- Participate in multi-professional meetings and scientific conferences as required.

Personal and People Development

- Develop and maintain continuing personal and professional development to meet the changing demands in the area of pharmaceutical services.
- Monitor own performance against agreed objectives and targets.
- Promote an enabling environment for staff development and training to meet required standards.

Management

- Contribute to the maintenance of an accurate database on pharmaceutical services in the Hospital.
- Identify and undertake any cost improvement measures as required.
- Promote a positive image for GHS.
- Provide leadership and mentorship to inspire junior colleagues for future development.

Health and Safety Responsibilities

- Take care of own safety and ensure the safety of other staff working within the unit.
- Promote adherence to health and safety policies, guidelines and protocols in the assigned location.

Quality Assurance

- Promote the establishment and monitoring of quality improvement systems for pharmaceutical services in the facility.

Further Information

- The post holder must at all times:
  - Work in accordance with the Code of Conduct and Disciplinary Procedures of the GHS.
  - Strictly adhere to the provisions of the Patient's Charter.
  - Adhere to GHS administrative policies and procedures.

JOB SPECIFICATION

Deputy Chief Pharmacist

Criteria	**Essential**	**Desirable**
Educational Qualification and Experience	Bachelor of Pharmacy from a recognized university plus five (5) experience on the grade of Principal Pharmacist or a total of thirteen (13) years continuous working experience as a Pharmacist.	Doctor of Pharmacy

Knowledge	– Good knowledge and understanding of current pharmacological/ biopharmaceutical and pharmaco-economic principles, disease state management, age appropriate therapy and other information pertaining to medical/ pharmaceutical care management plan. – Demonstrated knowledge and understanding of pharmaceutical therapy and direct patient care. – Knowledge of drug administration and health & safety guidelines. – Knowledge and understanding of laws, rules, acts and regulations in health care operations and clinical practices. – Experience in the use of research methodologies and tools to conduct clinical assessments and analyse trends relative to health care practices. – Good knowledge of the operations of other health care profession. – In-depth knowledge and application of ethical requirements of the practice. – Knowledge and understanding of medication therapy management including good experience in drug regimen/patients case reviews. – Adequate knowledge and experience in conducting therapeutic reviews of prescriptions to ensure pharmaceutical/clinical appropriateness of the treatment of patients. – Adequate knowledge and experience in public health programmes. – Must have a considerable blend of experience working in a Health Facility.	
Skills & Abilities	– Ability to maintain confidentiality. – Numerical ability/quantitative skills. – Ability to work under pressure, meet deadlines and multi-task in a fast paced environment. – Good initiative, flexibility and innovative skills. – Good negotiation, persuasion and conflict management skills. – Excellent communication, presentation and report writing skills. – Good knowledge and experience in case/project management. – Demonstrated knowledge in the use of Microsoft Office, Internet and other software and tools in pharmacy practice. – Demonstrated managerial, coaching, mentoring, counselling and interpersonal skills in a team setting.	
Personal Attributes	High level of Integrity, flexibility, enthusiasm, motivation, courteousness, trustworthiness, assertiveness, empathy.	

5. Chief Pharmacist

Title	Pharmacist
Grade	Chief Pharmacist
Responsible to	Head of Department
Accountable to	Head of Facility/Regional Director of Health Services
Job Purpose	Collaborate with the medical team and provide pharmaceutical care/medicine information to the patients and caregivers to ensure safe and cost-effective therapeutics in line with national guidelines and protocols.

Main Duties and Responsibilities

1. Contribute to the development of strategy/business plan for Pharmaceutical Services in assigned location/region as input into the overall corporate strategy and monitor its implementation to ensure compliance.
2. Provide input in the development of policies, standard operating procedures (SOPs), procedural manuals in managing the operations of the Pharmaceutical Services in assigned location to achieve targeted objectives.
3. Lead in the development and implementation of a comprehensive inventory control plan (i.e. drug retention and disposal guidelines/procedures) in line with best practices.
4. Collaborate with various clinical teams to develop optimum treatment plan to ensure safe, efficacious and cost-effective therapy to patients.
5. Assess prescriber's medication orders with respect to overall patient therapy to evaluate potential adverse drug reactions, improper drug selection, over dosage, medication use without indication etc.
6. Identify and resolve drug therapy problems and provide evidence-based patient-centered medication therapy recommendations as part of the interdisciplinary team.
7. Determine cost-effective and appropriate formulary alternatives for non-formulary drugs within assigned location/region.
8. Liaise with physicians in creating and managing the drug regimens of patients with chronic disease states (e.g. diabetes, asthma, etc.).
9. Provide advice on the pharmaceutical and pharmacodynamics properties of drugs including alterations of these parameters in 'special groups' of patients.
10. Design and maintain medication protocols for pharmacists and coordinate with clinical team members to ensure optimal services.
11. Evaluate newly implemented guidelines, procedures and policies and its impact on pharmacy services.
12. Evaluate potential adverse drug reactions, improper drug selection, over dosage, medication use without indication etc. and liaise with medical team to address and resolve therapeutic incompatibilities
13. Initiate innovations to improve the quality of pharmaceutical care in assigned location/region in accordance with approved standards.

14. Participate in public health campaigns on vaccinations, immunisation programmes, among others to create awareness on medications and its therapeutic outcomes.
15. Contribute to antimicrobial surveillance programme in the assigned location/region and monitor to ensure the implementation of appropriate antimicrobial prescribing within general practice.
16. Contribute to the clinical governance agenda of the hospital services and review policies /procedures relevant to pharmacy practice to ensure optimum care.
17. Collaborate with Hospital Management Team and provide technical advice in the development of the Hospital Medicine Formulary and monitor its implementation to ensure adherence to National Standard Treatment Guidelines (STG).
18. Assess/evaluate the quality of pharmaceutical operations of assigned location/region to ensure the provision of safe, accurate and efficient medication to patients.
19. Maintain a comprehensive database of new medicines/existing medicines to ensure their availability to meet patients' therapeutic needs.
20. Monitor and evaluate medicines related protocols and guidelines and propose service changes to improve therapeutic outcomes.
21. Develop Key Performance Indicators (KPIs), conduct performance appraisal for subordinate staff and provide input for career development and recommend performance incentives.
22. Establish performance reporting systems in assigned area and monitor to ensure that performance standards are aligned with approved strategies and changing conditions of medical therapeutic/pharmaceutical services.
23. Ensure that controlled substances are dispensed in compliance with approved legal requirements and inventory control guidelines.
24. Ensure that good clinical governance is integrated in all pharmacy practices and procedures including patient confidentiality and incident reporting.
25. Ensure the formulation and effective functioning of Medicines and Therapeutic Committee in Health facilities.
26. Ensure that emergency treatment/management protocols and guidelines are available and posted at vantage points.
27. Ensure the effective and efficient management of the Revolving Drugs Funds in the region.
28. Provide direct oversight in the procurement, storage, distribution and safety use of medicines within assigned location/region.
29. Prepare periodic reports on the state of pharmaceutical services for assigned location/region
30. Develop the annual operating budget of assigned location/region as an input into the preparation of the overall annual operating budget for pharmaceutical services.
31. Review and recommend for approval proposals to facilitate funding opportunities to support research works, education, outreach programmes and training activities.
32. Recommend payments for Approval for medicines supplied and for pharmaceutical services rendered within assigned location/region.

33. Review and analyse pharmacy related audit queries submitted by the Audit Implementation Committee and provide responses and solutions to prevent future occurrences.
34. Collaborate with External Auditors to ensure that all pharmacy-related audit issues are resolved.
35. Participate in the activities of the entity tender committee for the procurement of medicines to ensure that safe, efficacious and cost effective medicines are procured.
36. Perform any other official duties that are incidental in relation to your job.

Research & Development

- Facilitate and conduct operational research and clinical audits in assigned location and disseminate results for Management decision making.
- Conduct periodic surveys on the rational use of medicines and analyse the results to determine trends and adherence to the Standard Treatment Guidelines and propose solutions to irrational medicine use.
- Participate in research and development activities on pharmacy practice within the facility.
- Provide leadership and direct operational research and audit in pharmacy operations and disseminate the results.

Communication and Working Relationships

- Maintain effective communication with other team members in the facility.
- Maintain good relationship with pharmaceutical organizations and relevant regulatory bodies.
- Participate actively in clinical meetings.
- Attend performance review meetings and participate actively on issues related to pharmaceutical service.
- Participate in multi-professional meetings and scientific conferences as required.

Personal and People Development

- Develop and maintain continuing personal and professional development to meet the changing demands in the area of pharmaceutical services.
- Monitor own performance against agreed objectives and targets.
- Promote an enabling environment for staff development and training to meet required standards.

Management

- Contribute to the maintenance of an accurate database on pharmaceutical services in the Hospital.
- Identify and undertake any cost improvement measures as required.
- Promote a positive image for MOH/Agencies.
- Provide leadership and mentorship to inspire junior colleagues for future development.

Health and Safety Responsibilities

- Take care of own safety and ensure the safety of other staff working within the unit.
- Promote adherence to health and safety policies, guidelines and protocols in the assigned location.

Quality Improvement

– Promote the establishment and monitoring of quality improvement systems for pharmaceutical services in the facility.

Further Information

– The post holder must at all times:
  – Work in accordance with the Code of Conduct and Disciplinary Procedures of the MoH/Agencies.
  – Strictly adhere to the provisions of the Patient's Charter.
  – Adhere to MOH/Agencies administrative policies and procedures

PERSON SPECIFICATION

4. Chief Pharmacist

Criteria	Essential	Desirable
Educational Qualification and Experience	– Bachelor of Pharmacy from a recognized university – Master's Degree or equivalent relevant professional qualification from a recognised University – Five (5) years' work experience on the grade of Deputy Chief Pharmacist or a total of eighteen (18) years continuous working experience as a Pharmacist.	Doctor of Pharmacy
Knowledge	– Proven knowledge and understanding of current pharmacological/biopharmaceutical and pharmaco-economic principles, disease state management, age appropriate therapy and other information pertaining to medical/pharmaceutical care management plan. – In-depth knowledge and understanding of pharmaceutical therapy and direct patient care. – Adequate knowledge of drug administration and health & safety guidelines. – Knowledge and understanding of laws, rules, acts and regulations in health care operations and clinical practices. – In-depth experience in the use of research methodologies and tools to conduct clinical assessments and analyse trends relative to health care practices. – Knowledge and application of ethical requirements of the practice. – Knowledge and understanding of medication therapy management including good experience in drug regimen/patients case reviews. – Excellent knowledge and experience in conducting therapeutic reviews of prescriptions to ensure pharmaceutical/clinical appropriateness of the treatment of patients. – Must have a considerable blend of experience working in a hospital clinical department. – Proven knowledge and understanding in identifying and managing medications risk/ safety issues.	

Other Requirements	– Ability to pass an assessment interview – Availability of vacancy	
Skills & Abilities	– High ability to deal sensitively with patients' emotions/concerns and maintain confidentiality. – Numerical ability/quantitative skills. – Ability to work under pressure, meet deadlines and multi-task in a fast paced environment. – Exceptional initiative, flexibility and innovative skills. – Good negotiation, persuasion and conflict management skills. – Excellent communication, presentation and report writing skills. – Excellent knowledge and experience in case/ project management. – Demonstrated knowledge in the use of Microsoft Office, Internet and other software and tools in dispensary practice. – Demonstrated leadership, managerial, coaching, mentoring, counselling and interpersonal skills in a team setting.	
Personal Attributes	High level of Integrity, flexibility, enthusiasm, motivation, courteousness, trustworthiness, assertiveness, empathy.	

6. Specialist Pharmacist

Title	Specialist Pharmacist
Grade	Specialist
Responsible to	Head of Department/Senior Specialist
Accountable to	Head of Facility
Job Purpose	Provide specialist therapeutic service and technical advice in all aspects of specialized field to ensure safe and cost-effective therapy to patients/clients to achieve optimum quality outcomes and facilitate training and capacity building programs for pharmacists, pharmacy technicians and other health professionals.

Main Duties and Responsibilities

1. Provide inputs to the review, development, implementation and monitoring of therapeutic standards operating procedures (SOPs) to ensure adherence with professional guidelines, regulations and national policy to achieve objectives.
2. Play active role in the development of strategic plan of the assigned facility.
3. Develop pharmacotherapy plans on the use of medicines and use plans to provide specialist patient-centred care by assessing patient-specific information in order to optimise therapeutic outcomes/treatment.

4. Participate in clinical trials and audits when the opportunity avails itself in assigned health facility.
5. Review individual patient drug charts, prescriptions and medical information to identify pharmaceutical care issues and risks associated with the use of medicine regimes and provide specialist advice to medical staff on medication treatments, changes to regimes and alternative therapy and routes of administration.
6. Collaborate with medical team to provide multi-disciplinary care to patients by actively participating in consultant/specialist ward rounds and multidisciplinary team meetings.
7. Provide specialist advice on doses/course length of drugs, compounding/preparation of medicines including infusions and injections, drug interactions and any other problems with medicines.
8. Provide information, answers and advice to medical, nursing, other healthcare staff and patients in response to queries received on any aspect of patients' medicines.
9. Manage systems for reporting defects in medicinal products, Drug Alerts, Hazard notifications, medical gases, unlicensed medicines and Drug Recalls (**COSHH** assessments).
10. Assess the safety of medication regimens for efficacy and identify ways to decrease potential medicine interactions and toxicities.
11. Assess health/medicines related risks and potential high-risk areas in pharmaceutical/ health services delivery and provide technical support in the development of strategies to minimise/address these risks.
12. Develop and implement systems to facilitate the admission and discharge process to guide the review/ verify of in-patient and discharge prescriptions and offer counselling services to patients and care givers to ensure that patients are prescribed the right medicines on admission and discharge from the hospital.
13. Make inputs into the development, maintenance and review of the Medicines Formulary of assigned location to ensure clinically cost-effective prescribing.
14. Ensure that pharmacy staff complies with formulary guidelines, Drug and Therapeutic Committee decisions and other pharmacy related policies/procedures.
15. Ensure that medication errors are identified/captured promptly and the necessary action taken to protect patient and improve therapeutic outcomes.
16. educate patients, caregivers and the public on the safe and effective use of medications in order to promote optimal pharmacotherapy.
17. Participate provide technical advice on best practices to the Entity Tender Committee in the procurement of specialised pharmaceuticals to ensure that safe, efficacious and cost-effective medicines are procured to ensure that safe, efficacious and cost-effective medicines are procured
18. Contribute to the development of training materials and deliver training for medical and pharmaceutical staff in order to explain and promote formulary awareness.
19. Provide technical advice for formulation and development of policies relevant to area of Specialty.
20. Evaluate pharmacotherapy-related literature, databases and health information in order to translate findings into practice.
21. Conduct pharmacotherapy-related research using appropriate scientific principles and methodologies and disseminate/publish findings and pharmacotherapy-related information to impact on local/international in order to ensure optimal patient care.
22. Review scientific publications regularly to be informed of issues arising from specialised therapeutic methods.

23. Collaborate with statutory pharmaceutical organisations and other relevant bodies to address operational issues/concerns.
24. Comply with legislation, rules/regulations and new developments in pharmaceutical/health services and provide technical support to other specialised healthcare providers and team members.
25. Maintain a comprehensive database using Information Technology and safety systems on all therapeutic programmes for patient care to ensure effective and safe medication use and easy retrieval of information/ data.
26. Assess inventory needs of the pharmaceutical services to maintain adequate inventory levels at all times.
27. Prepare periodic reports on the state of pharmaceutical services.
28. Prepare the annual operating budget of assigned facility as an input into the preparation of the overall annual operating budget for pharmaceutical services.
29. Review and recommend for approval proposals to facilitate funding opportunities to support research works, education, outreach programmes and training activities.
30. Recommend payments for Approval for medicines supplied and for pharmaceutical services rendered within assigned location/region.
31. Review and analyse pharmacy related audit queries submitted by the Audit Implementation Committee and provide responses and solutions to prevent future occurrences.
32. Provide technical advice in planning of scientific workshops and other programmes on new developments/findings in changing trends in pharmaceutical services and contribute to the training of other specialized health care professionals.
33. Conduct effective performance appraisal of subordinates and provide input for their career development.
34. Perform any other official duties that are incidental in relation to your job.

Communication and Working Relationships

– Maintain effective communication with other team members.
– Maintain good relationship with pharmaceutical organizations and relevant regulatory bodies.
– Attend and make contributions at clinical/technical meetings
– Participate actively in clinical meetings.
– Attend performance review meetings and participate actively on issues related to pharmaceutical service.
– Participate in multi-professional meetings and scientific conferences as required.

Personal and People Development

– Develop and maintain continuing personal and professional development to meet the changing demands in the area of pharmaceutical services.
– Monitor own performance against agreed objectives and targets.
– Promote an enabling environment for staff development and training to meet required standards.

Management

- Contribute to the maintenance of an accurate database on pharmaceutical services in the Hospital.
- Identify and undertake any cost improvement measures as required.
- Promote a positive image of respective organization/agency.
- Provide leadership and mentorship to inspire junior colleagues for future development.

Research

- Participate in research and development activities on pharmacy practice within the facility.

Health Safety Responsibilities

- Take care of own safety and ensure the safety of other staff working within the unit.
- Promote adherence to health and safety policies, guidelines and protocols in the assigned location.

Quality Improvement

- Promote the establishment and monitoring of quality improvement systems for pharmaceutical services in the facility.

Further Information

- The post holder must at all times:
  - Work in accordance with the Code of Conduct and Disciplinary Procedures of the MOH/Agency.
  - Strictly adhere to the provisions of the Patient's Charter.
  - Adhere to MOH/Agency administrative policies and procedures.

PERSON SPECIFICATION

Specialist Pharmacist

Criteria	Essential	Desirable
Educational Qualification	– Bachelor of Pharmacy or its equivalent, – Membership from a recognized postgraduate college of Pharmacists/equivalent qualification – Registration of additional qualification and evidence of good standing with the Pharmacy Council of Ghana.	Doctor of Pharmacy
Experience	– Research experience	– Experience of working in a multi-disciplinary team environment – Experience of managing and organizing own work and that of the department

Knowledge	– In-depth knowledge and understanding of anatomy, physiology and pathophysiology including disease processes and drug-induced diseases. – Excellent knowledge and experience in evidence-based standards of care and clinical pathways. – Exceptional experience in conducting physical assessments and interpretation of laboratory tests, diagnostics and procedures. – In-depth knowledge and understanding of research methodologies, protocol designs, study designs including bio-statistical methods and interpretation – Demonstrated working experience in the use of specialised pharmacy software e.g. therapeutic drug monitoring software to individualise patients' doses. – Knowledge and understanding of laws, rules, acts and regulations in health care operations and clinical practices. – Knowledge and clinical skills in specialist clinical pharmacy. – Knowledge and understanding of medication therapy management including good experience in medicine regimen / patients case reviews. – Proven technical knowledge and experience in identifying and managing medications risk/safety issues.	
Skills & Abilities	– Ability to deal sensitively with patients emotions/concerns and maintain confidentiality. – Numerical and quantitative skills to resolve complex clinical issues. – Good initiative, flexibility and innovative skills. – Good negotiation, persuasion and conflict management skills. – Excellent communication, presentation and report writing skills. – Considerable knowledge and understanding of healthcare financial principles. – Knowledge and experience in project management. – Demonstrated knowledge in the use of Microsoft Office, Internet and other software and tools in pharmacy/health care practice. – Demonstrated leadership, managerial, coaching, mentoring, counselling and interpersonal skills in a team setting.	

Personal Attributes	High level of Integrity, flexibility, enthusiasm, motivation, courteousness, trustworthiness, assertiveness, empathy.	

3. Senior Specialist Pharmacist

Title	Specialist Pharmacist
Grade	Senior Specialist
Responsible to	Head of Department/Consultant Pharmacist
Accountable to	Head of Facility
Job Purpose	Provide specialist evidence-based, patient-centered medication therapy management and direct patient care for individuals including treatment assessment and monitoring for potential adverse drug reactions and interactions.

Main Duties and Responsibilities

1. Play active role in the review/development and monitoring of policies, standard operating procedures (SOPs), procedural manuals and work plans to ensure adherence with National policy to achieve objectives.
2. Participate in the development of strategic plan at the facility level.
3. Participate in situations that require companion diagnostics in order to enhance the value and effectiveness of therapy.
4. Participate in the identification of potential mechanisms of drug resistance in specialist area in order to design or modify pharmacotherapeutic regimens to improve therapeutic outcomes.
5. Participate in the development of treatment recommendations/guidelines for individual patients and groups of patients where evidence is conflicting or inconclusive.
6. Contribute to the establishment of therapeutic goals related to pharmacotherapeutic plans in order to determine appropriate treatment for patients in the specialist area.
7. Design or modify in consultation with the team evidence-based individualised pharmacotherapeutic plans based on the assessment of pertinent patient information.
8. Develop policies/programmes with prevention and monitoring strategies and monitor their implementation to ensure the safety of staff and patients during the preparation, administration and monitoring of toxic agents to optimise treatment outcomes.
9. Participate in the development of training and educational programmes to educate patients and Medical Team on specialty area medications and its complications, potential drug interactions, adverse effects and effective symptom management.
10. Assess the effectiveness, safety and affordability of patient medications and collaborate with the healthcare team to develop and optimise patient medication therapy in specialty area.

11. Liaise with the Medical Team and Infusion Centres to monitor drug utilisation, supportive drug therapy utilisation, adverse drug reactions, therapeutic regimens and patient /provider safety.
12. Liaise with Medical Team and other stakeholders to formulate drug-use guidelines, policies, procedures and formularies that are consistent with evidence, regulation and/or current practice guidelines and standards.
13. Optimise processes in order to ensure the availability of specialty area medications for patients.
14. Develop policies/programmes and monitor their implementation to ensure the safety of staff and patients during the preparation, administration and monitoring of toxic agents.
15. Provide technical advice on best practices in the procurement of specialised pharmaceuticals and develop systems to ensure effective use storage, dispensing, retention and disposal of medicines and other pharmaceutical products in specialised area to minimise waste and unnecessary exposure of hazardous drugs.
16. Provide technical advice in the management of specialised medicine catalogues for specialised and recommend changes to the catalogues as appropriate.
17. Monitor the operations of pharmaceutical services related to specialised area
18. Reconstitute and monitor drug administration in specialised area within assigned facility/unit
19. Participate actively in performance review meetings issues related to pharmaceutical service, clinical and mortality meetings.
20. Participate in multi-professional meetings and scientific conferences as required.
21. Conduct operational research in area of specialisation using appropriate scientific principles and methodologies and disseminate/publish findings and pharmacotherapy-related information to impact on local/international in order to ensure optimal patient care.
22. Provide technical expertise in investigational drug service programmes to contribute to area of specialty research and improvements in patients' healthcare.
23. Conduct trend analysis and review performance reports on pharmaceutical/health services and recommend appropriate changes in policy or procedures to improve efficiency and performance efficacy.
24. Prepare periodic reports on the state of pharmaceutical/health services within specialised area.
25. Prepare the annual operating budget of assigned facility as an input into the preparation of the overall annual operating budget for pharmaceutical services.
21. Review and recommend for approval proposals to facilitate funding opportunities to support research works, education, outreach programmes and training activities.
22. Recommend payments for Approval for medicines supplied and for pharmaceutical services rendered within assigned location/region.
23. Review and analyse pharmacy related audit queries submitted by the Audit Implementation Committee and provide responses and solutions to prevent future occurrences.
24. Review and analyse pharmaceutical audit queries submitted by the Audit Implementation Committee and provide responses and solutions to prevent future occurrences.
25. Collaborate with External Auditors to ensure that all pharmacy-related audit issues are resolved as well as operational, financial and administration compliance issues met.

26. Provide technical advice in planning of scientific workshops, programmes, seminars, training etc. on new developments/findings on diseases and changing trends in pharmaceutical services.
27. Conduct effective performance appraisal of subordinates and provide input for their career development.
28. Participate in the activities of the entity tender committee for the procurement of medicines to ensure that safe, efficacious and cost-effective medicines are procured.
29. Perform any other official duties that are incidental in relation to your job.

Communication and Working Relationships

- Maintain effective communication with other team members.
- Maintain good relationship with pharmaceutical organizations and relevant regulatory bodies.

Personal and People Development

- Develop and maintain continuing personal and professional development to meet the changing demands in the area of oncology and haematology pharmaceutical services.
- Monitor own performance against agreed objectives and targets.
- Promote an enabling environment for staff development and training to meet required standards.

Management

- Contribute to the maintenance of an accurate database on pharmaceutical services in the assigned facility.
- Identify and undertake any cost improvement measures as required.
- Promote a positive image of respective organization/agency.
- Provide leadership and mentorship to inspire junior colleagues for future development.

Research

- Participate in research and development activities on pharmacy practice within the facility.

Health and Safety Responsibilities

- Take care of own safety and ensure the safety of other staff working within the unit.
- Promote adherence to health and safety policies, guidelines and protocols in the assigned location.

Quality Improvement

- Promote the establishment and monitoring of quality improvement systems for pharmaceutical services in the facility.

Further Information

- The post holder must at all times:
  - Work in accordance with the Code of Conduct and Disciplinary Procedures of the MOH/Agency.
  - Strictly adhere to the provisions of the Patient's Charter.
  - Adhere to MOH/Agency administrative policies and procedures.

PERSON SPECIFICATION

Senior Specialist Pharmacist

Criteria	Essential	Desirable
Educational Qualification	– Bachelor of Pharmacy or its equivalent, plus a relevant post-graduate qualification to the level of fellowship from a recognized postgraduate college of Pharmacists/equivalent qualification – Registration of additional qualification and evidence of good standing with the Pharmacy Council of Ghana.	Doctor of Pharmacy
Experience	– Experience of working in a multi-disciplinary team environment – Experience of managing and organizing own work and that of the department – Record of training of other health professionals.	– Involvement in national health policy development – Research experience
Other Requirements	Ability to pass an assessment interview Availability of vacancies	
Knowledge	– In-depth knowledge and understanding of anatomy, physiology and pathophysiology related to specialised. area – Excellent knowledge and experience in evidence-based standards of care and clinical pathways. – Exceptional experience in conducting physical assessments and interpretation of laboratory tests, diagnostics and procedures as related to specialty area – Knowledge and understanding of research methodologies, protocol designs, study designs including bio-statistical methods and interpretation – Demonstrated working experience in the use of specialised pharmacy software e.g. therapeutic drug monitoring software to individualise patients' doses. – Knowledge and understanding of laws, rules, acts and regulations in health care operations and clinical practices. – In-depth knowledge and clinical skills in specialist clinical pharmacy. – Excellent knowledge and understanding of medication therapy management including good experience in medicine regimen / patients case reviews. – Proven technical knowledge and experience in identifying and managing medications risk/safety issues.	

Skills & Abilities	– Ability to deal sensitively with patients emotions/concerns and maintain confidentiality. – Numerical and quantitative skills to resolve complex clinical issues. – Exceptional initiative, flexibility and innovative skills. – Good negotiation, persuasion and conflict management skills. – Good communication, presentation and report writing skills. – Considerable knowledge and understanding of healthcare financial principles. – Knowledge and experience in project management. – Demonstrated knowledge in the use of Microsoft Office, Internet and other software and tools in pharmacy/health care practice. – Demonstrated leadership, managerial, coaching, mentoring, counselling and interpersonal skills in a team setting.	
Personal Attributes	High level of Integrity, flexibility, enthusiasm, motivation, courteousness, trustworthiness, assertiveness, empathy.	

4. Consultant Pharmacist

Job description

Title	Specialist Pharmacist
Grade	Consultant
Responsible to	Head of Department
Accountable to	Head of Facility
Job Purpose	Provide evidence based service as an autonomous practitioner within a team responsible for provision of leadership and expert pharmaceutical knowledge to pharmacy team and other health professionals in the facility and defined catchment area in accordance with local/ national standards and strategy

Main Duties and Responsibilities

1. Provide technical expertise/guidance in the development and implementation of strategy/business plan for the Pharmaceutical Services as input into the overall institutional and national corporate strategy.
2. Provide expert advice/direction in the review/formulation of policies, standard operating procedures (SOPs), procedural manuals, work plan and other support systems in managing the operations of the Pharmaceutical Services to achieve targeted objectives.
3. Provide expert advice in the development and maintenance of the national drug formulary and treatment guidelines and Essential Medicine List.
4. Provide expert clinical knowledge in case referrals for medicines optimisation within specialist area and manage/make referrals to other members in the multidisciplinary team as appropriate.
5. Ensure that medicines are used appropriately, safely and cost-effectively in accordance with approved institutional policy, standard operating procedures and medicines legislation.
6. Monitor medicines use within specialist area, including recording significant clinical interventions and risk management to identify and resolve all complaints.
7. Lead in clinical audits, quality improvement projects and development/implementation of treatment protocols and guidelines for use of medicines within Specialist Area.
8. Participate in clinical patient reviews with multidisciplinary teams, clinical meetings and/or clinics as appropriate in order to provide medicines-related advice to prescribers and other health care professionals.
9. Lead the planning, management and review of therapeutic programmes within the Hospital to ensure effective outcomes.
10. Appropriately manage challenging and ambiguous problems/uncertainty and make decisions with limited information to improve therapeutic needs.
11. Provide specialised advice and participate actively in quality improvement programmes and various administrative/clinical projects to improve pharmaceutical services delivery.

12. Lead the development, implementation and monitoring of protocols for medicines usage in response to clinical and business needs of the hospital and specialist area.
13. Analyse drug usage trends and implement cost improvement initiatives within specialist area.
14. Evaluate the appropriateness of medication therapies, assess their effectiveness and identify potential interactions or adverse effects on patient-specific medications for improvements.
15. Collaborate with senior medical staff to review patient treatments and propose specialist opinions on the performance of various medicine therapies with treatment protocols.
16. Provide appropriate support and management in clinical trials of medicines and unlicensed use of medicines when the opportunity avail s itself within specialist area in accordance with national and hospital policy.
17. Ensure a patient-focused approach to medicines management within specialist area and provide appropriate verbal and written information to patients about their medicines.
18. Evaluate medicines-related risks and potential high-risk areas in pharmaceutical services and provide specialised advice in the development of strategies to minimise/address these risks.
19. Provide expert opinion on Medical Board
20. Lead in pharmaceutical research to improve medicines use and pharmacy practice, publish such findings to inform drug utilisation reviews, evaluations and audits.
21. Review proposals form subordinates and recommend for approval to facilitate funding opportunities to support specialized research work, outreach programs and training activities
22. Provide oversight responsibility in research activities and reviews to develop medicine information handbooks/journals for national consumption.
23. Actively support and encourage other health professionals to work with relevant national agendas to improve patient satisfaction through safe and evidenced based use of medicines.
24. Collaborate with Development Partners in the implementation of programmes to reduce both incidence and prevalence rates of diseases in Ghana.
25. Liaise with Management Committees of facilities in the catchment area to review/assess the impact of National Programmes with respect to pharmaceutical service and come up with appropriate recommendations.
26. Introduce and implement systems to ensure compliance with legislation, rules/regulations and new developments in pharmaceutical/health services, and provide advance knowledge to other specialised healthcare providers and team members.
27. Review periodic reports on specialised medications therapies and provide expert advice to improve on pharmaceutical care.
28. Conduct drug evaluation exercises and provide expert opinion on findings to the Drugs and Therapeutic Committee.
29. Prepare the annual operating budget of assigned facility as an input into the preparation of the overall annual operating budget for pharmaceutical services.
30. Review and recommend for approval proposals to facilitate funding opportunities to support research works, education, outreach programmes and training activities.

31. Recommend payments for Approval for medicines supplied and for pharmaceutical services rendered within assigned location/region.
32. Review and analyse pharmacy related audit queries submitted by the Audit Implementation Committee and provide responses and solutions to prevent future occurrences.
33. Provide technical advice in planning of scientific workshops, programmes, seminars, training etc. on new developments/findings on diseases and changing trends in pharmaceutical services.
34. Contribute to the training of pharmacists, resident pharmacists and other healthcare professionals.
35. Conduct effective performance appraisal of subordinates and provide input for their career development.
36. Perform any other official duties that are incidental in relation to your job.

Communication and Working Relationships

– Maintain effective communication with other team members.
– Maintain good relationship with pharmaceutical organizations and relevant regulatory bodies.

Personal and People Development

– Develop and maintain continuing personal and professional development to meet the changing demands in the area of oncology and haematology pharmaceutical services.
– Monitor own performance against agreed objectives and targets.
– Promote an enabling environment for staff development and training to meet required standards.

Management

– Ensure the maintenance of an accurate database on pharmaceutical services in the assigned catchment area.
– Identify and undertake any cost improvement measures as required.
– Promote a positive image of respective organization/agency.
– Provide leadership and mentorship to inspire junior colleagues for future development.

Research

– Lead in research and development activities on pharmacy practice within the catchment area.

Health Safety Responsibilities

– Take care of own safety and ensure the safety of other staff.
– Promote adherence to health and safety policies, guidelines and protocols.

Quality Improvement

– Ensure the smooth functioning of systems for quality improvement in the assigned location.

Further Information

– The post holder must at all times:
    – Work in accordance with the Code of Conduct and Disciplinary Procedures of the GHS.

– Strictly adhere to the provisions of the Patient's Charter.
– Adhere to GHS administrative policies and procedures.

PERSON SPECIFICATION

Consultant Pharmacist

Criteria	Essential	Desirable
Educational Qualification	– Bachelor of Pharmacy or its equivalent, plus a relevant postgraduate qualification to the level of fellowship from a recognized postgraduate college of Pharmacists/equivalent qualification – Registration of additional qualification and evidence of good standing with the Pharmacy Council of Ghana.	At least five (5) peer-reviewed publications
Experience	– Minimum of five (5) years post-fellowship work experience – Experience of managing and organizing own work and that of the department – Record of training of other health professionals – Experience of working in a multi-disciplinary team environment	Involvement in policy development
Other Requirements	– Ability to pass an assessment interview – Availability of vacancies	
Knowledge	– Demonstrate advanced clinical experience in specialist area application, portfolio, interview, etc. – Proven experience of working at a strategic level with senior clinicians and managers across the wider health community. – Advance knowledge and experience in medicines related policy development and implementation. – Extensive knowledge and understanding of laws, rules, acts and regulations in health care operations and clinical practices. – In-depth experience in the use of research methodologies and tools to conduct clinical assessments and analyse trends relative to health care practices. – Excellent knowledge and understanding of medication therapy management including good experience in medicine regimen / patients case reviews. – Must have a considerable blend of experience working in a hospital clinical department. – Demonstrate advance expertise in all areas of medication management and / or clinical workflows. – Advance technical knowledge and experience in identifying and managing medications risk / safety issues.	

Skills & Abilities	– Ability to deal sensitively with patients' emotions / concerns and maintain confidentiality. – Numerical and quantitative skills to resolve complex clinical issues. – Exceptional initiative, flexibility and innovative skills. – Good negotiation, persuasion and conflict management skills. – Excellent communication, presentation and report writing skills. – Excellent knowledge and experience in project management. – Demonstrated knowledge in the use of Microsoft Office, Internet and other software and tools in pharmacy/health care practice. – Demonstrated leadership, managerial, coaching, mentoring, counselling and interpersonal skills in a team setting.	
Personal Attributes	Commitment to provide excellent customer service as required. Integrity, flexibility, enthusiasm, motivation, courteous, trustworthy, fair and firm	

APPENDICES

Appendix 1-Pharmacist Medicine Intervention Report Form

PRESCRIPTION INFORMATION: *(please tick all that apply)*

Status:

☐ new prescription ☐ repeat prescription ☐ hand written

☐ computer generated ☐ Other (Specify)

Origin of Prescription:

Presented by:

☐ Patient ☐ Patient Representative ☐ Nurse

☐ MD by phone ☐ Other (Specify)

Patient Sex:

☐ Female ☐ Male

Patient Age:

☐ Infant (<3yrs) ☐ Child (6-11yrs) ☐ Adolescent (12-17 yrs)

☐ Adult (18-64yrs) ☐ Elderly (65+ yrs) ☐ Unknown

TYPE & REASON FOR INTERVENTION: *(please tick all that apply)*

☐ Problem with prescription form ☐ Problem with item

Problem with prescription form:

☐ No Dr. signature ☐ No date ☐ No patient address

☐ No patient name ☐ No age

Problem with item:

Drug(s): ☐ Duplication

Dose: ☐ Too low ☐ Wrong ☐ Too high ☐ Missing

Others: □ drug item/brand □ Strength □ patient name

□ Contraindication □ Different from previous Rx □ Quantity

□ incorrect spelling □ Interaction □ Frequency of administration

□ Rx ambiguous □ Allergy

Strength: □ Wrong/Need clarification □ timing for dose (exc. duration)

□ Rx illegible/incoherent □ Not covered by NHIS □ Dosage form

□ supply/availability problem □ Possible ADR

Form: □ inconvenient dosage form

Drug(s) involved: _____ ¢

_____ ¢

_____ ¢

_____ ¢

Name Strength Form Directions Quantity Total Cost

Therapeutic Category of Drug(s):

_____

Disease condition: _____

Other (please state on reverse of form)

QUERY SOLVED BY CONSULTING: *(please tick all that apply)*

□ Physician/Doctor □ PMR □ Patient □ Drug Information Centre

□ Own reference source □ Other clinic authority contacted

□ Took own action – without doctor contact □ Consulted other information sources (please state):_____

_____

RECOMMENDATIONS: *(please tick all that apply)*

Change: □ Drug

Change: □ Form/route ***Rx:*** □ Clarify, no specific changes ***Drug:*** □ Stop

Dose: □ Increase □ Decrease

□ Strength □ Quantity □ Add missing information □ Add

□ Directions □ to Drug Plan Product

Total cost

OUTCOME *(please tick all that apply)*

Rx: □ Confirmed as written with specific intent

Patient/ □ Verbally counselled

Others: □ Resolved by phone call □ Not dispensed

Representative: □ Provided written information □ Resolved by letter

□ Changed due to Pharmacist's advice □ Took Rx away □ Resolved by personal visit □ Changed but not due to Pharmacist 's advice

□ Not dispensed-patient referred to doctor

Drug(s) involved:

_____ ¢

_____ ¢

_____ ¢

_____ ¢

Name Strength Form Directions Quantity Total Cost

Total cost

QUERY INITIATED BY: *(please tick all that apply)*

□ Pharmacist □ Other pharmacy staff □ Patient/Patient representative

□ Patient Medication Record (PMR) □ Other (state) _____

SERIOUSNESS OF PROBLEM:

Based on the available information, in your estimation of the seriousness of the impact, you not intervening have on the health of the patient

(please tick all that apply)

□ Potentially serious □ Type B: Major nuisance □ Minor serious □ Trivial

TIME TAKEN TO RESOLVE QUERY:

□ Approximate time taken (mins):_____ □ No. of internal calls made to re-

solve_____ □ No. of outside calls made_____

PERCEIVED PATIENT BENEFIT: *(please tick all that apply)*

□ Increased therapeutic effectiveness □ Prevent toxicity/side effects □ Improved compliance □ Improved monitory of therapy

Intervention ID No.: Date: _____

Pharmacist Performing Intervention:

_____

Name & Location of Doctor Responsible for Rx:

_____

_____

_____

Kindly outline any further relevant information or impediment encountered whilst performing the intervention on the prescription below.

(Please endeavour to attach a photocopy of the prescription to this form):

.....
.....
.....
.....
.....
.....
.....
.....
.....
.....

Intervention ID Number Format:

Kindly use the following number format to log in the Intervention ID; i.e. 0001/17, 0002/17 etc.

For example, the fifty fourth (54th) prescription intervention by SME Pharmacy for the year 2004 will have the following intervention identification number: SME 0054/17.

Prototype Pharmacy Department Unit Codes:

Use the respective code for the unit as the prefix before the ID number.

MAIN – Main Pharmacy **MED** – Medical / Drug Information **SCC** – Sickle Cell Clinic **SURG** – Surgical Pharmacy **O&G** – Obstetrics & Gynaecology Pharmacy **ADC** – Adherence Counselling **POLY** – Polyclinic Pharmacy **SME** – SME Pharmacy **PAED** –

Child Health Pharmacy **CHST** – Chest Clinic Pharmacy **MFT** – Manufacturing Unit

Appendix 2-Medication error reporting form

(A blame free reporting tool)

Please tick (√) the appropriate box. All fields must be filled. Detail of reporter is optional.

1.

Date of event.....

Time of event.....

2. Patient Details

Name.....Age.....

Sex..... Weight.....

Diagnosis.....

3. Type of Error

Prescribing..... Dispensing..... Administration.....

Others (specify).....

4. Location of Event

Ward..... Consulting room..... Pharmacy.....

Others (specify).....

5. Where event/error was detected

Ward..... Consulting room..... Pharmacy..... Others (specify).....

6. Details of medicines involved in the event

SN Dosage form.....Generic Name..... strength..... Frequency..... Duration.....

7. Please describe the error. Include the intervention/corrective measures taken

.....

.....

.....

.....

8. Indicate the possible error cause(s) and contributing factor(s)

Illegible prescription.....Wrong labelling on dispensing envelope or

bottle/container.....Look alike medication/packaging.....

.....Inadequate patient information.....

.....Others (Please specify).....

9. Which category made the initial error?

Doctor..... Nurse..... Pharmacist.....Pharmacy Asst..... Physician Asst.....

Others (specify).....

10. Which category detected the error or recognised the potential error?

Doctor..... Nurse..... Pharmacist.....Pharmacy Asst..... Physician Asst.....

Others (specify).....

11. Did the error reach the patient?

Yes / No

If yes

Summary of error outcome

Caused no harm, no need for monitoring

Caused no harm, monitoring required

Caused temporary harm, treatment required

Caused permanent harm

Near death event

Death

12. Details Of Reporter *(optional)*

Name of Facility

Name/Designation of Reporter

Mobile number

Appendix 3-Regional monthly returns on vaccines and sera

Region.....

Month.....

Type of Vaccine/Sera.....

Balance B/F.....

Quantity Purchased.....

Quantity Available.....

No.	Date	Name of Health Facility	Quantity Supplied	Remarks
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
		TOTAL		

Balance C/F.....

Prepared by:

Name .....

Signature .....

Rank .....

Date .....

Counter signed by:

Name .....

Signature .....

Rank .....

Date .....

Appendix 4-Institutional vaccines/sera monthly returns

Institution: .....

Month: .....

Type of Vaccine/Sera: .....

Balance B/F: .....

No.	Date	Name of Patient	Registration Number	Quantity Prescribed	Quantity Used	Remarks

Balance C/F .....

Prepared by:

Name .....

Signature .....

Rank .....

Date .....

Counter signed by:

Name .....

Signature.....

Rank .....

Date .....

Appendix 5-Returns Report

Returns/report for 20...

No	Region	Monthly Drug Bulletin												Quarterly Returns				RUM Returns				ARV, ASS Returns				Pharm. Staff	Annual
		J	F	M	A	M	J	J	A	S	O	N	D	1st	2nd	3rd	4th	1st	2nd	3rd	4th	1st	2nd	3rd	4th	Returns	Report
1	Northern																										
2	Upper West																										
3	Upper East																										
4	Brong Ahafo																										
5	Ashanti																										
6	Western																										
7	Central																										
8	Eastern																										
9	Volta																										
10	Greater Accra																										
11	Accra Psych. Hospital																										

Prepared by: **Counter signed by:**

Name..... **Name** .....
Signature ..... **Signature** .....
Rank ..... **Rank** .....
Date ..... **Date** .....

Appendix 6-The basic equipment needed for local small-scale manufacturing

1. Analytical balance
2. Autoclave (20L – 200L)
3. Beakers
4. Bottle washers
5. Burettes.
6. Capping machine (one for plastic tops and one for metal tops).
7. Colorimeter
8. Computers and printers
9. De-ioniser
10. Electric kettle
11. Electric sterilizer
12. Filling machines
13. Filter (coarse)
14. Filtration units (micro-organism or pathogen proof)
15. Fire fighting equipment
16. Funnel (glass, plastic and/or stainless steel with capacity 100 mL – 2L)
17. Glass and porcelain slabs
18. Glass, plastic or stainless-steel measures (250mL – 2L)
19. Hand de-capping tong
20. Homogeniser
21. Hot water bath
22. Liquid dispensers (automated or semi-automatic)
23. Measuring cylinders – glass or plastic 95mL, 10mL, 500mL, 1000mL)
24. Mortars and pestles (both porcelain and glass)
25. Optical inspection equipment e.g. the Apollo liquid viewer with magnifier
26. Oven with 250°C heating capacity
27. pH meter
28. Pipettes
29. Protective clothing
30. Source of heat (gas or electric)
31. Stainless steel spatulas
32. Stainless steel tanks with capacity 25 – 100 litres
33. Stirring rods (glass)
34. Tablet counters (electronic and manual)
35. Test tubes
36. Top loading balance
37. Ultraviolet spectrophotometer
38. Vacuum filters
39. Water still

Storage areas

- Pallets
- Handheld forklift
- Tally cards
- Ledger books

Weighing areas

- Small scale digital weighing equipment
- Weighing scales for large bulk materials

Quality control

- Reagents
- Instruments for quality control

And other relevant devices and tools

Appendix 7-Personnel qualified to be part of the local small-scale manufacturing team

Appropriately trained personnel

1. All personnel must be trained in the principles of the current codes of good manufacturing practices (GMP)

2. Personnel must receive appropriate training, retraining and validation of their training programmes

3. Newly recruited personnel must receive training appropriate to the duties assigned them

4. Training in quality assurance incorporating quality control and good manufacturing practices is essential

5. All personnel must undergo periodic health examination

6. Every member of the production team must be given a job description and must qualify for the job assigned them

Members of the production team

Category of Staff	Job Description
▪ Principal pharmacist ▪ Senior pharmacist	Technical director Quality assurance manager
▪ Senior pharmacist	Production manager
▪ Biochemist/Pharmaceutical chemist	Quality control manager
▪ Pharmacist	Supervisor
▪ Dispensing Technician/Technologist	Weighing, blending, packaging (Always checked by the supervisor)
▪ Technician / Technologist	Sampling
▪ Technician / Technologist	Cleaning of equipment
▪ Trained personnel e.g. orderly	Cleaning of premises

Appendix 8-Defective product complaint form

1. Complaint:

a. Complainant
b. Complaint
c. Date
d. Time

2. Identity of product

a. Name of product
b. Dosage form
c. Batch number
d. Manufacturing date
e. Expiry date
f. Source of product

3. Problem verification

a. Describe patient reaction

i. How used
ii. When last administered
iii. Duration of use
iv. Other medications
v. For what indication product is used
vi. Known allergy / Idiosyncrasies etc.

b. Describe product defect

i. Discoloured
ii. Tablet broken
iii. Bad consistency
iv. Did not dissolve
v. etc.

4. Report on preliminary investigation

Date
Time

5. Action taken after preliminary investigation

a. Continue use
b. Suspend, recommend alternatives and investigate
c. Inform management

6. Final investigation result/report

7. Action taken after final investigation

a. Recall
b. Continue use

Head of Dept:.....

Signature:.....

Date form was completed:.....

Appendix 9-CIVAS product requisition form

Section A

Name of patient.....

Age .....

Weight.....

Ward .....

Clinical team.....

Name of prescriber.....

Date .....

Time product is required.....

Signature of prescriber .....

Section B

Name of product .....

Dose .....

Name of additives .....

Route of administration .....

Infusion rate.....

Time of administration .....

Volume to be administered.....

Date of submission.....

Time of submission.....

Name of ward nurse/deliverer.....

Signature of deliverer.....

Section C

Name of receiving pharmacist .....

Date .....

Time .....

Signature .....

Name of CIVAS pharmacist.....

Date .....

Time of preparation of product .....

Product ID .....

Record Number.....

Name of additives .....

Strength .....

Quantity .....

Indications .....

Drug-drug interaction .....

Appropriateness of doses.....

Incompatibilities .....

Route of administration .....

Name of pharmacist in-charge .....

Signature.....

Official stamp.....

Appendix 10-CIVAS product dispatch form

Name of finished product.....

Batch Number.....

Expiry date .....

Time .....

Ward .....

Patient's name .....

Date dispatched .....

Name of dispatch officer.....

Signature .....

Name of recipient .....

Signature .....

Appendix 11-Dangerous drug record form

No.	Date Supplied	Name of Drug	Quantity Supplied	Name & Address of Recipient	Signature of Supplier	Signature/ Thumbprint of Recipient	Name & Address of Giver of Prescription

Prepared by:

Name .....

Signature .....

Rank .....

Date .....

Counter signed by:

Name .....

Signature .....

Rank .....

Date .....

Appendix 12-Tracer medicines list for district and regional hospitals

NAME OF FACILITY: ..... DATE: .....

No.	Generic Name	Available
1	Tab. Acetylsalicylic Acid 300mg	
2	Tab. Albendazole 200/400mg	
3	Tab. Aluminium Hydroxide 500mg/Tab. Magnesium Trisilicate 250mg	
4	Tab. Artesunate +Tab. Amodiaquine (base) Adult	
5	Tab. Artesunate +Tab. Amodiaquine (base) Children	
6	Tab. Artemether – Lumefantrine 20\120mg Adult	
7	Tab./Granules/Artemether – Lumefantrine 20\120mg Paediatric	
8	Tab. Chlopheniramine Maleate 4mg	
9	Tab. Co-trimoxazole 400mg + 80mg	
10	Tab. Ciprofloxacin 250/500mg	
11	Tab. Citerizine 10mg	
12	Tab. Diazepam 5/10mg	
13	Tab. Diclofenac 50/100mg	
14	Tab. Ferrous Sulphate 200mg/Tab. Ferrous Fumarate 322mg	
15	Tab. Folic Acid 5mg	
16	Tab. Furosemide 40mg	
17	Tab. Ibuprofen 200/400mg	
18	Tab. Methyldopa 250mg	
19	Tab. Metronidazole 200mg	
20	Tab. Nifedipine Retard 10/20mg	
21	Tab. Paracetamol 500mg	
22	Tab. Quinine 300mg	
23	Cap. Amoxycillin 250/500mg	
24	Cap. Doxycycline 100mg	
25	Susp. Albendazole 100mg/5ml	
26	Susp. Amoxycillin 125mg/5ml	
27	Susp. Chloramphenicol 125mg/5ml	
28	Susp. DihydroArtemisinin – Piperaquine 40\320mg	
29	Tab DihydroArtemisinin – Piperaquine 40\320mg	
30	Susp. Co-trimoxazole 200mg + 40mg/5ml	
31	Syr. Metoclopramide 1mg/ml	
32	Susp. Metronidazole 200mg/5ml	
33	Syr. Multivitamin	
34	Syr. Paracetamol 120mg/5ml	
35	Inj. Anti-Rabies Vaccine (ARV)/Serum	

36	Inj. Anti-Snake Serum (ASS) – West African Polyvalent	
37	Inj. Anti-Tetanus Serum (ATS) 1,500/50,000iu	
38	Inj. Benzyl Penicillin 1mu	
39	Inj. Ciprofloxacin 500mg/100ml	
40	Inj. Diazepam 5mg/ml	
41	Inj. Ergometrine 500micrograms/ml	
42	Inj. Oxytocin 10 IU	
43	Inj. Frusemide 10mg/ml	
44	Inj. Hydrocortisone 100mg	
45	Inj. Metronidazole 500mg/100ml	
46	Inj. Pethidine 50mg/ml 2ml	
47	Inj. Promethazine 25mg/ml	
48	Inj. Quinine 600mg/2ml	
49	Inj. Artemether	
50	IV. Cholera Replacement Fluid 5:4:1	
51	IV. Dextrose 5% 500ml	
52	IV. Dextrose 50% 250ml	
53	IV. Dextrose 5% in Normal Saline 0.9% 500ml	
54	IV. Ringers Lactate 500/1000ml	
55	IV. Normal Saline 0.9% 500ml	
56	Supp. Artesunate	
57	Supp. Diazepam 5/10mg	
58	Supp. Diclofenac 25/50/100mg	
59	Supp. Paracetamol 125/250/500mg	
60	Oral Rehydration Salt (ORS)	
61	Gutt. Chloramphenicol 1%	
62	Oc. Chloramphenicol 1%	
63	Sol. Povidone Iodine	

Appendix 13-Tracer medicines list for health centres

NAME OF FACILITY: ..... DATE: .....

No.	Generic Name	Available
1	Tab. Acetylsalicylic Acid 300mg	
2	Tab. Albendazole 200/400mg	
3	Tab. Aluminium Hydroxide 500mg/Tab. Magnesium Trisilicate 250mg	
4	Tab. Artesunate + Tab. Amodiaquine (base) Adult	
5	Tab./Suspension Artesunate + Tab. Amodiaquine (base) Children	
6	Tab. Artemether – Lumefantrine 20\120mg Adult	
7	Tab./Granules/Artemether – Lumefantrine 20\120mg Paediatric	
8	Tab. Chlopheniramine Maleate 4mg	
9	Tab. Co-trimoxazole 400mg + 80mg	
10	Tab. Diazepam 5/10mg	
11	Tab. Ferrous Sulphate 200mg/Tab. Ferrous Fumarate 322mg	
12	Tab. Folic Acid 5mg	
13	Tab. Ibuprofen 200/400mg	
14	Tab. Metronidazole 200mg	
15	Tab. Multivitamin A,B,C,E	
16	Tab. Paracetamol 500mg	
17	Cap. Amoxycillin 250/500mg	
18	Susp. DihydroArtemisinin – Piperaquine 40\320mg P	
19	Tab DihydroArtemisinin – Piperaquine 40\320mg	
20	Susp. Albendazole 100mg/5ml	
21	Susp. Amoxycillin 125mg/5ml	
22	Susp. Chloramphenicol 125mg/5ml	
23	Susp. Co-trimoxazole 200mg + 40mg/5ml	
24	Susp. Metronidazole 200mg/5ml	
25	Syr. Multivitamin A,B,C,E	
26	Syr. Paracetamol 120mg/5ml	
27	Syr. Promethazine Elizir 5mg/5ml	
28	Inj. Anti-Rabies Vaccine (ARV)/Serum	
29	Inj. Anti-Snake Serum (ASS) – West African Polyvalent	
30	Inj. Anti-Tetanus Serum (ATS) 1,500/50,000iu	
31	Inj. Chloramphenicol 1g	
32	Inj. Diazepam 5mg/ml	
33	Inj. Ergometrine 500micrograms/ml	
34	Inj. Oxytocin 10 IU	
35	Inj. Hydrocortisone 100mg	
36	Inj. Promethazine 25mg/ml	
37	IV. Cholera Replacement Fluid 5:4:1	

38	IV. Dextrose 5% in Normal Saline 0.9% 500ml	
39	IV. Normal Saline 0.9% 500ml	
40	IV. Ringers Lactate 500ml	
41	Supp. Diazepam 5/10mg	
42	Supp. Paracetamol 125/250/500mg	
43	Oral Rehydration Salt (ORS)	
44	Sol. Povidone Iodine	

Appendix 14-Institutional psychotropic quarterly drugs report

INSTITUTION: .....

QUARTER: .....

Date	Drug	Opening Stock	Quantity procured	Quantity Available	Quantity issued	Balance	Average Monthly Consumption	Expiry Date	Remarks

Balance B/F.....

Prepared by: **Counter signed by:**

Name..... **Name .....**

Signature ..... **Signature .....**

Rank ..... **Rank .....**

Date ..... **Date .....**

Appendix 15-Quarterly drugs report

REGION: .....

QUARTER: .....

No.	Generic Name	Expiry Date	Opening Stock	Quantity Purchased	Quantity Available	Quantity Used	Closing Stock	Unit Price	Value of Closing Stock
TOTAL VALUE									

Prepared by: **Counter signed by:**

Name..... **Name .....**

Signature ..... **Signature .....**

Rank ..... **Rank .....**

Date ..... **Date .....**

Appendix 16-Pharmacy staff returns

REGION: .....

DATE: .....

No.	Name of Staff	Nationality	Date of Birth	Date of First Appoint-ment	Date of Ap-pointment to Present Grade	Present Place of Work with Date	Post Graduate Education	Present Posting

Prepared by:

Name .....

Signature .....

Rank .....

Date .....

Counter signed by:

Name .....

Signature .....

Rank .....

Date .....

Appendix 17-Ghana Health sector tool for accreditation of hospital pharmacy

Ghana health sector tool for accreditation of hospital pharmacy

Code No.	Areas and Characteristics/Standards	Notes	3 (All)	2 (>½)	1 (≤½)	0 (Nil)	N/A
15	**CLINICAL SERVICES**						
15.1	**Pharmacy**						
	Infrastructure						
15.1.1	Existence of Pharmacy Unit or Department (available, duly registered if private, accessible, directional signs)						
15.1.2	Waiting/reception area (available, roofed, clean, seats comfortable, audio-visuals equipment, reading material)						
15.1.3	Arrangement of service area to promote easy flow of work						
15.1.4	State of department or unit (clean, adequate ventilation, adequate natural and artificial lighting)						
15.1.5	Workshop/work station (clean, adequate for workload, intact)						
15.1.6	Office/Restroom for staff (number, furniture, books and journal)						
15.1.7	Counselling area/room (available, adequate space, privacy)						
15.1.8	Store room (adequate space, shelves, cabinets, tidy and clean)						
15.1.9	Washroom for patients (clean, no offensive odour, hand washing facilities, toilet rolls)						
15.1.10	Directional signs (clear sign post, appropriately sited, labelled)						
15.1.11	Washroom for staff (clean, no offensive odour, hand washing facilities,						
	Utilities						
15.1.12	Water (clean, 24-hour supply - running or adequate						
15.1.13	Power Supply (regular - electricity, solar bio-gas)						
15.1.14	Telephone facilities (at least one functioning external line/mobile, intercom and or 2-way radio system.						
15.1.15	Additional telecom facilities (P.A. system, fax,						
	internet)						

Code No.	Areas and Characteristics/Standards	Notes	3 (All)	2 (>½)	1 (≤½)	0 (Nil)	N/A
	Planned Preventive Maintenance (PPM)						
15.1.16	Written schedule for planned preventive maintenance of equipment in Pharmacy.						
	Equipment and Logistics						
15.1.17	Fridges (functioning, separate for medicines, food and specimens)						
15.1.18	Mortars (available, clean and intact)						
15.1.19	Counting and measuring equipment (available, clean jars, functioning weighing scales						
15.1.20	Reference materials (EDL, STG, BNF)						
15.1.21	Drug Dispensing containers (envelopes, bottles, appropriately labelled)						
15.1.22	Computer(s) and printer(s)						
	Human Resource						
15.1.23	Pharmacists (available, number)						
15.1.24	Dispensing Technicians (available, number)						
15.1.25	Dispensing Assistants/Attendants (available, number)						
	Procedures and Service Delivery Process						
15.1.26	Guidelines, protocols, standard operating procedures, essential medicines list (availability, adherence)						
15.1.27	Summary of ADR seen and outcome of interventions						
15.1.29	Drug supply to wards/units (system to ensure 24-hour service, duty roster, records of supplies)						
15.1.30	Stock control (minimum, maximum, re-order levels, expiry flagging)						
15.1.32	Documentation of activities, processes and procedures						
15.1.33	Computerisation of activities (supplies and issues, etc.)						
15.1.34	Proper storage of medicines (insulin, anti-tetanus, anti-snake venom, anti-rabies, oil-based suppositories)						
	Monitoring Outcomes						
15.1.35	Monitoring of outcome Indicators						
	1. RUM indicators						
	2. Patient Waiting Time						
	3. Turn around Time						
	4. Patient Satisfaction Survey						
	5. Prescribers' Satisfaction Survey						

GLOSSARY

TERM	EXPLANATION
ABC value analysis	This is the classification of drugs into the following categories; A - Most expensive B - Moderately expensive C - Least expensive
Aseptic area	This is an area designed in such a way as to prevent the presence of viable micro-organisms
Aseptic procedures	These are procedures that are adopted to prevent the contamination of products and materials during processing
Auxiliary labels	These are additional labels (e.g. cautionary labels, advisory labels)
Batch number	This is a unique number given to a particular batch of products for the purpose of identification and audit
Client	The words "Patient" and "Client" have been used interchangeably in the document
Controlled stationery	This is stationery specifically designed for use in drug management
Counselling	Advice, guidance, direction and warning given to clients about their condition and/or medication
Dangerous drugs	All controlled drugs (i.e. prescription-only and pharmacy-only are classified as dangerous drugs
Date of expiry	It is the date indicated on a product by the manufacturer, beyond which the product should not be used. This expiry date applies only when the product is stored according to the manufacturer's specification
Dosage form	This is the form in which the drug has been formulated and which is suited for its route of administration
Dosing information (Dosage regimen)	This is the dose, the frequency and the duration of use of a medicine
Drug therapy failure	Failure to achieve expected treatment outcomes after drug administration

Drug interactions	This is the interaction of the drug with another drug or food, and which has the potential to modify the effect of the drug
Drugs	The word "Medicines" and "Drugs" have been used interchangeably in this document
Exemptions	These are categories of patients who are not required to pay for their medication e.g. paupers, prisoners
Extemporaneous preparations	These are products prepared for individual patients on request
Generic name of drug	This is the recommended international non-proprietary name of the drug
Medicines	The words "Medicines" and "Drugs have been used interchangeably in this document
Patient	The words "Patients" and "Clients" have been used interchangeably in this document
Proprietary name	This is the trade name of the drug
VEN system analysis	This is the classification of drugs into the following categories: - Vital drugs - Essential Drugs - Non-Essential Drugs

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2. Standard Treatment Guidelines
3. Ghana National Medicines Policy
4. Traditional Medicine Practice Training Manual
5. Drug and Therapeutics Manual (DTC)
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