

Hospital Pharmacy Administration
Central Administration of Pharmaceutical
Affairs

Egyptian Clinical Pharmacy Standards of Practice







2014

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Preface

Clinical pharmacy is a health science discipline in which pharmacists provide:-

- Patient care that optimizes medication therapy and promotes health, wellness, and disease prevention.
- The practice of clinical pharmacy embraces the philosophy of pharmaceutical care (ACCP definition 2008)

It is the practice of pharmacy in a multidisciplinary healthcare team

Clinical pharmacists work directly with doctors, other health care professionals, and patients to ensure that the medications prescribed for patients contribute to the best possible health outcomes as follows:-

With physicians

- Clinical pharmacist shall attend ward rounds and clinical meetings as a member of the healthcare team.
- Clinical pharmacist acts as an Auditor on physicians' prescribing habits
- Clinical pharmacist consults with the patient's doctors and other health care providers in selecting the medication therapy that best meets the patient's needs and contributes effectively to the overall therapy goals.
- Clinical pharmacist facilitates physician's decision making by participating in P&T committee (developing & updating formularies, updating clinical guidelines and conducting Pharmacoeconomic studies)

With Nurses

• Clinical pharmacist provide nursing staff with adequate information about, Medications and their therapeutic use, method of administration, potential adverse effects, and different dosage.

With patients

- Clinical Pharmacists provide direct patient care to the greatest extent possible in both inpatient and outpatient settings.
- Clinical Pharmacists are responsible for continuity of care for patients' medication therapy, Pharmacists and pharmacy departments should take a leadership role in developing and implementing policies and procedures for admissions, discharges, and transfers so that patients' medication therapy is well managed regardless of patient transitions across care settings

Clinical pharmacists practice is in many different health care environments: hospitals and their affiliated outpatient clinics, emergency departments, community pharmacies, doctors' offices, community-based clinics, and managed care organizations.

Clinical pharmacist is a primary source of scientifically valid information and advice on the best use of medications emphasizes that the clinical pharmacist serves as an objective, evidence-based source of therapeutic information and recommendations at three different levels:-

Before the prescribing process

- Clinical pharmacists participate in the development of prescribing policies and treatment guidelines, Medication formularies through Pharmacy & therapeutic committee.
- Clinical pharmacists are also actively involved in clinical trials at different levels: participating in ethical committees; study monitoring; dispensation and preparation of investigational Medications.
- Clinical pharmacists provide medication information by effectively searching, retrieving, and evaluating the literature and appropriately communicating and applying the information to health care professionals.

During the prescribing process

- Clinical pharmacists can influence the attitudes and priorities of prescribers in their choice of correct treatments.
- The clinical pharmacist monitors, detects and prevents harmful Medication interaction, adverse Medication reactions ad medication errors through evaluation of prescriptions' profiles.
- Clinical pharmacists are also actively involved in clinical trials at different levels: participating in ethical committees; study monitoring; dispensation and preparation of investigational Medications.

After the prescribing process

- Preparation of personalized formulation
- Communicating and counseling patients.
- Monitoring treatment response, check and improve patients' compliance with their medications.
- Medication use evaluation (MUE)
- Outcome research &Pharmacoeconomic studies

Clinical pharmacy services have been shown to:

- Identify clinically important Medication-related problems
- Reduce the incidence of clinically important Medication-related problems
- Improve patient education and concordance
- Improve prescribing
- Improve clinical outcomes of different medication regimens.
- Improve medication cost-effectiveness
- Reduce length of hospital stay

The Clinical pharmacist develops through experience, training and personal development the attitude, knowledge, skills, relationships and professional responsibilities necessary to provide an effective and efficient clinical pharmacy service.

Hospital Pharmacy administration (HPA), central administration of pharmaceutical affairs (CAPA) has introduced guidelines and procedures towards assisting proper application and Practice of clinical pharmacy in the Egyptian hospitals. These Guidelines for clinical pharmacy practice will serve as a tool for all to work conscientiously for good pharmacy practice and the benefit of patients.

This guideline focuses on Standards of clinical pharmacy practice which describes the work flow of Clinical pharmacy service and explanation of the necessary documentations involved. It is believed that such guidelines are able to steer good management practice in conductive environments towards fulfillment of customers' needs.

HPA, CAPA would like to convey gratitude to the Clinical & Technical Pharmacy Working Committee in the success of producing this guideline. Also, a special thanks to all parties that contributed during all stages of development and Publication of this guideline

This document will be approved and authorized by Dr Faten Abdel-Aziz
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بسم الله الرحمن الرحيم

قرار وزير الصحة والسكان رقـــــم (\ م \) لسنة ٢٠١٢

وزير الصحة والسكان:

بعد الإطلاع على القانون رقم ١٣٧ لسنة ١٩٥٥ بشأن مزاولة مهنة الصيدلـــة. وعلى قرار رئيس الجمهورية رقم ٢٤٢ لسنة ١٩٩٦ بتنظيم وزارة الصحة والسكان. وبناء على ما عرضه رئيس الإدارة المركزية للشئون الصيدلية.

Consequences (

مادة (1): تلتزم جميع المستشفيات الحكومية والخاصة بانشاء وحدة للصيدلة الاكلينيكية، وأخرى لمعلومات الدواء داخل المستشفى، على أن يعتبر ذلك من الاشتراطات الأساسية اللازم توافرها للترخيص بهذه المستشفيات.

وتحدد الاشتراطات الفنية لهذه الوحدات بمعرفة إدارة صيدلة المستشفيات بالادارة المركزية للشئون الصيدلية، وتنشر على جميع المستشفيات لمراعاة ما جاء بها.

صادة (٣): تمنح جميع المستشفيات القائمة وقت العمل بهذا القرار مهلة زمنية لا تتجاوز سنة من تاريخ نشر هذا القرار لتوفيق أوضاعها طبقا لأحكامه.

وتتولى الإدارة العامة للتفتيش وإدارات الصيدلة بالمحافظات التفتيش الدورى على الوحدات المذكورة بالتنسيق مع إدارة صيدلة المستشفيات بالادارة المركزية للشئون الصيدلية، وكذلك المتابعة والتنسيق مع الإدارات المعنية بالوزارة.

مادة (٣): ينشر هذا القرار في الوقائع المصرية، ويعمل به من اليوم التالي لتاريخ نشره.

في: ١٢/٦١-٦

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القاهرة : ۲ ش مجلس الشعب. ص.ب: ۲۱۰۱۱ – ت: ۲۹۰۷۰ – ۷۹۰۷۰ (۲۰۲) – فاکس: ۲۲۲۲۹ (۲۰۲۰)

Editorial Board

Clinical & Technical Pharmacy Working Committee constituting of: decision makers including clinical pharmacists, head of pharmacy administration of all governmental sectors, Audit members and academic supervisors. Where a serious of meetings is conducted to discuss clinical pharmacy standards of practice and tailor them to the situation of Egyptian governmental hospitals.

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Chapter 1

Introduction to Hospital Pharmacy

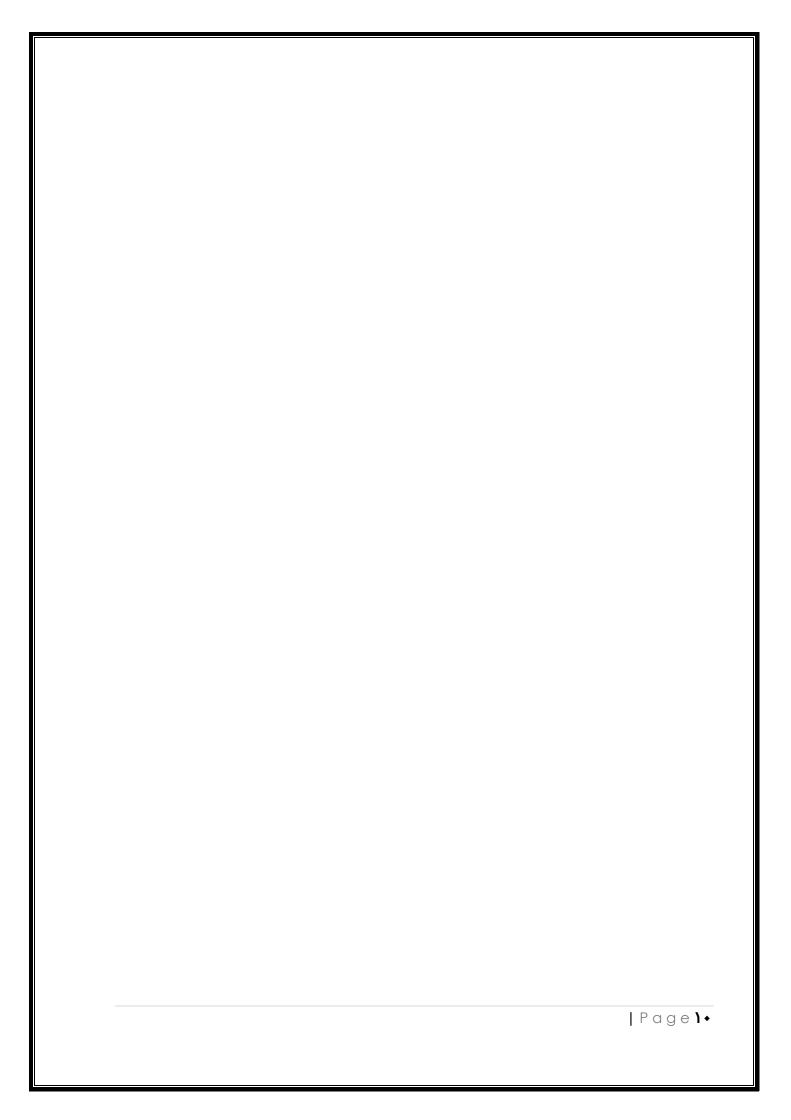
1.1 Definition

The department or service in a hospital which is under the direction of a professionally competent, legally qualified pharmacists, and from which all medications are supplied to the nursing units and other services, special prescriptions are filled for patients in the hospital, for ambulatory patients and out-patients, pharmaceuticals are manufactured in bulk, narcotic and other prescribed Medications are dispensed, injectable preparations prepared and sterilized, and professional supplies are often stocked and dispensed.

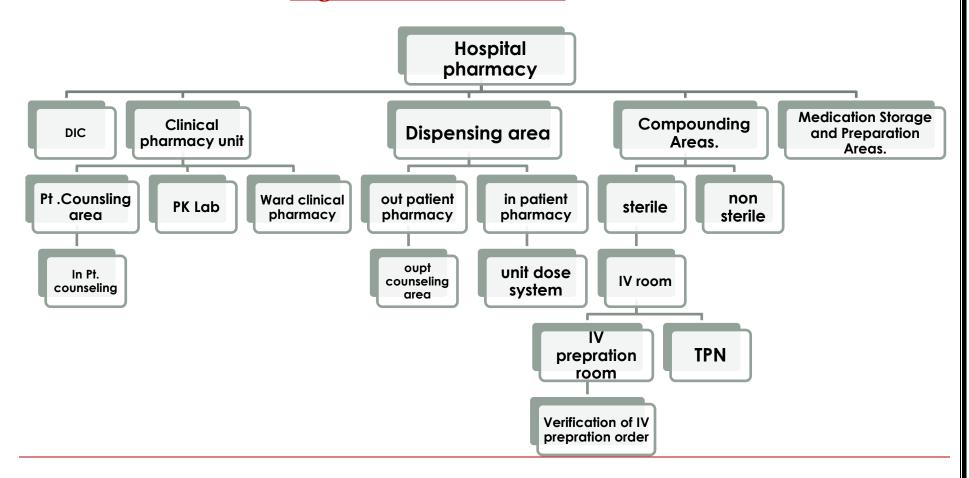
The mission of Hospital pharmacists is to help people make the best use of medications.

The elements of Hospital pharmacy services that are critical to safe, effective, and cost-conscious medication use in a hospital include: (Pharmacy & Services, 2013)

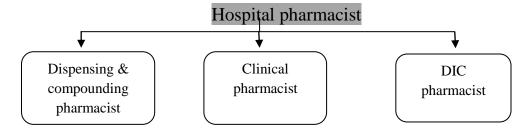
- (1) The procurement, distribution, and control of all pharmaceuticals used within the facility.
- (2) Medication-use policy development
- (3) The evaluation and dissemination of comprehensive information about Medications and their use to the institution's staff and patients.
- (4) Clinical service and patient care
- (5) The monitoring, evaluation, and assurance of the quality of Medication use.
- (6) Education & Research



1.2 Organizational Structure



1.3 Hospital Pharmacist job description



1-Role of hospital Pharmacist in P&T Committee

• Pharmacy & therapeutic committees

A group of physicians, pharmacists, and other health care providers from different specialties, who advise a managed care plan regarding safe and effective use of medications. The P&T Committee manages the formulary and acts as the organizational line of communication between the medical and pharmacy components of the health plan

Members: -

- ✓ Hospital manager or co-manager as the committee chairman
- ✓ Pharmacy director as the committee secretary
- ✓ Pharmacy member(s): clinical pharmacist, DIC pharmacist, inpatient/outpatient pharmacist or any other pharmacy representative(s)
- ✓ Practitioners from a variety of specialty
- ✓ Nursing department representative(s)
- ✓ Quality department representative
- ✓ Financial manager or representative
- ✓ Others: According to topics discussed e.g. infection control member, laboratory member, or IT member

Frequency of meeting

The committee members are called for a monthly meeting

Role of hospital pharmacist in P&T committee

("ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System," 1965)

Hospital pharmacist actively contributes in the pharmacy administration process through active participation in the pharmacy and therapeutic committees (PTCs)

A. Overseeing policies and procedures related to all aspects of medication use within an institution through:

- Addition to or deletion from the formulary,
- Developing medication use guidelines
- ➤ Methods for ensuring the safe prescribing, distribution, administration, and monitoring of medications
- ➤ The process for using nonformulary agents, investigational Medications, restricted use Medications, or controlled substances
- ➤ The process for managing Medication product shortages
- ➤ Written regulations governing the activities of medical sales representatives and use of Medication samples
- ➤ A written procedure to handle Medication product recalls
- B. Medication use evaluation (MUE),
- C. Adverse-Medication-event monitoring and reporting, medication-error prevention
- D. Pharmacist job description and work plan approval
- E. Continuous education & staff development
- F. Clinical trials & research activities

2- Clinical service & patient care

- Pharmaceutical care
- Clinical pharmacokinetics consultation services
- Education &training services
- Patient counseling

3- Medication distribution & control

Policies, P. (n.d.). ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control, 122–130.

Hospital pharmacists are responsible for the core process of Medication distribution all over the hospital, Medication distribution process includes:

- Procurement: Medication Selection, Purchasing Authority, making decisions regarding products, quantities, product specifications.
- Medication Storage and Inventory Control, Proper environmental control (i.e., proper temperature, light, humidity, and conditions of sanitation, ventilation, and segregation)
- Preparation of medications which includes both sterile and non-sterile products.

1- Preparation of non sterile products

Bulk Compounding, Packaging, and Labeling

- ➤ Prepackaging of oral solids, liquids, topicals and powders, for a unit dose distribution system according to the consumption rate and the inventory.
- ➤ Preparation of commercially unavailable formulations required for a group of patients such as pediatrics, geriatrics, intensive care unit patients and using nasogastric fed patients
- Labeling of the prepared products (generic name, dosage form, strength, batch number, expiry date etc.) and using Accessory labels (shake well, may not be refilled, and the like).

2- Preparation of sterile products including intravenous admixtures, Dialysis fluids, and irrigations) & Compounding Parenteral Nutrition Admixtures

The pharmacy is responsible for assuring that all such products prepared to be used in the institution are:

➤ Rational and free of incompatibilities, microbial and pyrogenic contaminants

- ➤ Correctly calculated and prepared (i.e., contain the correct amounts of the correct Medications)
- > Properly labeled, stored, and distributed.

3- Dispensing of medications

- ➤ The Patient's medical records profile must be reviewed by the pharmacist before dispensing the patient's medication(s).
- These includes the revision of (Patient's full name, date of hospital admission, age, sex, weight, height, hospital I.D. number, and provisional diagnosis or reason for admission, Lab. test results, Sensitivities, allergies, and other significant contraindications, medication history
- ➤ The pharmacist is requested to review the medications to be dispensed against the physician's original medication order to eliminate transcription errors (check dates of original orders, strengths, dosage forms, quantities, dosage frequency or directions, and automatic stop dates.
- The reviewing process will be including: Detection of potentially serious interactions, unintended dosage changes, medication duplications and overlapping therapies, and medications contraindicated because of patient allergies or other reasons
- ➤ The reviewing pharmacist is requested to document any identified problems or errors actions as a method of reporting to other healthcare professional for subsequent corrective actions
- The dispensing process includes providing special care to special orders (i.e., "stat" and emergency orders and those for nonformulary medications, investigational medications, restricted use medications, or controlled substances) these orders should be processed according to specific written procedures.
- ➤ There are different techniques can be used to dispense medications within the hospital premises. These techniques or system include

1- Unit dose dispensing system

- ✓ Medications are contained in, unit dose packages; in ready-toadminister form for not more than a 24-hour supply of doses.
- ✓ Monitoring of administration and Information to be recorded (the medication name, dose and route of administration, date and time of administration, and initials of the person administering the dose.)

✓ Counseling of the patient must be conducted to ensure understanding and compliance with his medication regimen

2- Floor stock

- ✓ In this system, all but the most unusual drug items are stocked on the nursing stations in all patient care areas.
- ✓ Floor stocks of drugs are minimized and limited to drugs for emergency use and routinely used "safe" items such as mouthwash and antiseptic solutions.
- **3- Individual Prescription Order System:** In this system, virtually all medications are dispensed by the pharmacist on individual prescription orders.

4- Medication Safety

- Medication error reporting
- Medication related problems (including adverse Medication reaction ADR) detection and reporting
- Disposal of Hazardous Substances (e.g. toxic or flammable solvents and carcinogenic agents).

5- Role of hospital pharmacist in quality use of medicines

- Participate in setting Guidelines, policies and procedures.
- Medication safety practices or goals.
- Patient and employee satisfaction surveys.
- Medication use evaluation MUE activities.
- Medication errors and Adverse Medication reactions ADR evaluations.
- Pharmacy performance measures/indicators.
- Quality management education and training.
- Job specific or general competence assessments.

Chapter 2

Establishment criteria of clinical pharmacy unit

2.1 Clinical Pharmacy service

Clinical pharmacy is the area of practice within the health organization in which the pharmacist, through his work within an interdisciplinary team, applies his clinical judgment to assure safe and appropriate use of Medications.

The clinical pharmacist is involved in medical rounds with the other health care professionals to provide the following service:

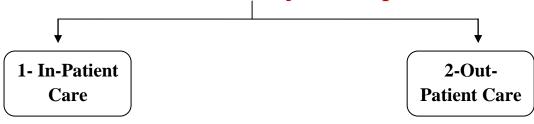
- Pharmaceutical care
- Answering Medication information queries to physicians & other health professionals
- Education &training services
- Patient counseling
- Participation in medication use evaluation.

In addition to the above mentioned functions, several other functions are being introduced in the field of clinical pharmacy, but rather in a specialized form. Examples of these are:

- Clinical pharmacokinetics.
- Total parenteral nutrition services.
- Clinical toxicology practicing in formal poison information centers.
- Clinical Medication investigations.
- Formal Medication therapy consultations.
- Specialized clinical pharmacy practice in various medical fields like oncology, nephrology, surgery, pediatrics, intensive care, and others.

Such specialization requires specialized training under what is called residency programs and others.

2.2 Clinical Pharmacist job description



1- In Patient Care

1- Ward pharmacist

1- Responsibilities

Must be involved in medical rounds with the other health care professionals and participates in:

Developing a pharmaceutical care plan

Therapy, M. (n.d.). ASHP Guidelines on a Standardized Method for Pharmaceutical Care, 273–275.

> Collecting and organizing patient-specific information

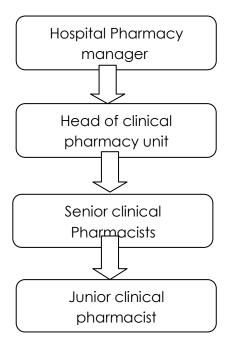
- ✓ Assures the Medication of choice for a particular patient condition is ordered& Selects medication products that are effective are costbeneficial, and promote patient compliance.
- ✓ Determines Medication therapy compliance with protocols, guidelines, or recommendations.
- ✓ Assures there are no contraindications for selected medication products (e.g., allergy, history of severe adverse reaction).
- ✓ Recommends medication discontinuation or dosage alteration when indicated.
- ✓ Identifies potentially significant Medication- Medication, -food, laboratory, and -disease interactions
- ✓ Obtains and uses clinical laboratory data to evaluate appropriateness of Medication product selection and/or dosing regimen.
- ✓ Provides and evaluates Medication therapy orders for appropriateness of dosage, route, interval, schedule, and duration throughout patient's hospital course

- > Determining the presence of medication-therapy problems
- > Summarizing patients' health care needs
- > Specifying pharmacotherapeutic goals
- > Developing a pharmacotherapeutic regimen and corresponding monitoring plan in collaboration with the patient and other health professionals
- > Initiating the pharmacotherapeutic regimen
- > Monitoring the effects of the pharmacotherapeutic regimen
- Documenting pharmaceutical care plan on a specially designed record
- Answering Medication information queries to physicians & other health professionals.
- Patient education and counseling.

The pharmacist's role is to

- ➤ Verify that patients have sufficient understanding, knowledge, and skill to follow their pharmacotherapeutic regimens and monitoring plans.
- ➤ Provide information orally and use visual aids or demonstrations to fill patients' gaps in knowledge and understanding.
- ➤ Document education and counseling on a specially designed counseling record.
- Providing in-service education for Pharmacy students, intern pharmacists, postgraduate pharmacists, pharmacy staff, pharmacy technicians and other health professionals

2-Qualifications



A- Junior clinical pharmacists:

A Scoring system (Appendix 1) was developed to be used as a structured and unbiased tool for careful section of the suitable candidates; **the scoring system is based on:**

1. <u>First need to have experience</u> as a hospital pharmacist for <u>at least</u> 1 year (in & out patient)

2. Knowledge (study degrees)

- ✓ Clinical Pharmacy Fellowship
- ✓ Board of Pharmacy Specialties
- ✓ Clinical Pharmacy Diploma
- ✓ PharmD
- ✓ Clinical pharmacy Master, and PhD
- ✓ Clinical pharmacy Bachelor
- ✓ Accredited courses from accredited university

3. Training for a period of minimum 6 months

- ✓ Including theoretical &practical part (case based) exam
- ✓ Until this stage the team is established till the period of reevaluation (to continue or not &chose another staff)
- 4. **Followed by a working period including practical bed rounds** under supervision (6 months)

Then re-evaluation by a clinical pharmacy consultant and senior clinical pharmacist (if present) to score the learning experience I.e. <u>Total</u> 1 year experience (Appendix 2)

B- Senior clinical pharmacist

Description

For the junior clinical pharmacist to be upgraded to a senior clinical pharmacist the following should be achieved:

- Have at least 3 years experience as Hospital pharmacist & 2 year experience as clinical pharmacist
- Passing the annual appraisal form with a minimum score of very good

Tasks

- The senior pharmacist should be able to provide all the tasks mentioned in the above job description
- Supervises the work of junior pharmacists
- Participates in training of pharmacy colleagues, junior clinical pharmacists ,pharmacy students and other health care providers
- Preparation & presentation of the monthly report of clinical pharmacy service to the quality department and the other departments
- Presentation of junior pharmacists evaluation to head clinical pharmacist
- Liaises with other senior pharmacists in day to day issues
- Assist the head clinical pharmacist in their tasks

c- Head of clinical pharmacy unit

Description

- Having Minimum 5 years hospital pharmacy experience and 2-3 years experience as a clinical pharmacists
- Passing the annual appraisal form with a minimum score of very good

Tasks:

- The head Clinical Pharmacist should be able to provide all the tasks mentioned under the senior pharmacist
- Participates in training of pharmacy colleagues, junior clinical pharmacists ,pharmacy students and other health care providers
- Attend P&T committee to present monthly report related to medication use issues in the hospital
- Participate in writing guidelines for Medication use within the hospital
- Prepares any medication related projects nominated by the quality department or other departments
- Assist pharmacy director in staff appraisal of staff under direct supervision

2- Pharmacokinetic consultation service

Therapy, M. (n.d.). ASHP Statement on the Pharmacist 's Role in Clinical Pharmacokinetic Monitoring, 275–276.

- ➤ <u>Designing patient-specific Medication dosage regimens</u> based on the pharmacokinetic and pharmacologic characteristics of the Medication products used, the objectives of Medication therapy, concurrent diseases and Medication therapy, and other pertinent patient factors (e.g., demographics, laboratory data) that improve the safety and effectiveness of Medication therapy and promote positive patient outcomes.
- ➤ Recommending or scheduling measurements of Medication concentrations
 in biological fluids (e.g., plasma, serum, blood, cerebrospinal fluid) or tissues in order to facilitate the evaluation of dosage regimens.
- ➤ Monitoring and adjusting dosage regimens on the basis of pharmacologic responses and biological fluid and tissue Medication concentrations in conjunction with clinical signs and symptoms or other biochemical variables.

- ➤ Evaluating unusual patient responses to Medication therapy for possible pharmacokinetic and pharmacologic explanations.
- ➤ <u>Communicating patient-specific Medication therapy information</u> to physicians, nurses, and other clinical practitioners and to patients orally and in writing, and including documentation of this in the patient's health record.
- ➤ Educating pharmacists, physicians, nurses, and other clinical practitioners about pharmacokinetic principles and appropriate indications for clinical pharmacokinetic monitoring, including the cost-effective use of Medication concentration measurements.
- ➤ <u>Developing quality assurance programs for documenting improved patient</u>

 <u>outcomes</u> and economic benefits resulting from clinical pharmacokinetic monitoring.
- ➤ <u>Promoting collaborative relationships with other individuals and</u>
 <u>departments involved in Medication therapy monitoring</u> to encourage the development and appropriate use of pharmacokinetic principles in pharmaceutical care.

*****You can utilize the following reference as a detailed guide for pharmacokinetics monitoring process:

https://www.hosp.uky.edu/pharmacy/formulary/criteria/Clinical_PKS_Manual-July_2009.pdf

2-Qualifications

- The same required qualifications for clinical pharmacists mentioned above.
- Specialized training for Recommending & interpretation of therapeutic Medication monitoring.

3- Others

- ➤ Participates in Medication use evaluation
- > Actively participates in writing or evaluating Medication therapy protocols.
- ➤ Suggests appropriate therapeutic alternatives for nonformulary Medications
- > Participates in research activities
- ➤ Active member in P&T committee

2- Outpatient care

Clinical pharmacists working in outpatient clinics especially that provide direct care to high-risk patients, including those with severe diabetes, those on anticoagulants, renal impairment and others.

1- Responsibilities

- Medication reconciliation
- Monitor patients according to key indicators
- Adjust medication doses as necessary,
- Improve patient compliance
- Repot medication errors
- Educate patients and providers about managing these conditions.

2- Qualifications

The same qualifications mentioned above.

2.3Clinical Pharmacy staff number

1-Ward clinical pharmacy staff

Three major factors drive changes to the staffing levels for clinical pharmacy services these include:

- 1- Range of clinical pharmacy services required
- 2- Availability of technicians and computer system
- 3- Complexity of care required (Linked to patient age, Range & Number of diagnosis plus Number & Type of medicines used
- 4- Hospital throughput which is a combination of Number of beds ,length of stay and occupancy ,usage of same day and ambulatory service

As follows

A	В	С
(High service departments)	(Moderate service departments)	(Low service departments)
ICU / ICCU / HDU	Internal medicine	Maternity / Obs & Gynae
PICU / Neonatal	departments	ENT
Renal Haemodialysis	Cardiac ward units	Orthopedics
Oncology care units	Pediatric ward	Long stay Psychiatric
	Acute psychiatric departments	Dermatology and plastic surgery
	General surgery	One day surgery units
	Chest diseases	
	department	
	Neurology ward	
	Endocrinology ward	

Minimum standard for staff number set by the committee where the number could be increase or decrease based on the above criteria

Medical specialty	Proposed number
ICU	1 pharmacist – 5 to 8 patients
Surgery	1 pharmacist- 15 to 20 patients
Internal medicine &others	1 pharmacist -12 to 15 patients

2-Outpatient pharmacy staff

1 Pharmacist /30 prescriptions in case of practicing patient counseling

Number decrease or increase according to :

- ✓ Availability of computer database for pharmacy work
- ✓ Expansion of the service like conducting patient counseling service

2.4 Facilities &infrastructure

1-Ward clinical pharmacy area

There shall be adequate space, equipment, and supplies that facilitate discussion and analyzing of patient data after finishing the daily clinical round (if possible it will be a working area in the ward inpatient pharmacy if not providing a valid working area in other place (in the library for example).

Conditioned that fulfills the following basic requirements:

- Shall be located in an area (or areas) that facilitate (s) the provision of services to patients and be integrated with the Facility's communication and transportation systems.
- Space and equipment, in an amount and type valid for clinical pharmacy activities
- With Furniture desks, chairs, Telephone, at least one Computer with internet access and Software for word processing, spreadsheets, databases and presentations, printer
- Current Medication information resources must be available. These should include appropriate pharmacy and medical journals and texts and Medication literature search and retrieval resources.

2-Pharmacokinetics Lab

Each hospital establish PK lab according to their need and number of patients supplied be this service and availability of Medications need monitoring

If service needed in hospital isn't exceeded devices capacity, central PK lab that serves certain geographical area will be more sufficient or Lab affiliated to ministry for all governmental hospitals

Facilities

- A separate room isn't required
- Separate area in the chemical lab

Types of equipments available

- HPLC system (PDA), (DAD), (UV, Fl)
- GC system
- GS-MS system

- Apparatus for SPE
- Solvent evaporator
- UV/VIS scanning spectrometer
- Centrifuge
- Ultra-centrifuge
- -80C freezer
- LC-MS system (to be purchased)

Medications to be monitored

- Methotrexate
- Vancomycin
- Aminoglycosides
- Digoxin
- Phenytoin
- Valproic acid
- Cyclosporine
- Mycophenolic acid.
- Theophylline

3-Technical criteria for Patient education area

- Education and counseling are most effective when conducted in a room or space that ensures privacy and opportunity to engage in confidential communication.
- If such an isolated space is not available, a common area can be restructured to Maximize visual and auditory privacy from other patients or staff or conducting at patient bed in case of discharged patient.
- The design and placement of desks and counters should minimize barriers to communication. Distractions and interruptions

The environment should be equipped with appropriate

- ➤ Learning aids, e.g., graphics, anatomical models,
- > medication administration devices
- > memory aids
- ➤ Written material, and audiovisual resources.

Chapter 3

Establishment criteria for Drug Information Center

3.1 Drug information providing service

(Concepts, Needs, & Activities, 1996)

The provision of medication information is among the fundamental professional responsibilities of pharmacists in health systems.

Medication information may be patient specific, as an integral part of pharmaceutical care, or population based, to aid in making decisions and valuating medication use for groups of patients (e.g., medication evaluation for formulary changes, medication-use evaluations).

To be an effective provider of medication information, the pharmacist must be able to

- 1. Perceive and evaluate the medication information needs of patients and families, health care professionals, and other personnel.
- 2. Use a systematic approach to address medication information needs by effectively searching, retrieving, and evaluating the literature and appropriately communicating and applying the information to the patient care situation.

A specially designed drug information request form should be produced to be used as a tool for documenting and retrieval which include the following:

- 1. Date and time received.
- 2. Requester's name, address, method of contact (e.g., telephone or beeper number), and category (e.g., health care discipline, patient, public).
- 3. Person assessing medication information needs.
- 4. Method of delivery (e.g., telephone, personal visit, mail).
- 5. Classification of request.
- 6. Question asked.
- 7. Patient-specific information obtained.
- 8. Response provided.
- 9. References used.
- 10. Date and time answered.
- 11. Person responding to request.
- 12. Estimated time in preparation and for communication.
- 13. Materials sent to requesters.
- 14. Outcome measures suggested (e.g., impact on patient care, improvements in medication use, and requester satisfaction).

3.2 Drug information pharmacist job description

(Concepts, Needs, & Activities, 1996)

- Providing medication information to patients & health care professionals by effectively searching, retrieving, and evaluating the literature and appropriately communicating and applying the information to the patient care situation.
- Establishing and maintaining a formulary based on scientific evidence of efficacy and safety, cost, and patient factors.
- Developing and participating in efforts to prevent medication misadventuring, including adverse Medication event and medication error reporting and analysis programs.
- Developing methods of changing patient and provider behaviors to support optimal medication use.
- Publishing newsletters to educate patients, families, and health care professionals on medication use.
- Educating providers about medication-related policies and procedures.
- Coordinating programs to support population based medication practices (e.g., development of medication-use evaluation criteria and pharmacotherapeutic guidelines).
- Coordinating investigational Medication services.
- Providing continuing-education services to the health care professional staff.
- Educating pharmacy students and residents.

Qualifications

- DIC pharmacist needs to have experience as a clinical pharmacist **before** being a DIC pharmacist to improve the clinical sense
- Pharmacy personnel should receive orientation and training on how to respond to Medication information requests and types of Medication information references and how to evaluate the literature and use evidence based medicine.
- Medication information specialists are pharmacists who have completed specialized training in Medication information, generally in the form of 1-year residency programs in Medication information provided by hospitals and other Medication information centers.
- Medication information specialists are skilled in locating and evaluating Medication information and in communicating with pharmacists, physicians, other health care providers, and patients.

3.3 Drug information center staff number

• The number of personnel required depends on the range of activities offered and the hours of service.

3.4 facilities &infrastructure

I. Setup and equipment

Begin as nucleolus even at area in the main pharmacy or the library provided by at least one working computer, valid net access and Current Medication information resources

And Upon expansion of the service it will need to provide:

A separate room with adequate space, where the following Basic equipment is required:-

- Furniture desks, chairs, shelving
- Communications telephones, facsimile, internet access
- Computers including external data backup, printer
- Software for word processing, spreadsheets, databases and presentations
- Photocopier
- Textbooks
- Electronic information resources
- Online information resources e.g. Lexi comp & Uptodate

II. <u>DIC – Resources</u> Appendix (12)

References can be categorized into:

-Primary sources

• These include journal publications on Medication-related subjects, such as reports of clinical Medication trials, case reports, and pharmacological research.

- **Secondary sources** (indexing and abstracting)
 - Include review articles, meta-analyses, indexes (Index Medicus), abstracts (International Pharmaceutical Abstracts), and combinations of abstracts and full-text reprints.

- Tertiary sources

• Include formulary manuals, standard treatment manuals, textbooks, general reference books, Medication bulletins, and Medication compendia.

VI Policy and Procedures (P and P)

It is important to have well defined P and P as it serves as a guide for:-

- ✓ Training and orientation of new employee.
- ✓ Insuring that tasks have been carried properly
- ✓ Evaluating job performance

Chapter 4

Clinical pharmacy standards of practice

4.1 Clinical pharmacy standards of practice

(Burke et al., 2008)

To be a competent clinical pharmacist, you must be able to complete the required task to the defined standard and to do this on every occasion that the task arises. This is why competence standards have been developed, so that there is a measurable standard for each of us to evaluate ourselves.

The Competency Standards for Clinical Pharmacists describe eleven functional areas covering a broad area of professional performance:

- 1. Medicine History Interview
- 2. Prescription Monitoring and Review
- 3. Recommendation of treatment changes
- 4. Developing a pharmaceutical care plan
- Prevention, Detection, Assessment and Management of Adverse Medication Reactions
- 6. Prevention, Assessment and Management of Medication Interactions
- 7. Prevention, identification, management and reporting of medication incidents
- 8. Provision of Medicines Information Advice by Pharmacists
- 9. Patient Medicine Education
- 10. Therapeutic Medication Monitoring (TDM)
- 11. Participating in formulary decisions and Medication use evaluation.

Under each functional area, elements of Competency describe in more detail the roles and activities in the professional workplace. The elements aim to integrate the knowledge, skills, attitudes and other important attributes of professional performance in the workplace.

In order to practice clinical pharmacy Multidisciplinary Working is required (refer to appendix 5) to take collaborative decision (from all health care professionals) for the achievement of optimum patient outcomes.

So the clinical pharmacist shall attend ward rounds and clinical meetings as a member of the healthcare team.

Clinical pharmacist competence is achieved when one possesses the knowledge, skills, and attitudes required to provide direct care to patients and to ensure rational medication use, Knowledge is obtained and clinical skills are developed through formal education and training programs, including doctor of pharmacy degree and postgraduate residency programs, lifelong learning, and continuing professional development.

Key clinical pharmacist competencies

- 1. Clinical problem solving, judgment, and decision making
- 2. Communication and education
- 3. Medical information evaluation and management
- 4. Management of patient populations
- 5. Therapeutic knowledge areas

1- Clinical problem solving, judgment, and decision making

- A combination of in-depth knowledge of diseases, expertise in Medication therapy, problem-solving skills and practical experience involving patients' use of medications is necessary in order to be a competent clinical pharmacist.
- Clinical pharmacists must be able to work with patients and other health care professionals to determine which treatments will best meet the patient's therapeutic needs.

2- Communication and education

- The clinical pharmacist should have the ability to effectively communicate with and educate patients and health care professionals to ensure optimal patient outcomes.
- Written communication is also important, it is the clinical pharmacist's responsibility to document medication reconciliation, clinical problem solving activities, therapeutic interventions, and patient education activities in the medical record.

3-Medical information evaluation and management

• Providing quality patient care requires a knowledge base that is continuously expanding and being updated.

- A clinical pharmacist must be able to identify situations beyond his or her own expertise or that require new information to reach a decision.
- This necessitates carefully defining the question and using a variety of information sources to derive the answer

4- Management of Patient Populations

- Many clinical pharmacists not only are involved in providing care to individual patients, but work within a health system or other organization to develop protocols and critical pathways that optimize the care of patient populations.
- These efforts may include analyzing Medication utilization evaluations, composing protocols for disease state management, and developing organizational policies and procedures that improve patient care and resource utilization.

5- Therapeutic Knowledge

- Clinical pharmacists must possess a therapeutic knowledge base of sufficient breadth and depth to effectively promote rational medication use.
- A clinical pharmacist must be competent in the therapeutic management of the many disease states that may affect a given patient, not simply those currently identified as active problems.



Medicine history interview upon admission

Prescription Monitoring and
Review (review each
medication for indication,
contraindication, Medication
interaction, dose, frequency,
duration &dosage form)

Recommendation of initial treatment changes according to patient specific information and therapeutic needs

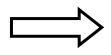
Developing a pharmaceutical care plan & solving DTPs



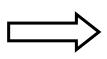
Prevention, identification,
management and reporting of
medication errors



Prevention, Detection,
Assessment and Management of
Adverse Medication Reactions



Assessment, reporting and Management of Medication Interactions



Patient Medicine Education

Clinical pharmacy standards of practice

Irish ("CLINICAL PHARMACY," 2009)

Standards	Procedure	Assessment method
1- Medicine History Interview	 Determine the ability of the patient to communicate appropriately Choose a suitable environment that allows privacy and confidentiality for the patient and minimizes the risk of interruption and distraction Establish the identity of the patient Introduce yourself Explain the purpose of the interview Questions must be relevant to the specific patient and tailored to obtain the necessary information. A standardized form should be used to record the information obtained and be signed and dated by the pharmacist who has taken the medicine history and be filed in the patient's medical notes and/ or form part of the patient's pharmaceutical care plan. Open-ended questions should be used to seek information on the following: Basic personal data History of present illness (HPI) Past Medical history (PMH) Family history 	 A local SOP exists of how to take a medicine history. A medicine history is documented or verified by a pharmacist by the next working day after admission to hospital. (Refer to appendix 3)

2- Prescription Monitoring and Review	 Social history (lifestyle , diet) Medication history (prescribed ,OTC medications , Herbal remedies) → past 3 months and chronic medication Medications being taken on admission Any Allergies The patient's prescription should be reviewed in conjunction with the administration record, the patient's notes, the medicine history and relevant laboratory test results. All current and recently prescribed Medications should be reviewed. Ensuring the prescription is appropriate with respect to: ✓ The patient's medical condition ✓ The patient's previous medicine ✓ Patient specific considerations e.g. pregnancy, nil by mouth ✓ Medication dosage and dosage schedule with respect to age, renal function, liver function ✓ Route, dosage form and method of administration Checking for medicine duplication 	 A local SOP exists for prescription monitoring and review. All patients' prescription charts are monitored and reviewed by a pharmacist by the next working day after admission and is repeated at regular intervals throughout the patient's admission The pharmacist assesses the patient's pharmaceutical needs and identifies the patient's pharmaceutical care issues.
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	Checking for actual or potential medicine interactions or incompatibilities	
	 Ensuring that administration times are appropriate e.g. with respect to food, other medicines, procedures 	
	• Checking the administration records to ensure that medicine is administered as prescribed	
	• Ensuring that the prescription clearly indicates the times of Medication administration.	
	• Ensuring that the duration of therapy is appropriate e.g. antibiotics, analgesics	
	• Ensuring that the prescription is cancelled when Medication therapy is intended to cease and that this is signed and dated	
	Ensuring that appropriate therapy monitoring is implemented	
3- Recommendation of treatment changes	Designing and individualizing comprehensive Medication therapy regimens requires clinical experience and Collaborating with patients,	A local SOP exists for Recommendation of treatment changes according to specific

	caregivers, and other health professionals to determine which treatments will best meet the patient's therapeutic needs.	treatment guidelines
	 Consultation with the prescriber to discuss and agree any suggested and necessary changes must be undertaken as soon as practical. 	
	Consultation and intervention in patient care should be documented in the patient's medical notes and pharmacy records where appropriate.	
	The pharmacist must follow up on consultations to ensure that problems are resolved.	
4- Developing a pharmaceutical care plan	 The standardized method for the provision of pharmaceutical care should include the following: ✓ Collecting and organizing patient-specific information, ✓ Determining the presence of medication- 	 The pharmacist formulates a plan for pharmaceutical care. This need to be recorded in a separate document. (Refer to appendix 3- Pt follow up sheet)
	therapy problems These include:	• The pharmacist implements, monitors and reviews the pharmaceutical care

a.	Untreated indications – the patient has a medical problem that requires medicine therapy but is not receiving a medicine for that indication	plan.
b.	Missing medicines e.g. patient prescribed digoxin but not prescribed an anticoagulant or Antiplatelet	
c.	Inappropriate Medication selection – the patient has a medicine indication but is taking the wrong medicine. The patient's treatment should be current best practice	
d.	Subtherapeutic dosage – the patient has a medical problem treated with too little of the correct medicine	
e.	Failure to receive medicine – the patient has a medical problem as the result of not receiving a medicine	
f.	Overdosage – the patient has a medical problem being treated with too much of the correct medicine	
g.	Actual or potential adverse Medication reactions or effects	
h.	Medication interactions – the patient has a medical problem that is the result	

of a Medication-Medication, Medication-food or Medication-test interaction

- i. Medicine use with no medical indication
- j. Lack of understanding of the medicine therapy by the patient
- k. Failure of the patient to adhere to the medicine regimen
- ✓ Summarizing patients' health care needs,
- ✓ Specifying pharmacotherapeutic goals
- ✓ Designing a pharmacotherapeutic regimen
- ✓ Designing a monitoring plan
- ✓ Developing a pharmacotherapeutic regimen and corresponding monitoring plan in collaboration with the patient and other health professionals,
- ✓ Initiating the pharmacotherapeutic regimen,
- ✓ Monitoring the effects of the pharmacotherapeutic regimen
- ✓ Redesigning the pharmacotherapeutic regimen and monitoring plan.

5- Prevention, Detection,Assessment andManagement of AdverseDrug Reactions(Pharmacovigilance)

- ➤ <u>In preventing and detecting ADRs pharmacist</u> should:
- Identify and monitor patients most susceptible to ADRs For example
 - ✓ Older patients
 - ✓ Paediatrics patients
 - ✓ Those with multiple diseases
 - ✓ Patients treated with a large number of Medications
 - ✓ Patients treated with medicines known to have a high incidence of adverse effects. Avoid use of these medicines where an equally effective and safer alternative exists or ensure they are used appropriately to minimize the risk.
 - ✓ Patients treated with medicines associated with serious adverse effects
 - ✓ Patients treated with medicines with a narrow therapeutic index
 - ✓ Patient treated with medicines with potential for multiple interactions
 - ✓ Patients with compromised Medication handling ability e.g. altered absorption, distribution, metabolism or excretion

- A local SOP exists for the monitoring and reporting of ADRs.
- Medicines with high incidence of adverse reactions or that are known to cause serious adverse reactions are closely monitored.
- Appropriate ADRs are reported using the Yellow Card Scheme (Refer to appendix 10) and delivered to Pharmacovigilance center

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 Admission of a patient to hospital due to an adverse Medication reaction is documented in the patient's medical notes

- ✓ Patients with compromised ability to take or use medicines e.g. dysphagic patients
- Check that patients are not exposed to unnecessary risk e.g. Medication use with no indication, disregard for stated warnings, special precautions, contra-indications
- Check that there are no Medication interactions with prescribed medicine, over the counter medicine, food or drink
- Ensure patients receive cautionary and advisory labels and education on the correct use, storage and disposal of their medicine at discharge
- Educate patients to recognize ADRs and what action to take should they experience an ADR
- Encourage patients to report ADRs
- Encourage medical and nursing staff to report ADRs
- Identify patients who have had previous ADRs, intolerance or hypersensitivity to a particular Medication or class of Medications
- Monitor patients on black triangle or unlicensed medicines

- Detect ADRS through routine Medication therapy monitoring e.g. extra-pyramidal symptoms caused by metoclopramide
- Monitor patients for delayed ADRs with both established and newer medicines
- When an ADR is suspected all possible sources of information should be considered. These include:
- 1. Patient details
 - ✓ Age, sex, ethnic background, weight and height
 - ✓ Diagnosis and other relevant comorbidities prior to reaction
 - ✓ Previous exposure to suspected medicine(s) or related medicine(s)
- 2. Medicine details, including non-prescription Medications, alternative treatments and recently ceased medicines
 - ✓ Name, dose, route of administration
 - ✓ Manufacturer, batch number
 - ✓ Time and date commenced
 - ✓ Date and time discontinued (if applicable) Indication for use
- 3. Adverse Medication reaction details
 - ✓ Description of reaction

- ✓ Time, onset and duration of reaction
- ✓ Complications and outcomes
- ✓ Treatment of reaction and outcome of treatment
- ✓ Relevant investigation results
- ✓ Post mortem result
- When a reaction has occurred the decision whether to continue treatment with the suspected medicine depends on the likelihood of the suspected medicine causing the reaction and the clinical significance of the reaction.
- When managing an ADR the following needs to be considered:
 - ✓ The condition of the patient
 - ✓ The risks and benefits associated with continuing therapy with a medicine known to have caused an adverse Medication reaction
 - ✓ The efficacy and safety of alternative treatments
 - ✓ Prophylactic use of other Medications to prevent future adverse reactions
- Pharmacists may make recommendations on

	treatment. A suspected ADR should be appropriately documented by the pharmacist. This includes: Documentation of the date and nature of the reaction in the patient's medical notes Documentation in allergy/ sensitivity section of patients prescription chart if appropriate Notification of Medical staff, including GP and original prescriber Medication Incident form Reporting all adverse reactions for black triangle Medications and any serious adverse reactions for established Medications to the Committee on Safety of Medicines (CSM) using the Suspected Adverse Medication Reaction form (yellow card system) The medical staff should inform the patient and/ or their carer of the ADR.	
6- Prevention, Assessment and Management of Medication Interactions	 Pharmacists should regularly monitor for potential and existing Medication interactions. This is important during: ✓ Medicine history interview. ✓ Prescription monitoring and review. 	 A local SOP exists for the prevention, assessment and management of Medication interactions. Details of known clinically significant interactions are documented in the

- ✓ Commencement of a new medicine.
- ✓ Cessation of a medicine.
- ✓ Therapeutic Medication monitoring
- Pharmacists need to maintain an up-to-date knowledge of common and clinically significant Medication interactions.
- They also need to be able to access up-to-date medicines information sources dealing with Medication interactions.
- When managing a Medication interaction the following factors must be considered:
 - ✓ Details of the interacting agents e.g. date of commencement.
 - ✓ Therapy monitoring details e.g. laboratory results.
 - ✓ Possible other causes e.g. renal impairment.
- Recommendations to manage an interaction may include:
 - ✓ Switching to an alternative agent.
 - ✓ Monitoring the patient without altering therapy.
 - ✓ Dose adjustment of the interacting agent(s).

patient's medical notes.

- Interactions with adverse consequences are reported according to the organization's incident reporting policy.
- Pharmacists offer guidance on timing of samples, dose adjustment and monitor relevant laboratory results and resultant therapeutic effects.

	 ✓ Altering the dosing schedule. ✓ Changing the route of administration. ✓ Stopping one or both of the interacting medicines. All suspected Medication interactions with adverse sequelae should be discussed with medical staff and documented appropriately. The patient should be notified to prevent future recurrence of the same interaction. 	
7- Prevention, identification, management and reporting of medication incidents	 A local SOP should be existed for the prevention, identification, management and reporting of medication incidents. Pharmacists work in collaboration with medical, nursing, and other relevant staff groups in the prevention, identification, management and reporting of medication incidents. All identified medication incidents are reported according to the organization's incident reporting policy and documented in the specified report form. 	 Medication incident or a near miss is reported according to the local policy/ procedure for reporting medication incidents or near misses. (refer to appendix 7- ME form) A pharmacist reviews all prescriptions for 'high risk' Medications (except in emergency situations) before the first dose is dispensed or administered. If a new allergy/ sensitivity is identified during the patient's admission, this is documented in the

8- Provision of Medicines Information Advice by Pharmacists	The Systemic approach to respond to Medication information enquiries:- Secure the demographics of the requestor Obtain appropriate background information Determine and categorize the ultimate question Develop an efficient search strategy Perform evaluation, analysis and synthesis Formulate a response at the appropriate level for the requestor Communicate the response in a written or verbal form as appropriate If appropriate follow up the response to determine if the response supplied contributed to patient care or if further information is required Advise the enquirer if further relevant information becomes available Medicines information enquiries should be	 Policies that support the safe use of medicines are implemented and adhered to. A local SOP exists for the provision of medicines information by pharmacists. The advice given should be documented in Medicines Information enquiry form (refer to appendix 6 DIR form)
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	recorded and filed according to local policy in an easily retrievable manner to allow access by other users and to prevent duplication.	
9- Patient Medicine Education	 ■ Medicine education may be necessary at different times: ✓ During an outpatient clinic visit ✓ On admission, beginning with the medicine history interview ✓ Throughout an inpatient stay ✓ Immediately prior to discharge or at discharge ■ Choose a suitable environment that allows privacy and confidentiality for the patient and minimizes the risk of interruption and distraction. ■ The mode of presentation will depend on the patient's needs, the person being counseled and the timing of education. ■ Education can incorporate the use of various techniques: ✓ One to one discussions ✓ Group teaching 	 A local SOP exists for patient medicine education Medicine education is documented in the patient's medical or multidisciplinary notes (refer to appendix 8 –Pt counseling record) Patients are provided with verbal and written information in a form they can understand

- ✓ Use of information resources e.g. consumer product information
- ✓ Audiovisual and educational displays
- The primary steps in education are classified into 4 stages:

Open discussion

- ✓ Identify the patient
- ✓ Introduce yourself
- ✓ Explain the purpose and expected length of the session

Gathering information and assessing needs

- ✓ Collect & organize patient specific information age, gender disease state, known allergies, Medication reactions, any exercise or diet habits, smoking
- ✓ Assess the patient's knowledge about their health problems and medicines and their physical and mental capability to use the medicines appropriately, the patient's literacy and numeracy skills.
- ✓ Ask the patient open ended questions about their perception of the purpose of each medicine, what the patient expects and ask

the patient to describe how he or she will use the medicine

Providing information and resolving problems

Information that should be discussed during a education session includes:

- 1. An overview about the disease if possible
- 2. Medication name, Class
- 3. Intended use, benefit of therapy (Cure or reduce symptoms)
- 4. Route, dosage forms, dosage, scheduling, regarding to meals (Tailor regimen to patient's life)
- 5. Medication Preparation
- **6.** Missed doses
- 7. Onset of action, duration of therapy
- **8.** Refill info.
- 9. Precautions, contraindications, interactions (including food & OTC), and possible Side effects
- 10. Actions if no response or ADR occur
- 11. Storage
- 12. Self Monitoring

	Summarizing and Closing discussion ✓ Summarize the significant information for the patient ✓ Assess the patient's understanding e.g. ask the patient to repeat the information given ✓ Ensure the patient has all the relevant information ✓ Supply medicine aids as necessary ✓ Ask the patient if they have any questions or if there is any information they did not understand ✓ Answer the patient's questions and clarify any information they did not understand ■ Based on the assessment of the patient's understanding determine if any follow-up is required This may include: Further education sessions e.g. referral to their community pharmacist for further education	
10- Therapeutic	 Therapeutic Medication Monitoring (TDM) is used by pharmacists to optimize therapy for 	• A local SOP exists for therapeutic
Medication Monitoring	medicines where there is a known, close	Medication monitoring.
(TDM)	relationship between serum concentration,	The SOP details
	therapeutic affect and adverse effect.	✓ how to request monitoring

- TDM may be indicated in the following patients:
 - ✓ Patients with renal impairment
 - ✓ Patients with hepatic impairment
 - ✓ Patients undergoing dialysis or hemofiltration
 - ✓ Patients with uncompensated cardiac dysfunction e.g. edema associated with heart failure
 - ✓ Patients with severe airways disease
 - ✓ Patients with diabetes
 - ✓ Obstetric patients
 - ✓ Older patients
 - ✓ Paediatrics patients
 - ✓ Neonatal patients
 - ✓ Obese/ undernourished patients
 - ✓ Burns patients
 - ✓ Cystic fibrosis patients
 - ✓ Surgical patients e.g. management of patients on lithium going for surgery
 - ✓ Patients showing signs of toxicity e.g. digoxin
 - ✓ Patients unresponsive to therapy to check for therapeutic levels e.g. Theophylline

- ✓ lists those Medications that require TDM
- ✓ how to identify patients who will benefit from TDM

Pharmacokinetics consults &TDM are properly documented by pharmacist (refer to appendix 9– PK initial consult and follow up)

- ✓ Overdose patients
- ✓ Patients treated with a Medication with a narrow therapeutic index
- ✓ Patients treated with a Medication with a high incidence of adverse effects
- ✓ Patients treated with a Medication associated with clinically significant interactions
- Accurate sampling is necessary to relate the measured serum concentration to therapeutic effect.
- When interpreting results the following should be considered:
 - ✓ Medication/ dose/ formulation/ schedule
 - ✓ Method of administration
 - ✓ Indication for treatment
 - ✓ Indication for TDM
 - ✓ Target serum concentration levels
 - ✓ Duration of current treatment
 - ✓ Time of last dose
 - ✓ Time of sampling
 - ✓ Prior Medication monitoring
 - ✓ Relevant laboratory results

	✓ Concordance	
	✓ Administration	
	✓ Clinical status of patient and recent progress	
	✓ Renal and hepatic function, cardiac status, age, weight etc	
	✓ Fluid balance	
	✓ Pharmacokinetic and pharmacodynamic properties of Medication and patient	
	factors that may influence these	
	✓ Concurrent medicines	
	✓ Concurrent disease	
	✓ Environmental factors e.g. smoking	
	 When appropriate, recommendations should 	
	be documented in the patient's medical notes	
	and pharmacy records.	
11- Participating in	 The three key elements are important for the 	A local SOP exists for the provision of
formulary decisions and	establishment and maintenance of a credible formulary. They are:-	formulary decisions and Medication use evaluation
Medication use evaluation.	1. A collaborative work relationship among	
	health-care professionals.	Pharmacists ensure medicine selection
	2. A defined medical staff (or physician-	follows local guidelines, formulary,
	provider network) that practices within that health-care setting.	regional contracts, pharmacoeconomic reviews and availability where

3. An interdisciplinary P&T committee as a committee of the medical staff.	applicable (Appendix 11).
 Techniques of formulary system manager fall into three general categories: 	ment
(1) Medication use evaluation	
(2) formulary maintenance	
(3) Medication product selection.	
 Medication Use Evaluation 	
✓ Medication use evaluation should be a pa	art of
the hospital's overall quality-assurance	
program.	
✓ The P&T committee should be involved in	in
the Medication use evaluation process.	
✓ Medication use evaluation should measur	
and compare the outcomes of patients wh	nose
treatment did, or did not, comply with	
approved criteria or guidelines.	
✓ Based on this comparative information:-	
> criteria or guidelines can be revise	ed,
compliance can be encouraged	
Educational programs can be initial	
Changes can be made to the formu	ulary
system.	

- ✓ Effective Medication use evaluation begins with Medication use criteria or treatment guidelines approved by the P&T committee on behalf of the medical staff.
- ✓ Medication use criteria are approved guidelines regarding how, or under what conditions, a Medication is recommended for use.

✓ There are three general types of criteria

1. Diagnosis criteria

➤ Identify indications that constitute acceptable uses for a formulary Medication within the health-care setting.

2. Prescriber criteria

➤ Identify prescribers approved to use specific formulary Medications or Medication classes. Examples

Include limiting the use of specific injectable antibiotics to infectious disease specialists or establishing cardiologists or emergency room physicians as the only approved prescribers for thrombolytic Medications.

3. Medication-specific criteria.

➤ Identify approved doses, frequency of

administration, duration of therapy, or other aspects that are specific to the use of a formulary Medication.

• Treatment Guidelines

Are similar to Medication use criteria, except that treatment guidelines focus on disease-based Medication therapy.

• Formulary Maintenance include :-

- > Therapeutic Medication class review.
 - ✓ The P&T committee reviews the use and therapeutic effects of several classes of Medication products every year.
 - ✓ For example, based on the number of adverse Medication reaction reports, new information in the medical literature, or Medication class expenditures, the committee can determine which classes of formulary Medications are worthy of reassessment.
 - ✓ The goal is to identify preferred agents based on effectiveness, toxicity, or cost differences within the same class.
- > Formulary Addition or Deletion
- ✓ This process typically involves submission of a request to the P&T committee by

- pharmacists or members of the medical staff.
- ✓ Consideration of a Medication for addition to the formulary should include a review of an evaluation report (monograph) prepared by the pharmacy.
- ✓ describing the effects of the proposed change on the quality and cost of patient care
- > Use of nonformulary Medications in unique patient situations.
- ✓ There should be an approved policy and procedure for obtaining approval for use of nonformulary Medications. This process should include the generation of information on the use of nonformulary
- ✓ Medications to enable the P&T committee to review trends in nonformulary Medication use, which may influence formulary addition or deletion decisions.
- ✓ The decision to approve the use of nonformulary Medications is separate from the decision to grant payment coverage for a Medication

Medication Product Selection

- ✓ Pharmacists and prescribers must understand the concept of therapeutic equivalence to ensure proper application of generic substitution and therapeutic interchange principles
- ✓ This includes evaluation and assessment of bioequivalence data; storage, dispensing, and administration characteristics; cost; and other relevant product information.

• Activation of clinical pharmacist role in outpatient pharmacy is challenging (on stages) :

- ✓ Outpt pharmacist start with focusing his role on patient counseling
- ✓ Medication error reporting
- ✓ Specify pharmacist with physician in the clinic (like anticoagulation clinic in heart institute)
- ✓ Starting with Elnafka section as it has lower number of patients allowing much time for pharmacist to verify the prescriptions

Chapter 4Documentation

Documentation

Any activity undertaken by a Clinical pharmacist that affects patient care should be documented making a permanent record of the pharmacist's concerns, actions and recommendations.

Documentation can be used to provide evidence of the effect of clinical pharmacy services on patient care. It can also be used to obtain adequate resources for continuity of service.

This may include:

1- Pt. history form

- For newly admitted patients in the beginning of (Appendix 3)

2- Clinical pharmacist follow up form

- For Resident patient follow up (Appendix 3)

3- Clinical pharmacist recommendation form in pt medical file

-Where Clinical pharmacist document his medication related notes in Patient medical file in case of physician unacceptance or difficulty to reach descion making physician (Appendix 4)

4- Medication Information Request form

- Where Pharmacist document Medicine Information enquiries and Response to patient specific questions from other members of the Healthcare team (Appendix 6)

5- Pt. counseling checklist (Appendix8)

- First one Educational tool for effective counseling session
- Second one is clinical pharmacist discharge checklist including items to be checked for discharged patient.
- Patient counseling form given to the patient.

6- Clinical pharmacist interventions monthly report (Appendix 5)

- Every pharmacist should document in the end of working day all his interventions in excel sheet (Appendix)
- In the end of each month will be a report where errors is calculated /no of doses

7- <u>Medication error report form (Appendix7)</u>

8- Adverse Medication reaction form (Appendix 10)

9- <u>Clinical Pharmacist evaluation form (Appendix2)</u>

After a period of 1 year clinical pharmacist is reevaluated to assess his/her perfermonance to judge if there is a professional progression or need for further learning and preparation as hospital pharmacy and to allow new members application

Documentation of clinical pharmacist activities is essential in specific forms but it will be on stages till advancing the service where will be extra complicated documentation system

Stage 1	Advanced stage
In the beginning of the service the clinical pharmacist needs ✓ Patient follow up form ✓ Form for documenting Clinical pharmacist interventions in patient record (if possible) ✓ Monthly record of clinical pharmacist interventions (for statistics) ✓ DIR form	After expansion of the service ✓ Separate Form for ME reporting ✓ PK order ✓ Report about benefits of clinical pharmacy service in terms of (total cost benefits, hospital stays, Number of deaths)

It is recommended to put clinical pharmacist progress notes in patient file which is just a notes not interventions or orders which have different forms

Appendices

Appendix 1

Scoring system of Clinical pharmacist selection

courses or lecs (Accredited certificates) from accredited university Max: 10 10 5 4- Work as clinical pharmacist or (make any clinical ph activities) No Inpt > 1yr Inpt < 1 yr Outpt Outpt Inpt > 1yr Inpt < 1 yr Outpt Inpt < 1 yr Inpt < 1 yr Outpt Inpt < 1 yr Outpt Inpt < 1 yr Inpt < 1 yr Outpt Inpt < 1 yr Outpt Inpt < 1 yr Inpt < 1 yr Inpt < 1 yr Inpt < 1 yr Inpt < 1 yr <th>No. of the contract of the con</th> <th>Excellent</th> <th>Very good</th> <th>Good</th> <th>pass</th> <th></th>	No. of the contract of the con	Excellent	Very good	Good	pass	
Max: 25 25 20 15 10	Max: 15	15	10	5	1	
3- Clinical pharmacy courses or lecs (Accredited certificates) Max: 10	S			armD	Diploma	
Courses or lecs (Accredited certificates)	Max: 25	25	20	15	10	
A- Work as clinical pharmacist or (make any clinical ph activities)	courses or lecs (Accredited certificates)					
pharmacist or (make any clinical ph activities) Max: 20	Max: 10	10	5			
Solution	pharmacist or (make any clinical ph activities)					
experience Max: 20 20 10 5 6- computer, English or soft skills certificates yes no Mention is skills certificates Max: 5 5 0 9- Clinical pharmacy exam evaluation (after training period of at least 4-6 months) Attendance assignments Active communicati on Practical exam (Case based) extra /10 /4 /4 /4			-	0.1.1		
6- computer, English or soft skills certificates Max: 5 5 0	experience	- ,		_		
skills certificates Max: 5 5 0 9- Clinical pharmacy exam evaluation (after training period of at least 4-6 months) Attendance assignments Active communicati on Practical exam (Case based) extra /10 /4 /4 /4	Max: 20	20	10	5		
9- Clinical pharmacy exam evaluation (after training period of at least 4-6 months) Attendance assignments Active communicati on Case based activities extra		yes	no			Mention it
Attendance assignments Active communicati on /10 /4 Practical exam (Case based) activities extra	skills certificates					
communicati on	Max: 5	ŭ				
/10 /4	Max: 5 9- Clinical pharmacy exam evaluate	tion (after tra	ining period			
	Max: 5 9- Clinical pharmacy exam evaluate	tion (after tra	Active communicati	Practical exam (extra
40	Max: 5 9- Clinical pharmacy exam evaluate	tion (after tra assignments	Active communicati on /4	Practical exam (extra
	Max: 5 9- Clinical pharmacy exam evaluate	assignments /10 /10	Active communicati on /4	Practical exam (extra
	Max: 5 9- Clinical pharmacy exam evaluate	tion (after tra assignments /10 /10 /10	Active communicati on /4 /4 /4	Practical exam (extra
	Max: 5 9- Clinical pharmacy exam evaluate	/10 /10 /10 /10 /10	Active communicati on /4 /4 /4 /4 /4	Practical exam (extra
/10 /10	Max: 5 9- Clinical pharmacy exam evaluate	tion (after tra assignments /10 /10 /10	Active communicati on /4 /4 /4 /4 /4 /4	Practical exam (extra
/10 /10	Max: 5 9- Clinical pharmacy exam evaluate	/10 /10 /10 /10 /10 /10 /10 /10 /10 /10	Active communicati on /4 /4 /4 /4 /4 /4 /4 /4 /4 /10	Practical exam (extra
/10 /10	Max: 5 9- Clinical pharmacy exam evaluate	/10 /10 /10 /10 /10 /10 /10 /10 /10 /10	Active communicati on /4 /4 /4 /4 /4 /4 /10 /10	Practical exam (extra

Appendix 2

Junior clinical pharmacist evaluation form

After 6 months each clinical pharmacist is evaluated in addition to ward practical exam on handling a case

The template for evaluating a clinical pharmacist is for use by **senior clinical pharmacist & physicians:** It should be revised to meet specific institutional. Requirements for clinical pharmacy practice prior to implementation. Specific numbers and types of patient interventions should be included and reviewed to reflect accurately the individual clinical pharmacist's practice responsibilities.

łe	Clinical Pharmacist	Supervisor
I. Gen	eral Performance Evaluation (including profession	nalism) 10 Marks
1-	Demonstrates appreciation of others' positions; at identify with others' perspectives; demonstrates of towards others.	-
2-	Acts in patients' best interests; acts in accordance profession's and practice site's code of ethics.	with the
3-	Clearly communicates thoughts; uses appropriate vocabulary for intended audience.	terminology and
4-	Arrives at practice site on time; meets deadlines for tasks and responsibilities.	or completion of
5-	Maintains confidential nature of patient- and/or s documents.	site-specific
6-	Demonstrates respect/regard for patients, superior other personnel, and property.	ors, colleagues,
	Holds oneself liable for tasks/duties/responsibilithe/she is responsible; does not blame others for mishaps.	
8-	Responds openly and positively to feedback; modinecessary	ifies behavior if
9-	Adheres to dress code (written or unwritten); attir	re is acceptable to

practice setting.	
10-Demonstrates confidence, i.e., acts and communicates in a self- assured manner, yet with modesty and humility	
11- Adhere to policies &procedures of clinical pharmacy department	
12- Document all his/her work	
13-Provide the required reports on time	
14-Perform clinical pharmacist responsibilities & duties as illustrated in job description	
15-Total Grade:	

II. Technical issues	40 Marks
1- Attends rounds and morning meeting early	and regularly
2- The ability of obtaining and interpreting par from patients' medication & medical history patient's condition, clinical laboratory data appropriateness of Medication product sele dosing regimes	and to assess to evaluate
3- Assures the Medication choice for a particul condition is appropriate	lar patient
4- Provides pharmacokinetic consultation for a requiring such monitoring.	agents
5- Demonstrate good therapy problems solving appropriate Medication therapy alternatives	
6- Regularly review the patient's medication for Medication use, response & toxicity	ile to monitor
7- Records recommendations, interventions, of appropriate activity in the medical record of activity report	
8- Reporting of medication errors & ADRs	

9- Contribute to pharmacy committees	
10- Respond timely to Medicines Information requests.	
11- Provides educational presentations to pharmacy staff, and other healthcare professionals.	
12- Provides Medication education and counsels patients on appropriate Medication use and storage	

VI. Ward Case presentation exam	50 Marks
1- Describe patient data including: family history, history illness, chief compliant, medication history Etc	of present
2- Demonstrates the ability to evaluate therapeutic plan	
3- Demonstrate ability of identifying and managing Medica problems	ation therapy
4- Demonstrate ability to suggest intervention in therapeut	tic plan
5- Explains the rationale (pharmacokinetic, Pharmacodyna best evidence etc) of his suggested intervention	amics of dugs/
6- Identifying appropriate monitoring parameters	
7- Mention references from standard resources	
8- Presentation skills	
9- Ability to handle questions	
10-Stay within time limit	
Total Grade:	

Clinical pharmacist follow up form

	•	Cas	e fo	ollo	w	υp					lin.	ete:			-1	
	Department: ICU							arma	dat:		- 1					
	Patient Data								11.							
Pt. name:		Seri				d no					Mod	icatio	n Hwe f	mess	mibai	l & OTC)
Admission date								-			Bellesi	Dry			pency	drug related problem
Wt.: Ht.:												200.0		-		
STATE														+		
Chief complaint :														+		
Cnier companie:										_				+		
														+		
Diagnosis:	_									-	_			+		
										_				+		
Fast Medical Hx:										_				+		
														+		
social habits :														+		
physical examination														_		
Culture/Other Invest	igatio	ns.									H	старе	utik pla	5		
test/date													Naalu	E		Progress Notes
																-
														_		
														_		
vital sign/date																
B.P																
heart rate																
resp. rate																
temp																
cemp																
								therap	90 DIN	sbleme						
					\vdash											
					_											
					<u> </u>											
					_											
					_											
				Dic	harge	et		Home		Linpat	tient		died			

	Current medication															
	drug/dose	6	equency						•	зув						monitoring
												_				
	Once only	medi	cations:							Intra	Wenet	us limiti	ndon i	beran	237	
date	Drug/dose		roste	up. Instit	action.	date			Lo	Photo	ed (Dec	g design				rate
				_												

Appendix 4 Clinical pharmacist intervention note in pt file

Dear	doctor responsible for patient named:		
Hosp	ital number:		Department:
•	eviewing patient medications it is found that the ed problem(s):	e patient	has the following Medication
1	☐ inappropriate indication	8	☐ Duplication
2	☐ inappropriate dose or regimen	9	☐ Discontinuation of needed medication
3	☐ Compliance/ nurse management problem	10	☐ Therapeutic failure
4	☐ Adverse Medication reaction	11	☐ Untreated medical condition
5	☐ Medication interaction ☐ Medication ☐ Food ☐ Lab☐ Habit ☐ Herb	12	☐ Lack of necessary Medication monitoring
6	☐ Contraindication	13	□Need for additional Medication therapy
7	☐ unnecessary medication	14	□Others
Ref	ient risk erences vsician comments Physician signature		
			Page ΦΛ

Clinical pharmacist daily intervention notes

Date	Code	Description	Recommendation	Physician name	Acceptance (Mention reason if rejected)
					,

Clinical pharmacist monthly interventions report (Excel Sheet)

Pharmacist Name: Ward Name:

Task: Part time/Full time Physicians:

Pt Medical record no.	Reason for admission	Type of errors (as drag list)	Interventions (as drag list)	Total No of interventions	Total No of interventions accepted	Intervention grade	Total No of DIR response	No of counseling sessions

Intervention grade

<u>Minor</u> Problems requiring small adjustments and optimization to therapy, which are not expected to significantly alter hospital stay, resource utilization or clinical outcome.

<u>Moderate</u> Problems requiring adjustments, which are expected to enhance effectiveness of drug therapy producing minor reductions in patient morbidity or treatment costs.

<u>Major</u> Problems requiring intervention, expected to prevent or address very serious drug related problems, with a minimum estimated effect on reducing hospital stay by no less than 24 hrs

Medication information request form

Requester name	Request Date:	
	Request time:	
☐ Physician (specialty): ☐Pharmacist	Desired respo	nse time:
	□Immediately	
□Dentist □Nurse	□Within 30 mi	
□Patient	□>1hr	
	☐More than a	day
Contacts:	Request sent :	
	□Oral	
	□Written	
	□E-mail	
Request		
Background question :		
Ultimate question :		
ommare question.		
Patient information (if needed)		
Name	Age:	
ID:	Gender: □M	□F
Weight: Kg Height:	Diagnosis:	
Medical History:		
Medication History:		
Allergies:		
This part is filled by Medication informati	on center Phar	macist
Request classification		
□Product identification		n interaction
Medication availability/substitutes	⊔Me	edication
stability/compatibility	□Administro	uli o m
□Cost □Dose		& precautions
□Use/indication	□Warnings □Pregnanc	-
		-
□Adverse effects/side effects		-
References		Answer
		Answered by:
		Date
		Time

Patient Name:	Unified MI	E Report Fo	orm		
Patient ID:		STEP 2/	8 What Are The	Possible Ca	uses?
		☐ Verbal Ord	4	□ Wrong Ab	
Department:			ger se medication		cimal point n- metric units
			medication	☐ Calculation	
Step 1/8 What type o		□ Confusing	product		owledge/Experience
(You can select more than one type)		package/la	abeling		iate storage conditions
Prescribing	☐ Wrong medication	□ Confusing		☐ Inappropri	iate dispensing area
☐ Wrong drug name	☐ Wrong patient		te patient information	☐ Environme	ental factors (Workload-
☐ Wrong dose/Conc./ rate	☐ Wrong concentration		te prescribing instructions	Noise - Po	or communication)
☐ Wrong route / dosage form	☐ Wrong Dosage form	☐ Misleading	g advertisement	☐ Lack of par	tient education or
☐ Medication without indication	☐ Inaccurate Labeling / Directions	☐ Lack of do☐ Illegible ha	cumentation (e.g. nursing		
	☐ Drug allergy ☐ Expired medication			☐ Other:	
☐ Drug interaction	☐ Other:	CTED 3/9	8 Which Medica	tion(c) Was	Tpyolyed2
	ministration				
☐ Inaccurate prescribing	☐ Wrong medication	This error is sp	ecific to certain medication	on(s)? OYes ONo	IF YES:
instructions	☐ Wrong patient		Generic name	Brand Name	DF & strength
☐ Therapeutic Duplication	☐ Wrong dose / conc.	Medication			
☐ Other:	☐ Wrong route / dosage form	1			
Transcribing	☐ Administered at wrong time				
☐ Wrong drug name	☐ Medication omitted	Medication			
☐ Wrong patient	☐ Medication given after	2			
☐ Wrong dose/Conc./ rate	physician order discontinued				
☐ Wrong route / dosage form	☐ Incorrect IV flow rate	Mention oth	er related concomitant m	edications (if any)?	
☐ Medication added or omitted	☐ Incorrect drug preparation	THE HEIGHT OUT	er related contonitation	curcucions (ii uniff.	
□ Other:	☐ Medication without prescription				
	☐ Storage problem				
	☐ Duplication of orders				
Who discovered the error?	☐ Other:		ion of the error		
O Physician O Pharmacist	O Nurse	about the me	be how the error occurred	and discovered? an	d what was wrong
O Patient O Other	O I don't know	about the me	edications		
Who was primarily responsible for t					
OPhysician O Pharmacist					
○ Patient ○ Other	○ I don't know				

Appendix 8 Patient counseling checklist

Counseling new patient

A-Opening discussion	1	Comments	2	Comments
Did the Pharmacist				
Welcome and approach the patient	nt			
o Review the record				
o Identify the patient?				
o Identify him/herself?				
 Asked if the patient has time to start session? 				
o Identify purpose of the counseling? and outline the session				

B-Gathering information and assessing needs	
Did the pharmacist asked open ended questions to:	
 1- Take history e.g.: basic patient info: name, address, tel. no., age, gender disease state, known allergies, Medication reactions, any exercise or diet habits, smoking 	
 2- Asses patient knowledge e.g.: (Prime questions) o What did the doctor tell you the medication was for? o How did the doctor tell you to take it? 	
 3- Asses beliefs, feelings, concerns, expectations, needs, will and ability to adhere e.g. What did the doctor tell you to expect 	
Did the pharmacist support right information and corrected the inaccurate information	

C-Providing information and resolving problems	
<u>Did the pharmacist</u> open the medication containers and show patient what the medication looks like, or demonstrate use?	
Did the pharmacist provided information covering	
(as possible):	
13. An overview about the disease if possible	
14. Medication name, Class	
15. Intended use, benefit of therapy (Cure or	
reduce symptoms)	
16. Route, dosage forms, dosage, scheduling,	
regarding to meals (Tailor regimen to	
patient's life)	
17. Medication Preparation	
18. Missed doses	
19. Onset of action, duration of therapy	
20. Refill info.	
21. Precautions, contraindications, interactions	
(including food & OTC), and possible <i>Side</i>	
effects	
22. Actions if no response or ADR occur	
23. Storage	
24. Self Monitoring	

Did the pharmacist give recommendations and made interventions to resolve patient problems (if any) e.g.: Adherence problems (schedule- dosage form- financial) Interactions, contraindications, allergies Life style (smoking – exercise- diet)	
D-Summarizing and Closing discussion	
Did the pharmacist: o Gain feedback and asked the patient to repeat what was understood (Just to make sure that I didn't leave anything out, please tell me how you are going to take your medication?)	
 Summarize and reinforced important information and actions 	
Gave the patient opportunity to ask questions	
Other closing actions e.g. Told patient when he is due back for refill Arranged for follow up and monitoring Provide patient with written information. Told patient to contact the pharmacist if there is any problems	

Did the pharmacist document the session?		
Communication skills		
How can you evaluate pharmacist communications skills: o Be friendly and empathetic		
 Control and direct session (Focus and avoid distractions) 		
 Asking: Balance between open and closed ended questions (Open is more frequent) 		
 Each Question completed before moving to the next. 		
 Active Listening: Patient talk most of the time 		
 Avoid suggesting during gathering phase. Not jump into conclusion without hearing all facts Avoid judging the person 		
 Read and respond to verbal and non verbal messages 		

Be Responsive:	
Empathetic response - Paraphrasing-	
reflecting- clarifying- Active feedback	
Advising:	
 Use understandable language 	
 Give specific directions and 	
Maintain OBJECTIVITY !!!	
 Give reasons for key advice 	
Emphasize key points	
 Being Assertive but not aggressive 	
 Verify patient's understanding 	
 Avoid information overload(short, 	
simple)	
Non verbal cues:	
1-Body language	
 Facial expressions 	
> Smiling	
• Eye contact	
 Posture- Space- Hand- Head 	
Gestures	
Professional Appearance	
1- <u>Tone of voice</u>	

Barriers		
Was any of the following barriers present:		
 Environment related barriers: Customer traffic 		
 Noise, interruptions Lack of privacy Pharmacist related barriers Anxiety - stress 		
 Anxiety - stress Lack of self-confidence Lack of knowledge or experience Bad perception of his role 		
 Patient related barriers Anger, sad, scared, nervous, embarrassed Language difference, Low education level Negative previous experience with health Distrust in pharmacists Hearing or visual impairment 	rel	
 Pharmacy Management or pharmacy system No support High workload 	<u>m</u>	
 Time Either the pharmacist or the patient do have time. 	not	

Scientific information		
Were the advices given and interventions made accurate and satisfactory		
Counseling aids		
Did the pharmacist used any counseling aids e.g.: Patient information Leaflets- slides- handouts- Adherence aids (measuring aids- tablet cutters- inhaler aids- glucose monitors-) medication cards		

Clinical Pharmacist patient counseling checklist on discharge

Date	Patient name
Department	Patient ID
Ward No	Gender
Room No	Age
	weight
	height
	Allergies

Check the following items

Item	No comment	Comment (intervention)
Co- morbidities		
Medications taken at home		
Lab tests		
Consultations (if any		
recommended		
medications to be		
added)		
Current medications		
(Check the following items)		
Appropriatores		
Appropriateness Dose		
Duration		
Directions		
Side effects		
Medication interactions		
Medications needed		
education		
·	I	

Pharmacist Sign	
-----------------	--

<u>P</u>	<u>Patient counseling form for the patient</u>	
Name:	Discharge Date:	Diagnosis:
Prescriber name:	Pharmacist name	

Name of		Time to Take Your Medicine						
Medication & the Form		Reason for Taking Medicine	ii ii ii ii ii ii	Bed Time	Common Side Effects	Special Instructions		

Δ	n	n	_	n	A	ix	Q
А	ν	D	e	П	u	IX	7

Room:	-	-	-	-	-	-	-	-	-	-
Name:	_	_	_	_	_	_	_	_	_	

Pharmacy Pharmacokinetic initial consult

Date/time-					<u> </u>	<u>.</u>
В.р	HR		RR		Temp.	
Consulted	for:					
Physician r	equesting	cons	ult:			
Vitals 24hrl/O: tolb=	-kg		total o	ut:		wt.:
<u>Labs :</u>						
BUN	Cr	e.cr	cl ml/min	Α	ST	ALT
Cultures: -						
Medication mcg/ml (c	_)			trough le	evel:
Recomme Maintance trough: Labs for foll Ph	dose: mcg/m llow up:	 าไ 				
						st signature:
						Page V Y

Pharmacy Pharmacokinetic follow-up

Date/tim	e				
lb=	total in: kg	1	otal	out:	wt.:
<u>Labs:</u>					
BUN	Cr	e.crcl ml/min		AST	ALT
Cultures:					
Dosing in	<u>formation</u>	<u>& Medicati</u>	<u>on le</u>	<u>vels</u>	
	on/dosage I (drawn			trough	n level:
<u>Recomm</u>	ended dos	sage:			
Plan: □ DC	dose asame do follow up: -	sage		adjust dosag 	
Pharmac	 ist to follow 	 v up tomori	row:		
				Pharma	cist signature:
					Page VΣ

Appendix 10 Pharmacovigilance ADR reporting (Yellow card)



Adverse Drug Reactions Reporting Form

* If you suspect that an adverse reaction may be related to a certain drug, or a combination of drugs, you should complete this form and send it to the address shown at the end of the card.

* Please report all serious and minor adverse reactions.

4 – Pati	ent D	etai)	<u>ls</u>
----------	-------	-------	-----------

A - I attent Details						
Name/ initials:(Optional)	Sex: □ Male	□ Fem	nale	Weight:	-kg	Age/age group:
B – Suspected Drug(s) Drug Name Concentration Used for (Generic & trade)	Dose	Rou	ite	Date started	Date stopped	Batch number
C – Suspected Reaction(s) •Please describe the reaction(s):						
•Date reaction(s) started:		Date re	eactions(s	s) stopped:		
•Does the Reaction Stopped after stopping	g the drug?	□ Yes	□ No	□Don't K	now	
•Does the Reaction Reappear after retaking	ng the drug?	□Yes	□ No	□ Don't K	Cnow	□ Did not retake the drug
•Was the reaction serious (based on the reasonable of the serious), specify one or more :	ons below)?	□ Yes	□ No	□ Don't K	Cnow	
□ Patient Died			threatenin		□ Hospita	
□ Prolonged Hospitalization	D				□ Perman	ent Disability
☐ Required intervention to prevent	Damage	□ Othe	er, specify			

D – List of other drugs taken (Please list any other d	rugs taken dur	ing the last 1	nonth prior to	the reaction-
other than the suspected drug/s)				
Drug Name Concentration Used for Dose (Generic & trade)	Route	Date started	Date stopped	Batch number
E – Reporter Details The One who fill in this form: □ Patient □ Physician Name: □ Physician	Specialty (if p	hysician)'		specify
Address: e-mail:	Telephone/ m	nobile :		
F- Any More Comments:				
 The information in this report is confidential and totally protected including You can send voluntarily the Adverse Drug Reactions (ADRs) Reports to th Reporting for ADRs is Vital for Safely usage of drugs. Enough information Country. 	both the Patient ar e Egyptian Pharm	nd Reporter idei accutical Vigila	ntity. nnce Center as per	the contact details below.
Head quarter: Pharmacovigilance Department -Egyptian Pharmaceutical Vigilance Center (EPVC)- Egyptian Drug Authority (EDA) 21 Abd Elaziz Al Souad st. – Manial El-Roda – Cairo, PO Box: 11451 [el: +2 02 23648046 / +2 02 23640368 / +2 02 23684381	Elkazino st, Tel-Fax: +2		ling, San Stefano nealth.gov.eg	or Family Health Centre, 2 , Alexandria
Extension (Tel):1303 Extension (Fax): 1300 Fax: +2 02 23684194 Website: www.cpvc.gov.cg Temporary website: http://cpvc.gov.cg.allium.arvixe.com/newdefault.aspx	➤ Cairo Regio Nasr City-Ci Tel: +2 010	airo	l-Azhar new spec	cialized hospital 6th district

FORMULARY ADDITION /CHANGE DOSAGE FORM REQUEST FORM

• G	Generic Name:	
• T:	rade Name:	
• D	Oosage Form: Strength:	
• N	Manufacturer:	
• Fe	ormulary Classification Class:	
• S1	ub Class:	
	herapeutic Use:	
• W	What drugs, currently in the formulary, will be replaced?	
• H	How is this drug superior to existing formulary drug?	
• Sl	hould this drug be restricted to use by certain members of the Medical Staff? If so, wh	nom and
	vhy?	
TA		
• (/	What will be the anticipated use rate if this drug is added to the formulary?	
• P:	Proposed by: (Consultant/ Clinical Specialist / Pharmacist.)	
- 1		
	Signature & stamp Date:	
	is is to confirm that after reviewing the above proposal P &T Committee has a upport the proposal	igreed to
;	Signature & stamp	Date:
Director	of Hospital	
Арр	proved Disapproved	
	Signature & stamp	
	P	age VV

FORMULARY DELETION FORM Generic Name: Trade Name: Dosage Form: ______ Strength: _____ Manufacturer: _____ Formulary Classification Class: Sub Class: Therapeutic Use: _____ **Justification for Deletion:** .Reference Paper/ Documents: • Proposed by:———— (Consultant/ Clinical Specialist / Pharmacist.) Signature & stamp Date: • This is to confirm that after reviewing the above proposal P &T Committee has agreed to support the proposal Signature & stamp Date: **Director of Hospital** Approved Disapproved Signature & stamp | Page VA

<u>Appendix 12</u> <u>Medication information resources</u>

INTERNET RESOURCES

J. Russell May, Pharm.D., Dianne B. May, Pharm.D. and Starr Bedy, PharmD Georgia Health System University and University of Georgia College of Pharmacy

GENERAL MEDICAL INFORMATION

MEDLINEplus http://medlineplus.gov



- Articles, pamphlets, and fact sheets
- Provided by the National Library of Medicine



Healthfinder www.healthfinder.gov



- Gateway information primarily from government agencies
- Some information also available in Spanish
- Provider U.S. Department of Health & Human Services

Flu.gov www.flu.gov



- Information available in multiple languages, including Spanish
- Provider U.S. Department of Health & Human Services

The Federal Citizen Information Center www.pueblo.gsa.gov/ health.htm



- Health-related pamphlets (free or minimal cost)
- Not searchable, but in alphabetical order

PDR Health www.pdrhealth.com



Some Medication information, but mainly by brand name

Medilexicon www.medilexicon.com



Searchable database of medical abbreviations

Mayo Clinic †

www.mayoclinic.com/

Note: Grand Rounds Webcasts

The Merck Manuals Online Medical Library http://www.merck.com/mmpe/index.html



- May be to technical for the average patient
- Contains photographs and audio/video

Merck Source www.mercksource.com



- Language is geared towards patients
- Includes 3D animations, an Over-the-Counter Medication guide, and a medical dictionary (NOT searchable)

DISEASE SPECIFIC

Florida AIDS Education and Training Center www.faetc.org





Pocket guides for HIV treatment

National Kidney Foundation www.kidney.org

American Cancer Society www.cancer.org

American College of Cardiology www.acc.org

American Academy of Pediatrics www.aap.org

American Diabetes Association www.diabetes.org

American Lung Association www.lungusa.org

American Heart Association www.heart.org

National Mental Health Association www.nmha.org

Arthritis Association www.arthritis.org

GUIDELINES

National Guideline Clearinghouse www.guideline.gov



- Provides a searchable database (topic, keyword, or disease)
- Results include a summary of the clinical guideline and a link to the full text
- Site is updated weekly
- Provided by a partnership Agency for Healthcare Research and Quality (AHRQ), the American Medical Association (AMA) and others

The Cochrane Collaboration www.cochrane.org

- Provides systematic reviews of randomized controlled trials
- Each review provides a structured abstract, objectives, methods, results, and potential implications for practice

Health Services Technology Assessment Texts (HSTAT) http://hstat.nlm.nih.gov



- This site contains clinical practice guidelines and consumer health brochures
- Links to a variety of resources e.g. databases, full text publications
- Provided by the National Library of Medicine

Medscape www.medscape.com



Section for pharmacists includes adverse Medication event reporting, Medication interaction checker

Agency for Healthcare Research and Quality www.ahrq.gov



Provides patient directed information for weight loss and smoking cessation

Centers for Disease Control and Prevention (CDC) www.cdc.gov



Provides guidelines for appropriate use of vaccines and statistics on many diseases

World Health Organization http://www.who.int/en/



Information available in several languages, including French and Spanish

National Institutes of Health (NIH) www.nih.gov





- Provides material that is not available from other sources
- News & press releases, full text publications, disease information, and support groups
- An agency of the Public Health Services includes 27 distinct institutes/centers with a different healthrelated area of focus

e.g. www.nhlbi.nih.gov = asthma guidelines

PRESCRIPTION, OTC, AND HERBALS

ClinicalTrials.gov www.clinicaltrials.gov



Registry of ongoing clinical trials of medications and other interventions

Food and Medication Administration (FDA) www.fda.gov

- Therapeutically equivalent generic and trade name products
- New and Generic Medication Approvals provides information on new Medications on the market
- MedWatch Adverse Event Reporting Program
- Consumer information, Medication recalls and Medication shortages

Lact Med http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT





- Searchable database
- Safety of medications for use in breastfeeding women
- Provider American Academy of Pediatrics

Global RPh www.globalrph.com





- Information on preparing and administering IV Medications
- Online calculators
- Medical abbreviations (list)

HerbMed www.herbmed.org

- Linked access to scientific data in the form of abstracts from PubMed
- Contains information on over 120 different herbs. May be too in depth for consumers because of links to scientific publications
- The Natural Medicines Comprehensive Database

www.naturaldatabase.com

- Scientific names, uses, safety, effectiveness, mechanism of action, adverse reactions, interactions and references
- Provided by the Pharmacist's Letter

The Herbs Index http://my.Webmd.com



- monographs in lay language
- Provider WebMD

ConsumerLab.com www.consumerlab.com

- Can test quality of herbal products
- Privately held company, not affiliated with manufacturers of health and nutrition products
- Requires a subscription

www.dailymed.nlm.nih.gov



Online package inserts

www.warfarindosing.org



Online dosing calculator

The Partnership for a Medication-Free America www.Medicationfreeamerica.org

National Clearinghouse for Alcohol and Medication Information www.health.org **Professional Pharmacy Organizations**

American Association of Colleges of Pharmacy www.aacp.org

American College of Clinical Pharmacy www.accp.org

American Pharmaceutical Association www.aphanet.org

American Society of Consultant Pharmacists www.ascp.org

American Society of Health-Systems Pharmacists www.ashp.org

Institute for Safe Medication Practice www.ismp.org

National Association of Chain Medication Stores www.nacds.org

National Community Pharmacists Association www.ncpanet.org

National Council on Patient Information and Education www.talkaboutrx.org

Other Resources

- www.amazon.com
- www.half.com
- www.quizlet.com
- www.Medicationstore.com

Journal Websites - CHEST http://chestjournal.chestpubs.org

Manufacturer Websites (google the brand name)

Infectious Diseases www.cid.oxfordjournals.org

New Medication Updates www.centerwatch.com/Medication-information/fda-approvals/

2- Books

No.	Book Name	Author
1	AHFS Medication Information Essentials	ASHP
2	Applied therapeutics, the clinical use of Medications	Mary Anne Koda-Kimble
3	Handbook of Applied therapeutics	Mary Anne Koda-Kimble
4	Pediatric Dosage Handbook: Trade names	Carol K. Taetomo
5	Medication Information Handbook: Dentistry	Richard R. Wynn
6	Medication Information Handbook: Oncology	Dominic A. Solmando
7	Medication Information Handbook: Pocket Medication Information	Charles F. Lacey
8	Medication Information Handbook:	Lacy, Charles F.

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Lexi-comp's Medication Information	
Medication Information: aguide for	Patrick M.
pharmacist	Malone
Pharmacotherapy principles and practice	Marie Chisholm
Pharmacotherapy Casebook	Terry Sch
Medications in pregnancy and lactation	Gerald G. Briggs
Medication errors	Cohan, Michael R.
Martindale (V1 and V2)	
Medication induced diseasaes	James E, Tisdale
Medications facts and comparisons	
Medication Interaction facts	
Medication Interaction facts: Herbal	
supplements and food	
Medication prescribing in Renal Failure	George R. Aronoff
Adverse Medication reaction	Lee, Anne
Goodman and Gillman's pharmacologic	
basics of	
Handbook of institutional pharmacy	Brown, Thomas R
practice	
Pharmacotherapy: A Pathophysiologic	Joseph T. Dipiro
Approach	
	Beardsley, Robert S.
Neofax: A Manual of Medications used in	Young, Thomas E.
neonatal care	
	Medication Information: aguide for pharmacist Pharmacotherapy principles and practice Pharmacotherapy Casebook Medications in pregnancy and lactation Medication errors Martindale (V1 and V2) Medication induced diseasaes Medications facts and comparisons Medication Interaction facts Medication Interaction facts: Herbal supplements and food Medication prescribing in Renal Failure Adverse Medication reaction Goodman and Gillman's pharmacologic basics of Handbook of institutional pharmacy practice Pharmacotherapy: A Pathophysiologic Approach Communication skills in pharmacy practice

Procedure for Multidisciplinary Working.

The pharmacist shall attend ward rounds and clinical meetings as a member of the healthcare team. And A local SOP exists for the participation of pharmacists in ward rounds and clinical meetings. This includes description of the pharmacist's role.

Before participating in a ward round the pharmacist must prepare by monitoring and reviewing all patients' prescriptions conjunction with medical notes and relevant laboratory test results if possible prior to the ward round. This allows the pharmacist to:

- > Gain knowledge of the medicine and disease states likely to be encountered on the ward round.
- Consider the aspects of the patient's medicine therapy likely to be discussed.
- > Organize questions to ask to address issues the Clinical Pharmacist wants to raise
- > Prepare the patient pharmaceutical care issues they wish to raise with medical staff.

Appropriate communication skills must be used when discussing medicine related problems with other healthcare professionals, the patient and their family.

The ward round provides the opportunity to:

- Contribute information regarding the patient's medicine therapy e.g. suggestions for monitoring.
- ➤ Investigate unusual medicine orders or doses
- > Assimilate additional information about the patient, which may be relevant to their medicine therapy e.g. social circumstances
- > Detect ADRs and interactions.
- Participate in discharge planning.

At the end of the ward round or clinical meeting the pharmacist follows up any outstanding issues including:

- > Responding to any enquiries generated.
- > Communicating changes in medicine therapy to relevant personnel and patient.
- ➤ Completing necessary documentation e.g. discharge information, medication incident forms
- > Considering the impact of changes to the pharmaceutical care plan and adapting the care plan as required.
- > Discussing changes to therapy with the patient and other healthcare professionals if appropriate.
- Organize timely writing of discharge prescription

Appendix 14

Developing a plan for Expansion:

- -Each institution will need to set its own plan for implementation of clinical pharmacy which fulfill the following stages, Training stage preparation stage, implementation stage (which will be gradual)
- Each institution will be responsible on training & evaluation of their pharmacy personnel to be competent to provide direct patient care.
- -Each pharmacy manager should provide statistical reports of clinical pharmacist activities evaluation, Medication errors reports.

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American guidelines

http://www.ashp.org/Import/PRACTICEANDPOLICY/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/MedicationTherapyandPatientCare.aspx

http://www.ashp.org/DocLibrary/BestPractices/OrgGdlStndMethod.aspx

http://www.ashp.org/DocLibrary/BestPractices/OrgGdlDocPMR.aspx

http://www.ashp.org/DocLibrary/BestPractices/OrgGdlPtEduc.aspx

http://www.accp.com/docs/positions/whitePapers/pos2.pdf

http://www.ashp.org/DocLibrary/BestPractices/SpecificStPKMonitor.aspx

http://www.ashp.org/Import/PRACTICEANDPOLICY/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/MedicationTherapyandPatientCare.aspx

http://www.ashp.org/DocLibrary/BestPractices/OrgGdlStndMethod.aspx

http://www.ashp.org/DocLibrary/BestPractices/OrgGdlDocPMR.aspx

http://www.ashp.org/DocLibrary/BestPractices/OrgGdlPtEduc.aspx

http://www.accp.com/docs/positions/whitePapers/pos2.pdf

http://www.ashp.org/DocLibrary/BestPractices/SpecificStPKMonitor.aspx

Irish guidelines

http://www.hscboard.hscni.net/medicinesmanagement/Medicines%20Management%20Forum/Standards/001%20Clinical%20Pharmacy%20Standards%20-%20PDF%201MB.pdf

Australian guidelines

http://ippr.shpa.org.au/scripts/cgiip.exe/WService=SHPAJP/ccms.r?PageID=10077

http://cpd.shpa.org.au/lib/pdf/clinicaltem.pdf

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