هيئة الدواء المصرية
الإدارة المركزية لرعاية الصيدلية
الإدارة العامة للممارسات الدوائية والصيدلية

EGYPTIAN GUIDE FOR ONCOLOGY PHARMACY PRACTICE

Volume I

2022

Egyptian Drug Authority

Central Administration of Pharmaceutical Care

General Administration for Drug Utilization and Pharmacy Practice

Egyptian Guide for Oncology Pharmacy Practice

Volume 1

2022

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ACKNOWLEDGEMENTS

First and foremost, we would like to acknowledge and give our warmest thanks to **Prof. Dr. Tamer Esam,** chairman of the Egyptian Drug Authority (EDA) for his support and for providing guidance concerning this guide.

We would also like to extend our gratitude to **Dr. Rasha Ziada,** EDA assistant chairman for technical development and capabilities building affairs for her extremely valuable support and sincere motivation.

With immense gratitude, we acknowledge the support and help of **Dr. Shereen Abdelgawad,** head of the Central Administration of Pharmaceutical Care who didn't stop to supply us with her great opinions, and recommendations.

"Egyptian Guide for Oncology Pharmacy Practice" would not have been possible without the support and guiding of the **Editorial Board members**. Their assistance is greatly appreciated and it has been a great help in developing this informative guide.

With great appreciation, we would like to send our special thanks to **Prof. Dr. Nirmeen Sabry,** for her great contributions and precious comments.

These great efforts would have never reached hospital oncology pharmacists without the cooperation and support of different authorities, ministries and sectors represented by:

- **University Hospitals**
  - Counsel of University Hospitals:
    National Cancer Institute.
- **Ministry of health through the participation of:**
  - General Authority for Health Insurance:
    Nasr City Cancer Center
  - Specialized Medical Centers:
    Minia Oncology Center
    Tanta Oncology Center
    Nasser Institute
    Qabbary Hospital
- **Academia represented by:**

  Faculty of Pharmacy, Cairo University

- **Private Sector:**

  Shefa Al-Orman Hospital Administration.

We would like to thank the cooperative **phase 3 commenters** who helped us to reach the best possible form of this work and to put the final touches that gave the guide a great blend between academia, guidelines and practice: (**Alphabetically**)

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PREFACE

Cancer has an enormous impact on the social fabric and economy of Egypt. A large number of Egyptians live with the effects of cancer, require repeated active treatment and have continuing needs for cancer care resources and support services. This increased demand and the complexity of survivors' health needs impacts the planning and development of multidisciplinary health services.

Oncology pharmacy, a patient-focused practice, addresses the pharmaceutical care of both adults and children living with cancer. The provision of direct patient care by oncology pharmacists includes patient interviews, observation and contribution to the selection, modification and monitoring of patient therapy.

As for all medications, the goal of drug administration in cancer therapy is to ensure delivery of the right drug to the right patient in the right dose and dosage form at the right time to achieve predefined outcomes improving the patient's length and/or quality of life.

Achieving this goal requires a comprehensive, systematic approach by a multidisciplinary team. A physician, pharmacist, nurse, and other health care providers comprise a team that must work together to ensure patient safety and optimal treatment outcomes. In this role, the oncology pharmacist provides an integral service as a member of the patient care team.

As a member of the cancer care team, oncology pharmacists possess unique skills, which are founded on a specialized knowledge base. It includes knowledge of best practices, appropriate dosages, delivery techniques, formulations and routes of administration of anti-cancer drugs. Also, critical care understandings of acute and long-term drug toxicities, management of cancer-related and drug-related complications, drug interactions, safe handling of hazardous drugs.

As a member of a cancer research team, the oncology pharmacist can participate in and manage clinical trials, and the understanding and interpretation of research methodologies and outcomes. For the sake of the development and to rationalize oncology drug use "The Egyptian Guide for Oncology Pharmacy Practice (EGOPP)" is designed.

The principal objective of this guide is to unify, improve, and standardize the oncology pharmacy contribution to patient care through the development of a structured, systematic approach to oncology pharmacy practice. The Egyptian Guide for Oncology Pharmacy Practice (EGOPP) is a working document, and it is organized into two volumes.

Volume one addresses the following four chapters

- Oncology Pharmacy Administrative services.
- Standards for Oncology Pharmacy Distribution services.
- Guide for Compounding sterile preparations and Safe handling of hazardous drugs.
- Oncology Pharmacy Clinical Practice in.

Cancer care is dynamic and oncology pharmacy is and will continue to provide leadership in this important area of speciality practice. So, the **Egyptian Guide for Oncology Pharmacy Practice (EGOPP)** will be regularly reviewed, built upon and expanded to ensure that it continues to be fit for this purpose.

Finally, the Egyptian Guide for Oncology Pharmacy Practice (EGOPP) regulatory documents will be effective immediately after their release in various Oncology Pharmacy services.

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LIST OF ABBREVIATIONS

ABHR	Alcohol-based hand rub
ACPH	Air changes per hour
ADEs	Adverse Drug Events
ALL	Acute lymphoblastic leukemia.
AML	Acute myelogenous leukemia
API	Active Pharmaceutical Ingredient
ASCO	The American Society of Clinical Oncology
ATG	Anti-Thymocyte Globulin
BMT	Bone marrow transplantation
BSC	Biological Safety Cabinets
BUD	Beyond-use date
CACI	Compounding Aseptic Containment Isolator
CAI	Compounding aseptic isolator
CML	Chronic myelogenous leukemia
CMV	Cytomegalovirus
COPD	Chronic Obstructive pulmonary disease
COSA	Clinical Oncological Society of Australia
COVID-19	Coronavirus Disease 2019
C-PEC	Containment Primary Engineering Control
C-SCA	Containment segregated compounding area (C-SCA)
CSP	Cyclosporine
CSPs	Compounded Sterile Preparations (CSPs)
CSTDs	Closed system transfer devices
FDA	Food and Drug Administration
GVHD	Graft-versus-host disease
HD Ara-C	High-dose Cytarabine
HDMTX	High-dose methotrexate
HDs	Hazardous Drugs
HEPA	High efficiency particulate air
HIPEC	Hyperthermic Intraperitoneal Chemotherapy
HIV	Human immunodeficiency virus
HVAC	Heating, ventilation and air-conditioning
IPA	Isopropyl alcohol
ISO	International Organization for Standardization.

ISOPP	International Symposium on Oncology Pharmacy Practice
IVLFZ	Vertical Laminar Flow Cabinet
LAFWs	Laminar Airflow Workbench
M.M	Multiple myeloma
MPA	Mycophenolic acid
MTX	Methotrexate
NCCN	The National Comprehensive Cancer Network
NIOSH	National Institute for Occupational Safety and Health
NSF	National Sanitation Foundation
PCP	Pneumocystis carinii pneumonia
PECs	Primary Engineering Controls
PPE	Personal Protective Equipment
QOL	Quality Of Life
RABS	Restricted Access Barrier Systems
SCA	Segregated compounding area (SCA).
SHPA	Society of Hospital Pharmacists Australia
SOP	Standard operating procedure
TACE	Trans-arterial Chemoembolization
TBI	Total body irradiation
TKI	Tyrosine Kinase Inhibitor
UV lamp	Ultraviolet lamp

GLOSSARY

Active pharmaceutical ingredient (APl)	Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans.
Ambulatory Clinical oncology pharmacist	As a member of the clinical oncology pharmacy team, serves as an essential resource to the healthcare team, outpatients and/or day-care patients and their caregivers by using his or her extensive specialized knowledge.
Anteroom	A room equipped with two doors, with a system/procedure that allows only one door to be open at any given time, which allows passage or movement of people or things from one environment to the other, while keeping the two environments isolated from one another.
Anti-cancer drugs	The wide range of drugs (therapeutic options) used in the treatment of malignant diseases, including categories such as hazardous drugs, immunotherapies, targeted drug therapies, hormonal treatments, etc.
Aseptic compounding process	All activities leading to completion of a final compounded sterile preparation, including hand and forearm hygiene, garbing, introduction of products and materials into the clean room, disinfection of the containment primary engineering control, use of aseptic techniques for compounding preparations in the containment primary engineering control, and verification and labelling of the compounded sterile preparations. The purpose of the process is to maintain the sterility of a preparation or drug compounded from sterile components.
Aseptic technique	Steps in the aseptic process, including all manipulations performed inside the containment primary engineering control by compounding personnel.
Assessment	Action of assessing and defining an employee's performance and competency.

Best Practices	A technique or methodology that through experience and research has proven to reliably lead to the desired result. A commitment to best practices is a commitment to using all the knowledge and technology at one's disposal to ensure success. Best practices have 5 key components: best skills, best processes, best solutions, appropriate resources, and continuous improvement.
Beyond-use date (BUD)	Date and time after which a compounded sterile preparation cannot be used and must be discarded (because of a risk of loss of sterility).
Biological safety cabinet (BSC)	Airflow workbench that is ventilated to protect personnel, hazardous compounded sterile preparations and the immediate environment.
Centralized Unit-Dose Drug Distribution System (CUDD)	All in-patient medications are dispensed in unit doses and all the medications are stored in the central area of the pharmacy and dispensed at the time the dose is due to be given to the patient. Medications are retransferred from the pharmacy to the indoor patient by medication cards.
Chemotherapy	The treatment of disease by chemical means and currently used to describe drug (chemical) therapy of cancer.
Classified space	An area that maintains an air cleanliness classification based on the International Organization for Standardization (ISO).
Competencies	Significant job-related knowledge, skills, abilities, attitudes and judgments required for competent performance of duties by members of a profession.
Compounding	The act of preparing a pharmaceutical preparation, through preliminary work, to put it into a usable state.
Compounding aseptic containment isolator (CACI)	Isolator used specifically for compounding hazardous sterile preparations and designed to protect personnel from any undesirable exposure to airborne medicinal products during compounding and transfer of hazardous material and drugs and to provide an aseptic environment for sterile preparations.
Compounding procedure	Procedure that describes all steps to be followed in the compounding of sterile preparations and performed according to a particular packaging method (e.g., syringe filled for intravenous use, elastomeric preparation).
Compounding protocol	Protocol that describes all steps to be followed in the compounding of a specific sterile preparation, with which the compounder must comply. The protocol must include all of the information to be recorded in the preparation log.

Containment	Arrangement of equipment to contain the particles of hazardous products within the chosen space.
Containment primary engineering control (C-PEC)	A device that provides an ISO Class 5 environment for the exposure of critical sites during aseptic compounding and that is designed to minimize airborne contamination of hazardous products, to protect workers and the environment from exposure to hazardous drugs.
Containment secondary engineering control (C-SEC)	The room with fixed walls in which the C-PEC is placed. It incorporates specific design and operational parameters required to contain the potential hazard within the compounding room.
Critical area	Work area inside a containment primary engineering control ensuring ISO Class 5 air quality, where personnel compound sterile preparations and where critical sites are exposed to unidirectional airflow from a high-efficiency particulate air filter.
Critical site	Any surface likely to come into contact with a sterile drug or liquid (e.g., vial septa, injection sites) or any exposed opening (open vials, needle hubs) and likely to be in direct contact with the ambient air, with air filtered by means of a high-efficiency.
Decentralized Unit-Dose Dispensing	This operates through small satellite pharmacies located on each floor of the hospital.
Dispensing	The process of preparing and giving medicine to a named person on the basis of a prescription. It involves the correct interpretation of the wishes of the pre- scriber and the accurate preparation and labeling of medicine for use by the patient.
Dispensing Oncology Pharmacist	As a member of the oncology pharmacy team, reviews and ensures safe distribution of the anticancer regimen as well as supportive treatment to adult and pediatric oncology patients.
Drug Distribution	The process of providing a drug to an individual authorized to administer medications and licensed as a healthcare provider pursuant to an order issued by an authorized prescriber.
Doff	To remove PPE.
Don	To put on PPE.
Dose banding	A predetermined standard dose that will be dispensed when an individual's calculated dose is within a specific range or band. All calculated doses within a certain band are substituted with the standardized dose indicated for that dose range.

Drug Use Evaluation (DUE)	The prospective or concurrent analysis of the patterns of use of drugs against a predetermined set of criteria, followed by an assessment, implementation of corrective action, and reassessment.
Drug-Related Problems	Drug-related problems (DRPs), defined as 'an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes, constitute a frequent safety issue among hospitalized patients leading to patient harm and increased healthcare costs.
Extravasation	The escape of a vesicant or irritant hazardous drug from a blood vessel into surrounding tissues resulting in damage to the tissue.
Facilities	All devices, rooms and spaces that are organized, arranged and modified to ensure suitability for the activities to be conducted therein. In the context of sterile compounding, facilities include the clean room and the anteroom.
Formulary List	A list of medicines approved for use in a specific healthcare setting.
Formulary Manual	A manual containing clinically oriented, summary pharmacological information about a selected number of medicines. The manual may also include administrative and regulatory information on medication prescribing and dispensing.
Formulary System	The principles, criteria, procedures, and resources for developing, updating, and promoting the formulary (essential medicines) list.
Clinical practice guidelines	Statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.
High-efficiency particulate air (HEPA) filtration	An extended-medium, dry-type filter in a rigid frame, having a minimum particle collection efficiency of 99.97% for particles with a mass median diameter of 0.3 μm when tested at a rated airflow in accordance with MIL STD 282 using IEST Recommended Standard RP-CC00l.5.
Hospital Pharmacy	The department of the hospital which deals with procurement, storage, compounding, dispensing, testing, packing, and distribution of drugs.
Hyperthermic Intraperitoneal Chemotherapy (HIPEC)	It is a type of hyperthermia therapy used in combination with surgery in the treatment of advanced abdominal cancers.

In-patient	Are those patients, who require hospitalization i.e. get themselves admitted in the hospital, stay there for treatment till they are discharged.
Inpatient clinical oncology Pharmacist	As a member of the clinical oncology pharmacy team, serves as an essential resource to the healthcare team, inpatients in hospital wards and their caregivers by using his or her extensive specialized knowledge.
Inventory	The total stock kept on hand at any storage point to protect against uncertainty, permit bulk purchasing, minimize waiting time, increase transportation efficiency, and buffer against seasonal fluctuations.
Inventory control	The function of supply management that aims to provide sufficient stocks of medicines at the lowest costs possible
IV admixture pharmacist	As a member of the oncology pharmacy team he/she is responsible for the sterile compounding of anticancer treatments and related supportive care medications.
Medication Error	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.
Medication Profile	An ongoing record of patient-specific information used to monitor drug therapy. This record includes all medications prescribed and dispensed to the patient.
Medication Reconciliation	The process of identifying the most complete and accurate list of medications a patient is taking and using to provide correct medications for the patient anywhere within the organization. The process includes comparing prescriber's medication orders at the interfaces of care to that list, bringing discrepancies to the prescriber's attention, and, if appropriate, making changes to the orders including omissions, duplications, interactions, and name/dose/route confusion. Other steps in medication reconciliation include updating the medication list as orders change during the episode of care and communicating the updated list to the patient and the next known provider of care.
Medication Use Evaluation (MUE)	A performance improvement method that focuses on evaluating and improving medication use process with the goal of optimal patient outcomes. MUE may be applied to a medication or therapeutic class, disease state or condition, a medication use process (prescribing, preparing and dispensing, administering, and monitoring) or specific outcomes

Oncology pharmacist	The person who undergoes the first and second levels of competencies (mentioned later in Chapter 1) where he/she is trained on different oncology pharmacy practice in each setting and took rounds in each department in the institute or hospital.
Out-patient	Patients not occupying beds in a hospital or clinics, health centers, and other places. In oncology, it may include patients receiving some chemotherapy protocols and blood transfusion.
Personal protective equipment (PPE)	Items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.
Pharmaceutical Care	The directly responsible provision of drug therapy to achieve definite outcomes that improve a patient's quality of life.
Pharmacy Practice	The discipline of pharmacy which involves developing the professional roles of pharmacists. Pharmacy practice offers practicing pharmacists in-depth useful reviews and research trials and surveys of new drugs and novel therapeutic approaches.
Pre-Printed Orders	Templates that specify the medicines and procedures required by a protocol. Pre-printed orders are intended to ensure accurate and consistent treatment of all patients on a protocol
Protocol	A formal written document describes a standard treatment or regimen. Components of a protocol include patient eligibility, baseline and treatment tests, pre-medications, treatment delivery details, dose modifications, precautions, and the evidence supporting the treatment.
Research oncology pharmacist	As a member of the oncology pharmacy team, he/she is responsible for coordinating the processes related to oncology investigational drug studies, serves as the medication expert to all involved in these research studies.
Trans-arterial Chemoembolization (TACE)	A procedure in which the blood supply to a tumor is blocked after anticancer drugs are given in blood vessels near the tumor. Sometimes, the anticancer drugs are attached to small beads that are injected into an artery that feeds the tumor. The beads block blood flow to the tumor as they release the drug.
Pharmacovigilance	The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.

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CHAPTER I

ONCOLOGY PHARMACY ADMINISTRATIVE SERVICES

1. INTRODUCTION

Pharmacist is considered to be a part of a big cycle of patient care & an integral part of clinical decision making which includes professional medical staff, nurses and medical team assistants. This cycle of care ensures optimal medical care for patients in general and for Cancer patients in Specific.

Oncology pharmacy is cancer patient centered service, where the pharmacist role is to be identifying patients 'drugs need including treatment management protocols, supportive and palliative care and preventing drug related problems. Also, clinical research which finally leads to improve outcomes for patient and whole community. Proper implementation of Oncology Pharmacy service is important to ensure patient`s safety, optimization of medication use, and close monitoring and follow up for the patients during receiving their medications and after treatment.

The main goal of this chapter is to develop a structured, unified, standardized approach to oncology pharmacist's contribution to cancer patient care. So, we'll go over the following titles:

- Oncology pharmacy mission, vision, goals and objectives.
- Oncology pharmacy Staff. (Suggesting career path)
- Facilities and equipment for oncology pharmacy.
- Hospital committees and their roles
- Policies and procedures
- Medication use evaluation
- Medication safety
- KPIs for oncology pharmacy practice and their importance

2. ONCOLOGY PHARMACY MISSION, VISION, VALUES AND GOALS

2.1.Mission

To work effectively with other healthcare professionals to conquer cancer by providing excellent, safe, and evidence-based pharmaceutical care for each cancer patient we serve.

2.2.Vision

To establish Egypt as the regional leader of oncology pharmacy in Africa and the Middle East.

2.3.Values

2.3.1. Excellence: continuously striving for the highest quality of performance and outcome.

- Strive to do our best.
- Commit to high quality.
- Build an environment that learns from mistakes.
- Take initiative.
- Self-motivate.

2.3.2. Integrity steadfast adherence to moral and ethical principles.

- Behave ethically, honestly and fairly
- Do the right thing
- Set a good example; be a role model

2.3.3. Accountability: being held responsible for one's actions.

- Accept responsibility for your mistakes.
- Recognize and accept the consequences of one's actions
- Accept personal responsibility for actions, activities and work
- Manage resources in a responsible, transparent manner

2.3.4. Collaboration: work in teams to achieve excellence in education, research, patient care and service.

- Pursue opportunities to collaborate within the college and inter-professionally
- Be a team player
- Place interests of the team above your own interests

- Learn with and from each other

2.3.5. Continuous Learning:

- Demonstrate a commitment to lifelong learning
- Create an atmosphere of team learning.
- Strive to be an effective organization that acquires, and transfers knowledge
- Maintain competence and enhance skills in areas of expertise

2.3.6. **Diversity in People and Thinking:** Embracing inclusiveness, access and equity for all; recognizing and appreciating the totality of the many ways individuals are similar and different in an atmosphere that promotes and celebrates individual and collective achievements.

- Respect different opinions, experiences, backgrounds and perspectives
- Acknowledge and appreciate our differences
- Encourage different approaches to problem-solving

2.3.7. **Kindness:** Feeling and exhibiting concern and empathy for others.

- Treat everyone with respect, open-mindedness, confidence and caring
- Selflessly serve others
- Be sensitive to the needs of others

2.4.Goals

2.4.1. In collaboration with the health care team, provide comprehensive medication management to oncology patients following a consistent patient care process.

- Interact effectively with cancer patients, family members, and health care teams to manage oncology patients' medication therapy.
- Collect, analyze and assess information on which to base safe and effective medication therapy for oncology patients.
- Design or redesign safe and effective patient-centered therapeutic chemotherapy and supportive care regimens and monitoring plans (care plans) for oncology patients.
- Ensure implementation of therapeutic regimens for chemotherapy and supportive care and care plans for oncology patients by taking appropriate follow-up actions.

- Document direct patient care activities appropriately in the medical record
- Demonstrate responsibility to oncology patients
- Manage transitions of care effectively for oncology patients.

2.4.2. Manage and facilitate delivery of medications to support safe and effective drug therapy for oncology patients.

- Prepare and dispense anti-cancer and hazardous medications for oncology patients following best practices and the organization's policies and procedures.
- Manage aspects of the medication-use process related to formulary management for oncology patients, including anti-cancer medications.

2.4.3. **Demonstrate ability to manage formulary and medication-use processes for oncology patients, as applicable to the organization.**

- Prepare or revise a drug class review, monograph, treatment guideline, policy, or protocol related to care of oncology patients.
- Participate in a medication-use evaluation related to care for oncology patients.
- Participate in the review of medication event reporting and monitoring related to care for oncology patients.
- Identify opportunities for improvement of the medication-use system

2.4.4. Demonstrate ability to conduct a quality improvement or research project.

- Demonstrate understanding of a specific project topic to improve care of oncology patients or a topic for advancing the pharmacy profession or oncology pharmacy.
- Develop, and implement a quality improvement or research project to improve care of oncology patients or for a topic for advancing the pharmacy profession or oncology pharmacy.
- Effectively develop and present, orally and in writing, a final project report suitable for publication at a local, regional, or national conference related to care for oncology patients.

2.4.5. Demonstrate leadership skills for successful self-development in the provision of care for oncology patients.

- Demonstrate personal, interpersonal, and teamwork skills critical for effective leadership in the provision of care for oncology patients.

- Apply a process of ongoing self-evaluation and personal performance improvement in the provision of care for oncology patients and management of one's own oncology pharmacy practice.

2.4.6. Demonstrate management skills in the provision of care for oncology patients.

- Explain the elements of the pharmacy enterprise related to oncology and their relationship to the health care system.
- Explain factors that influence departmental planning.
- Contribute to oncology departmental management.
- Contribute the oncology pharmacist's perspective to technology related decisions.
- Manage one's own oncology care practice effectively.

2.4.7. **Provide effective medication and practice-related education to oncology patients, caregivers, health care professionals, and the public.**

- Establish yourself as a go-to person for oncology pharmacy-related information and resources within your organization.
- Design effective educational activities related to care of oncology patients
- Use effective presentation and teaching skills to deliver the educational material related to oncology pharmacy.
- Appropriately assess effectiveness of education related to care of oncology patients.

2.4.8. To write and submit for publication pertinent medication-use information on cancer-related topics.

- Write an article for a publication on a cancer patient -related topic.
- Submit an article on a cancer patient-related topic for a peer-reviewed publication**.**

3. ONCOLOGY PHARMACY STAFF

3.1. Organizational structure: for oncology pharmacy staff

(Specialized oncology centers)

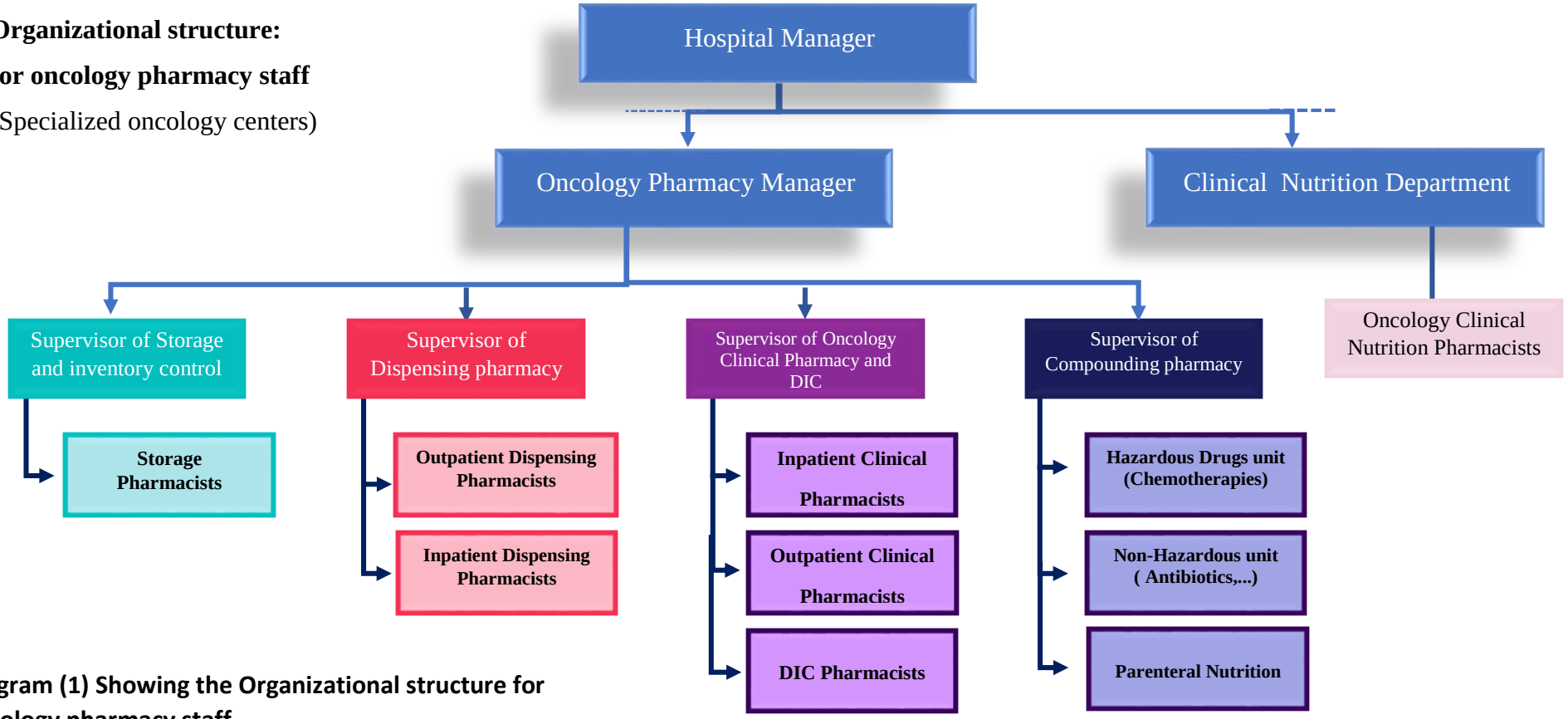


Diagram (1) Showing the Organizational structure for oncology pharmacy staff

3.1.1 Structure of oncology pharmacy may differ in the multispecialty hospitals depending on service availability and applicability.

3.1.2 The oncology pharmacy service should be staffed by sufficient numbers of legally qualified pharmacists. Technical and support personnel are also required to facilitate the mission, goals and objectives of the program.

3.1.3 Oncology pharmacy manager:

The pharmacist who is responsible for the oncology pharmacy service should demonstrate professional leadership and inspire oncology pharmacy staff toward achievement of best practices. He/she should provide vision in area of cancer care and understand the requirements needed for pharmaceutical care of the cancer patients.

Requirements and Skills:

- Egyptian licensed pharmacist.
- Should have at least 5 years of experience in practice as oncology pharmacist.
- Have the Knowledge of oncology disease states, familiarity with evidence-based treatment, including standard-of-care treatment guidelines.
- Basic knowledge of compounding and sterile preparation principles, stability, compatibility, administration.
- Basic Knowledge of safe handling, administration, and disposal of hazardous medications
- Experience of reimbursement practices (payment models and patient assistance programs).
- Ability to communicate effectively with department staff and healthcare professionals.
- Ability to develop and implement policies and internal workflow processes including the key performance indicators (KPIs).
- Familiarity with availability, structure, and design of clinical trials.
- Post-graduate certification in oncology pharmacy, is recommended.
- Must have an accredited certification in healthcare administration, health systems pharmacy administration or business administration

Responsibilities of oncology pharmacy manager:

- Development and implementation of the mission statement.
- Implementation and enhancement of the oncology pharmacy service
- Actively working with or as a part of hospital or health-system leadership to develop and implement policies and procedures.
- Ensure effective KPI standards for delivery of pharmaceutical care services.
- Ensure medication safety and evidence-based practice.
- Implementation of education programs and research initiatives.
- Implementation of standards for staff performance and progression mentoring and developing oncology pharmacy staff and performance assessment.
- Appropriate management of resources to meet the relevant goals and objectives.
- Representing the oncology pharmacy service within the institution and the community it serves such as active participation in standing committees.
- Giving a commitment to sharing knowledge and expertise in the community.

3.1.4 The Supervisor:

A well-trained pharmacist who is responsible for the managing and leading a specific team in oncology pharmacy service, in one of the following settings: clinical oncology pharmacy team, compounding pharmacy team, dispensing and services team, nuclear pharmacy and inventory services team.

Requirements and Skills:

Each team supervisor`s role is differing from one to another in the above four departments according to the special requirement of each field but generally

- The supervisors should have 3 years of experience as a specialized pharmacist.
- They should demonstrate professional leadership.
- English proficiency.
- Communication skills.
- Presentation skills.
- Business writing.
- Critical thinking, and problem-solving skills

Common supervisory tasks include:

- Ensure that Policies and procedures covering all activities are developed, regularly reviewed, updated and always followed
- Helping the team understand performance targets and goals
- Training or ensuring that workers are properly trained for their specific roles
- Scheduling work hours and shifts.
- Coordinating job rotation and cross-training.
- Sharing guidelines updates.
- Assisting in resolving emergencies.
- Identifying and resolving workplace problems.
- Providing reports and activity updates to management.

3.2. Possible career path for oncology pharmacists

3.2.1 The purposes of the oncology pharmacy career path:

- To assist in the development of oncology pharmacy related services.
- To inspire oncology pharmacists to go above and beyond their daily tasks and responsibilities.
- To retain and keep the highly qualified oncology pharmacists through advancing their careers.
- To recognize, honor, and appreciate the key performers in the field

3.2.2 Promotion criteria

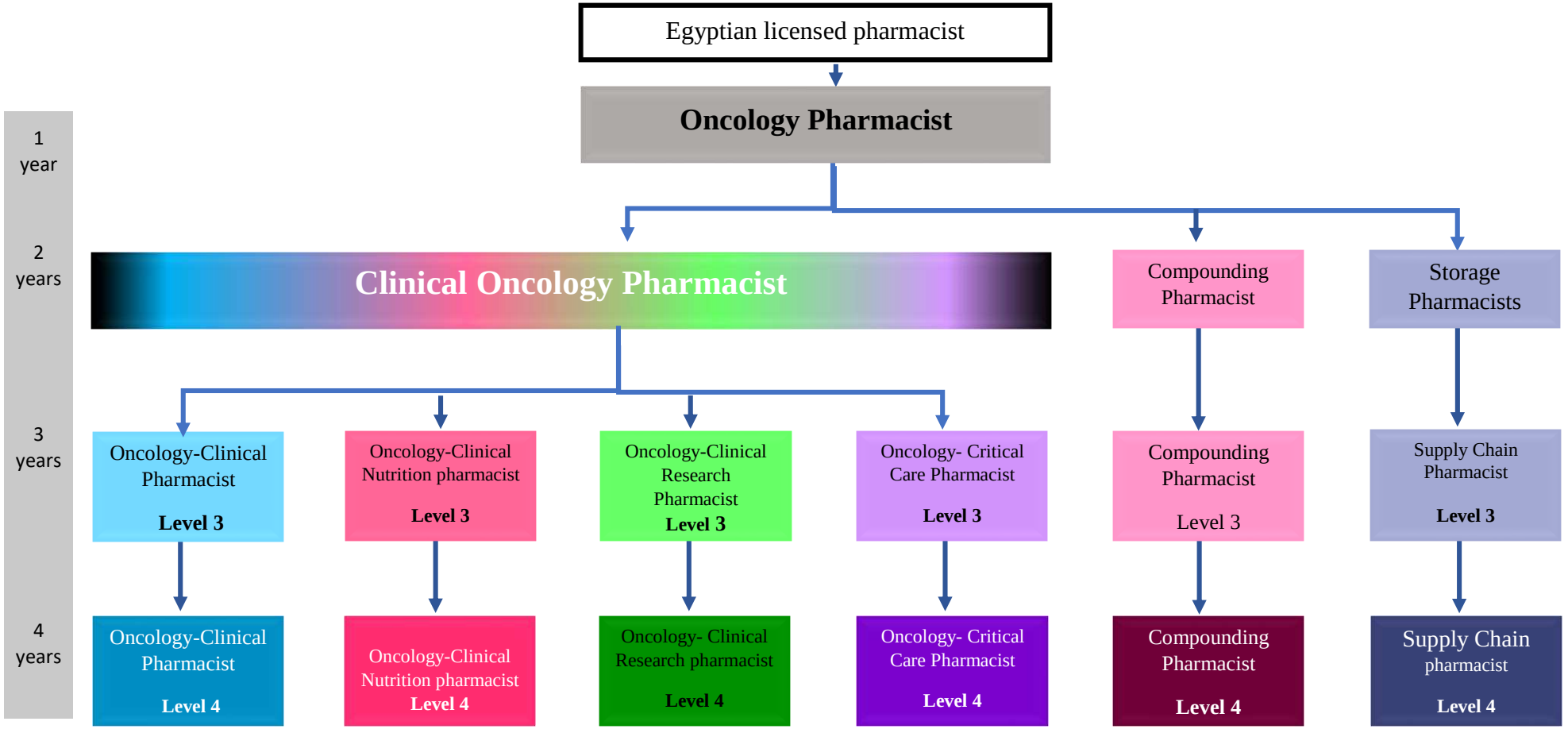
The followings are the key factors that influence promotion criteria:

- Education.
- Experience.
- Extent of impact in the specialty.
- Research activities and publications.
- Organizational and administrative activities.
- Recognition (Awards, Honors; Invited Talks.).
- General personal skills (communication skills, languages, scientific writing, etc.).

3.2.3 Specialties that may be pursued:

1. Oncology Clinical Pharmacy
2. Precision Oncology
3. Oncology Critical Care pharmacy
4. Supply Chain
5. Oncology Clinical Research
6. Oncology Clinical Nutrition
7. Compounding pharmacy
8. Nuclear Pharmacy

3.2. Oncology Pharmacy Career Path



Oncology Pharmacist Career Path: Oncology Clinical Pharmacist

Eligibility Requirements	Duties
LEVEL 1	
1. Prerequisite: Egyptian licensed pharmacist. **2. You will receive an oncology pharmacy training in the following areas:** • Storage and inventory (**2 months**). • Dispensing and patient counselling (**3 months**). • IV admixture pharmacy (**3 months**). • Inpatient / outpatient clinical pharmacy rounds (**4 months**). • Clinical nutrition unit (if applicable) (**3 months**).	• Fulfill the requirement of all the training modules in the log book within the stipulated time frame. • Undertake the training programme with positive attitudes and commitments. • Acquire knowledge and skills by performing required tasks, observing, reading and asking questions. • Actively participate in professional development programme to keep abreast of current knowledge. • Adhere to the hospital / institution policies and procedures.
LEVEL 2	
1. Prerequisite: **Level 1** Certificate 2. At least two years of hands-on experience the following patient-care settings (oncology or hematology) based on the provided services: • Adult malignancies. • Pediatric malignancies. • Bone Marrow Transplantation (BMT). • Surgical Oncology. 3. Must pass successfully an internal practical evaluation per each rotation. 4. Specialized oncology pharmacy diploma is recommended.	**Under the supervision of your preceptor, you have to**: • Collect necessary subjective and objective information for the patient, including oncology diagnosis and treatment history. • Evaluate the regimen on the basis of disease and patient characteristics and published literature. • Review and adjust anticancer therapy orders as appropriate on the basis of patient-specific information. • Assess drug-complementary alternative care and drug-disease, drug-drug, and drug-food interactions. • Review supportive care medications and laboratory results associated with the chemotherapy regimen • Recommend appropriate practice setting (inpatient vs. outpatient) for treatment. • Provide symptom management and supportive care. • Participate in interprofessional patient care (may include rounds). • Coordinate chemotherapy administration with nursing staff. • Educate patients and caregivers on anticancer therapy, supportive care medications, symptom management, safe handling, administration. • Monitor and evaluate the pharmaceutical care plane

LEVEL 3	
1. Prerequisite: Level 2 Certificate 2. You must fulfill one of the following: A. Board certification in oncology pharmacy (BCOP) **AND** 3 years of experience as an oncology clinical pharmacist. B. Fellowship in clinical pharmacy- oncology **AND** one year of experience as an oncology clinical pharmacist. C. Master degree in clinical pharmacy (oncology related) **AND** 2 years of experience as an oncology clinical pharmacist.	**In addition to the previous routine roles, you should** • Educate interprofessional healthcare team members and trainees. • Assist with policy, guideline, and/or drug monograph development. • Participate in hospital committees (e.g., pharmacy and therapeutics). • Ensure that practice meets regulatory requirements, certifications, and accreditations. • Contribute to institutional and collaborative research and scholarly activities. • Participate in institutional review board and feasibility committees to review potential protocols.
LEVEL 4	
1. Prerequisite: Level 3 Certificate 2. PhD in clinical pharmacy (oncology related) **OR, alternatively**, you should publish at least two high-quality field-related original studies in indexed journals. 3. **Four** years of experience as an oncology clinical pharmacy specialist are required. 4. MBA is recommended. 5. (4) Letters of support: 1 from the head of oncology pharmacy department, 2 from Medical Oncology Consultants, 1 from other health care professional in support of clinical practice expertise. 6. Evidence of national recognition may include: • Visiting lecturer. • Awards, Honors and Invited Talks • Service on editorial boards. 7. Evidence of Contribution to public health knowledge by providing information about cancer prevention, screening, and early detection.	**In addition to the previous roles, you should** • Participate in clinical trials • Participate in institutional review board and feasibility committees to review potential protocols. • Review the clinical trial treatment plan and ensure that no protocol deviations occur. • Have a deep knowledge of clinical trials available at the institution. • Provide recommendations for the appropriateness of a clinical trial versus another treatment regimen. • Provide a consistently high level of clinical services at all times to ensure optimal comprehensive patient care for a specific patient population. • Provide advice or suggestions for improvement according to objectives. • Formulate plans to implement recommendations and overcome objections. • Assessing the pros and cons of possible strategies.

***General Notes:**

1. To pass from one level to the next, you must pass a level-specific EDA Exam.
2. The EDA Exam for each level will be available in October, 2022.
3. More information about this career path and EDA exam will be clarified later.

4. FACILITIES AND EQUIPMENT FOR ONCOLOGY PHARMACY

There shall be suitable facilities to enable the receipt, storage, and preparation of anti-cancer medications require special handling conditions of sanitation, temperature, light, moisture, ventilation, pressure, air changes per hour, segregation, and security to ensure medication integrity and personnel safety throughout the hospital.

4.1 **Facilities**

4.1.1 **Pharmacist In-Charge Office (Manager of Oncology Pharmacy office):**
Room for the pharmacist in-charge to perform administrative work shall be provided. It shall be strategically located to allow supervision.

4.1.2 Meeting / Discussion Room
Space for discussion and routine administrative meetings shall be made available.

4.1.3 Wash rooms (Staff) for male and female with separate changing room, and toilets facilities shall be provided.

4.1.4 Storage Room
The following minimum elements, in the form of cabinets, and/or separate rooms shall be required:

- Bulk storage
- Refrigerated storage
- Secure storage for narcotics and controlled drugs
- Storage for documents required by relevant legislation.

4.1.5 **Dispensing Rooms and Dispensing Counters**.

4.1.6 **Clinical Pharmacy Room**

4.1.7 **Patient Counseling Room**

4.1.8 **Clean room for hazardous Preparation**

4.1.9 **Clean room for Non-hazardous preparations**

4.2 Equipment:

- Refrigerator, with thermometer
- Computers with stable Internet access
- Printers and Scanner.
- Balance
- Personal Protective Equipment (PPE)
- Alarm System, Cold Chain
- Alarm System, Electrical Supply
- Alarm System, Fire
- Air-conditioner
- Calculators
- Chair (adequate number)
- Clock
- Racks and shelves
- Shoe rack
- Thermometer: Room and Refrigerator
- Mirrors

5. HOSPITAL COMMITTEES

5.1 The Pharmacy and Therapeutics (P&T) Committee

The pharmacy & therapeutics (P&T) committee is responsible for developing, managing, updating, and administering the drug formulary system for a managed care organization (MCO) or hospital.

5.1.1 Pharmacy and Therapeutics (P&T) Committee's role and responsibilities

- The P&T committee provides an evaluative, educational, and advisory service to the medical staff and organizational administration in all matters about the use of available medications.
- The P&T committee should be responsible for overseeing policies and procedures relating to all aspects of medication use within an institution, medication-use evaluation (MUE), adverse drug event monitoring and reporting, and medication error prevention.
- The P&T committee's organization and authority should be outlined in the organization's medical staff bylaws, medical staff rules and regulations, and other organizational policies, as appropriate.
- The P&T committee may also find subcommittees that address specific therapeutic areas to be beneficial (e.g., pediatrics, antimicrobial, Biosimilar, or pharmacogenomics subcommittees).
- The P&T committee should use a structured, evidence-based process in the evaluation of medications for formulary consideration.
- The P&T committee should be provided with information that reflects a thorough, accurate, and unbiased review and analysis of the evidence available in the scientific literature. The evaluation process should encourage objective consideration of clinical and care delivery information, facilitate communication, foster positive patient outcomes, and support safe and effective medication ordering, dispensing, administration, and monitoring.
- P&T committees should be involved in the organization's approach to ensure the pharmacy can provide medications promptly, support patient access to medications, and provide continuity of care.

- The P&T committee should also review available information on medication or patient safety events reported by a clinical pharmacist or another health caregiver to identify ways to prevent medication events and disseminate the information to healthcare providers and, when appropriate, patients.
- Adverse effects, preparation issues, sound-alike or look-alike potential, practitioner safety, and dose or administration challenges should all be carefully considered by the P&T committee or subcommittees to ensure the institution can meet the standards.

5.1.2 P&T committee membership:

- Actively participating physicians, affected stakeholders, and other prescribers.
- pharmacists.
- Nurses.
- Administrators.
- Quality-improvement managers.
- Other healthcare professionals and staff participate in the medication-use process.

5.1.3 Oncology drug formulary

- A formulary is a continually updated list of available medications and related information, representing the clinical judgment, resulting from a review of the clinical evidence, of physicians, pharmacists, and other clinicians in the diagnosis, prophylaxis, or treatment of disease and promotion of health.
- List of approved medications either anticancer or supportive medications e.g., anti-infective, antithrombotic agents, medications for pain management, etc.), listed by specific criteria for use protocol and includes medication therapy monographs for medications and the indications for medications.

5.1.3.1 **Formulary medicine use policies address the following items:**

- How medications are reviewed for addition to or deletion from the formulary, including who performs the reviews.
- How and when drug class reviews are conducted.
- The process for developing, implementing, and monitoring medication use guidelines.

- Methods and policies for ensuring the safe procurement, prescribing, distribution, administration, and monitoring of medications.
- The process for using non-formulary agents within the hospital and health system.
- The process for managing radiopharmaceuticals.
- The process for managing drug product shortages.

5.1.3.2 **Evaluating medications for inclusion in the formulary**

- The P&T committee should use a structured, evidence-based process in the evaluation of medications for formulary consideration.
- Information used in the formulary decision-making process should be provided to the P&T committee in a written document with a standard format (e.g., a drug monograph, drug review, or drug evaluation document)
- **Pharmacoeconomic evaluations** can and should be conducted in some cases when reviewing new medications. these evaluations should explicitly state the perspective of the analysis (e.g., patient, healthcare provider, payer) and should include consideration of all costs and consequences relevant to that perspective.

5.2 Tumor board

5.2.1 Tumor board responsibilities

- Tumor boards (TBs) are recognized as an effective approach in cancer care to improve the quality of healthcare processes and patient outcomes by Improved adherence to clinical guidelines, improved diagnostic accuracy, and modified care decisions.
- Tumor boards can be held to discuss any type of cancer case, they are usually reserved for patients who have exhausted the standard of care and are seeking new treatment options, as well as those with rare tumor types for which there may not be a standard of care.

5.2.2 Tumor board membership

The members of Tumor boards (TBs) and their attendance at meetings depend on several factors which include hospital size and cancer type. In general, professionals eligible to participate as members of the TB are

- Medical and radiation oncologists.
- Surgeons, radiologists, pathologists.
- Nurse specialists, nuclear medicine specialists.

- Palliative medicine physicians, pharmaceutical experts.
- Nutritionists, and psycho oncologists.

Hospitals may have two versions of tumor boards:

- One where all cases are discussed briefly.
- Another where only specific complex cases are discussed in depth.

Multidisciplinary team meetings are also known as tumor boards

5.2.3 Workflow of the tumor board

1. The coordinator Collects data, sends it to the specialist, and schedules a meeting
2. The specialists present the patient's medical history, each specialist then provides significant clinical data and references, evaluates cases, and participates in a collaborative case discussion.
3. Make final decision on treatment then Document discussion and decisions
4. The meeting may be daily or weekly according to cases
5. The indicators should be defined to assess the impact and the performance of TBs more consistently

Mini-tumor boards are defined as meetings of a smaller group of specialists who discuss cases and/or treatment plans when there are not enough specialists to represent all areas of care of patients with cancer.

5.2.4 Tumor board and clinical practice guidelines

- High-quality guidelines in cancer care are developed by multidisciplinary panels of experts, are based on scientific evidence when evidence is available, and provide the rationale for specific recommendations, are easily available, and useful in the health care delivery system at the point of care, and provide a source of education for medical professionals and the patient and their family.
- Tumor boards allow discussion, dissemination, and implementation of general clinical practice guidelines (such as those from the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology, the European Society of Medical Oncology, Advanced Breast Cancer, etc.)

6. POLICIES AND PROCEDURES

A pharmacy manager shall establish current written policies and procedures to provide pharmacy staff with clear direction on the scope and limitations of their functions and responsibilities.

- The main purpose of the policies and procedures is to provide safe and effective medication use for the patients served by the institution.
- Policies and procedures must be consistent with the goals and objectives of the oncology pharmacy services.

Policies and procedures manual development

- Oncology pharmacy staff must establish the manual content of policies and procedures, providing detailed descriptions of all activities in the pharmacy.
- The supervisor for different specialities must ensure the compliance with these policies and procedures.
- Procedures must be clear, must follow a standard format and must include an index for easy access to information when it is needed.

Policies and procedures should:

- Cover all pharmacy functions (e.g., administrative, operational, and clinical) & Consistent with the general hospital's policies and procedures.
- Include a statement of the pharmacy's mission, philosophy, or values (e.g., the pharmacy's mission or vision statement)
- Concentrate on operational policies and procedures to guide and direct all pharmacy services.
- The manual shall be reviewed by pharmacy staff on a regular basis.
- The manual shall be accessible to pharmacy department personnel as well as other hospital employees.
- All pharmacy personnel should be familiar with its contents.
- All pharmacy personnel shall follow those policies and procedures.

- All committees in the hospital/institute that involved in making decisions concerning medication management and use, shall have at least one pharmacist as a member. This includes the Pharmacy & Therapeutics (P&T), infection-control, patient care, medication-use evaluation, medication safety, nutrition, pain management, and information technology committees, as well as the institutional tumor board (or their equivalents) committees.

O**ncology pharmacy policies and procedures should handle the following:**

1. Roles and responsibilities of oncology pharmacy staff
2. Requirements for best practices and consistency in performance.
3. Direction for orientation of new pharmacists
4. Requirements and methods to promote optimal medication use.
5. Procurement & Purchasing procedures
6. Storage conditions policies.
7. Transport & Transfer Activities
8. Prescribing policies.
9. Dispensing policies.
10. Verbal orders policy.
11. Medication error reporting policies and procedure.
12. Medication Return policy
13. Compounding hazardous and Non-hazardous preparations procedures.
14. Aseptic technique procedure.
15. Recall of final compounded sterile preparations policy and procedure.
16. Safe handling of hazardous medications policies and proceduresز
17. Cytotoxic spill management policies and procedures.
18. Beyond use date establishing and saving policy
19. Immunization policy program for both cancer patients and hospital employees.
20. Waste disposal policy.

7. MEDICATION USE EVALUATION(MUE)

7.1 Goals, objectives, and definitions

- MUE is a systematic and interdisciplinary performance improvement method with an overarching goal of optimizing patient outcomes via ongoing evaluation and improvement of medication utilization, various terms have been employed to describe programs intended to achieve this goal; in addition to MUE, drug use evaluation (DUE) and drug utilization review (DUR) have also been used. MUE may be differentiated in that it emphasizes improving patient outcomes and quality of life.
- MUE may focus on patient-centered therapeutic outcomes (e.g., clinical events, quality of life) or process elements related to appropriate medication usage (e.g., prescribing, dispensing).

7.2 Roles and responsibilities in the MUE process

- The roles of pharmacists and other healthcare professionals in MUE may vary according to the practice setting, organizational goals, and available resources. The organizational body (e.g., quality management or QI committee, pharmacy, and therapeutics committee) responsible for the MUE process should have, at a minimum, a prescriber (most commonly a physician), pharmacist, nurse, and an administrator or health-system representative. and its steps may be described using the FOCUS-PDCA model framework.

7.3 Drug utilization review and cost

- There shall be an ongoing program for monitoring drug utilization and costs to ensure that medications are used appropriately, safely, and effectively and to increase the probability of desired patient outcomes. drug utilization studies (DUS) and cost analysis of anticancer drugs became an inevitable tool in health economics.
- Drug use is a complex process since optimal benefits of drug therapy in patient care may not be achieved because of under-use, overuse, or misuse of these drugs. Inappropriate drug use may also lead to increased cost of medical care, antimicrobial resistance, adverse effects, and patient mortality. Hence, in recent years, DUS has become a potential tool to be used in the evaluation of health care systems.

7.4 Indicators of need for MUE at different steps in the medication-use process

Step	Indicators
Prescribing	• Market entry or withdrawal of approved drug products • Regulatory actions such as drug recalls, market withdrawals, or safety alerts Publication of guidelines or high-impact studies that may change treatment patterns • New organizational interventions to improve medication therapy, such as changes to protocols orformularies • Changes in use of, or requests for, nonformulary medications Changes to pharmacy clinical services to improve medication therapy • Introduction of or changes in quality indicators, such as those published by the Centers for Medicare & • Medicaid Services, or other regulatory or accrediting bodies
Dispensing	• Signs of process failures, such as wasted medication or delayed medication deliveryIncorrect medication preparation • Dosing that requires clinician preparation or compounding • Ensuring compliance with regulatory requirements (e.g., United States Pharmacopeia Chapters 795, 797,800)
Administration	• Medication misadventures related to medication delivery systems • Multiple medication concentrations, units of measure, or infusion rates
Monitoring	• Adverse events, including medication errors, preventable adverse drug reactions, and toxicity • Signs of treatment failures, such as unexpected readmissions and bacterial resistance to anti-infectivetherapy • Patient dissatisfaction or deterioration in quality of life attributable to drug therapy
Systems Management andControl	• Procurement requirements, specialty pharmacy requirements, Risk Evaluation and Mitigation Strategy(REMS) programs, restricted distribution channels, or other access challenges • Drug shortages requiring replacement or therapeutic substitutionDiversion of controlled substances • Lack of standardization or confusion within the medication use process Changes in contracts, cost or spending on drugs • Organizational priorities such as budget constraints or cost saving initiatives

8. MEDICATION SAFETY

8.1. Medication errors

8.1.1. Definitions

- Medication error is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is under the control of the health care professional, patient, or consumer (National Coordinating Council for Medical Reporting and Prevention, (NCCMERP), 2012), Such events mciv be related to professional practice, healthcare products, procedures, and systems"
- Medicine errors cause considerable patient morbidity, mortality, and increased healthcare costs.
- The Joint Commission on Accreditation of Health Care Organization reemphasized the importance of the analysis of error reports to prevent future errors with the implementation of additional patient safety standards that address the development of a culture of safety.
- Medication errors should be closely monitored due to the narrow therapeutic index of chemotherapy, the cancer patient's comorbidity, and disease complications.

8.1.2. Medication Errors Classification

medication errors can be classified as prescribing errors, transcription errors, dispensing errors, administration errors, or monitoring errors.

- **Intercepted medication error ('near miss')**

  The events in the treatment process before reaching the patient would have resulted in a 'potential' ADR. The intervention has prevented actual harm being caused to the patient, e.g. a wrongly prepared medicine was not administered to the patient because the error was noticed by the nurse.

- **Potential medication error**

  A potential medication error is the recognition of circumstances that could lead to a medication error, and may or may not involve a patient.

8.1.3. The Intention of Medication Error Reporting

- The reports will be analyzed quantitatively and qualitatively for identification and prioritization of error medication stages, their effect on the patient, and their root causes. Hence corrective actions targeted priority areas and root causes to prevent a recurrence and were removed before they could reach or harm patients.
- **The reporting aims to improve patient safety services through the following objectives:**

  1) Determine the baseline rates of medication errors in the hospital;

  2) Recognize the major types of medication error;

  3) Reduce risks of medication errors through the application of prevention strategies.
- Educational and training programs on medication errors reporting and importance are required for pharmacists, drug prescribers, and nurses (administrating drugs) to reduce drug errors and to improve patient safety.

8.1.4. Keys to Error Prevention Examples

- Patient Education as part of any error prevention program.
- Prior Authorization programs are used by managed health care systems as a tool to assist in providing quality, cost-effective prescription drug benefits.
- Bar Coding is an electronic technology tool that can help ensure that the right medication use and administration
- Electronic Prescription Record.
- Electronic DUR, pharmacists can conduct prospective online drug utilization reviews.
- Automated Medication Dispensing.

8.2. Adverse Drug Reaction Reporting

8.2.1 Definitions

WHO: “Any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or the modification of physiological function”

FDA: For reporting purposes, FDA categorizes a serious adverse event (events relating to drugs or devices) as one in which "the patient outcome is death, life-threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent, or permanent), congenital anomaly, or required intervention to prevent permanent impairment or damage."

ASHP defines a significant ADR as any unexpected, unintended, undesired, or excessive response to a drug that

1. Requires discontinuing the drug (therapeutic or diagnostic).
2. Requires changing the drug therapy.
3. Requires modifying the dose (except for minor dosage adjustments).
4. Necessitates admission to a hospital.
5. Prolongs stay in a health care facility.
6. Necessitates supportive treatment.
7. Significantly complicates diagnosis.
8. Negatively affects prognosis.
9. Results in temporary or permanent harm, disability, or death.

Pharmacists in organized health care systems should develop comprehensive, ongoing programs for monitoring and reporting adverse drug reactions (ADRs)

8.2.2 **ADR-monitoring and reporting program should include the following features:**

- Information regarding suspected ADRs should be reported to the pharmacy for complete data collection and analysis, including the patient's name, the patient's medical and medication history, a description of the suspected ADR, the temporal sequence of the event, any remedial treatment required, and sequelae.
- High-risk patients should be identified and monitored. High-risk patients include but are not limited to pediatric patients, geriatric patients, patients with organ failure (e.g., hepatic or renal failure), and patients receiving multiple drugs
- The cause(s) of each suspected ADR should be evaluated based on the patient's medical and medication history, the circumstances of the adverse event, the results of **dechallenge and rechallenge** (if any), alternative etiologies, and a literature review.

- A method for assigning the probability of a reported or suspected ADR (e.g., confirmed or definite, likely, possible, and unlikely) should be developed to categorize each ADR.
- Educational programs can be conducted as morning "report" discussions, newsletters, "grand rounds" presentations, algorithms for treatment, and multidisciplinary reviews of drug-use evaluations. Patient confidentiality should be preserved.
- Reporting of adverse drug reactions **to pharmacovigilance center at EDA**
- An overall goal of the ADR process should be the achievement of positive patient outcomes

8.3. Safe handling of hazardous medications

8.3.1. Definition

- Hazardous drugs (HDs) are defined by their association with genotoxicity, carcinogenicity, teratogenicity, fertility impairment or reproductive toxicity, and/or serious organ toxicity at low doses.
- Healthcare workers may be exposed to HDs at many points during manufacture, distribution, receipt, storage, transport, compounding, and administration, as well as during waste handling and care of treated patients. All workers involved in these activities, as well as in equipment maintenance and repair, have the potential for contact with the uncontained drug.
- The examples of control in the context of hazardous drugs include the following:
  - Accommodation in a different position within the organization that does not involve the handling of hazardous drugs (elimination, substitution),
  - Biologic safety cabinets (engineering controls),
  - Educational programs (administrative controls),
  - Gloves and gowns (personal protective equipment [PPE])
  - **In Chapter 3**, these safety considerations will be explained in greater depth.

9. KEY PERFORMANCE INDICATORS OF ONCOLOGY PHARMACY

9.1 Key Performance Indicators (KPIs)

9.1.1 Definition of an Indicator:

- Oxford's Dictionary definition of KPI: A quantifiable measure used to evaluate the success of an organization, employee, etc. in meeting objectives for performance.
- In health care settings Quality indicators are measurement tools, screens, or flags that are used as guides to monitor, evaluate, and improve the quality of patient care, clinical support services, and organizational functions that affect patient outcomes.

9.1.2 Importance of KPIs in oncology pharmacy practice to:

- Monitor and improve the performance.
- Measure the improvement.
- Set and achieve goals within timelines.
- Pay attention to real world status.
- Improve quality of patient care.
- Improve patient satisfaction and outcome.
- Prioritize the area of improvement.
- Recognize success.
- Cost effectiveness

9.2 Health Care Quality Measures

Measures used to assess and compare the quality of health care are classified as either as:

- Structure measures.
- Process measures.
- Outcome measures.

9.2.1 Data Sources for Health Care Quality Measures

- Before you decide which quality measures to report, it is helpful to know what kinds of data you will need to produce the scores for the measure.

- There are many challenges with regard to the quality of the available data. These challenges can be categorized into four key aspects: (1) completeness, (2) comprehensiveness, (3) validity and (4) timeliness.

9.2.2 Domains of Health Care Quality:

According to the Institute of Medicine (IOM), there are six aims for the health care system. Quality of care can be measured on specific domains:

- **Safe**: Avoiding harm to patients from the care that is intended to help them.
- **Effective**: Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and misuse, respectively).
- **Patient-centered**: Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- **Timely**: Reducing waits and sometimes harmful delays for both those who receive and those who give care.
- **Efficient**: Avoiding waste, including waste of equipment, supplies, ideas, and energy.
- **Equitable**: Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

9.2.3 Examples of Oncology Pharmacy KPIs:

Measurement Area	What to measure?	Indicator	Equation	Data Source
General Administrative Measures	*Pharmacist* workload	*Pharmacist* to patient ratio	- The number of *Pharmacists* divided by the number of patients/ tickets served for a specific time period. ***This indicates whether the facility—or even a certain division—is under- or overstaffed.	- Admission office records - HR records
	*The word *pharmacists* above can be replaced by any other pharmacy staff members needed to calculate their work load per patient/ ticket/ etc per unit time.			
	Putting plan for staff needs	Number of required pharmacists at a certain pharmacy (Inpatient, outpatient, mixing or any).	**"Service target method"** can be used. ***Workload indicators for staffing needs method (WISN)*** - To calculate the number of pharmacists needed for a certain pharmacy: . **Identify the number of hours available for each pharmacist/year (*staff available time*).** (Daily working hours* Number of annual working days after subtraction of weekends, holidays and annual leaves). . **Identify the different tasks taken by each pharmacist.** ▪ Write a list of all tasks performed by pharmacist in a certain pharmacy. ▪ Calculate the time required annually to perform each task in minutes (***activity standard for each task***). (Time required to perform a certain task in minutes* No. of times task repeated daily* Total number of days task performed annually). ▪ Repeat calculations for each task in the previous list. ▪ To get the number of pharmacists required for a certain task: (Divide staff available time/ activity standard= ***Standard workload***). ▪ The total number required is the sum of staff needed for all tasks in this category. After getting the number of pharmacists required to operate certain	- Pharmacy Supervisor, *(to be aware of daily performed tasks).* - HR Specialist.

Procurement & Inventory Control.	Availability of chemotherapy drugs/ Completeness of drug formulary.	Percent of medications requested to be added to drug formulary (Non-formulary Medications).	- (Number of requested medications for addition/ Total number of formulary medications) *100	- Physician's formulary addition request form. - Drug Formulary.
Storage	Medication loss/ waste.	Percent of expired units of a certain drug.	- (Number of Expired units/ Total number of units available) *100	- Inventory checklists (Expiration dates report).
Prescribing	Compliance of physicians to use preprinted orders	Percent of protocols received written on other forms (other than preprinted orders).	- (Number of protocols received by the pharmacy for dispensing written on other forms for a certain period of time/ Total Number of protocols received for the same period) *100	- Medication orders rejected by the dispensing pharmacy due to using improper forms used.
Dispensing	Accuracy of dispensing process.	Percent of units incorrectly dispensed.	- (Total number of incorrectly dispensed units (one of the dispensing errors) per month/ Total number of dispensed units)*100.	- Medication error reports. - Pharmacy dispensing records.
	Errors related to dispensing process.	Ratio of dispensing medication errors to total oncology pharmacy medication errors.	- Number of dispensing medication errors in certain period: total number of medication errors reported in the same period.	- Medication error analysis reports
Preparation & Safe Handling	Chemotherapy spills.	Percent of splash occurrence inside the BSC per shift.	▪ (Number of splashes occurred/ Total number of preparations for one shift) * 100.	- Pharmacy preparation records. - Spill Reports.
		Number of chemotherapy spills that happened in one week.	▪ Number of chemotherapy spills reported in one week. ▪ Number of spill kits used/ opened in one week.	- Pharmacy preparation records. - Spill Reports.
	Spill management awareness.	Percent of trained staff on spill management measures.	▪ (Number of trained staff on proper spill management/ Total number of staff dealing with chemotherapy) * 100.	-
	- Number of destroyed vials.			
	Cost Savings.	Total amount of money saved due to pharmacists' mixing of chemotherapy drugs per month.	▪ For details about calculating cost savings refer to chapter 3. ▪ For this indicator cost saving is calculated for one month.	- Pharmacy preparation records.
Administration	Follow up of proper administration of chemotherapy medications.	Percent of patients for whom a pharmacist performed administration follow ups monthly.	▪ (Number of patients a pharmacist performed administration follow ups at least once/ total number of patients followed up) * 100.	- Clinical pharmacy reports.

	Administration medication errors.	Percent of administration medication errors per month.	▪ (Number of administration medication errors/ Total number of reported errors in a certain month) * 100.	- Medication errors reports.
Patient Satisfaction	Patients' satisfaction with certain pharmacy service.	Percent of patients satisfied with service provided.	▪ (Number of satisfied patients/ Total number of patients asked) *100	- Questionnaires
Clinical Pharmacy Services Measures	Medication reconciliation services	Percent of medication reconciliations performed by a pharmacist for <u>new admissions</u> in one month	▪ (Number of medication reconciliations performed for new admissions monthly/ total number of new admissions for the same month) * 100	- Admission office. - Pharmacy reports (Example: Medication reconciliation forms).
		Percent of medication reconciliations performed by a pharmacist during <u>patient discharge</u> in one month	▪ (Number of medication reconciliations performed for discharged patients monthly/ total number of discharged for the same month) * 100	- Patient record department reports. - Pharmacy reports (Example: Medication reconciliation forms).
	Pharmaceutical care plan initiation\ developing.	Percent of patients that clinical pharmacist set/ developed a pharmaceutical care plan from total admission or total cases reviewed by a clinical pharmacist monthly.	▪ (Total number of patients that a pharmacist developed a pharmaceutical care plan in one month/ Total number of admitted patients or those with medications reviewed by a clinical pharmacist for the same month) * 100.	- Clinical pharmacy reports. - Admission office.
	Clinical pharmacist outcomes.	Number of interventions provided by clinical pharmacist during clinical rounds.	▪ Number of interventions provided for physicians during clinical rounds in a certain month.	- Clinical pharmacy reports.
		Acceptance percent of clinical pharmacy interventions.	▪ (Number of accepted clinical pharmacist interventions in one month/ total number of interventions for the same month) * 100.	- Clinical pharmacy reports.
	- Number of patients reviewed or seen at clinic			
Medication Safety.	Presence of Safety Culture inside the institution.	Number of adverse drug reaction reported.	▪ Total number of medication errors reports received per month.	- ADR reports received.
		Number of medication errors reported.	▪ Total number of medication errors reports received per month.	- Medication error reports received.
	Degree of participation/ awareness of other healthcare professionals in	Ratio of errors reported by non-pharmacists to errors reported by pharmacists.	▪ Number of errors reported by non-pharmacists: Number of errors reported by a pharmacist for the same period of time	-

	maintenance of safety culture.			
	Severity of errors consequences. OR Degree of pharmacy control of medication use process.	Percent of medication errors that didn't reach the patient.	▪ (Number of medication errors reported classified as A, B, and C/ Total number of errors reported for the same period of time) * 100.	- Clinical pharmacy (Medication error) reports.
	Corrective actions availability.	Percent of corrected medication errors.	▪ (Number of corrected medication errors/ total number of errors for the same period of time) * 100.	- Clinical pharmacy (Medication error) reports.
DT Committee.	DTC Meetings.	Number of DTC held annually.	Number of DTC meetings held in one year.	- DTC monthly meeting moments.
		Ratio of DTC meetings attended by a clinical pharmacist to the total number of committee meetings held.	▪ Number of committee meetings attended by a clinical pharmacist: Total number of committee meetings held.	- DTC meetings' attendance reports.
		Number of recommendations presented by the DTC.	▪ Number of recommendations written in meeting moments of a certain month.	- Meeting moments report.
Patient Education/ Counseling.	Patient education/ counselling activities.	Percent of inpatients educated upon discharge.	▪ (Number of patients counseled upon discharge in one month/ Total number of patients discharged in the same month) * 100.	- Clinical pharmacy reports/ forms of patient counseling signed by the patient. - Patient records department reports.
		Percent of outpatients counselled after getting their medications monthly.	▪ (Total number of counselled outpatients in one month/ total number of patients served for the same time) * 100.	- Pharmacy records. - Dispensing cards. - Counseling forms.

- This table provides examples of indicators that can be used to measure oncology pharmacy practices. Each institution should set its indicators and how to measure.

هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
الإدارة العامة للممارسات الدوائية والصيدلية

CHAPTER II

ONCOLOGY MEDICATION MANAGEMENT AND USE

1. INTRODUCTION

A fundamental purpose of pharmaceutical services in any setting is to ensure the safe and appropriate use of drug products and drug-related devices. Fulfillment of this responsibility is enhanced through the pharmacist's involvement in all aspects of the use of drugs. The pharmacist must work as a member of the healthcare team.

The establishment of a good working relationship with medical, allied health and nursing staff, as well as community health professionals, patients and their careers are the basis of successful clinical practice.

The pharmacist responsible for the overall service to an oncology unit is referred to as the oncology pharmacist. The role of oncology pharmacists has expanded to be experts in optimizing the benefits of drug therapy, their role as an essential member of the interdisciplinary team extends to seven major key elements of medication management that include: procurement, storage, prescribing, transcribing, distribution, preparation, dispensing, administration, documentation and monitoring.

This chapter covers the key required information needed as guidance for oncology pharmacists in different processes related to oncology medication management and use. By merging between different processes included in medication use process, and medication management cycle provided from GAHAR and JCI. To ensure providing the most safe and effective oncology pharmacy practices. **This chapter will cover the following:**

1- Selection and Procurement.
2- Transport, transfer and Receiving of Oncology Medications.
3- Storage.
4- Ordering/ Prescribing and Reviewing.
5- Preparation.
6- Dispensing.
7- Distribution.
8- Administration.
9- Documentation.
10- Monitoring.

Figure 2.1: ashp guidelines on preventing medication errors in hospitals. This diagram is a modification of the joint commission's medication management system.

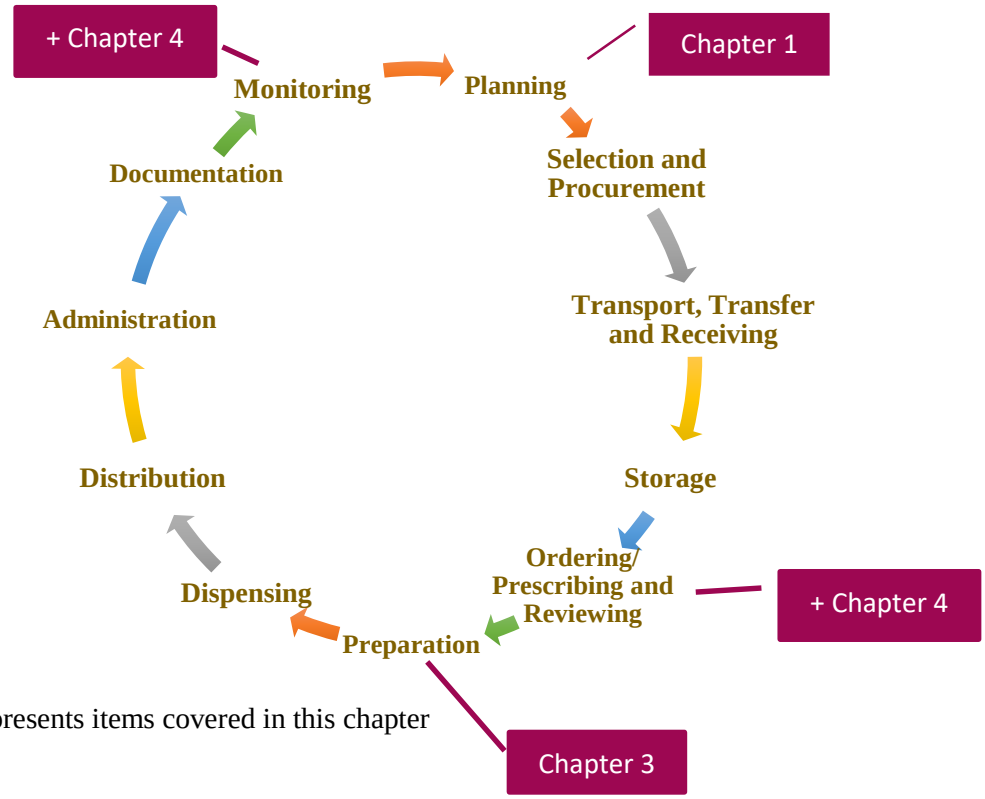


Diagram 2.2: represents items covered in this chapter

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2. SELECTION AND PROCUREMENT OF ONCOLOGY MEDICATIONS

- Pharmaceutical procurement is a complex process which involves many steps, agencies, ministries and manufacturers. Egyptian authority for unified procurement (UPA) plays a central role in drug selection and procurement at the national level.
- On a hospital level, the hospital pharmacy and specifically oncology pharmacist, shall be responsible for the procurement, distribution, and control of all oncology related drug products used in the hospital for inpatient and ambulatory oncology patients.
- Policies and procedures governing these functions shall be developed by the pharmacy with input from other appropriate hospital staff and committees.
- Oncology hospital pharmacists play a vital role in ensuring that a functional, safe, cost-effective and reliable hospital formulary is designed.
- Their perspective in the entire procurement process, starting with the decisions of the drug and therapeutic committee about medicines policy and use within the hospital, will help with the identification of high-risk medicines, link procurement with patient need, and guarantee the implementation of appropriate procedures to reduce vulnerability in the supply chain.
- **WHO Criteria for Selection of Essential Medicines:**

  Essential medicines: are those satisfy the healthcare needs of the majority of population; they should therefore be available at all times in adequate amounts and the appropriate dosage forms.

  The choice of these medicines depends on many factors, such as:

  1) Pattern of prevalent diseases (*Type of tumors treated*).
  2) Treatment facilities.
  3) Training and experience of available personnel.
  4) Financial resources.
  5) Genetic, demographic and environmental factors.

- Each selected medicine must be available in a form in which adequate quality, including bioavailability can be ensured; its stability under the anticipated conditions of storage and use must be established.
- When two or more medicines appear to be similar in the above respects, the choice between them should be based on a careful evaluation of their relative efficacy, safety, quality, price and availability.
- In cost comparison between medicines, the cost of the total treatment, not only the unit cost of the medicine, should be considered. (*Refer to Pharmacoeconomics chapter, volume II on this guide*).
- Any new medication required to be added to hospital's Drug Formulary must gain approval of P&T committee, according to institution's policy and procedures.
- The impact of and compliance with the formulary should be periodically reviewed (e.g., through drug-utilization reviews), and the P&T committee should regularly review the formulary for safety information.
- There shall be policies and procedures for the procurement, control, and use of non-formulary medications required for patient care.
- A well-controlled formulary of approved medications shall be maintained and regularly updated by the P&T committee.
- Diagram 2.2: represents the process of addition of new medication to hospital's drug formulary. Process steps may differ from one place to another.
- **<u>Drug Shortages:</u>**

  Each institution should have its own drug shortage policy that is clearly stated, well known to all integrating departments and following laws and regulations.

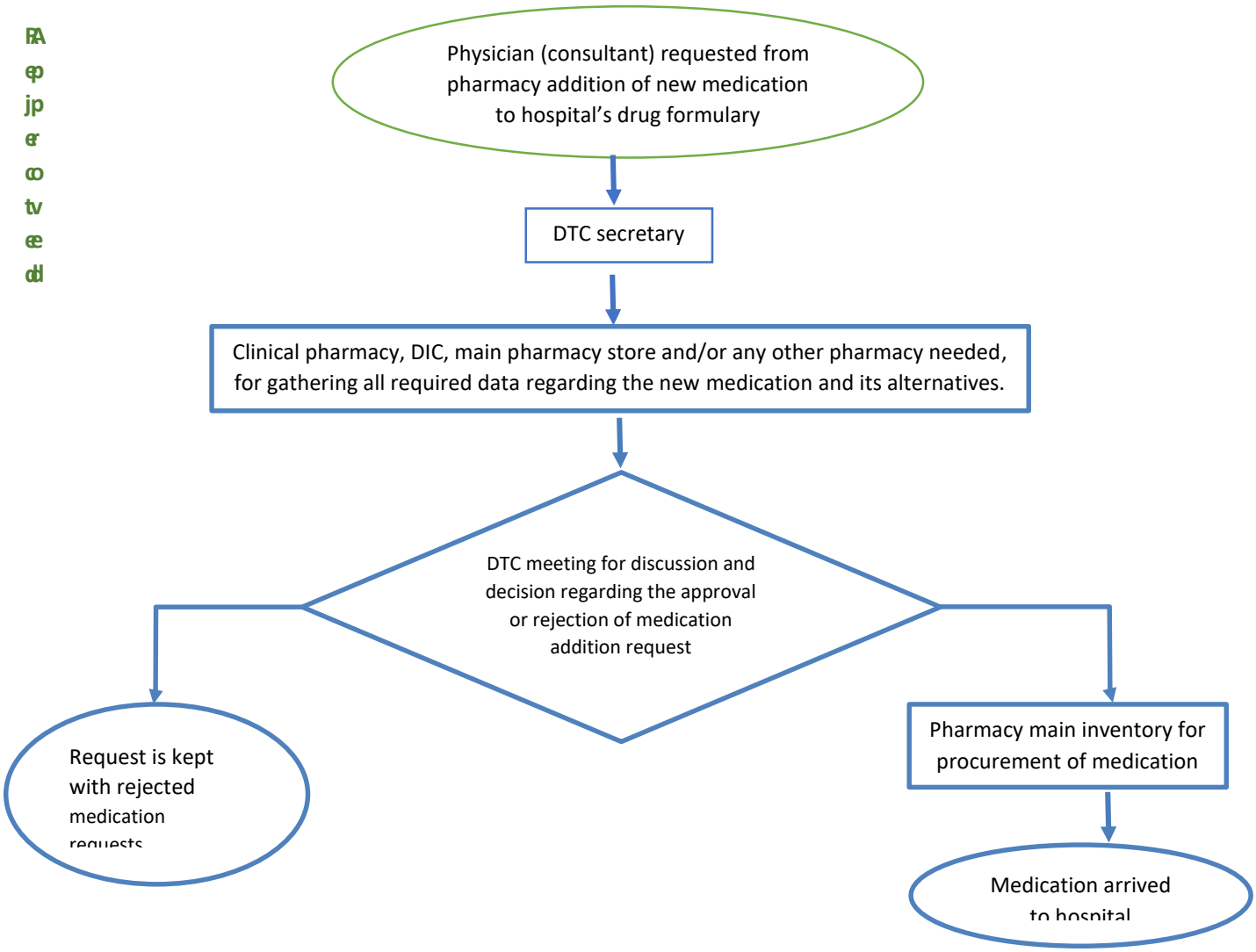


Diagram 2.3: Workflow diagram describing addition of new medication to hospital's drug formulary

3. Transport, transfer and Receiving of Oncology Medications

- **Transport** of oncology medications from manufacturer to institution is not always controlled by the oncology pharmacist. But the role of oncology pharmacist for control of such process can be emphasized in the process of receiving of those medications.
- **Responsibilities of drug manufactures** regarding packaging, labeling and materials used should be set by upper regulatory authorities according to laws and regulations.

- **Transfer** of medications inside the institution to pharmacies, wards, theatres and departments should maintain the stability, safety and security of medications.
- Personnel used to deliver medications should be reliable and carefully chosen.
- For **chemotherapy** medications, special arrangements are required and the carrier must be made aware of the hazardous contents. Storage, handling and packaging requirements must be maintained and checked.
- When items requiring **refrigeration** are transported, care must be taken to maintain the cold chain at all times, using pharmacy approved cool bags/boxes as appropriate.
- **Receiving** control should be under the care of pharmacy, and the pharmacist must ensure that records and forms provide proper control upon receipt of medications. Complete accountability from purchase order initiation to medication administration must be provided.
- Oncology pharmacists responsible for the **receiving process** of oncology medications must assure that:
    - Persons involved in receiving and inventory control should be informed of the possibility of surface contamination on cytotoxic vials.
    - Staff should wear single use chemotherapy gloves when handling cytotoxic medications.
    - Staff should wash their hands after handling of cytotoxic medications (contaminated items such as gloves should be disposed with hazardous waste).
    - Proper training of involved persons about spill management.
    - Oncology pharmacy should provide checklists containing items that need to be checked upon receiving medications provided by the manufacturer. Checklists done according to institution requirements and following rules and regulations of proper receiving checks. Checklists can include but not limited to:

    - Product Status: Example:
        - Product units (Vials, IV bags, Ampoules, Tablets, Bottles… etc) are intact.

- At proper storage temperature (can be checked by seeing the transport vehicle if containing air condition or ice packs are used for products requiring low temperatures, products is not hot or feezed…. etc).
- In a proper physical appearance.
- In suitable package.
- Vehicles used are following requirements.

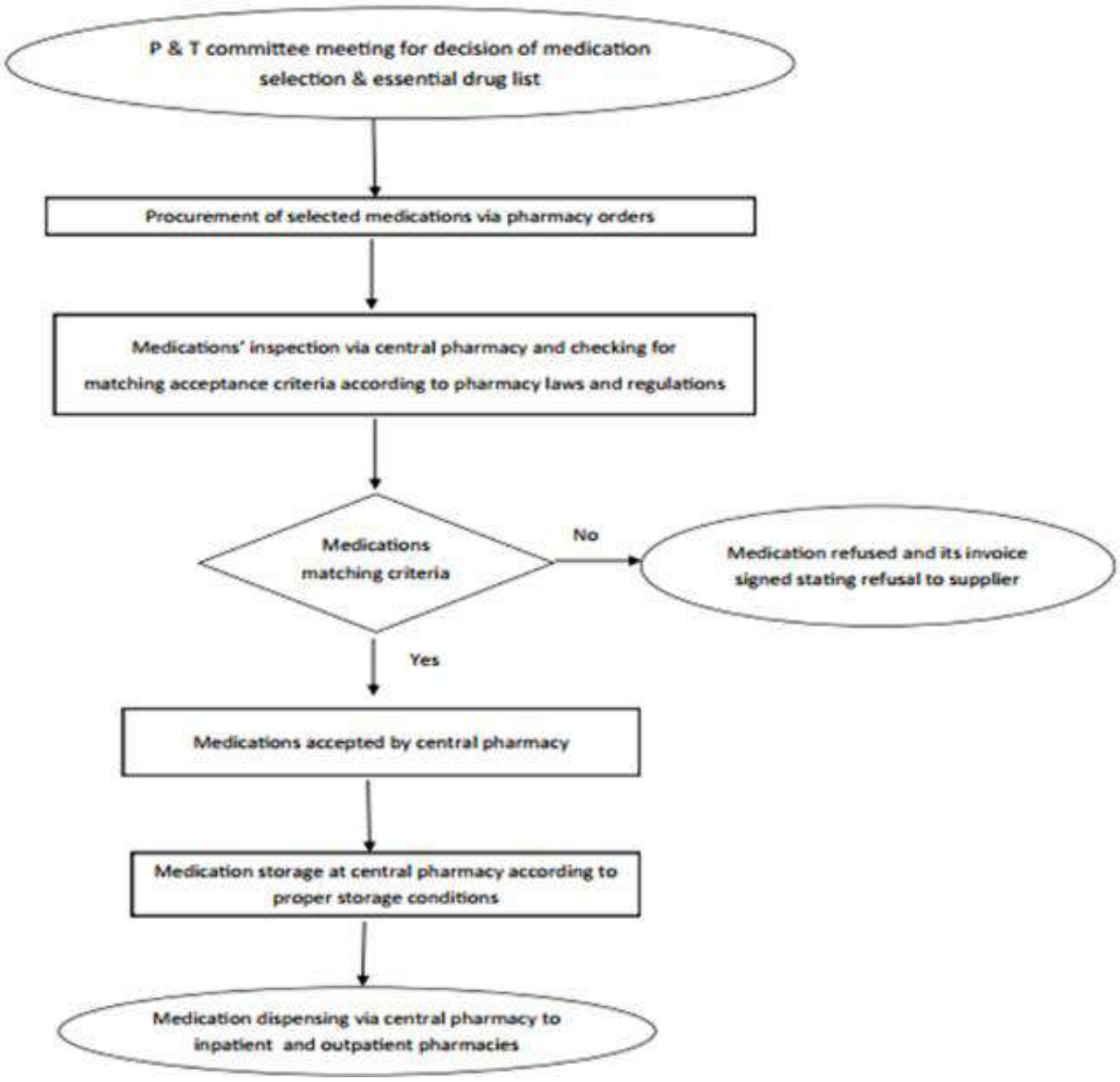


Diagram 2.4. showing medication procurement, receiving and dispensing from central pharmacy inside the institution

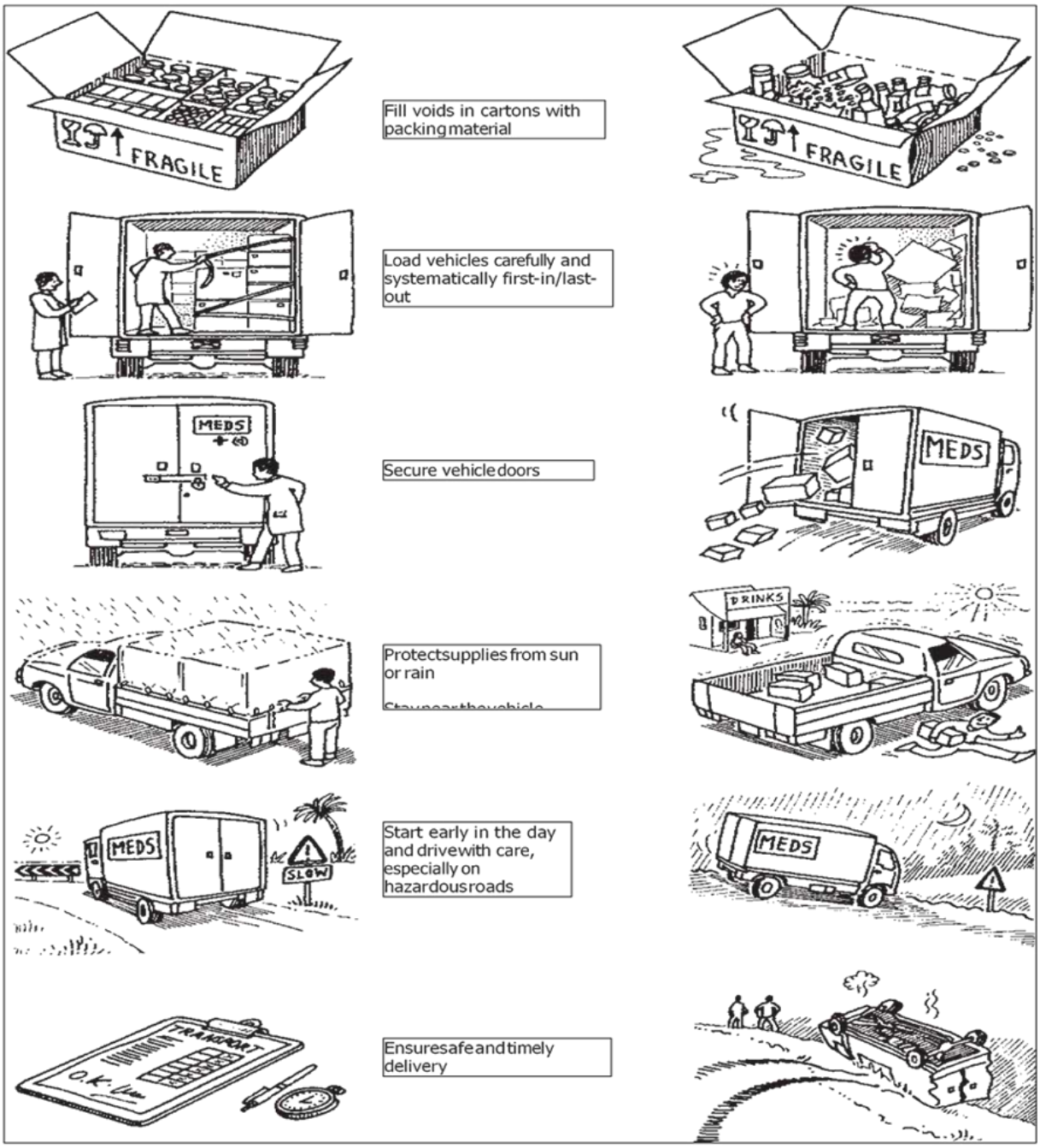


Diagram 2.5.: diagram showing ideal conditions for transport of medications from manufacturer to institution

4. STORAGE OF ONCOLOGY MEDICATIONS

- Storage is an important aspect of the total drug control system. Proper control is important wherever medications are kept, whether in general storage in the institution, pharmacy or patient-care areas (including satellite pharmacies, nursing units, clinics, emergency rooms, operating rooms, recovery rooms, and treatment rooms).
- All medications (including investigational drugs, patient's medication(s) from home, and within the pharmacy and throughout the hospital) shall be stored under proper conditions of sanitation, temperature, light, humidity, ventilation, regulation, and security.
- The following must be checked and maintained for proper storage management wherever medications are present within the institution:

- Disinfectants and drugs for external use are stored separately from internal and injectable medications.
- Proper environmental control (i.e., proper temperature, light, humidity, conditions of sanitation, ventilation, and segregation) must be maintained wherever drugs and supplies are stored in the institution.
- Medications are not being overstocked.
- Controlled substances and narcotics are kept in secure locations.
- Safety also is an important factor, and proper consideration should be given to the safe storage of poisons and flammable compounds.
- Externally brought medications should be stored separately from internal medications.
- Refrigerators used for medications storage should not contain any items other than medications, and should be kept in a secured, separate compartment.
- Separation of hazardous and non-hazardous medications is recommended. As well as separation of high alert, highly concentrated, look-alike and sound –alike medications.
- No outdated medications are stocked.
- Standards of *neatness and cleanliness are consistent* with good medication handling
- Patient medications no longer required are returned to the pharmacy.
- Medications that may be required on an urgent or emergency basis are in adequate spaces and proper supply.

5. ORDERING/ PRESCRIBING OF ONCOLOGY MEDICATIONS

- Prior to writing any medication order by a prescriber/physician whether for outpatient or inpatient settings, prescribers should verify the availability of the medication in the institutional formulary (i.e., Cancer drug formulary CDF) (Refer to Chapter I).
- Prescribing of the anti-cancer medications or supportive medications by the physician is submitted in electronic (if available) or written form.
- Standards of the prescription forms for different settings, must be unified and approved for each setting/department throughout the hospital.
- Different types of prescribers hold different prescribing rights. It is important for pharmacy department to be able to identify which products each type of prescriber is entitled to prescribe. Example: oncology consultants only are authorized to prescribe chemotherapy for patients for the first time, while oncology specialists can repeat the cycle after checking labs and patient status and can discontinue medications as well.
- **Verbal orders (**Whether face-to-face or over the telephone):
    - **For Chemotherapy**, *except for discontinuing treatment*, medication-use systems **should not** permit healthcare providers to use or accept verbal orders to commence or modify a chemotherapy medication.
    - Medicines must only be administered without a written prescription in exceptional circumstances, e.g. an emergency arrest situation.
    - **Strict regulations** and stated policy and procedures must be followed to apply proper dispensing via verbal orders by physicians. Also, special situations for verbal orders must be clarified to all healthcare providers.
    - Orders must be written and signed by physician as soon as possible according to institutions' regulations.
- **Emergency medications:**
    - Chemotherapy itself is not an emergency medication. Most oncologic emergencies can be classified as metabolic, hematologic, structural, or side effects from chemotherapy agents.

- Prescribing policy in emergencies must be written clearly, and must be defining the authorized personnel for dispensing and handling of drugs.
- Policy for emergency administration must be developed in the institution.
- Make sure that crash carts are available in all patient areas with medications and supplies regularly checked.
- Identify which antidotes, reversal agents, and rescue agents can be administered immediately in emergencies to prevent patient harm.
- Ensure all appropriate antidotes, reversal agents, and rescue agents are readily available, directions for use/administration readily available in all clinical areas where the antidotes, reversal agents, and rescue agents are used.

6. DISTRIBUTION OF ONCOLOGY MEDICATIONS

- The primary distribution management goal is to maintain a steady supply of pharmaceuticals and related supplies to facilities where they are needed while ensuring that resources are used in the most effective way.
- Effective pharmaceutical distribution relies on good system design and good management. Oncology pharmacist must ensure the presence of a well-designed and well-managed distribution system through assuring that it:

    1. Maintain a constant supply of medicines.
    2. Keep medicines in good condition throughout the distribution process.
    3. Minimize medicine losses caused by spoilage and expiry.
    4. Maintain accurate inventory records.
    5. Rationalize medicine storage points.
    6. Use available transportation resources (such as vehicles, ice boxes and other transportation related resources) as efficiently and effectively as possible.
    7. Reduce theft and fraud.
    8. Provide information for forecasting medicine needs.

- Medication distribution is the responsibility of the pharmacy. The pharmacist, with the assistance of the P&T committee and the department of nursing, must develop

comprehensive policies and procedures that provide for the safe distribution of all medications and related supplies to inpatients and outpatients.

7. PREPARATION OF ONCOLOGY MEDICATIONS (COMPOUNDING PHARMACY)

Compounding sterile non-hazardous medications:

- The preparation of medications (pharmacy compounding) has always been an integral part of the practice of pharmacy. It is essential to the delivery of health care and allows for personalized therapeutic solutions to improve patient care.
- Sterile non-hazardous preparations include but not limited to total parenteral nutrition, hydration protocols, chemotherapy pre-medications, and antibiotics.
- For the minimum requirements regarding facilities, and policies (Refer to Chapter 3).

Compounding sterile hazardous medications:

- Sterile hazardous preparations include antineoplastic drugs since these drugs account for the majority of hazardous sterile preparations undertake in the pharmacy. Also, any drug mentioned in the NIOSH list.
- For the minimum requirements regarding facilities, and policies (Refer to Chapter 3).

Compounding non-sterile preparations:

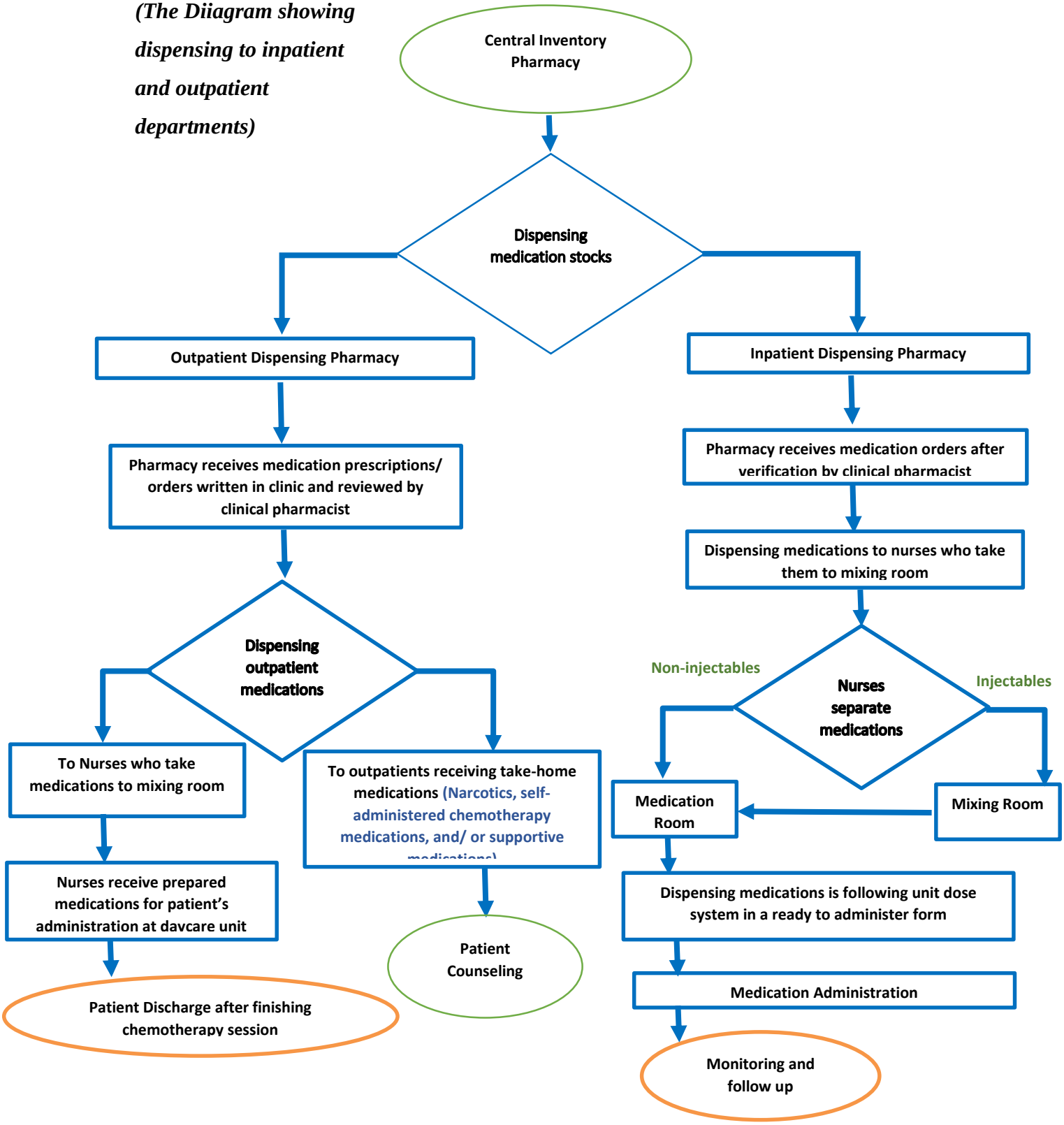
Examples for non-sterile preparations: Topical preparations for extravasation and preparations used for chemotherapy-induced and/or radiation therapy-induced Oral mucositis.

8. DISPENSING OF ONCOLOGY MEDICATIONS

In any dispensing point, all medications (including supportive and chemotherapy whether oral or parenteral throughout the hospital) shall be stored under proper conditions of sanitation, temperature, light, humidity, ventilation, regulation and security.

Dispensing to inpatient or outpatient department:

(The Diiagram showing dispensing to inpatient and outpatient departments)



- The hospital should set a well-known policy and structure for defining inpatient and outpatient pharmaceutical services, and specify which type of oncology patients will be served on each part.
- **Clinical Pharmacy Checks**
    - A patient medication history must be taken from the patient and documented on first cycle of chemotherapy or when the protocol is changed.
    - All prescribed cancer therapy and associated supportive care medications (by any route of administration) must be clinically verified by a pharmacist prior to dispensing and administration to, or by, a patient. Verification must be performed according to the protocol and the patient's treatment plan and individual parameters.
    - The oncology pharmacist ensures that all appropriate prescriptions for medications for use at home are written (e.g. oral oncology medications, corticosteroids, antiemetics, hematopoietic stimulating factors, etc.).
    - Oncology clinical pharmacist should verify the medication order against the treatment protocol, the patient's medication profile, reconciled across all interfaces care in the hospital and the **patient's h**ealth record.
    - The five "P"s should be followed to successfully verify a cancer therapy medication order:
        1. Patient details and dosing variables.
        2. Prescription/medication order.
        3. Protocol and scheduling.
        4. Prescribed medication, dose calculations and administration.
        5. Patient organ function and laboratory blood tests.
    - The pharmacist responsible for the verification must sign and date each cancer medication order to confirm verification has been completed. Where electronic medication management systems are in use the pharmacist must ensure that electronic verification is performed securely and in line with local procedures and state legislation.

- The pharmacist must ensure regular review with the patient that captures any changes to the patients' usual medications or commencement of new medications. The pharmacist must maintain an up-to-date treatment history relating to all chemotherapy medications, doses, variations and treatment dates.
- The oncology pharmacist should resolve any question(s) regarding the anti-cancer medication order(s) with the prescriber and should document the resolution in the patient's health record.
- Details of clinical pharmacy activities will be discussed in (chapter 4).

- **<u>Dispensing to Outpatient</u>**

  Dispensing medications in the outpatient setting differs from that provided to inpatients. In a simple way this guide will cover two types of patients served by outpatient pharmacy:

  - Patients receiving take home medications (Injectables and non-injectables).
  - Patients receiving chemotherapy in daycare unit.

- **Patients receiving take home medications (oral or injectables)**
  - Before dispensing take home medications to oncology patients, oncology pharmacist must assure that prescription for take-home medications in the "Outpatient setting" include at least the following information:
    - Patient name, date of birth, gender, and identification code (if electronic entry data system is available).
    - Body weight, height, and/or body surface area.
  - Medication prescribed is advised to be written clearly in Generic name or International Non-Proprietary Name (INN name).
  - Dose calculations needed i.e. calculation according to body surface area, body weight, or an absolute dose.
  - Dose modifications required i.e. reduction in the case of impaired organ function or other parameters must be indicated
  - Route and duration of administration.

- Diagnosis and protocol used.
- Dates and/or days and times to administer if required by treatment regimens for more than one day.
- Date and physician signature or in the case of an electronic request, clear identification of the ordering physician using secure release.
- Multimorbidity and the associated use of multiple medications (polypharmacy), is common in oncology patients. The risk of adverse effects and harm increases with increasing numbers of medications so outpatient follow-up card is highly recommended (Appendix 1. Follow-up card).

- **Patients receiving chemotherapy medications at day care unit:**
  - **Daycare unit** is designed to look after the patients who have been advised short therapies/procedures and do not require night stay in hospital. Such patients are given treatment in daycare center during the day time so that patient is able to go home the same day.
  - ***Advantages of daycare unit:***
    - Presence of experienced oncologist, pediatric oncologist, hematologist and Pain and palliative care specialist. All staff; nurses, technicians, pharmacists and others are trained in oncology care. This makes it very helpful for patients to explain about their problems and clarify their doubts.
    - Daycare services are economical to patients and saves their time. There is no disruption of their daily routine. Admission and night stay charges can be avoided.
    - Patient can recover well in the comfort of their home after getting treatment done during the day. With near and dear ones around, people feel happier and tend to respond well to treatment and in turn they recover faster.
  - There should be clear policies and procedures set by each institution having a daycare unit for the pharmaceutical care services provided to daycare unit patients that is well known to all healthcare team.
  - Vials needed for chemotherapy preparation, have to be dispensed to the compounding room to be prepared. Mixing instructions to be written clearly to

the compounding pharmacist by the senior compounding pharmacist and reviewing the dispensing form.

- In the absence of a treatment protocol, the clinical pharmacist should refer to the physician (prescriber) to raise this issue to a Tumor board committee inside the institute for further check of the medication order against two independent literature sources.
- After then, further steps must be followed to look forward about the importance of enrollment of this new drug in the hospital formulary or not.

- **<u>Dispensing to inpatients:</u>**

- Diagram 2.4 represents the whole dispensing process
- Pharmacist must verify that inpatient medication order, include at least the following information:

a) The patient's name, age, file number, and ward location.
b) The generic name of the medication.
c) Dosage and dose calculations if needed.
d) Route and frequency of administration (proper instructions for administration).
e) Duration of treatment (i.e. Stop date has to be mentioned).
f) Name of prescriber.
g) Date and time the order was written.
h) If pediatric patient, the weight of child provisions shall be made for sending the medication orders to the pharmacy department.
i) Medication orders should be canceled automatically when a patient goes to surgery and orders shall be rewritten postoperatively. All orders should be reviewed and rewritten by the physician when a patient change to service.

- Before dispensing to the medication rooms or compounding rooms, the pharmacist who reviews the medication order should not be the same pharmacist involved in the final product verification. Two independent checks and verification of the drug order needed to be dispensed.

- **UNIT DOSE SYSTEM**

- Unit-dose systems are a pharmacy-coordinated method for dispensing and controlling medications, including both oral and injectable or infusion medications which are handled through a separate central IV admixture program.
- The following distinctive elements are basic to all unit dose systems:
    - Medications are contained in single unit packages;
    - Dispensed in as ready-to-administer form as possible;
    - For most medications, not more than a 24-hour supply of doses is delivered to or available at the patient-care area at any time.
- The proper procedure for implementation of unit-dose system within the institute, include the following:
    - Proper transfer to the medication room in the acute patient care area of packaged medications that were dispensed from the central pharmacy. Medication shall be delivered to the ward from the pharmacy with the least amount of delay.
    - The following information shall be indicated on the individual dosage package:
        a. Name of medication
        b. Strength
        c. Expiry date
        d. Batch/lot number.

The individual medication doses to be scheduled, prepared, distributed, and administered on a timely basis. Unit-dose carts or medication trays shall be used as medication storage facilities on the ward.

Labeling of received medications: In every particular tray/box or zip bag for a specific patient, this shall be labeled properly with the patient's name, patient`s file number, or hospital number and location,….etc.

✓ Unit dose medication management systems may be *manual* or *automated*.

✓ Automated unit dose systems further reduce the risk of certain types of medication errors.

- ✓ Drug supply packages (Unit-dose system) for each patient on a 24-hour basis, to the medication room in the ward to be dispensed to the ward medication room, where the pharmacist is responsible for the preparation and dispensing of patients` specific medication to nurses prior administration.
- ✓ The final written instruction form is written by the Ward/Clinical Pharmacist to nurses for proper administration.
- ✓ Economic Impact of unit-dose systems:

There is a needed ***cost*** for applying the ***dispensing unit dose system*** (especially the Automated Unit Dose System), and ***a capital*** needed ***for renting or purchasing equipment for dispensing, labeling, and tracking*** (which often is done by computer). But the ***benefits outweigh the cost*** spent is too much more, that is shown in the following:

1- Minimize drug waste and pilferage.
2- Enhance the billing accuracy.

- **MEDICATION RETURN POLICY**

For unused medications, medication distributed from the pharmacy, but no longer required, and need to be returned to the pharmacy:

- Policies and procedures for returning medications to stock shall be developed by the multidisciplinary team of the P&T committee in the hospital.
- Medications must not be returned to stock unless the integrity of the medication and proper storage of the medication in the patient care area is confirmed.
- All topical, liquid, or injectable medication shall not be re-dispensed upon return to the pharmacy unless the previously dispensed product is in a sealed dosage unit.
- The following medications shall be discarded upon return to the pharmacy:
  a. Opened ophthalmic/otic/nasal drops/ointments.
  b. Opened creams, ointments, lotions.
  c. Opened liquid medications.
  d. Used inhalation products, unless cleaned and sterilized.
  e. Opened multi-dose and single-dose vials.
  f. Used IV admixtures.

g. Medications handled by patients.
h. Medications returned by ambulatory patients.

9. ADMINISTRATION

- Administering medications inside the hospital is generally the responsibility of nursing staff. In some circumstances medications should be administered by physician such as anesethia medications.
- The "rights" of medication administration include right patient, right drug, right time, right route, and right dose.
- Medications should be safely and accurately administered according to laws and regulations.
- Educate and support nursing and medical staff on the administration of cancer therapies
- Advise patients and/or carers on the administration of cancer therapies and supportive care medicines, ensuring information is tailored to patient literacy level
- Provide advice to health professionals and patients and/or carers on the safe handling of cancer therapies
- **Nurses are advised to:**
  - Be vigilant when preparing medications.
  - Check for allergies.
  - Use two patient identifiers at all times. Always follow agency policy for patient identification.
  - Assessment comes before medication administration.
  - Be diligent in all medication calculations.
  - Avoid reliance on memory; use checklists and memory aids
  - Communicate with your patient before and after administration.
  - Ensure medication has not expired.
  - Always clarify an order or procedure that is unclear.

10. DOCUMENTING

- Documentation is a very important part for assuring quality of care.
- All mediation related processes must be documented according to laws and regulations using institution specific documents, forms, checklists, records…. Etc either paper based or electronic.
- All documentation must be legible and organized in a standardized format.
- Examples:
  - The pharmacy verification process must be documented in an up-to-date local procedure which outlines the individual systematic checks that pharmacists are required to undertake when verifying cancer medication orders prior to dispensing, supply and administration.
  - The pharmacist should document that they reviewed and verified the anti-cancer medication(s).
  - The primary patient healthcare record and all documentation applicable to the prescribing, dispensing and administration of cancer treatment should be readily accessible to all staff at the point of care and be up-to-date

11. MONITORING

- All Processes related to medication use should be regularly checked and quality improvements are done. Examples:
  - The pharmacy department should maintain regular inspection on medication storage areas throughout the institution.
  - When verifying a prescription, the pharmacist must ensure that the prescription is valid, the medicine is clinically appropriate for the patient and information is provided to the patient to ensure safe and appropriate use of the medicine.
  - A pharmacist must take reasonable steps to ensure that the dispensing of a medicine is consistent with the medical needs of the person for whom the prescription or order is intended.
  - Ensure that the prescribing, preparation, dispensing and administration of clinical trial medicines adheres to the trial protocol.

- Clinical verification of an order or prescription for cancer therapy by a pharmacist provides assurance that the prescribed treatment is accurate and appropriate for the patient and their specific cancer diagnosis.
- Clinical pharmacy monitoring may include:
    - Response and toxicities to cancer therapies
    - Organ function
    - Therapeutic drug levels
    - Cumulative dosing
    - Adherence to therapy and ensure cancer and
    - Supportive care medicines are adjusted appropriately
- A step-wise, process-driven approach to clinical verification of cancer therapy is essential to minimize medication errors and optimize safety in the process of providing cancer therapy.
- Any identified discrepancies, anomalies or errors must be clarified and resolved with the prescriber. All significant interventions should be documented in the patients' healthcare record.
- For more details refer to (chapter 4)

SPECIAL ISSUE: NARCOTICS MANAGEMENT

- Policies and procedures for the handling of narcotics, have to be written inside the hospital and educated to all the healthcare providers according to Egyptian laws and regulations.
- Narcotics undergo regular external and internal inspections, also audit for the waste products of their use i.e., wasting of partially used or wasted vials, ampoules, etc..
- **Proper storage and security of controlled drugs**

  An authorized pharmacist(s) has/have to be defined and known to all the healthcare system in the organization, who will be responsible *for receiving, storage, preparation and dispensing of these medication(s) or under his authorization*. Also, a responsible pharmacist must be defined for the *waste products or return of unused medications.*
- He/she is responsible for ensuring that the products are *under his/her constant supervision* or *securely locked with access only by the responsible practitioner*.

هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
الإدارة العامة للممارسات الدوائية والصيدلية

CHAPTER III

COMPOUNDING STERILE PREPARATIONS AND SAFE HANDLING OF HAZARDOUS DRUGS

1. INTRODUCTION

The compounding of medications is a fundamental part of pharmacy practice. Compounding and dispensing sterile preparations of correct ingredient identity, purity (freedom from physical contaminants such as precipitates and chemical contaminants), strength (including stability and compatibility), and sterility are the responsibility of all compounding pharmacist.

Exposure to hazardous drugs in the workplace may be associated with acute and short-term reactions as well as long-term effects. This guide is intended to assist compounding pharmacist in producing high-quality sterile preparations while minimising the risk of patient harm and compounding personnel repercussions. The following are the objectives of this manual:

- Standardization of all polices, requirements and procedures related to sterile compounding hazardous and non-hazardous preparations.
- Raising awareness and building capacity about aseptic technique and other compounding issues to minimize harm including death, to patients that could result from
    - Microbial contamination (no sterility).
    - Excessive bacterial endotoxins.
    - Variability from the intended strength of correct ingredients.
    - Physical and chemical incompatibilities.
    - Chemical and physical contaminants.
    - Use of ingredients of inappropriate quality.
- Raising awareness and capacity among all personnel who work with HDs. In addition to clarifying the basic practises, facilities, equipment, and safety precautions to:
    - Minimize exposure to personnel.
    - Minimize contamination of the work and patient-care environments.
- Create and develop a better compliance strategy.

2. PERSONNEL

2.1.Supervisor of compounding pharmacy

- **Supervisor of compounding pharmacy** is a pharmacist designated to supervise activities related to the compounding of sterile hazardous and non-hazardous preparations. This person works with the pharmacy manager and with the compounding personnel.
- The compounding supervisor develops, organizes and oversees all activities related to sterile- preparation compounding. These responsibilities are delegated by the pharmacy manager.
- Sterile compounding supervisor should be a member in the P&T committee. And also, be a member of committee responsible for checking & acceptance of medical supplies used in compounding.

2.1.1. Qualifications of compounding pharmacy supervisor

- The supervisor should have 3 years of experience as a compounding pharmacist.
- Must have successfully completed training (i.e., courses) in the compounding of sterile preparations, as well as maintaining current knowledge and competencies.
- The Supervisor of compounding pharmacy must also have the competency required to manage a safe, high-quality sterile-preparation compounding area.

2.1.2. The compounding pharmacy supervisor ensures that:

- A personnel training and assessment program is implemented.
- Personnel know and fully comply with policies and procedures.
- Appropriate measures are taken to ensure the safety of personnel during each preparation.
- The facilities and equipment used to compound sterile hazardous and non-hazardous preparations comply with all regulations and are properly maintained and calibrated.
- The available, recognized scientific literature is used to determine stability and to establish the beyond-use date (BUD) for each sterile preparation.
- A quality assurance programme is implemented and followed to ensure that preparation activities are carried out in accordance with best practises, scientific standards, existing data, and relevant information.
- Key performance indicators for the compounding pharmacy are properly assessed.

2.2.Compounding Pharmacists

- Compounding Pharmacist is a pharmacist who prepares sterile preparations for patients

of the hospital where the pharmacist is employed.

- When more than one pharmacist is involved in dispensing a compounded sterile preparation, responsibilities toward the patient are shared between them.

2.2.1. Compounding pharmacist qualifications and requirements

- **Compounding pharmacists** should have 1 year of training to become an oncology pharmacist, the training includes 3 months in the IV admixture Pharmacy.
- Successfully pass a written exam in addition to having a complete workplace training program.
- The initial training includes the following:
  - Hand hygiene
  - Garbing
  - Cleaning and disinfection
  - Decontamination and deactivation.
  - Calculations, measuring, and mixing
  - Aseptic technique. (Assessment of aseptic techniques, based on Visual observation)
  - Achieving and/or maintaining sterility
  - Use of equipment
  - Documentation of the compounding process
  - Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow.
  - Proper use of primary engineering controls (PECs).
  - Proper donning and doffing.
  - Overview of entity's list of hazardous drugs(HDs) and their risks
  - Review of the entity's SOPs related to handling of HDs
  - Response to known or suspected HD exposure
  - Spill management
  - Proper disposal of HDs and trace-contaminated materials.
  - Principles of movement of materials and personnel within the compounding area.
- Any compounding pharmacist who has successfully completed the initial workplace training and assessment program may begin work in the compounding of sterile preparations. Pharmacists with limited experience may require additional training and supervision.
- The assessment results and any corrective measures imposed must be recorded.

2.3.The compounding pharmacist must

1. Perform compounding/admixing activities.
2. Ensure compliance with policies and procedures handled the sterile preparations.
3. Ensure compliance with required rules relating to asepsis, cleanliness and safety.
4. Ensure that all records related to ongoing activities are completed.
5. Ensure that all data required for monitoring and reproducing the preparation are recorded.
6. Ensure that the equipment, instruments used are properly cleaned and maintained;
7. Ensure that there is a compounding procedure/worksheet for each preparation produced.
8. Ensure the accuracy of calculations and measurements.
9. Ensure that all required verification and quality control measures are performed to ensure the safety, quality and sterility of each preparation.
10. Ensure that preparations are labelled appropriately.
11. Ensure that the final preparation is properly stored until delivery to the patient.
12. When a preparation must be recalled, notify the pharmacist at any pharmacy where the product was dispensed.

2.3. Before dispensing or releasing a preparation to the patient, ensure that all standards of practice associated with dispensing the preparation have been met

2.4.Cleaning Staff

Whether they're referred to as janitors, housekeepers, cleaning workers, or cleaners, these important employees and their employers play a vital role in maintaining workplace hygiene. They are capable of carrying out tasks such as: Mopping floors, removing trash, cleaning surfaces, moving furniture and lifting bulk material to clean an area, and disinfecting tasks. To ensure sterility and safety, the compounding pharmacy supervisor should provide and develop appropriate training and assessments for the cleaning staff.

3. COMPOUNDING NON-HAZARDOUS STERILE PREPARATIONS

3.1.Facilities and equipment

3.1.1. Facilities

3.1.1.1.Dimensions

Areas designated for the compounding of sterile preparations must be large enough to

- Facilitate compounding.
- Allow cleaning and disinfecting without constraint.
- Ensure good flow of personnel, equipment and materials.

3.1.1.2. Lighting

The lighting must be sufficient and fixtures located so as to

- Facilitate the sterile compounding process.
- Allow verification at all stages of compounding

3.1.1.3. Heating, ventilation and air conditioning system for controlled rooms (clean room, anteroom)

- The air in controlled rooms must be “clean,” and levels of airborne particulates must be controlled. Thus, the facility’s heating, ventilation and air conditioning (HVAC) system must be designed to minimize the risk of airborne contamination in controlled rooms.
- It must also be designed to achieve and maintain the appropriate ISO class for clean rooms and anterooms.
- The air supplied to areas used for sterile preparations must pass through a high-efficiency particulate air (HEPA) filter to ensure a very high level of sterility.
- All sources that generate particles must be controlled to achieve and maintain the ISO class for clean rooms and anterooms used to compound sterile preparations.
- The air quality in controlled rooms must comply with ISO 14644-1, according to the specifications listed in appendix (2), under dynamic operating conditions.
- At the bottom of the walls, return air intakes should be installed to force particles to flow downward.
- An air conditioning system must be included in the HVAC system to help ensure the comfort of personnel wearing personal protective equipment (PPE).

3.1.1.4. Windows and openings

- Controlled rooms **must not have** windows opening directly to the exterior of the building.
- If there are any windows, they must be properly sealed.

3.1.1.5. Compounding areas

- Compounding areas must have at least two separate controlled rooms, enclosed and physically separated by a wall: a clean room, where the PEC (BSCs) is located, and an anteroom, located before the clean room.

a. Cleanroom (non-hazardous sterile preparations)

- The clean room is a room in which atmospheric properties (temperature, content of particles and microorganisms, air pressure, airflow, etc.) are controlled. The room is designed to minimize the introduction, generation and retention of particles.
- The clean room contains the primary engineering controls (PEC), it is used only for the compounding of sterile preparations.
- To reduce the risk of introducing viable and non-viable contaminants into the clean room, it must be physically separated from the rest of the pharmacy and other non-controlled areas by walls, doors, and pass through.
- To enable verification of activities, one or more observation windows should be installed. Such windows reduce the number of times that individuals must enter and exit the clean room.
- Access to the clean room is restricted to personnel with specific responsibilities in it.
- **Rrequirements that must be met in the clean room:**
  - Relative to the anteroom the clean room must be kept under **positive pressure**.
  - The pressure differential must be at least 5.0 Pa (ideally between 5.0 Pa and 12.5 Pa, equivalent to 0.02 to 0.05-inch water column) relative to the anteroom.
  - ISO Class 7 air quality must be maintained.
  - There must be at least 30 or more air changes per hour (ACPH).

b. Anteroom

- The anteroom is located between the clean room and the non-controlled areas of the

pharmacy, acting as a transition space.

- The anteroom is separated into two spaces **by a visible demarcation line**:
  - A space or area referred to as "dirty," located at the entrance to the anteroom, in the section adjacent to the non-controlled area;
  - A space or area referred to as "clean," adjacent to the dirty area on one side and the clean room on the other. It is important to take these "clean" and "dirty" areas into account when traversing the anteroom and when donning and removing PPE.
- The pharmacy should have a system in place that only allows one door to be open at a time.
- To prevent accidents involving personnel entering or leaving through the doors, the doors between the clean room and the anteroom must have windows.
- **Requirements that must be met in the ante-room for the compounding of non-hazardous sterile preparations:**
  - Positive pressure relative to the non-controlled area adjacent to the anteroom.
  - A notification system must be installed in each pressure monitor to alert pharmacy personnel when pressure differentials deviate from specifications.
  - ISO Class 8 air quality must be maintained in the anteroom.
  - There must be at least 20 air changes per hour (ACPH).
- **The use of an anteroom**
  - The anteroom is the location for activities with higher generation of particulates, such as garbing, and hand hygiene.
  - Activity in the anteroom shall be kept to a minimum and shall be limited to those activities that are essential to or that directly support the work undertaken in the clean room.
- Access of supplies, equipment and personnel into the clean room shall be through the anteroom.
- **Anteroom Contents**

The contents of the anteroom must be limited to facilitate maintenance and to maintain the target ISO air quality classification.

The anteroom must contain the following items:

- PPE, placed in the correct order to allow users to follow the correct garbing sequence.
- Hands-free sink, ideally made of stainless steel or other material not harmed by cleaning

products and large enough to allow users to wash their hands and forearms without touching the sides of the sink, with minimal splashing.

- Soap dispenser (cartridge or disposable, non-refillable unit).
- Nail picks.
- Alcohol-based hand rub (ABHR) with persistent activity and its dispenser.
- Hand-drying system (Lint-free towels (preferred) with a dispenser)
- Mirror or other means to verify garbing.
- Clock.
- Waste container.
- Eyewash station, if available (if not located in the anteroom, the eyewash station must be installed nearby);
- Pass-through for transferring products into the clean room and/or a cart reserved for use in the "clean" area of the anteroom and the clean room.

3.1.1.6. Materials and finishes (See appendix 3,4)

- The surfaces of ceilings, walls, floors, doors, door frames, shelves, counters and cabinets in controlled areas must be smooth, impervious, non-friable, free from cracks and crevices, non-porous and resistant to damage from cleaning and disinfecting products. These characteristics make them easy to clean and disinfect, as well as preventing the accumulation of microorganisms and non-viable contaminants.
- Any holes, cracks or breakage in ceilings, walls, floors, doors, door frames, shelves, counters and cabinets must be repaired and sealed at the earliest opportunity.
- Dust-collecting overhangs, such as door sills, utility pipes, windowsills, window curtains and window blinds, must be avoided.
- In the clean room and the anteroom, joints between the ceiling and walls should be free of sharp corners where foreign substances could accumulate. This can be achieved by coving the ceiling to the wall or by caulking.
- In the clean room and anteroom, the floor must be coved up the side wall, (10–15 cm).
- There must be no carpets, rugs, "sticky mats" or ant fatigue mats.

3.1.1.7. Accessories

- **Ceiling fixtures**

- In controlled areas ceiling fixtures must be recessed and flush-mounted.
- The external surface's material, must be washable and smooth.

- **Plumbing**

- Water sources, sinks and drains must not be located in a clean room
- The ante-room must not contain floor drain(s).

- **Control systems**

- Control systems indicating the temperature and differential pressure between controlled areas should be positioned together. Functional parameters require constant monitoring, so the controls should be installed where it is easy for personnel to take frequent readings.
- Control systems must be connected to a notification system to alert personnel when operating parameters are outside pre-set limits. This allows personnel to make the necessary adjustments quickly while avoiding contamination of controlled areas and the problems that may result, including service interruption.
- Instruments for measuring differential pressure between controlled areas must be calibrated at least once a year or as recommended by the manufacturer.

3.1.1.8. Furniture

- All furniture in the clean room and anteroom, as well as the floor and wall surfaces, must be designed and placed to facilitate cleaning and disinfecting.
- All movable furniture must be cleaned and disinfected before it is placed in the clean room.
- Chairs used in controlled areas must be made of smooth, non-friable, non-porous, washable materials that are resistant to damage from cleaning and disinfecting products. Some chairs are specifically designed for use in clean rooms, and these should be the preferred choice.

- **Pass-through and/or cart**

- A pass-through should be installed for transferring products into and out of the clean room.
- It is recommended that the pass-through be equipped with an interlocking system that prevents both doors from being open at the same time.

- If there is no pass-through, the **clean room cart** may be used to transport materials from the "clean" area of the anteroom into the clean room.

3.1.1.9. Signage

- Each room must be identified with appropriate and informative signs (e.g., pictograms depicting the need for special care, hazards, restricted access, dress code).

3.1.2. Equipment

3.1.2.1.Primary Engineering Control

- The PEC ensures an ISO Class 5 air quality environment for the exposure of critical sites when sterile preparations are being compounded.
- PEC options for non-hazardous sterile preparations include LAFWs, Class II biological safety cabinets and CAIs. (**For more details regarding Biological Safety Cabinets classification see appendix 5**)
- **Before a PEC is used**,
    - Personnel must read and understand the user's manual
    - The PEC must be installed according to the manufacturer's recommendations and certified by a qualified certifier.
- A PEC must operate continuously during every sterile compounding activity. If the PEC has been turned off, it must be allowed to run for at least 30 minutes, or as recommended by the manufacturer, before cleaning, disinfection and compounding of sterile preparations are undertaken
- The PEC must provide a work area with unidirectional airflow and quality meeting ISO Class 5 or better under dynamic operating conditions.
- The working surface of the PEC must be resistant to damage from cleaning and disinfecting products and must be changed if it becomes damaged.
- If a CAI is in use, the recovery time recommended by the manufacturer (i.e., the waiting time required to achieve ISO Class 5 air quality after materials have been transferred, before aseptic processing is started) must be observed when transferring products from the clean room to the manipulation area.

- Location of primary engineering control and other furniture:

Table (2) Minimum Requirements for Placement of PEC for Compounding Non-Hazardous CSPs

PEC Type	Device Type	Placement for Compounding Category 1 CSPs	Placement for Compounding Category 2 CSPs
LAFS	LAFW	Unclassified SCA	ISO Class 7 positive pressure buffer room with an ISO Class 8 positive pressure ante-room
	IVLFZ	N/Ab	
	BSC	Unclassified SCA	
RABS	CAI or CACI	Unclassified SCA	
Pharmaceutical isolator	Pharmaceutical isolator	Unclassified SCA	ISO Class 8 positive pressure room

3.1.2.2.Other devices, or accessories related to the compounding of sterile preparations

- Equipment used to compound sterile preparations must be clean and disinfected by a sterile disinfectant such as 70% isopropyl alcohol.
- The decision to place equipment, instruments or accessories not directly related to sterile-preparation compounding (carts, cabinets, computer monitors, etc.) in the clean room depends on whether such placement will have an impact on maintaining environmental conditions in the clean room (air quality control, surface sampling, etc.).
- All necessary devices, instruments and accessories must be cleaned and disinfected before being placed in a controlled area.
- Maintenance of devices, instruments and accessories must be recorded in the general maintenance log.
- **Carts**

- If carts are used, one cart must be reserved for the “dirty” area of the anteroom and must remain there. A second cart, dedicated to the “clean” area of the anteroom, may enter the clean room.
- Supplies are disinfected while they are being transferred onto the clean room cart.
- Carts used to bring supplies into the anteroom from outside the controlled area shall not cross the demarcation line. Likewise, carts taken into the anteroom from the clean room shall not be moved beyond the clean side of the demarcation line.

- Carts should be cleaned and disinfected **daily.**

- **Refrigerator and freezer**

- The refrigerator and freezer used to store medications should be commercial biomedical grade units, Domestic refrigerators and freezers must not be used.
- Refrigerators and freezers used for storing medications must not be used to store food. Ideally, refrigerators and freezers are placed outside controlled areas.
- Depending on workflow, refrigerators may be placed in anterooms, provided there is control of particulates through the use of air returns and provided the number of air changes per hour is sufficient to maintain the required ISO air quality classification.

- **Temperature and temperature control**
  - The tested storage temperature in these units must meet the following parameters:
  - Controlled refrigeration temperature: 2°C to 8°C
  - Controlled freezing temperature: –25°C to –10°C
  - Accurate temperature probes (gauges or sensors) must be installed to indicate the actual temperature.
  - A notification system must be installed in each refrigerator and freezer to alert pharmacy personnel when temperatures deviate from specifications.
  - Refrigerator and freezer temperature readings must be recorded on a form stored in the general maintenance log, unless the units are equipped with a continuous temperature recorder.
- Temperature probes must be maintained and calibrated at least once a year or in accordance with the manufacturer's instructions. Calibration of these instruments must be noted in the general maintenance log.

- **Camera and computer equipment**

- Audio-visual and computer equipment used for verification during compounding (camera, monitor, pedal system) is allowed in the clean room under certain conditions.
- The installation and use of accessories (monitor, camera) that can be maintained and repaired without compromising the controlled area is preferred. Equipment cables must be covered to facilitate cleaning.

- **Communication system**

- A functional communication system (intercom, telephone or other) may be installed to

allow verbal communication between the various controlled areas and the pharmacy.

- These devices should be used in "hands-free" mode, must be easy to clean and disinfect and must be resistant to damage from cleaning and disinfecting products.

- **Waste containers**

- A sufficient number of easy-to-clean waste containers of suitable size and made of materials resistant to damage from cleaning and disinfecting products must be available.
- The waste shall be collected in appropriate bags and removed with minimal agitation. The waste containers must be emptied when filled till two third capacity and cleaned at least once a day, at a time when no compounding is occurring

3.1.2.3.**Personal protective equipment and clothing**

- Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck (e.g., gowns)
- Low-lint, disposable covers for shoes
- Low-lint, disposable covers for head that cover the hair and ears, and if applicable, disposable cover for facial hair
- Face mask, Sterile powder-free gloves

3.1.3. Cleaning, Disinfecting, Decontamination, and Deactivation:

3.1.3.1.General

- In the clean room and the anteroom, cleaning and disinfecting procedures must be strictly followed.
- Policies and procedures for cleaning and disinfecting tasks must be developed, and cleaning and disinfecting personnel must be trained and assessed on correct application of these policies and procedures.
- Only trained and qualified cleaning and disinfecting personnel may be allowed to clean the controlled area.
- Cleaning should be performed from the "cleanest" area to the "dirtiest" area (i.e., from the closed end of the clean room toward the anteroom exit).
- Forms or schedules used to document cleaning and disinfecting activities, as per established policy, must be retained in the general maintenance log**. (See appendix 6)**.

3.1.3.2. Different purposes

a. Cleaning agent

An agent used for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.

b. Disinfectant

A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria.

c. Sporicidal agent

A chemical or physical agent that destroys bacterial and fungal spores when used at a sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.

d. Decontamination

Decontamination involves the transfer of a hazardous drug contaminant from a fixed surface (e.g., Counter, bag of solution) to a disposable surface (e.g., wipe, cloth). The wipe is then contained and discarded as hazardous waste.Many solutions can be used for decontamination, for example, 70% isopropyl alcohol, sterile water, hydrogen peroxide and sodium hypochlorite.

e. Deactivation

- Deactivation is the treatment of a hazardous drug to create a less hazardous agent, for example, by chemical deactivation. The material safety data sheets for some hazardous drugs recommend sodium hypochlorite for this purpose, usually as a 2% solution.
- This compound will corrode stainless steel surfaces, so it must then be neutralized with sodium thiosulphate or removed with a germicidal detergent.
- Sodium hypochlorite also has an additional germicidal effect for disinfection.

3.1.3.3. Equipment used for cleaning and disinfection

- To avoid cross-contamination and to protect cleaning and disinfecting personnel, equipment must be specifically designated for cleaning areas used for compounding non-

hazardous sterile preparations.

- Non-shedding equipment must be used for cleaning the controlled areas.
- This equipment (mop heads, towels, etc.) should be disposable.
- If reusable accessories are used, one set of accessories must be dedicated to cleaning ISO Class 5 areas and a separate set dedicated to cleaning ISO Class 7 and 8 areas.
- Cleaning equipment and supplies (mop handle, outside of bottles, etc.) must be disinfected before each entry into a controlled area.

3.1.3.4. Garbing of cleaning staff

- Cleaning and disinfecting personnel must comply with the pharmacy's hand hygiene and garbing procedure before entering sterile compounding areas and performing housekeeping duties.
- Housekeeping personnel must also don gloves and shoes cover before starting their work.

3.1.4. Facility maintenance

- Facility maintenance involves keeping the compounding areas operational within specifications or bringing facility systems, including HVAC, back to satisfactory operating conditions after an interruption. Maintenance must be also performed on equipment within the facility. Facility maintenance activities must be recorded in the general maintenance log.
- The efficiency of HEPA filters in the ventilation system must be tested during facility certification (at least every 6 months), and filters must be replaced periodically as recommended by the manufacturer.

3.1.4.1.Maintenance of primary engineering control

- PECs must be maintained in accordance with the manufacturer's recommendations but certified according to the testing standards, Criteria for PEC testing includes:
    - Every 6 months.
    - When relocated.
    - After major repairs.

  - When viable air sampling indicates that the PEC may not be in compliance with specifications.

- If a PEC on wheels is moved (e.g., to clean under the wheels) and then moved back to exactly the same place, re-certification is not necessary.
- PEC pre-filters must be accessible. They should be inspected every 6 months and replaced if necessary or as recommended by the manufacturer. Washable pre-filters must not be used.
- HEPA filters shall be verified during installation and certification to ensure there are no leaks or damage to the filters after they have been transported or installed.
- Preventive maintenance for PECs and other equipment must be performed when no compounding is in progress, before cleaning and disinfection operations.
- All PEC maintenance and certification, including maintenance of filters and pre-filters, must be documented in the general maintenance log (paper-based or computerized).
- The compounding pharmacy supervisor must ensure that PEC maintenance and certification have been performed.
- The supervisor must review the results or ensure that the results have been reviewed and corrective measures taken, as appropriate. The supervisor must sign the maintenance form.

3.2. Production

3.2.1. Conditions that affect aseptic processing

Personnel with any of these conditions are prohibited from participating in sterile compounding activities or entering sterile compounding areas until the condition is resolved:

- Uncontrolled weeping skin condition
- Burns to the skin, including sunburns
- Cold sores (active herpes simplex viral infection)
- Conjunctivitis (viral or bacterial)
- Active respiratory infection with coughing, sneezing or runny nose.
- Other fresh wounds.

3.2.2. Personal hygiene

Personal hygiene and garbing are essential to maintain microbial control of the environment. Most microorganisms detected in cleanrooms are transferred from individuals. Squamous cells are normally shed from the human body at a rate of 106 or more per hour, and those

skin particles are covered with microorganisms. Individuals entering a compounding area must be properly garbed and must maintain proper personal hygiene to minimize the risk of contamination to the environment and/or CSPs.

3.2.2.1. **Hand washing procedures**

a. Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner (Brushes must not be used for hand hygiene).

b. Wash hands and forearms up to the elbows with soap and water for at least 30 seconds. A closed system of soap (i.e., non-refillable container) to minimize the risk of extrinsic contamination must be readily available or in close proximity to the sink.

c. Dry hands and forearms to the elbows completely with low-lint disposable towels or wipers.

d. Apply an alcohol-based hand rub to dry skin.

e. Apply product to one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry.

f. Allow hands to dry thoroughly before donning sterile gloves (Hand dryers must not be used). **(See appendix 7)**

3.2.2.2. Requirements for Getting Dressed

- Sterile gloves must be donned in a classified room.
- Skin must not be exposed inside the ISO Class 5 PEC (e.g., gloves must not be donned or doffed inside the ISO Class 5 PEC exposing bare hands).
- Donning and doffing garb **(See appendix 8,9)** should not occur in the ante-room or the SCA at the same time. The minimum garbing requirements include:
  - Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck (e.g., gowns or coveralls), covers till below knee
  - Low-lint, disposable covers for shoes
  - Low-lint, disposable covers for head that cover the hair and ears, and if applicable, disposable cover for facial hair
  - Face mask
  - Sterile powder-free gloves
  - If using a RABS, such as a CAI or CACI, disposable gloves (e.g., cotton, nonsterile, sterile) should be worn inside gloves attached to the RABS sleeves.

- Sterile gloves must be worn over gloves attached to the RABS sleeve

- Gowns must be replaced immediately if it becomes visibly soiled or if its integrity is compromised.
- Gowns and other garb must be stored in a manner that minimizes contamination (e.g., away from sinks to avoid splashing).
- When personnel exit the compounding area, garb must be discarded.
- Gowns may be re-used within the same shift if the gown is maintained in a classified area or inside the perimeter of an SCA.
- Gloves must be sterile and powder free. (See appendix 10: gloving technique)
- Application of sterile 70% IPA to gloves must occur regularly throughout the compounding process and whenever nonsterile surfaces (e.g., vials, counter tops, chairs, or carts) are touched.
- All gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected.
- Gloves should be replaced every 30 minutes.
- The RABS sleeves and gloves and the pharmaceutical isolator gauntlet sleeves and gloves should be changed per the manufacturer's recommendations and as defined in the facility's SOP.

3.2.3. Before entering the anteroom

a. Remove personal outer garments (e.g., coat, hat, jacket, scarf, sweater, vest, boots and outdoor shoes);
b. Remove jewellery, studs and other accessories from fingers, wrists, forearms, and face (this includes personal electronic devices or accessories, such as cell phone, iPod and earbuds.
c. Tie up long hair.
d. Remove nail polish and other nail applications (nail extensions and other synthetic nail-lengthening products are prohibited).
e. Ensure that natural nails are kept short and trimmed.
f. Ensure that skin of hands and forearms is undamaged.
g. Change into dedicated, low-shedding apparel suitable for the controlled area (e.g., scrubs).
h. Wear pants that fully cover the legs.

i. Wear closed shoes and socks;
j. Wash hands.

3.2.4. Conduct in controlled areas (clean room and anteroom)

- In controlled areas, the following measures should be taken.
- Food items, drinks, chewing gum, candy and cigarettes are prohibited.
- Not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area.
- All access doors to controlled areas must be kept closed.
- Hand hygiene and garbing procedures must be followed by all personnel in the controlled areas.
- Only essential conversations are allowed, to minimize the risk of particulate contamination. Coughing, sneezing and talking in the direction of the LAFW should also be avoided.

3.2.5. Compounding sterile preparations

3.2.5.1.General

- The aseptic compounding process includes all activities related to completion of the final sterile preparation, including:
    a. Performing hand and forearm hygiene.
    b. Garbing of personnel.
    c. Disinfecting and introducing products and equipment into the clean room.
    d. Disinfecting the PEC.
    e. Disinfecting and introducing products and equipment into the PEC.
    f. Using aseptic techniques to compound sterile preparations in the PEC.
    g. Verifying, labelling and packaging final compounded sterile preparations.
- Personnel must develop work techniques to minimize the risk of cross-contamination and microbial contamination, to avoid errors and to maximize performance of the PEC.
- The number of people in the clean room and anteroom must be limited to the minimum number required to perform aseptic compounding activities.
- Exposure of critical sites must be limited to a PEC that maintains ISO Class 5 air quality requirements.

3.2.5.2. Pre-preparation

Before the compounding of sterile preparations begins, the pharmacist must ensure that:

- Calculations are correct, and the right drugs, equipment, and devices have been chosen.
- Worksheets and labels are done and counterchecked.
- Starting materials are gathered and counterchecked
- Starting materials are sprayed and swabbed with alcohol 70% when put into pass box.

3.2.5.3. During preparation

a. Cleaning of the cabinets:

1. Wear PPE before entering the clean room
2. The cabinet shall be cleaned at the start and the end of each work session
3. Wipe all internal surfaces with sterile alcohol 70% before the start of each work session.
4. The top surface of the cabinet shall be cleaned first, followed by the left and right side and lastly, the working bench
5. The top surface, left and right side and working bench of the cabinet are wiped from the least contaminated area to the most contaminated area using overlapping strokes
6. All soiled wipes shall be thrown into the clinical waste bag
7. After the completion of aseptic preparation, clean the cabinet according to the above procedure using sterile alcohol 70%.

b. Aseptic Processing

- When preparing compounded sterile preparations, compounding personnel must follow strict aseptic procedures.
- Compounding must occur in the critical area (15-20 cm from the front of the PEC) to ensure the sterility of the preparation.
- Each preparation must be completed from start to finish before compounding of another preparation is begun.
- Before reintroduction into the PEC or after contact with a microbiologically contaminated surface, gloved hands must be disinfected with sterile 70% isopropyl alcohol.
- If gloves are torn, they must be removed and hand and forearm hygiene performed

before new gloves are donned. Even without tearing, gloves must be changed regularly.

- Products and supplies must be intact, dry and unsoiled. Otherwise, the products and supplies must be discarded.
- All containers (e.g., bags of solution, vials and ampoules) must be examined before use. Products exhibiting turbidity, cloudiness or particulates must not be used.
- All equipment with surfaces that can be disinfected must be disinfected with sterile 70% isopropyl alcohol before being introduced into the PEC.
- During equipment disinfection, non-shedding wipes or sterile swabs should be changed regularly.
- Vials must be properly arranged and not allowed to accumulate in the PEC to reduce the risk of errors and reduce turbulent air flow from the PEC.
- The compounding pharmacists must perform the following activities:
  - Ensure that all compounded sterile preparations comply with compounding protocols.
  - Verify the identity of the ingredients (drug and diluent).
  - Verify the volume of the ingredients (drug and diluent).
  - Regularly verify the quality of the manipulations.
- **<u>Withdrawal of Solution from Ampoule</u>**

a. Cleaning and Preparation of Ampoule

- Make sure that the ampoule and contents of the ampoule are in good condition, i.e., intact, not expired, clear and no foreign particles
- If the ampoule head contains drug solution, tap the head to ensure that it is empty. If tapping does not work, then invert the ampoule upside down.

b. Fixing Needle to Syringe

- Unwrap the syringe pack and the needle pack
- Hold both the needle and the syringe in one hand
- Fix the syringe to needle with special precaution not to touch the critical sites
- Put the syringe and needle aside to be used later.

c. Breaking the Ampoule

- Swab the neck of the ampoule with alcohol 70%
- Break the ampoule neck; use sterile dressing to prevent injury.
- Discard the ampoule neck immediately into the sharps bin

d. Withdrawing Solution from Ampoule

- Insert the needle into the ampoule cautiously, avoiding contact between the needle and the ampoule neck. Position the needle in the shoulder area of the ampoule so that the bevel tip is facing downwards
- Hold the ampoule in one hand and syringe in the other. Pull the plunger back with the thumb and index finger to withdraw the required volume of drug solution into the syringe using the 'non touch' technique
- Remove air from the syringe and measure the volume of the contents.

- **<u>Adding Diluent to a Vial Containing Powder</u>**

a. Place the vial on the bench. Swab the rubber bung with alcohol 70%
b. Position the syringe at 45° and place the needle (attached to the syringe) on the rubber bung of the vial with the bevel pointing upward
c. Push the needle down and at the same time, pierce the needle through the rubber bung
d. Push the plunger down slowly until the entire diluent is transferred into the vial
e. Pull the plunger to its initial position. This will ensure that there is no pressure difference within and outside the vial
f. Pull the needle slowly out of the rubber and discard the needle into the sharps bin
g. Let the vial stand and swirl for a few minutes in order to dissolve the powder

- **<u>Withdrawing Drug Solution from a Vial</u>**

a. Swab the rubber bung with alcohol 70%.
b. Pull in the required volume of air into the syringe.
c. Place the vial upright in a vertical position and hold firmly.
d. Position the syringe at 45^0 and place the needle (attached to the syringe) on the rubber bung with the bevel pointing upward
e. Push the needle down and at the same time, pierce the needle through the rubber bung
f. Invert the whole set with the vial on top of the syringe.
g. Pull the plunger slightly downwards and then, push upwards slowly to withdraw drug solution into the syringe. Repeat this 'pulse technique' until the entire solution is transferred into the syringe.
h. Place the vial on the working cabinet bench top and pull out the needle from the vial.
i. Remove air bubbles and adjust to the required volume withdrawn.

- **Procedure of Drug Reconstitution in IV drips.**

a. Remove caps of drip bottles and swab the rubber bungs with sterile alcohol 70%
b. A needle with 0.2 μm filter (if applicable) is fix at the injection port of IV drip bottle.
c. Draw out the volume of drug required from vial or ampoule
d. Inject the drug into the drips bottle.
e. Remove syringe, Swab the rubber bungs with alcohol and seal.
f. Label the drip bottle.

Cleaning

a. Remove all broken ampoules, needles and syringes from working bench and floor, and dispose them into a sharps bin.
b. Spread water for injection liberally on the bench and wipe with wipers until dry
c. Start swabbing the BSC as detailed in the cleaning procedure

3.2.5.4. Post-admixing procedure

a. Verification of final compounded sterile preparations

- At the completion of compounding, before release and dispensing, the CSP must be **visually inspected** to determine whether the physical appearance of the CSP is as expected (e.g., it is inspected for evidence of inappropriate visible particulates or other foreign matter, discoloration, or other defects).
- The CSP must be visually inspected to confirm that the CSP and its labelling match the prescription or medication order.
- The inspection also must include a visual inspection of container–closure integrity (e.g., checking for leakage, cracks in the container, or improper seals). CSPs with observed defects must be discarded, or marked and segregated from acceptable units in a manner that prevents them from being released or dispensed.
- **Second verification:** Each preparation must be inspected by a person other than the individual who performed the aseptic compounding. This person must inspect each unit for evidence of particulates, verify the clarity, colour and volume of the solution, check the container for possible leaks and verify its integrity.
- When a CSP will not be released or dispensed on the day of preparation, a visual inspection must be conducted immediately before it is released or dispensed to make sure

that the CSP does not exhibit any defects, such as precipitation, cloudiness, or leakage, which could develop during storage.

b. Labelling of final compounded sterile preparations

The label must contain the following:

- Compounding Pharmacist name.
- Emergency contact information of the compounding pharmacy
- Active ingredient(s) and their concentrations.
- Diluent type and volume.
- Storage conditions.
- Beyond use date (BUD).
- Route of administration.
- Total volume.

c. Packaging of CSPs

- Packaging materials should protect CSPs from damage, leakage, contamination, degradation, and adsorption while preventing inadvertent exposure to transport personnel.
- If the CSP is sensitive to light, light-resistant packaging materials must be used

d. Storage

- The storage temperature for final compounded sterile preparations or products used in preparations must be controlled and kept within known limits regardless of the season.
- A biomedical refrigerator must be available for storing products, ingredients and final compounded sterile preparations that need to be refrigerated.
- The unused preparations returned from the patient care unit to the pharmacy may be reused if it can be shown that they have been properly stored (at the correct temperature, with protection from light, etc.) and there is no evidence of tampering.
- Products that have been stored **must** be inspected before use for evidence of deterioration.

e. Recall of final compounded sterile preparations

- Immediately notify the health care providers of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin…...)
- Determine the severity of the problem and whether a recall is necessary.
- The causes of the problem leading to the recall must be reviewed, and corrective and preventive measures must be identified and implemented.
- Adverse events potentially associated with the quality of the CSP should be reported to the appropriate regulatory body.

f. Returned products

- Dispensed products that were returned and had left the control of the preparation establishment shall be destroyed
- Where any doubt arises over the quality of the product, it shall not be considered suitable for re-use. Any action taken shall be appropriately recorded.

4. SAFE HANDLING OF HAZARDOUS ANTI-CANCER DRUGS

4.1.Background

4.1.1. Definition of a hazardous drug

Drugs are classified as hazardous when they possess any one of the following six characteristics:

- Carcinogenicity.
- Developmental toxicity (including teratogenicity).
- Reproductive toxicity.
- Genotoxicity.
- Organ toxicity at low doses.
- Structure and toxicity profile that mimics existing drugs determined hazardous by exhibiting any one of the previous five toxicity types.

4.1.2. Determining Whether a Drug Is Hazardous

NIOSH's approach to evaluating the hazard potential of a drug includes:

- Reviewing FDA databases to identify drugs that have the potential to meet the NIOSH definition of hazardous drug;
- Reviewing molecular properties and information in the manufacturer-provided drug package insert to identify information relevant to making a determination about adding a drug on the list or removing a drug from the list.
- Assessing, integrating, and synthesizing evidence from human, animal, and in vitro studies of drug toxicity;
- Using the procedures' molecular property, toxicity, and hazard characterization criteria to decide whether to add or remove a drug from the list.
- Allowing for reconsideration of a NIOSH decision to place a drug on the List or to remove a drug from the List.

4.1.3. Developing a Facility-Specific List of Hazardous Drugs

- An entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles.
- The entity's list must be reviewed at least every 12 months. Whenever a new agent or dosage form is used, it should be reviewed against the entity's list.

4.1.4. Potential opportunities of exposure based on activity(2)

Table (3): Potential opportunities of exposure based on personnel activity

Activity	Potential Opportunity of Exposure
Receiving	• Contacting HD residues present on drug containers, individual dosage units, outer containers, work surfaces, or floors
Dispensing	• Counting or repackaging tablets and capsules
Compounding and other manipulations	• Crushing or splitting tablets or opening capsules • Pouring oral or topical liquids from one container to another • Mixing components • Constituting or reconstituting powdered or lyophilized HDs • Withdrawing or diluting injectable HDs from parenteral containers • Expelling air or HDs from syringes • Contacting HD residue present on PPE or other garments • Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs • Maintenance activities for potentially contaminated equipment and devices
Administration	• Generating aerosols during administration of HDs by various routes (e.g. Injection, irrigation, oral, inhalation, or topical application) • Performing certain specialized procedures (e.g., intraoperative intra peritoneal injection or bladder instillation) • Priming an IV administration set
Patient-care activities	• Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid contaminated clothing, dressings, linens, and other materials
Spills	• Spill generation, management, and disposal
Transport	• Transporting of HDs between pharmacy and administration area.
Waste	• Collection and disposal of hazardous waste and trace contaminated waste

4.1.5. Health effects of occupational exposure to hazardous drugs

4.1.5.1.Acute effects

NIOSH concluded that "Various acute toxic effects of antineoplastic agents are well documented in patients treated with high doses of these agents. These include such effects as nausea, rashes, hair loss, liver and kidney damage, hearing loss, cardiac and hematopoietic toxicities and others. Some of these effects have been documented in workers handling antineoplastic agents. A number of studies have shown these effects to be more prevalent in workers exposed to the antineoplastic agents than in control populations."

4.1.5.2.Chronic effects:

NIOSH concluded that "Only a limited number of studies have examined chronic health effects related to occupational exposure to antineoplastic agents. However, chronic effects in patients treated with these agents are well documented. Other areas where chronic effects may be seen are in effects on fertility and the observation of cancer in health care workers handling antineoplastic agents."

4.1.5.3.Effects on fertility and reproductive outcomes:

NIOSH concluded that "Effects on fertility and reproductive health have been seen in a number of studies, mainly in female nurses."

4.1.5.4.Association of exposure to antineoplastic agents with cancer:

NIOSH concluded that "There is a limited amount of evidence in the literature concerning occupational cancer related to antineoplastic agents. There are a few case reports that have appeared in the literature and two epidemiological studies that address this issue. In addition, Sessink et al (1993) have calculated the risk of excess cancer in workers exposed to cyclophosphamide."

4.1.6. Medical surveillance and health assessment

4.1.6.1.General

- Medical surveillance is part of a comprehensive exposure control program complementing engineering controls, safe work processes, and use of PPE. Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program.
- Medical surveillance can also be viewed as a secondary prevention tool that may provide a means of early detection if a health problem develops.
- Tracking personnel through medical surveillance allows the comparison of health variables over time in individual workers, which may facilitate early detection of a change in a laboratory value or health condition.
- Medical surveillance programs also look for trends in populations of workers. Examining grouped data compared with data from unexposed workers may reveal a small alteration or

increase in the frequency of a health effect that would be obscured if individual workers' results alone were considered.

- Medical surveillance evaluates the protection afforded by engineering controls, other administrative controls, safe work processes, PPE, and worker education about the hazards of the materials they work with in the course of their duties.
- The data gathering elements of a medical surveillance program are used to establish a baseline of workers' health and then to monitor their future health for any changes that may result from exposure to HDs.
- Methods used to assess exposure history include a review of:
    - Records of HDs handled, with quantities and dosage forms
    - Estimated number of HDs handled per week
    - Estimates of hours spent handling HDs per week and/or per month
    - Performance of a physical assessment and laboratory studies linked to target organs of commonly used HDs, such as a baseline complete blood count.
- Development of a follow-up plan for workers who have shown health changes suggesting toxicity or who have experienced an acute exposure. This follow-up should include evaluation of current engineering and administrative controls and equipment to ensure that all systems are appropriately and accurately implemented.

4.1.6.2.Pre-Placement Medical Examinations

- The most valuable test in a laboratory assessment is a complete blood count with differential. This allows for a determination of any pre-existing blood condition that may place the worker at increased risk when handling HDs.
- Other laboratory testing (liver function tests and kidney functions tests) may sometimes be appropriate.
- If the medical examination reveals a problem, the personnel should be ruled out.
- This examination should be conducted only at the discretion of the physician, as a function of the medical history obtained, or as part of a formal surveillance program with well-defined goals.

4.1.6.3.Periodic Medical Examinations

- The medical, reproductive, and exposure history should be updated on a periodic basis.

- Health assessment shall be carried out **every 6 months** to prevent possible product contamination from occurring and monitor exposure to cytotoxic drugs.
- If the medical examination reveals a problem, the personnel should be ruled out.
- Biological monitoring to determine blood or urine levels of specific HDs is not currently recommended in surveillance protocols, but may have a role in the follow-up of acute spills with a specific agent.

4.1.6.4.Post-exposure Examinations

- Post-exposure evaluations are tailored to the type of exposure (e.g., spills or needle sticks from syringes containing HDs).
- An assessment of the extent of exposure is made and included in an incident report.
- The physical examination focuses on the involved area of the body, as well as other organ systems commonly affected (i.e., for a spill, the skin and mucous membranes of the affected area; for aerosolized HDs, the pulmonary system).
- The examination may involve assessment and documentation of symptom complaints, physical findings, chest X-ray, and laboratory values (such as a blood count) to determine whether there is a deviation from the expected norms.

4.1.7. NIOSH Hierarchy of Controls

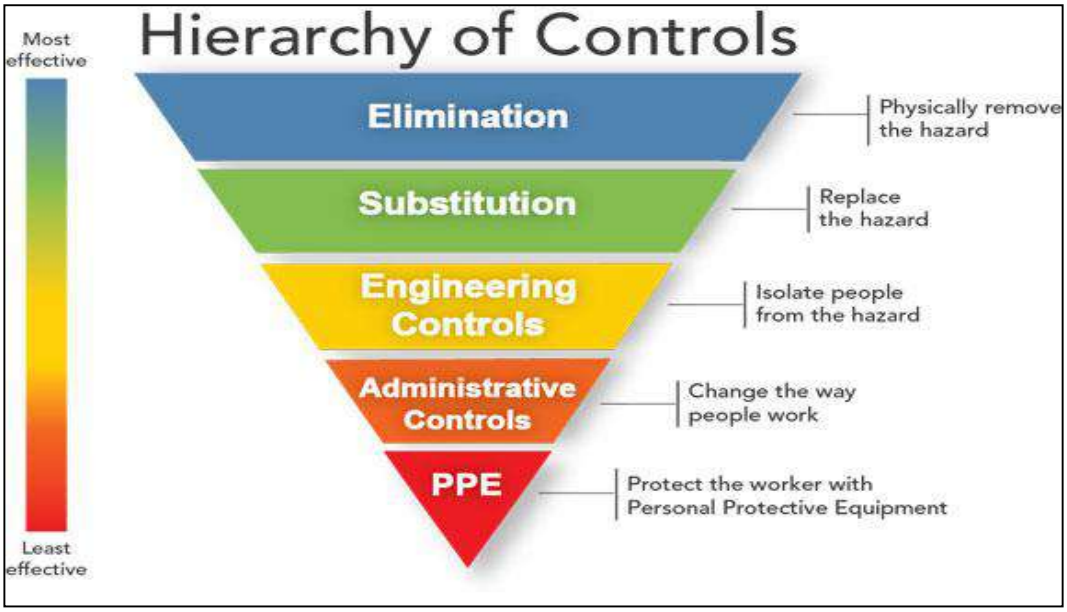


Figure (5) NIOSH Hierarchy of Controls

Hazardous drugs should be handled in a manner to ensure:

- The safety of personnel
- The accuracy and appropriateness of the drug and dose
- Protection of the patient
- Protection of the environment
- Minimum exposure of hazardous drugs to pharmacy personnel, nursing staff, allied health staff and patients.

4.1.8. Receipt and storage of hazardous products:

4.1.8.1.Receipt of hazardous products

- All antineoplastic hazardous drugs (HDs) and hazardous Active Pharmaceutical Ingredients (APIs) must be unpacked in a neutral/normal or negative pressure environment.
- Products used for preparations must be unpacked outside of controlled areas to limit the introduction of dust and particles into the controlled areas.
- Packaging within delivery containers (e.g., cartons, bubble wrap, foam, and filling materials) that has not come into direct contact with product vials may also be considered not chemically contaminated and may be discarded in regular waste containers. These materials should not be used for other purposes.
- **If the shipping appears damaged:**

- Seal container without opening and contact the supplier
- If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous" If the supplier declines return, dispose of as hazardous waste

- **If a damaged shipping container must be opened**

- Seal the container in plastic or an impervious container
- Transport it to a C-PEC and place on a plastic-backed preparation mat
- Open the package and remove undamaged items
- Wipe the outside of the undamaged items with a disposable wipe
- Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous"
- If the supplier declines return, dispose of as hazardous waste (Deactivate,

decontaminate, and clean the C-PEC) and discard the mat and cleaning disposables as hazardous waste

- If a spill has occurred inside the container, box or outside bag, then all packaging materials must be considered chemically contaminated and must be discarded in a hazardous (cytotoxic) waste container.
- Manufacturer's boxes or individual packaging that has been in direct contact with vials containing hazardous products is to be considered chemically contaminated and must be discarded in a hazardous (cytotoxic) waste container.
- For unpacking intact hazardous products that have been received from the supplier sealed in impervious plastic, one pairs of chemotherapy gloves are required
- For unpacking potentially damaged hazardous products, the following garb is required:
    - Two pairs of chemotherapy gloves
    - Gown approved for the compounding of hazardous sterile preparations
    - Hair, face, beard and shoe covers
    - Eye protection (goggles) and a face shield or full face-piece respirator
    - Chemical cartridge respirator

4.1.8.2.Storage of hazardous products:

- HDs must be stored in a manner that prevents spillage or breakage if the container falls.
- Do not store HDs on the floor.
- HD must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure.
- Hazardous drugs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH).
- Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH.
- For final hazardous compounded sterile preparations or hazardous products used for such preparations, the storage temperature must be controlled and must remain within the limits and within the range specified by the BUDs of final preparations and products, regardless of the season.
- Products that have been stored must be inspected before use, for evidence of deterioration.

4.2. Cytotoxic drug reconstitution

You should check the facilities and equipment specifications mentioned in section (3) and consider the following differences:

4.2.1. Engineering controls

- All C-PECs used for manipulation of sterile HDs must be externally vented.
- Sterile HD compounding must be performed in a C-PEC that provides an ISO Class 5 or better air quality, such as a Class B II or III BSC or CACI.
- Class II type B2 BSCs are minimally required for use with volatile chemotherapies.
- A horizontal laminar flow cabinet **must not** be used to prepare hazardous drugs because of the risk of aerosolized drug particles being propelled out of the cabinet on to personnel and into the room.
- A BSC or CACI used for the preparation of HDs must not be used for the preparation of a non-HD unless the non-HD preparation is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions.
- The C-PEC must be located in a C-SEC, which may either be an ISO Class 7 buffer room with an ISO Class 7 ante-room (preferred) or an unclassified containment segregated compounding area (C-SCA).
- A C-PEC should operate continuously, 24 hours a day. If the C-PEC has been turned off, it must be allowed to run for at least 30 minutes, or as recommended by the manufacturer, before decontamination, cleaning and disinfection and then compounding of hazardous sterile preparations are undertaken.
- The clean room must be physically separated from the rest of the pharmacy and from other non-controlled areas, to reduce the risk of introducing viable and non-viable contaminants into the room and the spread of hazardous drug contamination outside the room.
- Many hazardous drugs can volatilize at room temperature. Therefore, they must be stored within a negative-pressure room.
- **Rrequirements that must be met in the clean room (hazardous sterile preparations)**:

- Maintain **negative pressure** to prevent air that might be contaminated by hazardous products from leaving the clean room.
- The pressure differential between the anteroom and the clean room must be at least 2.5 Pa to maintain unidirectional airflow from the anteroom to the clean room.

- The pressure in the anteroom must be **positive**. The pressure differential must be at least 5.0 Pa relative to the pharmacy adjacent to the anteroom.
- Ensure that construction quality is sufficient to guarantee that controlled rooms are airtight.
- Regardless of the two preceding principles, do not depressurize the clean room excessively to prevent non-filtered air from penetrating through gaps in the construction (since no room will be perfectly airtight).
- Protect pharmacy personnel (by means of air exhausts).
- An **eye wash station** should be located in the anteroom and a **safety shower** should be readily accessible. Eyes that become contaminated should undergo sustained irrigation with either a commercial eye irrigation solution or sodium chloride (0.9%). Due to the potential for water pressure damage to the eye, it is not recommended to irrigate the eye directly with running water from a tap (ISOPP Standards of Practice 2007).
- The return air from the clean room must be externally vented.
- The temperature in the controlled rooms must be less than or equal to 20°C, taking into account employees' comfort once all clean room garb (including PPE) has been donned.

Shared anteroom

The sole anteroom is connected to both clean rooms for the compounding of sterile preparations (hazardous and non-hazardous) and is shared for hand hygiene and garbing activities of personnel working in the two clean rooms.

4.2.2. Personal protective equipment and clothing

4.2.2.1.Gloves

- Two pairs of chemotherapy gloves are required for compounding sterile HDs.
- Two pairs of chemotherapy gloves are required for administering injectable antineoplastic HDs.
- Chemotherapy gloves must be powder-free because powder can contaminate the work area and can adsorb and retain HDs.
- Before using gloves, make sure they are free of physical defects. Gloves with pinholes or weak spots should not be used. Chemotherapy gloves should be replaced every 30 minutes and whenever they become torn, punctured, or contaminated.

- Hands must be washed with soap and water after removing gloves.

4.2.2.2.Gowns

- Gowns should be disposable and shown to resist permeability by HDs.
- Disposable gowns made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials.
- Gowns must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit.
- Gowns must not have seams or closures that could allow HDs to pass through.
- When handling HDs, cloth lab coats, surgical scrubs, isolation gowns, or other absorbent materials are not appropriate protective outerwear because they allow HDs to permeate and can trap spilled drugs against the skin, increasing exposure.
- Clothing may also retain HD residue from contact, and may transfer to other healthcare workers or various surfaces.
- Potentially contaminated clothing must not be taken home under any circumstances.
- Gowns must be changed per the manufacturer's information for permeation of the gown.
- If no permeation information is available for the gowns used, change them every 2-3 hours or immediately after a spill or splash.
- Gowns worn in HD handling areas must not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.

4.2.2.3. Head, Hair, and Shoe Covers

- Head and hair covers (including beard and moustache, if applicable), shoe covers, and sleeve covers provide protection from contact with HD residue.
- When compounding HDs, a second pair of shoe covers must be donned before entering the C-SEC and doffed when exiting the C-SEC.
- Shoe covers worn in HD handling areas must not be worn to other areas to avoid spreading HD contamination and exposing other healthcare workers.

4.2.2.4. Mask

- Surgical masks do not provide respiratory protection against drug exposure and therefore

should not be used when respiratory protection from hazardous drug exposure is required.

- For most activities, an N95 or N100 mask will protect against airborne particles.
- N95 or N100 masks offer no protection from vapours, gases and little protection from direct liquid splashes.
- A chemical cartridge respirator with a pre-filter must be worn in the presence of vapours, gas and particles (e.g., dust) or if there has been a spill. A cartridge that protects against the chlorine found in chlorinated disinfectants used for cleaning the C-PEC or for chemical decontamination after a spill may also be considered, to help prevent irritation of airways.
- Any mask must first be fit-tested.
- The mask must be changed at the earliest of the following: after 3.5 hours of continuous compounding work, after each removal or if contamination has occurred or is suspected.

4.2.2.5.**Disposal of Used Personal Protective Equipment**

- Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs.
- PPE must be placed in an appropriate waste container and further disposed of per local regulations.
- PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC.
- Chemotherapy gloves worn during compounding must be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.
- **De-gowning sequence**
  1. Remove outer layer of gloves, dispose into cytotoxic waste bag in the clean room
  2. Mask
  3. Footwear
  4. Gown
  5. Head cover
  6. Inner pair of chemo gloves
  7. Wash hands and dry

4.2.3. Production

(See the previously mentioned details and consider the following points)

Important Tips for compounding hazardous drugs[)]:

- Use syringes with sufficient capacity to avoid filling more than 75% of the barrel length of the syringe, but small enough to measure the contents with acceptable accuracy, as follows:
  - 3 mL syringe no more than 2.3 mL
  - 5 mL syringe no more than 3.8 mL
  - 10 mL syringe no more than 7.5 mL
  - 20 mL syringe no more than 15 mL
  - 30 mL syringe no more than 22.5 mL
  - 60 mL syringe no more than 50 mL
- Avoid pushing too much air into the vial. This is to avoid positive pressure being developed in the vial, which could lead to aerosolization of the cytotoxic drug
- Techniques and devices used in the safe and accurate withdrawal of hazardous drugs from a vial should support minimizing the production/release of hazardous drug aerosols and vapours, maintaining the sterility of hazardous drugs and preventing leakage/spillage
- Whenever possible, hazardous drugs should be drawn into syringes using closed-system drug transfer devices with locking connections.
- Check reconstituted solutions to ensure complete dissolution before withdrawal from the vial/ampoule or when storing for future use.
- Adjust solution volume and/or eliminate any air bubbles in the syringe before taking the needle out of the vial.
- Luer-locking syringes should be used, whenever possible.
- Cap needles upon filling using a hands-free system or attach a luer-tip.
- Close attached intravenous sets and secure from any hazardous drug leakage.
- Visually inspect the final product for particulate matter, physical incompatibility or leaks. In some provinces, a licensed pharmacist must inspect the final product. Pharmacists should routinely inspect all products for **intrathecal use** with the **aid of a lamp**.

4.2.4. Post admixing procedure:

4.2.4.1.Verification (see section 3)

4.2.4.2. Labelling of final hazardous compounded sterile preparations

Each container for a hazardous compounded sterile preparation must be labelled. A label must be affixed to each prepared unit.

a. Compounding pharmacist must label the following items:

- Final hazardous compounded sterile preparations.
- Each unit of a hazardous compounded sterile preparation for an individual patient, along with required auxiliary labels.
- Each unit of hazardous sterile preparations compounded in batches (with, at a minimum, drug name, concentration, route of administration, batch number and bud).

b. Labelling:

The label must contain the following information, at a minimum:

- Compounding Pharmacist name
- Emergency contact information of the compounding pharmacy
- Active ingredient(s) and their concentrations.
- Diluent type and volume
- Storage conditions
- Beyond use date (BUD)
- Route of administration
- Total volume.
- Hazardous warning sign.

4.2.4.3. Packaging:

- Appropriate packaging must be used for all preparations to be delivered to patients or other health care providers. Preparations to be delivered must be packaged and labelled to ensure the safety of both the patient and the shipper. The package must be appropriate to maintain the stability and integrity of the preparation.
- Put each final hazardous compounded sterile preparation in a clear plastic bag (or an amber bag, if the preparation must be protected from light).

5. BEYOND USE DATE AND SAVING POLICY

5.1.Background:

- **Beyond-use Date**: Either the date, or hour and date, after which a CSP must not be used. The BUD is determined from the date/time that preparation of the CSP is initiated.
- **Expiration Date:** The time during which a product can be expected to meet the requirements of the monograph, or maintain expected quality under the specified storage conditions.
- **The BUD must not be later than the earliest of the dates determined by the two criteria:**
  - Expiration date based on chemical and physical stability according to reference texts
  - Storage time related to risk of microbial contamination.
- The BUDs for CSPs are based primarily on factors that affect the achievement and maintenance of sterility, which include, but are not limited to, the following:
  - Environment in which the CSP is prepared (e.g., PEC in a cleanroom suite or SCA)
  - Aseptic processing.
  - Storage conditions (e.g., packaging and temperature)
- The results of the stability studies published in the international publications should be carefully compared with the conditions of the local production in terms of solvent, container, temperature, humidity, light, concentrations and transport conditions if applicable. The extrapolation of the results should be justified[19].

5.2.CSP Categories

- According to USP 797 there are two categories of CSPs, Category 1 and Category 2, primarily based on the conditions under which they are made, the probability for microbial growth, and the time period within which they must be used.

Table (4) CSP categories

	Category 1 CSPs	Category 2 CSPs
	Buildings and Facilities	
Placement of the primary engineering control (PEC)	Not required to be placed in a classified area	Required to be placed in a classified area
BUD		
BUD assignment	≤12 hours at controlled room temperature (20°–25°) or ≤24hours if refrigerated(2°–8°)	>12 hours at controlled room temperature (20°–25°) or >24 hours if refrigerated(2°–8°)

Table (5) BUD for Category 2 CSPs

Preparation Characteristics	Storage Conditions		
Aseptically processed CSPs	**Controlled Room Temperature (20°–25°)**	**Refrigerator (2°–8°)**	**Freezer (−25° to −10°)**
	Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days

5.3.Beyond-use dates for commercially available products according to type of container

5.3.1. Open ampoule

- No storage of an open ampoule is permitted; as such, no BUD applies.

5.3.2. Single-dose vial

- A single-dose vial will be labelled as such by the manufacturer.
- If the vial is punctured in a PEC that maintains ISO Class 5 air quality, the BUD is 12 hours.
- Once the vial is removed from the ISO Class 5 PEC, it must be discarded.
- To properly manage risk, a label must be affixed to the vial indicating the time of initial needle puncture.
- The contents of a vial may not be divided for the sole purpose of extending stability.
- If the vial or another single-dose container is opened or punctured in an environment with air quality worse than ISO Class 5, the BUD is 1 hour.

5.3.3. Multiple-dose container

- A multiple-dose container will be labelled as such by the manufacturer.
- Multiple-dose containers usually contain a preservative.
- The BUD is 28 days, unless otherwise specified by the manufacturer.
- If there is visible contamination before 28 days (or the manufacturer's expiry date), the container must be discarded.

5.4.Consider the following factors when establishing the beyond-use date:

- The patient's rights protection.

- The availability of qualified and trained Persons.
- Checking the trusted information resources (BC Cancer stability charts, STABILIS)
- Strict Aseptic Processing.
- Standardized procedures.
- Appropriate storage conditions considering stability, sterility issues.
- Finally, you should know that one size does not fit all.

5.5.Drug saving policy

5.5.1. Drug Saving Justifications

- Dose fractions.
- Returned Preparations (Ex: Severe side effects, case deterioration and/or death)
- **Vials Overfill**: "a volume that slightly exceeds the content indicated in the labelling. The excess volumes are meant to be sufficient to permit withdrawal and administration of the labelled volumes".
- Case rescheduling:(Scheduling the similar protocols on the same day).
- Appropriate establishing of the BUDs.

5.5.2. Internal oversight

- Pharmacy manger should design an excel sheet **(See appendix (11))** to count and control the saved vials flow (**see appendices**).
- The saved vials should be subtracted from the consumption rate to figure out the real consumption rate.
- The saved vials should be counted and returned to the main store **(Weekly or Monthly according to the workload).**
- The higher manger can determine a sum of money as a reward to which persons are pursuing policies related to aseptic processing, safe handling, and savings.

6. PHARMACY AS A CO-ORDINATION CENTRE

6.1.Transport and delivery of hazardous compounded sterile preparations:

- Policies and procedures must be developed and implemented for the transport of hazardous compounded sterile preparations and their delivery to patient care units, pharmacists and patients.
- A policy for return of expired or unused hazardous compounded sterile preparations from the patient care unit in a health care facility must also be developed.
- In health care facilities**, unused preparations returned** from the patient care unit to the pharmacy may be reused if it can be shown that they have been properly stored (at the correct temperature, with protection from light, etc.) and there is no evidence of tampering.
- Hazardous compounded sterile preparations must be transported in **rigid containers** marked "Cytotoxic" and designed to minimize the risk of cracking or failure of the preparation containers.
- All personnel involved in transporting hazardous compounded sterile preparations must be trained in the procedures for such transport and for spills or accidental exposure.

6.2.Administration

- HDs must be administered safely using protective medical devices and techniques. Examples of protective medical devices include needleless and closed systems. Examples of protective techniques include spiking or priming of IV tubing with a non-HD solution in a C-PEC and crushing tablets in a plastic pouch.
- **IV set Priming**

- Removing air from the tubing with a compatible solution, followed by priming.
- It is recommended to be performed by the pharmacist inside the engineering controls.
- Appropriate PPE must be worn when administering HDs.
- After use, PPE must be removed and disposed of in a waste container approved for trace-contaminated HD waste at the site of drug administration.
- Equipment (such as tubing and needles) and packaging materials must be disposed of properly, such as in HD waste containers, after administration.
- Luer-locking devices should be used, whenever possible.
- Administration into certain organs or body cavities (e.g., the bladder, eye, peritoneal

cavity, or chest cavity) often requires equipment for which locking connections may not be readily available or possible.

- Liquid formulations are preferred if solid oral dosage forms are not appropriate for the patient. If HD dosage forms do require manipulation such as crushing tablet(s) or opening capsule(s) for a single dose, personnel must don appropriate PPE and use a plastic pouch to contain any dust or particles generated

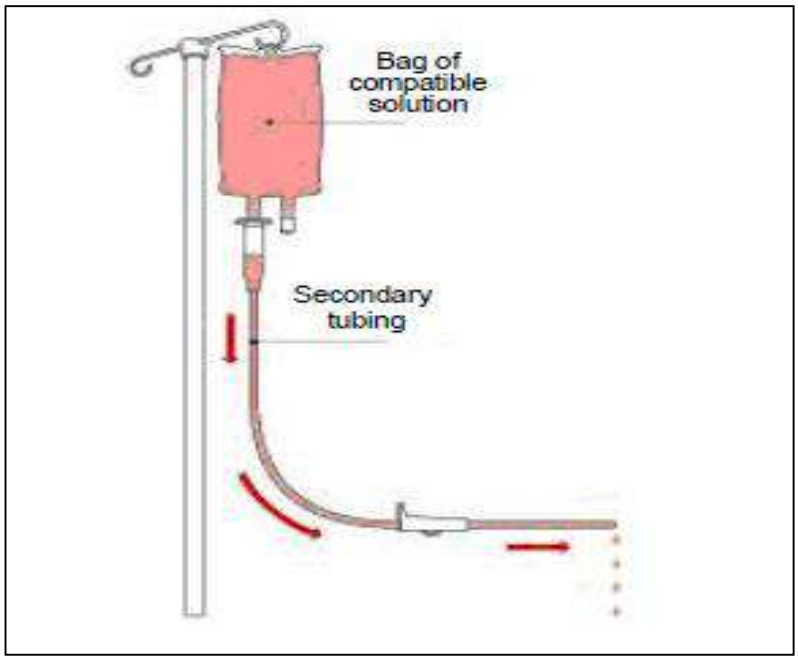


Figure (6) represents iv set priming

6.3.Handling drugs with special route of Administration

6.3.1. Handling oral drugs

- Hazardous drugs for oral use must be handled in a manner which avoids skin contact or powdered drug into the air and cross-contamination with other drugs.
- Additional precautions include:

a. Use of protective gloves to dispense oral hazardous drugs is recommended.
b. Hands must be washed thoroughly after each dispensing.
c. Designated counting trays should be used and cleaned after each use.
d. Suitable containers for dispensing must be used to avoid any adverse storage effects on the hazardous drug childproof caps must be used when dispensing non-blister packs of containers of oral chemotherapy for use outside the health care setting.

e. All layers of packaging and containers must have a hazardous warning label.

6.3.2. Intrathecal administration

- A dated and annually reviewed procedure for the safe dispensing, release and receipt of intrathecal drugs should be available.
- A register lists the designated, trained, and authorised personnel to prescribe, dispense, release, check and administer intrathecal chemotherapy.
- For all aspects of storage, prescription and administration of intrathecal chemotherapy current documented procedures are in place.
- The intrathecal prescriptions are screened by a pharmacist and preferably double checked and signed by a clinical pharmacist.
- Labels have the route of administration printed clearly in the largest font size possible.
- For Vinca alkaloids, a clear warning of the consequences of administration by other routes has to be added i.e. **„For Intravenous Use Only - fatal if given by other routes ".**

6.3.3. Other routes of administrations and specific therapies

- **Trans-arterial chemoembolization (TACE), hyperthermic intraperitoneal chemotherapy (HIPEC) and intravesical**
- Specific administrations of anticancer drugs require extra attention from all the staff (including pharmacist) involved in conducting the procedure. Pharmacists should give advice to make sure that a proper way of handling of the anticancer drugs and waste is carried out and that all the necessary PPEs and devices are used.

6.4. Hazardous Drug Spills

- Hazardous drug spills should be cleaned up immediately by properly trained personnel following established policies and procedures for spill management and clean up.
- Spill kits, containing all materials and equipment necessary to clean a spill, should be available and readily accessible at each area where hazardous drugs are received, stored, prepared and administered. Spill kits may be assembled or purchased.
- Key components of a spill kit include:

- 2 pairs of protective gloves
- Impermeable protective gown, hair and shoe covers
- Safety glasses or splash goggles

- NIOSH approved respirator mask
- Absorbent plastic backed sheets or spill pads
- Incinerable absorbent material (e.g. Gauze pads, spill towels, absorbent polymer)
- Decontaminating agent (e.g. Detergent and water or commercial equivalent decontamination towelettes)
- At least 2 sealable plastic waste bags marked "hazardous drug waste"
- Warning sign and plastic "caution tape" (e.g. To quarantine spill area)
- Disposable scoop (e.g. For collecting glass fragments)
- Puncture-resistant container (e.g. For glass fragments)
- Instructions on the management of a hazardous drug spill
- Institutional report forms for recording the spill incident.

- All individuals who routinely handle hazardous drugs should be trained in proper spill management and cleanup procedures and should be required to demonstrate competence in spill management. Training and competency assessment should be documented.
- The circumstances and handling of each hazardous drug spill should be documented. Health care personnel exposed during spill management should complete an incident report or formally document the hazardous drug exposure.

6.5.Waste management

- Ensure that medications and sharp or pointed instruments are disposed of safely, in compliance with environmental protection laws in force in the jurisdiction;
- Ensure that medications to be destroyed are safely stored in a location separate from other medications in inventory.
- Develop and implement a procedure for destruction of pharmaceutical waste.

Hazardous Drug Waste

- Written policies governing the identification, containment, collection, segregation and disposal of hazardous drug waste materials should be established and maintained.
- All hazardous drug waste should be separated from general waste.
- All hazardous waste should be separated between breakable and non-breakable and placed in specially marked thick plastic bags or leak-proof containers specifically labeled containers labeled with the hazardous drug hazard symbol. Receptacles should be kept in

all areas where hazardous drugs are prepared or administered.

- Contaminated needles, syringes, ampoules, broken glass, vials, intravenous sets and tubing, intravenous and intra vesical catheters should be placed into designated leak-proof and puncture proof sharps containers that clearly and visibly display the hazardous drug symbol. They are placed in the BSC as needed, and when full, are transferred to the oncology waste container.
- Non-breakable contaminated materials including disposable gowns gloves, gauzes, masks, intravenous bags etc. should be placed in 4 ml thick, sealed plastic bags, hard plastic or hazardous drug containers that clearly and visibly display the hazardous drug hazard symbol. When full, they are placed in the oncology waste container.
- Institutional procedures should be in place to ensure hazardous drug waste is collected, stored and removed from the facility in an appropriate manner.
- Hazardous drug waste should be disposed in accordance with all applicable provincial, federal and local regulations for the handling of hazardous and toxic waste.
- Un-reconstituted or unopened vials, ampoules, or bottles should be returned with permission to the distributing agent.

7. A BETTER COMPLIANCE STRATEGY

- It's time for best practices to become common practice in today's hospitals and health systems for compounding sterile hazardous and non-hazardous drug. That's why our team remains resolute in our efforts to create and develop solutions that may help you solve high-level challenges and drive better performance.
- **Perform a thorough gap analysis (using this suggested strategy):**

1. Read and absorb this guide carefully.
2. Determine and list your activities (Sterile hazardous/non-hazardous).
3. Compare your pharmacy's current procedures with this guide and other recommended sources.
4. Identify the bottom line/ minimum requirements.
5. List your needs.
6. Categorize your needs to two main classes:

a. Easy to accomplish

- Develop hazardous drug list.
- Cleaning, decontamination, disinfection and deactivation
- Proper hand washing techniques.
- Teach staff correct policies and procedures.
- Make suitable PPE available.
- Develop and implement a systematic competency evaluation process.
- Run it by the higher managerial stuff (Remember, be persuasive using a high quality evidences).

b. To be planned (One year)

Primary and Secondary engineering controls

7. **Follow up and evaluate the progress.**

هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
الإدارة العامة للممارسات الدوائية والصيدلية

CHAPTER IV

CLINICAL ONCOLOGY

PHARMACY PRACTICE

1. INTRODUCTION

For many years, the pharmacist's activities were exclusively directed to dispensing and handling drugs, but the initiatives to promote the role of the pharmacist in the clinical pharmacy are increasing. Proper education and development of clinical skills allowed them to evolve their roles and responsibilities in healthcare. Furthermore, technology was able to free this profession from purely administrative activities.

In oncology, due to the complexity of chemotherapy treatment protocols, targeted therapy, immunotherapy and cellular therapy, the diverse oncology drugs launched onto the market annually, and the use of supportive medications, the presence of the pharmacist in the multidisciplinary team is essential to contribute to patient safety.

Management and prevention of problems related to oncology drugs are particularly important due to the excessive cost, high toxicity, and narrow therapeutic index of antineoplastic drugs, in addition to the patients' state of health. With the presence of a properly trained clinical pharmacist, it is possible to provide education to other team members on medications and institutional protocols and to manage drug administration, monitoring, and patient education.

Studies Documenting the Value of the Oncology clinical Pharmacist

Perceptions and expectations of healthcare providers towards clinical pharmacy services at a tertiary cancer center in Qatar, healthcare professionals in the cancer center in Qatar, NCCCR, have a positive perception towards the role of clinical pharmacists in appropriate therapeutic management and patients' education and significant role in optimized dosing of chemotherapy. Most of the healthcare providers (74%) perceived the increasing interest in clinical pharmacy services. Also, they expected

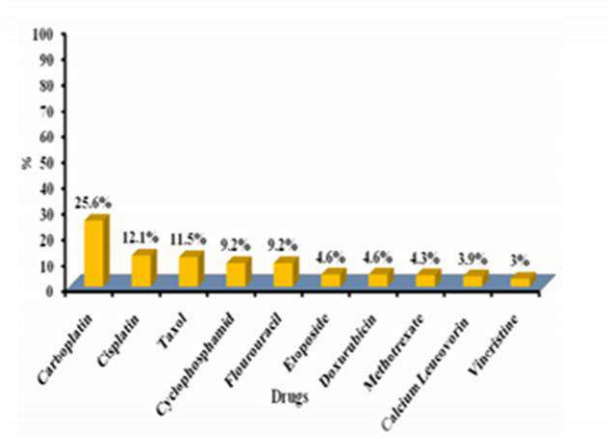
- Providing consultations regarding appropriate medication choices (82%);
- Providing information about medication availability and shortages (82%)
- Assisting in the prescribing of cost-effective drugs by providing
- Pharmacogenomics information routinely (75%), and
- Participating actively in research activities (74%).
- Overall, healthcare providers have a high level of trust in the clinical pharmacists' abilities.

Another Egyptian study demonstrated Rates and types of prescribing errors and related interventions in oncology, oncology trained pharmacist, it's the study on Alexandria Main University Hospital, about Types and quantities of prescribing errors.

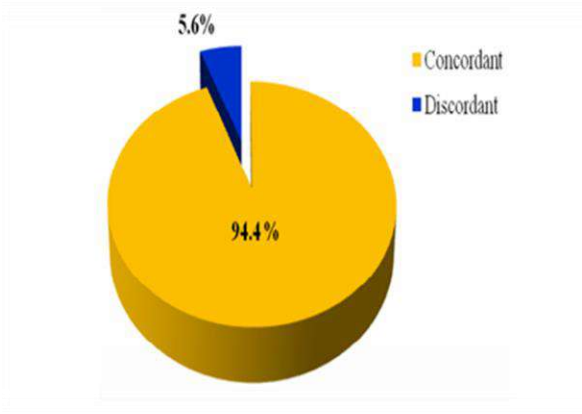
The methodology of this study is reviewing 700 chemotherapy medication orders in 42 days, it was found that on average, pharmacists reviewed the17 medication orders /day of the top 10 drugs involved in the chemotherapy medication orders errors.

Among the reviewed medication orders, a total of 462 prescribing errors were detected and therefore the proportion of errors in chemotherapy medication orders was 66% and the physician/pharmacist percent concordance was 94.4% as shown in this figure

The top 10 drugs involved in chemotherapy medication orders errors and in interventions (Adult Oncology Clinic, Main Hospital, Alexandria)



Distribution of physician/pharmacist concordance/discordance after interventions (Adult Oncology Clinic, Main Hospital, Alexandria)



2. PROFESSIONAL KNOWLEDGE AND SKILLS OF HEMATOLOGY/ONCOLOGY PHARMACIST

The American College of Clinical Pharmacy describes oncology clinical pharmacists as practitioners who provide comprehensive medication management and related care for patients in all health care settings. Clinical pharmacists work with physicians, other health professionals, and patients to ensure that prescribed medications contribute to the best possible health outcomes.

They are also involved in the assessment of care, including medication history and reconciliation, counseling patients, supporting the healthcare team, and monitoring and evaluating therapies for their appropriateness and effectiveness. The Hematology/Oncology Pharmacy Association (HOPA) developed a scope-of-practice document that details the competencies and training of oncology clinical pharmacists.

2.1.Basic knowledge required for oncology clinical pharmacists

Oncology clinical pharmacists require basic knowledge related to:

- Tumor type.
- Epidemiology.
- Clinical features of the cancer disease and risk factors.
- Diagnosis including pathology and histologic subtypes.
- How treatment may differ by subtype, staging, and grade.
- Different anti-cancer medications, their mechanism of action, and adverse effect.
- Treatment options including the risks and benefits of various therapies.
- Basic knowledge of clinical trials and research.4
- Continuous education and professional specialization programs are to keep personnel informed about the latest developments in science and technology.
- Oncology clinical pharmacists should regularly contribute to relevant clinical activities such as ward rounds, ward meetings, case presentations, journal clubs, and lectures.

- Oncology clinical pharmacists should use the principles of scientific inquiry and be prepared to think analytically, clearly, and critically while solving problems during daily practice. They should be able to systematically find, appraise, and apply information to make informed, evidence-based decisions.

2.2.TEAM WORK

The oncology Clinical pharmacist should work as a member of the healthcare team. The establishment of a good working relationship with other health professionals, patients, and/or carers, as well as other stakeholders, forms the basis of successful clinical practice.
Ex: the Collaborative Physician-Pharmacist–Managed Multiple Myeloma Clinic improves guideline adherence and prevents treatment delays model, the physician, and clinical pharmacist made treatment recommendations that encompassed all key clinical areas identified as interventions necessary based on national guidelines.
These included venous thromboembolism (VTE) risk stratification and prophylaxis, anti-infective drugs indicated (antiviral, antibacterial, and prophylaxis for Pneumocystis jirovecii pneumonia [PJP]), bisphosphonate use for bone health (drug, dose, dose adjustment, contraindication, and monitoring), and timely and appropriate administration of vaccinations. at admission, discharge, and transfer.

3. COMPREHENSIVE PHARMACEUTICAL CARE PROGRAM

3.1.Medication history taking and reconciliation of hematology/oncology patient

Medication history taking and reconciliation include an effective process to reduce errors and harm associated with loss of medication information during new admission, transitions of care, and discharge. It is a collective and collaborative, multidisciplinary, and professional responsibility.

- A complete list of a patient's current medications, allergies, and medication sensitivities should be obtained and documented upon admission to the organization in all relevant sites of care.
- Patients transferred between services or levels of care should have all medications reconciled. If a new medication is prescribed or changes are made to the current

regimen, the patient's medication list in the health record should be updated, and a copy of the updated list provided to the patient.

Medication history taking and reconciliation, the oncology clinical pharmacists must have readily accessible information on:

- Diagnosis and stage of cancer or disease and patient vital signs.
- Risk Factors and Comorbidities.
- Cancer therapies regimen including medicines and doses, and other relevant treatment modalities such as radiotherapy and surgery.
- Intent or goal of treatment (i.e. Curative, palliative).
- Type of treatment relative to other modalities (e.g. Adjuvant, neo-adjuvant).
- Height, weight, and body surface area.
- Relevant laboratory and clinical diagnostic measurements (e.g., renal function, pulmonary function, left ventricular function, mutation testing).
- Reported signs and symptoms of toxicity.
- Preferred supportive care therapies (e.g., Pre-medications, antiemetics).
- Cumulative medicine doses where appropriate (e.g. Anthracyclines, bleomycin, Carmustine).
- Past cancer therapies.
- Oral chemotherapy.

A complete list of medications should be given to the patient upon discharge and communicated to the next known provider or service when the patient is referred or transferred to another setting, service, practitioner, or level of care within or outside the organization.

3.2.Pharmaceutical care plan.

The American Society of Health-System Pharmacists (ASHP) published guidelines in 1990, 1993, 1996, and 2002 to describe a pharmacist's role not only in safe handling, preparation, and dispensing of drugs but also in pharmaceutical care plan as the health professional who

is directly responsible for the provision outlined for medication-related care to achieve definite outcomes that improve a patient's quality of life.

This role has a direct impact on patient care and helps the patient in the recovery phase between treatment cycles and adherence to chemotherapy treatment schedules essential for optimal treatment and outcome.

The care plan that is created and agreed upon includes the systematic analysis of all drug-related questions concerning therapy and follows the widely used SOAP formula that has received multi-professional recognition:

- **S** = subjective: the patient 's subjective complaints and problems are described or inquired about and then documented.
- **O** = objective: identifiable and measurable, objective parameters and symptoms are determined and documented.
- **A** = Assessment: the objective and subjective content are systematically analyzed according to information, actions are demonstrated and discussed.
- **P** = Plan: A care plan with defined therapeutic objectives is created after a preliminary assessment and the necessary measures are precisely defined

3.2.1. Oncology and hematology pharmacy clinical practice examples:

- Medical solid oncology/Hematology Inpatient or ambulatory (outpatient, daycare, and emergency room)
- Critically ill oncology patients.
- The palliative care and survivorship.
- Surgical and inside operation room.
- Pediatric medical oncology departments inpatient and ambulatory (outpatient, daycare, and emergency room).
- Hematopoietic stem cell transplantation

3.2.2. Day in the Life of an Inpatient Oncology Clinical Pharmacist

3.2.2.1.Review all patients who were admitted.

- Review laboratory data, diagnostic data, medical specialist notes, nursing notes, and concurrent medications for appropriateness and potential medication-related problems, (e.g., potential drug interactions, dose adjustments for organ dysfunction).
- Provide new medication change recommendations to the physician before rounds.

3.2.2.2.Round with the team

- Answer drug information questions.
- Provide new medication change recommendations based on the team's discussion of each patient.

3.2.2.3.Pharmacist's Patient Care Process

Collect necessary subjective and objective information for the patient, including oncology diagnosis and treatment history.

Assess

- Evaluate the regimen based on disease and patient characteristics and published literature.
- Review and adjust anticancer therapy orders as appropriate based on patient-specific information.
- Assess drug-complementary alternative care and drug-disease, drug-drug, and drug-food interactions.
- Review supportive care medications and laboratory results associated with the chemotherapy regimen (e.g., hydration, nausea, and vomiting medications).

Plan

- Recommend appropriate practice setting for treatment.
- Provide symptom management and supportive care.
- Do transition planning, including assisting with transitions of care, medication reconciliation.
- Facilitate access to medications (e.g., work with prior authorization coordinators and financial counselors, coordinate with retail or specialty pharmacies).

Implement

- Participate in interprofessional patient care (may include rounds).
- Coordinate chemotherapy administration with the nursing staff.
- Educate patients and caregivers on anticancer therapy, supportive care medications, symptom management.

Follow-up: Monitor and Evaluate

- Conduct ongoing monitoring of efficacy, toxicity, and organ function, and provide recommendations for adjustments as needed.
- Conduct therapeutic drug monitoring and adjust therapy.
- Perform discharge counseling.

3.2.3. Day in the Life of ambulatory (outpatient, daycare, or emergency room) Oncology Clinical pharmacist

- On admission, check the patient's daily schedule and begin reviewing new orders, amending the patient's profile, and performing medication reconciliation.
- Carry out tasks associated with the daily clinic.
- Assist clinicians with selecting appropriate chemotherapy regimens and supportive care.
- Review pathology reports, laboratory values, and concurrent medications for appropriateness.
- Communicate with the prescribing physician about any interventions, impending plans, and with the nurse to ensure that medication administration is as efficient as possible.
- Medication-related problems (e.g., potential drug interactions, the requirement of genetic alteration for drug Indication, dose adjustments for organ dysfunction)
- Manage adverse effects caused by chemotherapy or disease (e.g., chemotherapy-induced nausea and vomiting, pain, infection risk).
- Educate patients about chemotherapy and what to expect.
- Conduct a follow-up interview with patients following chemotherapy administration to identify adverse events and manage them.
- Answer any drug information questions from the healthcare team.

- Proactively review chemotherapy orders for accuracy and appropriateness
- Perform medication reconciliation on discharge.
- Perform discharge counseling.

The perfect care plan and interventions related to prescription has a direct impact on patient care

3.2.4. The oncology patient's care plan:

- Patient details, patient parameters (vital signs), body surface area (BSA), prescribed medication, allergy, dose calculations and doses with obesity especially with (hematology patient and bone marrow transplantation), patient organ function (liver and kidney), and laboratory blood tests.
- Reviewing concurrent medications and last patient visit summary.
- Clinical features of cancer disease (subtype, staging, and grade)
- The care plan and interventions related to prescription of a drug that is unsuitable for administration and suggestion of a change in the pharmaceutical protocol or route of administration
- **The patient care plan is carried out in accordance with the following guidelines:**
- Protocols and scheduling of treatment (1^{st} line or 2^{nd} line)
- Guidelines for treatment of cancer by site
- Guidelines for detection, prevention, and risk reduction
- Guidelines for supportive care
- Tumor lysis syndrome – pre-hydration and post-hydration
    - Cancer pain management.
    - Antiemetic (adult and pediatric)
    - Cancer-associated venous thromboembolic disease
    - Cancer- and chemotherapy-induced anemia.
    - Blood products transfusion especially in hematology and BMT patients.
    - Cancer-related Fatigue.
    - Oral mucositis management.

- Distress Management.
- Hematopoietic Growth Factors.
- Management of Immunotherapy –related toxicities
- Palliative Care.
- Prevention and treatment of cancer–related infection.
- Smoking –associated risks for patients with cancer.
- Survivorship.
- Healthy lifestyle and physical activity.
- Nutrition and weight management.

- Guidelines for Specific Populations (HIV and older adult oncology.
- Adolescent and Young Adult (AYA) Fertility and reproductive oncology endocrine consideration.
- Bone marrow transplantation.
    - Allogenic transplant, autologous transplant, and haploidentical transplant
    - Pre-transplant, and post-transplant supportive care.
    - Acute and chronic GVHD complication.
- Radiotherapy supportive care (with BMT or hematology /oncology patient)
- Pediatric oncology.
- Chemotherapy therapy during pregnancy (e.g., Breast Cancer Treatment during Pregnancy) or targeted therapy during pregnancy (e.g., CML & Tyrosine Kinase inhibitor (TKI) therapy).
- Some chemotherapy, immunotherapy, biological therapy, targeted therapy needed for special supportive care medications.
- Psychosocial care for the patient and their families.
- Conduct ongoing monitoring of efficacy, toxicity, and organ function, and provide recommendations for adjustments as needed.

3.2.5. Medication efficacy and safety may be affected by a specific complication of cancer patients for examples:

- Patients whose clinical state or condition may affect medication absorption or disposition, alter dosage requirements (oral to IV) or predispose them to adverse drug reactions or medication toxicity (e.g., Busulfan).
- Patients with organ dysfunctions that may affect anti-cancer drug metabolism or elimination, and malnourished who prone to toxicities (e.g., hypoalbuminemia with ifosfamide, hepatic or renal dysfunction) Pharmacokinetics (PK).
- If changes in the clinical condition of the cancer patient (e.g. altered kinetics of drug absorption, distribution, metabolism, or excretion) necessitate an alteration in drug therapy or dosage.
- Patients with comorbidities which may limit drug dosing (e.g. cardiac dysfunction and anthracycline drugs) or which may affect outcome from systemic therapy (e.g. diabetes, COPD).
- Patients on multiple drug therapy (in addition to the many drugs used for cancer treatment) patients taking non-cancer medications with a narrow therapeutic index (e.g., aminoglycosides and digoxin) or drugs with a high likelihood for drug interactions with the cancer treatment drugs.
- Patients taking medications in doses greater or less than recommended in the treatment regimen or by the manufacturer or other recognized references. Includes chemotherapy, immunotherapy, biological therapy, targeted therapy, and associated supportive care medications.
- For optimal antineoplastic dosage administration, the patient's nutritional state is critical. A cooperative effort by pharmacists, dieticians, and nurses is required to maintain proper nitrogen balance and any difficulties of substrate metabolism of the cachectic cancer patient, such as hyperglycemia, lipid metabolism, and maintaining a neutral or positive nitrogen balance. (Nutrition chapter)
- Induction cycle chemotherapy for AML or ALL is more intensive than many other cancer treatments and may be associated with a different symptom burden, impaired quality of life, and moderate psychological distress.

3.2.6. Oncology clinical pharmacists' roles in the P&T committee, the Tumor Board, and the antimicrobial-stewardship programme:

3.2.6.1. Oncology clinical pharmacists' roles in the P&T committee

- The oncology clinical pharmacist's participation in the P&T committee and the formulary system has a direct impact on the care plan.
- The oncology clinical pharmacist's participation in the P&T committee includes the development of clinical care plans and medication management (e.g., delegation and practice protocols, restrictions, and clinical pathways).
- The oncology clinical pharmacist has a role in selecting new medications being considered are found to be therapeutically equivalent to existing alternatives (i.e., generic medication and Biosimilar having equivalent efficacy and safety), for the cost-minimization approach is appropriate.
- Oncology clinical pharmacist has an assessment role of the data available in the scientific literature about the medication for addition to or deletion from the formulary or a new medication-use policy
- **Medication safety includes reporting adverse drug events, monitoring de-challenge and rechallenge, first dose monitoring, and reporting medication errors.**

  Oncology clinical pharmacists have a crucial role in reporting ADRs and medication errors which leads to fast management and in turn resulted in the reduced number of morbidity and mortality cases, moreover, clinical pharmacists could discuss the prescribed medication with the physician to change it if it isn't suitable for the patient, thereby improving the patients' outcome.
- **<u>Pre-printed Medication Orders: Chemotherapy Preprinted Orders (PPOs)</u>**

  Chemotherapy Preprinted Orders (PPOs) protocol-specific order forms on which a standard chemotherapy order is pre-printed. PPOs help to simplify and standardize the ordering process of chemotherapy as a strategy for preventing prescription errors and ensuring patient safety**.**

- **Educational programs and training for achievement highly skilled staff, high staff qualified, optimized financial performance, better patient outcomes, fewer medical errors.**
- According to pharmacy regulations and procedures, the oncology clinical pharmacist should document the patient's pharmaceutical care and all activities, and the data is collected and analyzed before being discussed in the P&T committee.

3.2.6.2. Oncology clinical pharmacists' roles in the tumor board

- As a pharmaceutical expert, the clinical oncology pharmacist participates in multidisciplinary team meetings as a researcher, and critically evaluating scholarly papers about the efficacy and safety of cancer treatments.
- After the final decision on treatment with the tumor board meeting, the clinical oncology pharmacist should follow the care plan process and monitoring the patient response.
- The outcomes of these meetings could be used in research studying the impact on survival rates, quality of life, and patient satisfaction.
- **Tumor board and Clinical practice guidelines:**

  Oncology clinical pharmacists are well-positioned to collaborate in inter-disciplinary guideline development as medication experts and scholars. The development of a clinical practice guideline should begin with the synthesis of all available biomedical evidence addressing the guideline topic. A more recent variant of a tumor board is called **a Molecular Tumor board**.

  The pharmacist proceeds with explaining in detail the recommended treatment including mechanism of action, dose, administration, side effects, drug interactions, and treatment recommendations are also summarized in writing and given to the patient along with (precision genomics program) PGP contact information.

  Example: Pharmacogenomics studies have affected dosing in certain antineoplastic. With the discovery of the thiopurine methyltransferase allele in pediatric acute lymphoblastic leukemia patients, the Food and Drug Administration (FDA) changed labeling for 6-mercaptopurine to require genetic testing to be

performed to determine if a dose decrease is needed. Pharmacists at the St Jude Children's Research Hospital, now routinely individualize doses of 6-mercaptopurine based on thiopurine methyltransferase genotype and clinical tolerance. (*precision oncology chapter*)

3.2.6.3. Oncology clinical pharmacists' roles the antimicrobial-stewardship program

- Oncology clinical Pharmacists have played a key role in the antibiotic selection, dosing, and pharmacokinetic monitoring, especially in febrile neutropenic patients. pharmacist Interventions have demonstrated a shortened number of total days of antibiotics used and improving clinical outcomes in the management of infectious disease (septic shock, sepsis, invasive fungal infection, and viral infection as CMV and COVID-19).Studies have demonstrated before and- after effects from pharmacist-led improve clinical outcomes with multidrug-resistant gram-positive and gram-negative microorganisms (antibiotic-stewardship program, antimicrobial drug use control and pharmacoeconomic) monitoring antibiotics uses with restriction forms and assessing a patient's ability to tolerate oral medications and diet can expedite the conversion of intravenous antibiotics to the oral formulation, This takes place in cooperation with the hospital's infection control committee.
- Nurse education about antimicrobial administration and safety requirements.

3.2.7. Other Services that had a direct impact on patient care can be shared by oncology clinical pharmacists as:

- The role in administering vaccinations, oncology pharmacists can interview patients before initiation of chemotherapy to assess with the physician the need for influenza, diphtheria, tetanus, pneumococcal vaccines, post-transplant immunization education, and vaccine ordering.
- The role of Creating and updating extravasation protocols and guidelines is one of the first duties of any oncology pharmacist.
- The role in establishing a cancer-associated thrombosis clinic, which provides care for patients receiving anticoagulants so oncologists are not required to schedule these patients in their clinics for routine monitoring of anticoagulation.

- ***Impact of oncology clinical pharmacists in pharmacist-managed anticoagulation services example****:* A review of over 5,000 breast cancer patients seen in pharmacist-managed anticoagulation services demonstrated 65.6% of patients were within the therapeutic range as opposed to 56.7% of patients who were not seen by pharmacists

3.3.Follow-up: monitor and evaluate

- Because of the lower therapeutic index, there are numerous safety concerns with chemotherapy, as well as the need for continuous monitoring with all medications.
- Conduct ongoing monitoring of efficacy, toxicity, and organ function, and provide recommendations for adjustments as needed (Cumulative dosing).
- Monitor adherence to the anticancer regimen (monitoring parameters before and after administration of the medication).
- Practice antimicrobial stewardship.
- Document pharmacists' patient care process in the electronic medical record (EMR) or paper documentation.
- Adherence ensures cancer and supportive care medicines are adjusted appropriately For Example:
    - Monitor the patient's ability to tolerate hydration regimens, electrolyte abnormalities, possible tumor lysis syndrome, control of nausea, vomiting, and other acute side effects via patient interview and routine monitoring of chemicals labs and vital signs.
    - Gastrointestinal toxicities, such as diarrhea and mucositis with antineoplastic antimetabolites like **Fluorouracil and Irinotecan**.
    - Intrathecal administration of vincristine can cause acute central neurotoxicity and lethal outcomes.

3.3.1. Pharmaceutical care is based on a system by which drug-related problems are detected, solved, and prevented.

- Needing pharmacotherapy, not yet prescribed, especially for supportive care of predictable treatment-related toxicities.
- Taking medication for an inappropriate indication.

- Taking an inappropriate dose of an indicated medication.
- Experiencing an adverse drug reaction, including drug-induced disease or drug sensitivity, Therapeutic duplication
- Experiencing a drug-drug, drug-food, drug-lab test interaction, or allergy to a drug or not taking or receiving the drug prescribed or non-compliance, due to lack of understanding or a lack of financial resources
- Drug dependency
- Many anti-cancer drugs are administered at a maximum tolerable dose, the upper limit of which is usually defined as unacceptable toxicity or first dose-reaction**.**
- To reduce the substantial burden of iatrogenic harm associated with medications and maximize the effect of future clinical decision support systems on reducing errors in the hospital setting, prescribing systems will need to monitor for those types of errors that are likely to occur together.
- As shown in the figure that explains Examples for the "**Prescribing, dosing, dispensing, preparation, monitoring, and transcribing" section, medication errors** may also cause adverse drug reactions. Pharmacists and nurses have demonstrated the ability to assess potential adverse drug reactions by 50% and 40%.

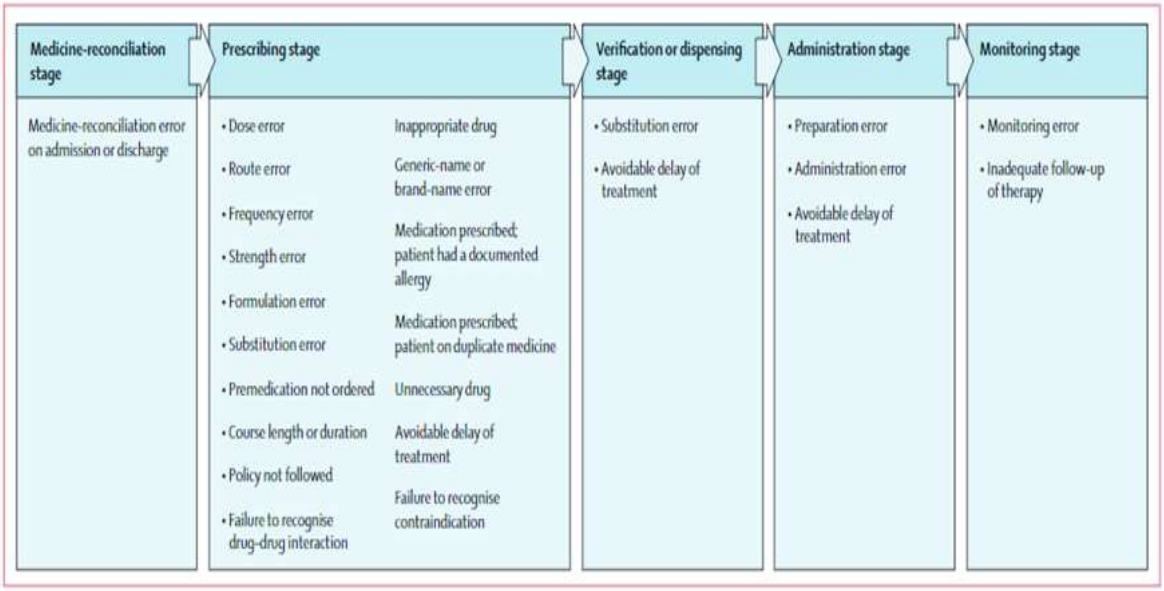
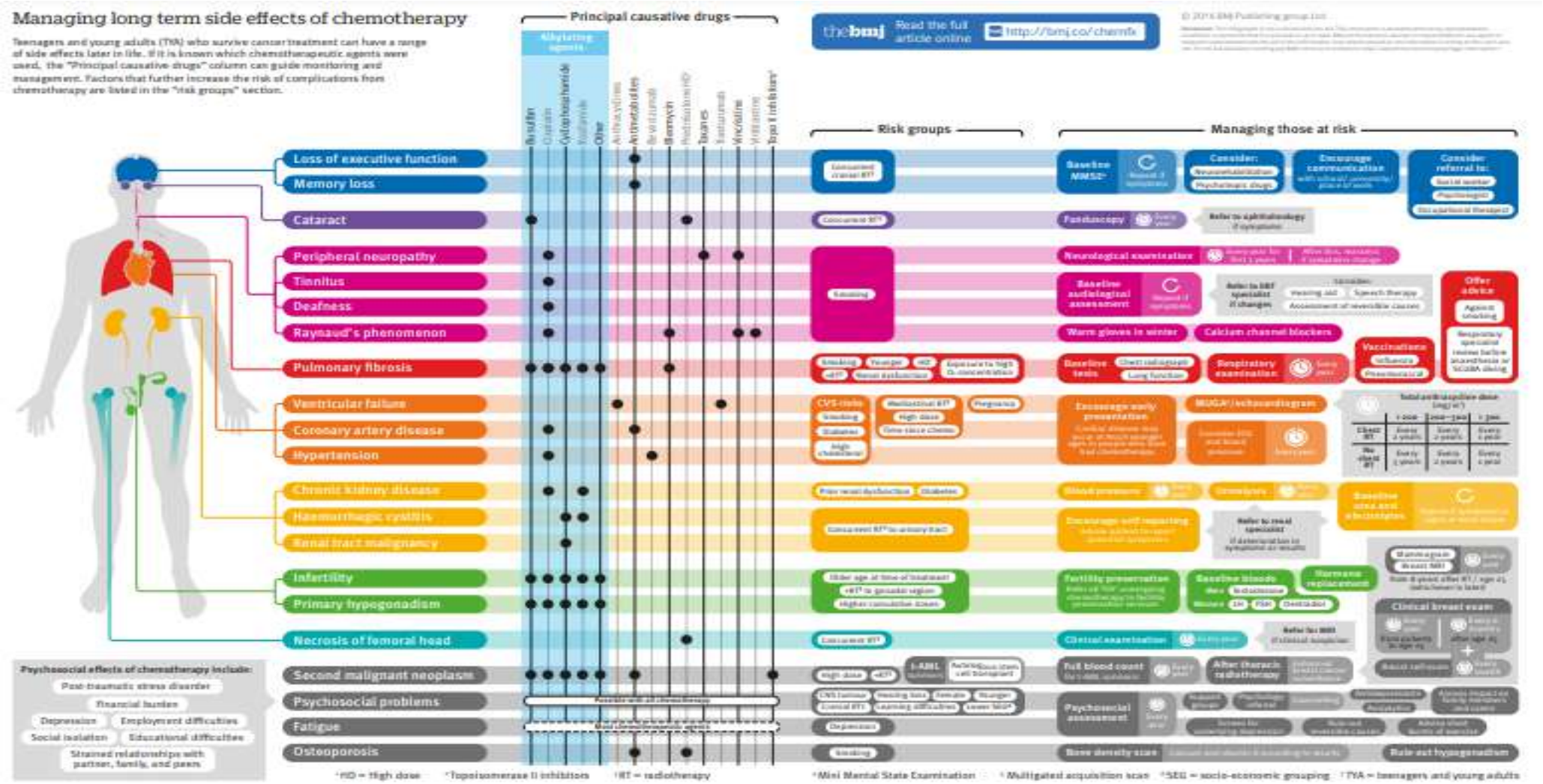


Figure (7) flow chart showing medication error types according to stage in the medication use process


Managing long term side effects of chemotherapy
Teenagers and young adults (TYA) who survive cancer treatment can have a range of side effects later in life. If it is known which chemotherapeutic agents were used, the "Principal causative drugs" column can guide monitoring and management. Factors that further increase the risk of complications from chemotherapy are listed in the "risk groups" section.
Principal causative drugs
thebmj Read the full article online http://bmj.co/chemfx
Risk groups
Managing those at risk
Loss of executive function
Memory loss
Cataract
Peripheral neuropathy
Tinnitus
Deafness
Raynaud's phenomenon
Pulmonary fibrosis
Ventricular failure
Coronary artery disease
Hypertension
Chronic kidney disease
Haemorrhagic cystitis
Renal tract malignancy
Infertility
Primary hypogonadism
Necrosis of femoral head
Second malignant neoplasm
Psychosocial problems
Fatigue
Osteoporosis
Psychosocial effects of chemotherapy include:
Post-traumatic stress disorder
Financial burden
Depression
Employment difficulties
Social isolation
Educational difficulties
Strained relationships with partner, family, and peers
Baseline MMSE*
Consider:
Encourage communication
Consider referral to:
Fundoscopy
Refer to ophthalmology
Neurological examination
Baseline audiological assessment
Refer to ENT specialist if changes
Offer advice
Warm gloves in winter
Calcium channel blockers
Vaccinations
Baseline tests
Respiratory examination
Encourage early presentation
MUGA* / echocardiogram
Refer to renal specialist
Fertility preservation
Baseline bloods
Hormone replacement
Clinical examination
Clinical breast exam
Full blood count
After thoracic radiotherapy
Psychosocial assessment
Bone density scan
Rule out hypogonadism
*HD = high dose
*Topoisomerase II inhibitors
†RT = radiotherapy
*Mini Mental State Examination
*Multigated acquisition scan
*SEG = socio-economic grouping
*TYA = teenagers and young adults

3.3.2. Chemotherapy administration monitoring and nurse education for chemotherapy safety requirements

- Both patients and health professionals are at risk of adverse health outcomes if chemotherapy is not administered safely with patients across inpatient and outpatient.
- Chemotherapy can be administered through several routes (oral, subcutaneous, intramuscular, intraperitoneal, and IV). Of these, IV remains the most common method of nursing administration and carries the highest potential for environmental contamination.
- The wearing PPE, nurses who administer chemotherapy can prevent exposure by using techniques and equipment designed to prevent contamination.
- Nurses should always wear gloves before touching the outside of a chemotherapy bag or syringe because of the high likelihood of surface contamination that can occur during administration.
- In failing to use gloves, the nurse can suffer dermal absorption in addition to spreading the contamination to the pump and the surrounding environment.
- Oncology Nursing Society recommends regular decontamination of all equipment (eg, infusion pumps) involved with administration. Hands should be washed thoroughly after removing PPE.
- Continuous infusion bags should be changed only when empty. The bag should be inverted and placed into a chemotherapy disposal bag and then removed from the spike.
- Nurses often ask for information on compatibilities with multiple infusion lines, scheduling and sequencing, infusion rates, volume issues to prime IV lines properly, manipulating concentrations in fluid restriction, or even changing the type of carrier solutions in cases of metabolic abnormalities.
- In cases of delayed infusion time or delay in delivery, discussion on infusion rates to make up infusion time needs to occur, especially where short time frames are given for drug stability.
- Nurses who used to administer chemotherapy need to update their practical and theoretical knowledge including drug calculations, protection from light medication,

rate of infusion (intravenous (IV) push or infusion), and management of side effects, especially in the case of extravasations, as well as providing supportive care such as antidotes and protocols in the case of extravasation, high dose methotrexate (HDMTX) toxicity, or other side effects of the drug as Chemotherapy-induced peripheral neurotoxicity (CIPN) ranks among the most common non-hematological dose-limiting toxicities of several widely used cytotoxic chemotherapeutic agents, including platinum compounds, vinca alkaloid, and bortezomib.

- Pre-hydration and forced-diuresis protocols in high-dose chemotherapy regimens.
- Infusion of monoclonal antibody drugs, such as rituximab and trastuzumab, may require prophylaxis with such medications as corticosteroids, antihistamine, and acetaminophen to avoid anaphylactic or allergic reactions.
- The nurse should be educated about the causes of fever which may be due to blood products transfusion, cytokines, or other drugs such as ATG, HDAra-C & amphotericin -B.
- During chemotherapy administration, the nurse can monitor the patient's ability to tolerate hydration regimens, electrolyte abnormalities, possible tumor lysis syndrome, control of nausea, vomiting, and other acute side effects via patient interview and routine monitoring of chemicals and vital signs
- **After Administration**
    - Flush IV line, ensure brisk blood return before removing peripheral IV device, flush/maintain vascular access device according to institution policy.
    - Safe handling and disposal of hazardous waste according to institution policy.
    - Document in the medical record the medications given, patient education, and patient response, including any adverse events.
    - Ensure patient has appropriate discharge instructions, anti-nausea medications, and education, and emergency contact information of physician's office in event of an emergency.

3.4.**Patient care consultation**

- Clinical oncology pharmacists should be available for patient care consultation requested by cancer patients, and relatives, physicians, nurses, or other patient care staff (Phone or email).
- Patient care consultations should involve the tasks of patient education, medication histories, and reconciliation, or a complete pharmaceutical care evaluation.

3.5.**Patient education and counseling**

The clinical oncology pharmacist should counsel cancer patients and their family members to address any concerns about the drug therapy, to provide specific drug information required for safe and appropriate drug therapy, to offer suggestions for the prevention or management of potential side effects, and to promote compliance.

3.5.1. **Patient education and counseling include presenting:**

- Basic clinical information including the disease state
- Lifestyle modification
- Storage medication.
- Side effects and interactions
- Monitoring and follow-up of the drug.

- Clinical oncology pharmacists should be sensitive to the emotional aspects of the burden of cancer when planning for patient counseling and education. – (Patient counseling at Least once/cycle by the oncology pharmacist).
- Patient education is essential to empower the patient in their care, and educated patients have also played a role in catching medication errors themselves, especially if receiving repeated cycles. Patients have detected omitted premeditations, wrong infusion intervals, leaking infusions, and incorrect doses, especially of oral medications.
- Verbal instructions should be supplemented with written information (such as medication information sheets) and other aids as required, (e.g. audiovisual and compliance aids).
- Oncology Clinical pharmacists can counsel new chemotherapy patients with a review of all the patient's medications, including prescriptions, over-the-counter, vitamins, alternative therapy, and herbal products, for drug–chemotherapy interactions, drug-drug interactions, duplicate therapy, and potential side effects.

- Counseling services can also include patient expectations at clinic visits, education on adverse effects, compliance with supportive care medications, and any lifestyle modifications, such as contraception, diet, and fall-prevention precautions in the elderly.
- Patients should be advised to always wash their hands after handling their oral anti-cancer drug.
- When to call the physician or go to the emergency department of the local hospital (e.g. when a potentially serious adverse drug reaction occurs or an important side effect persists greater than 24 hours).
- Patient education is paramount to support successful oral treatment and it can play a prime role to help reduce outpatient and inpatient hospital visits and decrease the administration and home-care costs.
- Many physical therapists with oncology clinical pharmacists recommend daily stretching exercises for women who have had breast cancer surgery to help stop scar tissue from building up, which can limit the shoulder's range of motion.
- Depression and anxiety are the most common psychological problems observed among oncology patients so repetitive counseling by pharmacists was effective in improving each domain of QOL, and decreasing anxiety and depression for cancer patients

3.5.2. Oral chemotherapy: patient education and counseling

- Patient education before the start and during oral chemotherapy treatment is an essential part of assisting patients with adherence and should include education about:
  - Storing, handling, and disposing of oral chemotherapy
  - Concurrent cancer treatment and supportive care medications.
  - Possible drug/drug and drug/food interactions and possible side effects.
  - The plan for missed doses.
  - Dosing requirements
  - Monitoring parameters
  - Blood testing requirements
- **Example:** TKI therapy and mutation analysis and management of TKI toxicities and drug interaction. After a short period of only 4 months with close monitoring by the oncology clinical pharmacist increased treatment adherence, reduced adverse

symptoms experienced by patients and complaints, and showed significant molecular remission as indicated by lower expression of the Philadelphia chromosome genes in RT-PCR. The results of this study offer practical information relevant for treatment strategies, especially in low-income communities, known to have poor treatment adherence due to reduced physician monitoring.

- **Monitor adherence**
  - Pill counts
  - Verification with refill
  - How to be safe with exposure hazard and proper disposal for return of empty containers of oral drugs
  - Accidentally dropping a pill or capsule would require gloves or a paper towel to retrieve before being disposed of in a hazardous waste receptacle.
- **Adverse effect and more serious adverse effects education examples:**
  - Diarrhea as *Capecitabine* (Xeloda)
  - Shortness of breath, hypotension as (Erlotinib) Tarceva
  - Hematological – white blood cells and platelets (6-Mercaptopurine)
  - Cardiac – congestive heart failure (Imatinib, TKI)
  - Dermatological – sores and rashes, mucositis (Busulfan)
  - The hand-foot syndrome can occur with *Capecitabine*
  - Skincare education, such as decreasing exposure to hot water, friction, and trauma in early therapy, avoidance of tight-fitting shoes, and rigorous exercise are helpful prevention tactics, as are moisturizing with appropriate pressure in grade 0 and educating patients on the application of creams and gels if these rashes progress to 1-3 grades.
  - *Thalidomide* for **Multiple myeloma** (MM) is contraindicated in pregnant females (may cause severe birth defects or embryo-fetal death if taken during pregnancy.
  - The use of chemotherapy is a known risk factor for the development of venous thromboembolism. Certain chemotherapy agents, such as fluorouracil and *Capecitabine*, are known to interact specifically with warfarin.
  - *Tamoxifen* has been associated with an increased risk of thrombosis (stroke and pulmonary embolism).

4. PRACTICE OF ONCOLOGY CLINICAL PHARMACISTS IN A SPECIAL POPULATION

4.1.The role of oncology clinical pharmacist in Critically ill oncology patients:

The critical care clinical pharmacist and the oncology clinical pharmacist work together to optimize pharmacotherapeutic, monitoring plans screening patient medication profiles for preventable ADEs and drug-drug interactions is a fundamental task. Hemodynamic monitoring, renal dose, bleeding complications, responding to medical emergencies (stroke, code blue, and therapeutic hypothermia), and deep Antimicrobial regimens for critically ill oncology patients can be particularly complex, as patients may require empiric and/or targeted therapy for multidrug-resistant gram-positive and gram-negative microorganisms, as well as fungal and viral pathogens. Specialized consultant teams (e.g., cardiology, infectious diseases, nephrology, etc.) are also available when necessary.

4.2. The role of oncology clinical pharmacist as part of the palliative care team.

Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with a life-threatening illness, through the prevention and relief of suffering utilizing early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial, and spiritual. To address the explicitly stated physical, psychosocial, and spiritual problems in this definition, a multidisciplinary treatment team is inevitably required.

Type of interventions:

- Starting a drug for symptom/complaint
- Stopping a drug (that was given as prophylaxis)
- Enhancing medication adherence
- Optimizing palliative sedation
- Explaining/solving reimbursement issues

Therapeutic advice

- Optimizing dosage
- Explaining side effects
- Drug switch
- Choice of drug

- Explain the mechanism of action of a drug
- Optimizing route of administration
- Drug-interactions
- Duplicate therapies,

The addition of a pharmacist to a community-based multidisciplinary palliative care team offers various benefits to the team, patients, and carers. By boosting team members' knowledge and capabilities, a pharmacist's key role can help to reduce medication errors by improving medication adherence and symptom management for patients

4.3. The oncology clinical pharmacist practice in pediatric oncology

- Pediatric oncology pharmacists should offer pharmaceutical care that takes into consideration the unique clinical characteristics of the child and their diagnosis that may impact on drug side effects and acute and long-term toxicities.
- Pediatric cancer patients are distinct from their adult counterparts in that the majority of children (approximately 80%) will be cured of their cancer. Childhood cancers tend to be more aggressive and progress more rapidly than adult cancers. But, with some exceptions, childhood cancers respond better to certain treatments than adult cancers do.
- Pediatric oncology pharmacists should be trained specifically in pediatric hematology-oncology care.
- The diagnosis of cancer in a child impacts the immediate family and society as a whole. Families are extensively involved in the treatment of their dependent children. For these reasons, the family should be included in all treatment-related discussions and are important partners in achieving desirable pharmaceutical care outcomes.
- Dosing accuracy is especially important in the treatment of infants and children. The pediatric oncology pharmacist should understand the importance of dosing guidelines and tracking the cumulative doses of all anti-cancer drugs.
- The pediatric oncology pharmacist should contribute to the care of pediatric oncology patients by determining appropriate dosages, delivery techniques, formulations, and routes of administration for drugs used in the treatment of childhood cancers, as well as assuring the safe handling of hazardous drugs.
- **Some recommendations for clinical oncology pharmacists:**

- Providing the medication reconciliation service. Pediatric hematology-oncology patients are likely to use supportive drugs during cancer treatment and can take medications for other morbidities (e.g., asthma, convulsion).
- In the prescriptions, carefully check the doses prescribed by physicians, especially that of antineoplastic agents. The doses of the antineoplastic drugs are calculated based on the weight and body surface area of the patients.
- Checking the days and duration of treatment based on pediatric chemotherapy protocols.
- Checking the administration route of antineoplastic drugs (e.g., **vincristine must be administered only intravenously; intrathecal administration is almost always fatal**)
- Ensuring that all supportive drugs needed for treatment are prescribed (e.g., corticosteroid eye drops when patients have treated with high dose cytarabine; sodium bicarbonate for urine alkalization when high dose methotrexate is used; mesna concomitantly cyclophosphamide; mannitol and electrolytes when cisplatin is prescribed).
- Monitoring serum levels of methotrexate after infusion in high-dose and assess the need for folinic acid rescue therapy (e.g., acute lymphoblastic leukemia and osteosarcoma protocols).
- Development of an institutional protocol for the rational use of antiemetics based on existing guidelines for the prevention and treatment of chemotherapy-induced nausea and vomiting in childhood.
- Checking the serious drug interactions between antineoplastic agents and other drugs (e.g., methotrexate and sulfamethoxazole-trimethoprim) and duplicity between the drugs prescribed.
- Pay attention to the final concentration of the diluted drug, the drug-diluent compatibility, and their infusion rate. In some cases, the ideal concentration of the drug in the solution for children is different from that of adults. Antineoplastic and anti-infective drugs increase the risk for phlebitis.
- Monitoring for adverse drug reactions and notify them in pharmacovigilance services.
- Involving in multidisciplinary rounds.

- Providing discharge counseling, especially if the child is discharged with medications that she/he has not used before. Educational materials can be used as a strategy in these cases.

4.4. The oncology clinical pharmacist role in surgical and inside operation room for example in the pediatric oncology setting:

- Patient assessment and checking allergy profile for all patients before surgery,
- Participate in the policy of antimicrobial prophylaxis in preoperative patients at the surgical department (Neuro-Oncology, general oncology, and orthopedic oncology surgeries). participate in the establishment and clinical decision support in surgical guidelines and protocols and monitoring the safety and efficacy.
- Preparing all medications like narcotics, sedatives used in the preoperative area, intraoperative and postoperative area by calculating all doses for all medications after arranging with the Anesthesia Department.
- Activate the medication reconciliation process and ensure that patients take their medications especially chronic patients before Surgery.
- Re-dose of an antimicrobial prophylaxis medication inside operation Rooms.

4.5.5- the oncology clinical pharmacist practice in bone marrow transplantation:

A bone marrow transplant is a procedure to replace damaged or destroyed bone marrow with healthy bone marrow stem cells.

- **There are three kinds of bone marrow transplants**:
  - Autologous bone marrow transplant.
  - Allogeneic bone marrow transplant. (Non-malignant and malignant diseases)
  - Umbilical cord blood transplant.

  Before the transplant, chemotherapy, radiation, or both may be given.
- **The (Bone marrow transplant) BMT clinical pharmacist** is an integral member of the multidisciplinary HCT team who provides a variety of pharmacy and educational services to the healthcare team, the patient, and caregivers to optimize collaborative, patient-centered care focused on patient safety.

4.5.5.1-The BMT clinical pharmacist intervention aim to:

- Optimize patient outcomes by providing comprehensive medication management, including the economical provision of medication-related care.

- Maximize patient and caregiver comprehension of medication administration and side effects.
- Provide the multidisciplinary team with evidence-based clinical decision support.

The BMT clinical pharmacist activities:

Medication management and monitoring

- Provide thorough medication review,
- Participate in interdisciplinary rounding,

Manage chemotherapy processes:

- Assistance with treatment planning and review or preparation of order set and policy documents

Assist with therapeutic drug monitoring:

- Immunosuppressants, anti-infectives, anti-seizure medications, anticoagulants, chemotherapeutic agents, etc.

Provide medication therapy management:

- Diabetes, hypertension, dyslipidemia, etc.

Manage anti-infective therapies and promote stewardship:

- Prophylaxis and treatment recommendations; Monitoring.

Patient Care Assist in symptom management:

- Supportive care,
- Pain/palliative care
- Optimize graft-versus-host disease management
- Facilitate post-transplant vaccine administration

Transition Planning

- Assist with transitions of care:
- Provide medication reconciliation
- Collaborate on discharge planning and management Facilitate transitions to hospice/palliative care where appropriate
- Facilitate access to medications available through patient assistance programs.

Research and Quality Improvement

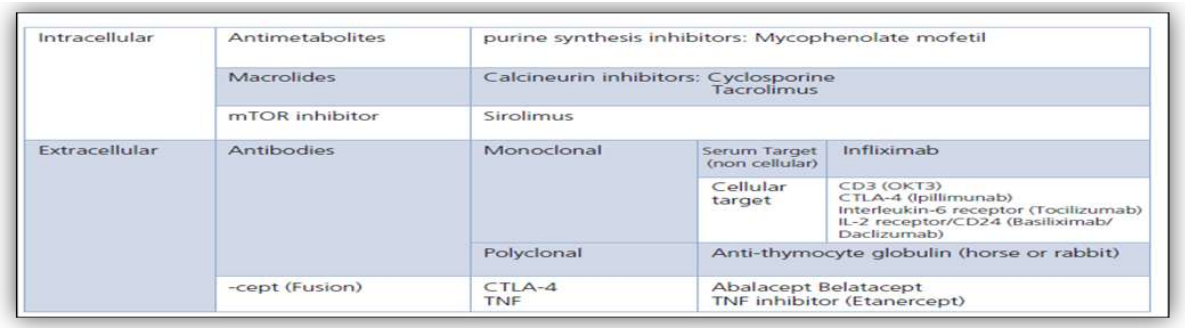
- Contribute to institutional and collaborative research and scholarly activities

- Assist with policy/guideline development
- Serve as patient & professional advocate
- Monitor, evaluate, and report transplant-related outcomes to assist in improvements to clinical practice.

- The BMT clinical pharmacist has an important role in the most common types of HCT problems, such as toxicities resulting from pre-transplant conditioning regimens, immunological problems [rejection or graft-versus-host disease (GVHD)], infections, and malignancy relapsed disease.
- The BMT clinical pharmacist performed a role in the Pre-engraftment phase due to acute toxicity caused by high-dose chemotherapy only or with / TBI-containing regimens: Nausea, vomiting, diarrhea, mucositis and pain management
- Infections (bacterial, fungal, and viral infection)
  Preventive measures are taken to minimize exposure to viruses, bacteria, and other pathogens during the transplant period. These may include some or all of the following:
    - HEPA-filtered rooms
    - Isolation precautions
    - Strict handwashing for all healthcare workers
    - Use of Personal protective equipment outside the room for the recipient
    - Restriction of visitors
    - Diet and hygiene
  - Fluid Overload& cardiotoxicity
  - Hepatic& renal toxicity
  - Sinusoidal obstructive syndrome (Veno-occlusive Disease (VOD)
  - Microvasculature in transplant complications **as** diffuse alveolar damage &alveolar capillary hemorrhage
  - Lung: Interstitial pneumonia syndrome (IPS)
  - Blood Group Incompatibilities and Hemolytic Complications of Hematopoietic Cell Transplantation (HCT).

4.5.5.2.The BMT clinical pharmacist plays a role in early post-engraftment (Engraftment typically occurs between days 14 and 28 post-transplant).

- Documentation of Engraftment and Characterization of Chimerism after HCT
- Monitoring if: Signs and symptoms of acute GVHD (e.g.: skin, liver, and/or GIT)
- Pharmacologic Prevention of Acute Graft-versus-Host Disease (MTX + CSP or MTX + ATG + MPA) as T-cell Depletion medication to Prevent Graft-versus-Host Disease figure



Intracellular	Antimetabolites	purine synthesis inhibitors: Mycophenolate mofetil		
	Macrolides	Calcineurin inhibitors: Cyclosporine Tacrolimus		
	mTOR inhibitor	Sirolimus		
Extracellular	Antibodies	Monoclonal	Serum Target (non cellular)	Infliximab
			Cellular target	CD3 (OKT3) CTLA-4 (Ipillimunab) Interleukin-6 receptor (Tocilizumab) IL-2 receptor/CD24 (Basiliximab/ Daclizumab)
		Polyclonal	Anti-thymocyte globulin (horse or rabbit)	
	-cept (Fusion)	CTLA-4 TNF	Abalacept Belatacept TNF inhibitor (Etanercept)	

- Monitoring calcineurin inhibitor toxicity (IV or oral), monitoring drug level, drug-drug, and drug-food interaction.
- Antifungal, antiviral & PCP prophylaxis.
- Cytomegalovirus Infection& prophylaxis.
- Management of GVHD (adding immunosuppressive medications to current GVHD prophylaxis).

4.5.5.3. The BMT clinical pharmacist plays a role in long-term recovery and complication.

- Chronic Graft-versus-Host Disease – Clinical Manifestations and Therapy.
- Gastrointestinal and Hepatic Complications.
- Kidney and Bladder Complications of HCT
- Endocrine Complications Following HCT
- Complications Following HCT.
- Nutrition Support of the HCT Recipient.
- Growth and Development after HCT.
- Vaccination of Allogeneic and Autologous Hematopoietic Cell Recipients.
- Nursing Role in HCT.
- Patient education & caregiver inHCT.
- Assessment of Quality of Life in HCT Recipients.

- HCT for Childhood((Non-malignant and malignant diseases)

Repetitive counseling by pharmacists is effective in improving quality of life and decreasing anxiety and depression with Hematopoietic Cell Transplantation (HCT) which remains a high-risk, intensive, life-prolonging treatment that may be the best option for patients with few alternatives, even when the outcome includes the possibility of significant morbidity. HCT may be associated with a variety of serious biological, psychological, social, and spiritual complications.

5. DRUG INFORMATION: FROM EDUCATION TO PRACTICE

5.1.Drug information skills

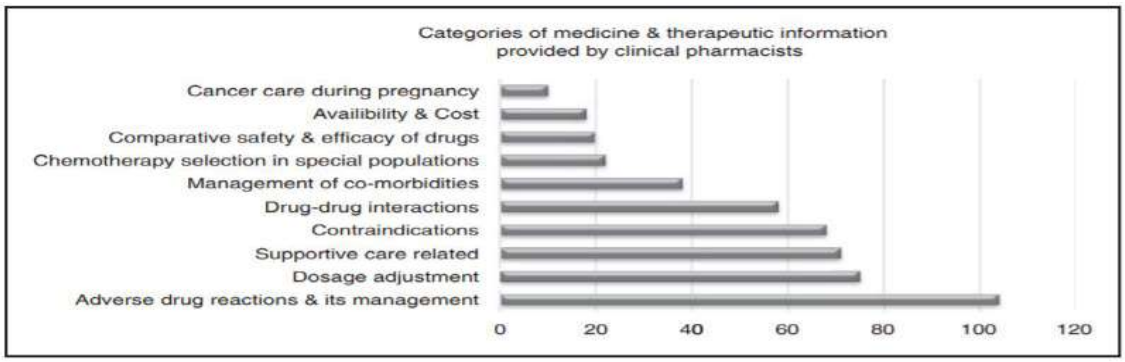
The oncology pharmacist should be able to retrieve and evaluate the relevant literature and integrate new information with existing information to establish recommendations for appropriate drug use. critical appraisal skills are required by the oncology pharmacist to integrate information and evidence with individual patient medication decisions integration of pharmacotherapeutic, pharmacokinetics, pharmacodynamics, economic, and ethical considerations.

The oncology pharmacist should provide information on drugs used in cancer care by:

- Responding to drug-related questions posed by oncology staff and patients.
- Providing information related to a specific patient's pharmacotherapy.
- Recommending oncology drug-related references and patient counseling materials.
- Participation in activities of the pharmacy and therapeutics committee and participation in other oncology-based committees as appropriate and regarding approved drug therapy per disease site.
- Advising providers on medication-related policies, procedures, and education projects.
- Assisting in the formulary decision and participating in drug use evaluation.
- Publishing the newsletter, drug information booklets, and provide an education program. Participation in programs that report and attempt to prevent adverse drug reactions and medication errors.

- Use a systematic approach to address drug information needs by effectively searching, retrieving, and critically evaluating the literature (i.e., assessment of study design, statistics, bias, limitations, applicability).
- Subscribe to appropriate email listservers (e.g., Food and Drug Administration Drug Information Updates, National Guideline Clearinghouse, Centers for Disease Control and Prevention, Medline Plus).
- Maintain active membership in local, state, and national pharmacy associations/societies.

- **An example of a query for medicine and therapeutic information categories is shown in this figure.**



- **Resources used to answer medicine and therapeutic information service as:**

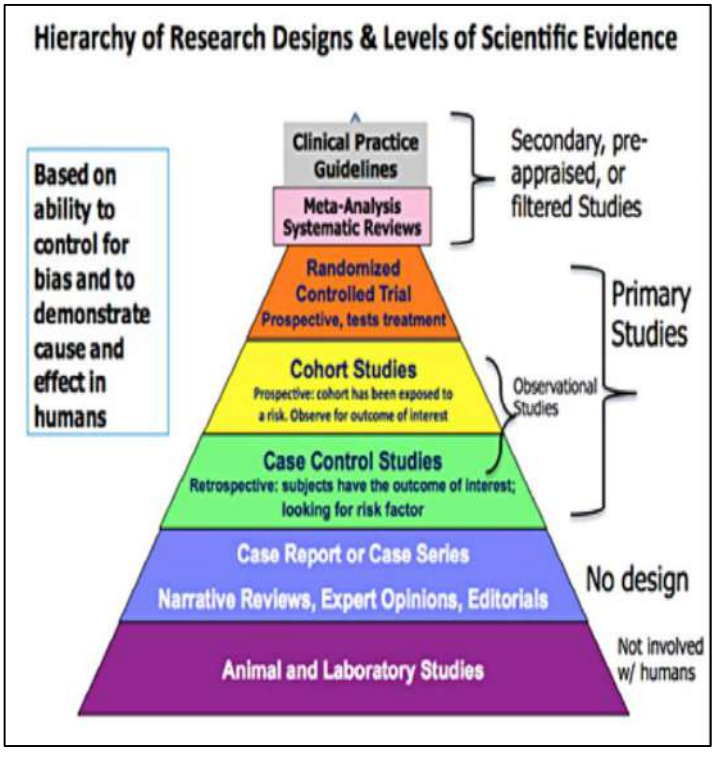
Reference searched from	**Purpose/type of MTI** may be
Primary resources • Annals of Oncology Literature • British Journal of Cancer • Journal of Clinical Oncology • Journal of Oncology Pharmacy Practice.	Literature
Tertiary resources • American Society of Clinical Oncology Educational Book • The American Cancer Society's Oncology in Practice • Handbook of injectable drugs by Lawrence Tressels • Lexi comp drug information	• Clinical Management • Administration guidelines, storage and stability instructions • Drug monographs with a more clinical focus

handbook for oncology	
Internet resources	
• www.cancercare.on.ca (Ontario Cancer Care Online Port, Canada) • www.bccancer.bc.ca (British Columbia Cancer Agency Online, Canada) • www.eviq.org.au (Cancer Care Unit, NSW, Australia) • www.ncbi.nlm.nih.gov (PubMed) • National Comprehensive Cancer Network Guidelines • (Latest versions) • Micromedex (online, offline, Mobile)	• Drug monographs • Drug monographs and practice guidelines • General reference, administration protocols, supportive care, clinical evidence • Literature search, clinical evidence • Drug and dose selection for general and special population, practice guidelines • Dosage adjustment, ADRs, administration guidelines, drug interactions.

MTI: medicine and therapeutic information; ADRs: Adverse drug reactions.

- **Evidence-based medicine of literature**

- Clinical practice guidelines
- Systematic review/meta-analysis
- Randomized controlled trials
- Cohort study
- Case-control study
- Cross-sectional study
- Case report/case series
- Expert/opinion.



- **Respect the copyright**

  The value of upholding copyright and Check the copyright statement of the author

5.2.Education and staff development.

- Regular attendance of the clinical oncology pharmacist at oncology/oncology pharmacy specialty conferences and education meetings should be encouraged to maintain the currency of the oncology pharmacist's specialist knowledge. New information should be shared with colleagues.
- Educate the nurses about drug administration (especially new drugs and high alert medication)**.**
- Practice in the clinic Professionalism and ethics, communication and teamwork, drug administration and patient care, leadership and management, and education and research are the five domains of expertise for oncology pharmacists.
- Joining professional organizations:
  - National Comprehensive Cancer Network (NCCN)
  - The Australia and New Zealand Children's Hematology and Oncology Group
  - American Society for Blood and Marrow Transplantation (ASBMT).
  - American Society of Clinical Oncology (ASCO).
  - American Society of Hematology (ASH).
  - British Oncology Pharmacy Association (BOPA).
  - Clinical Oncology Society of Australia (COSA).
  - European Society of Bone Marrow Transplantation (EBMT).
  - European Society of Medical Oncology (ESMO).
  - The European Hematology Association (EHA).
  - Hematology/Oncology Pharmacy Association (HOPA).
  - Hematology Society of Australia and New Zealand (HSANZ).
  - International Society of Oncology Pharmacy Practitioners (ISOPP).
  - Multinational Association of Supportive Care in Cancer (MASCC).
  - The Children's Oncology Group (COG).
  - The International Society of Pediatric Oncology (SIOP).

6. ONCOLOGY PHARMACY AND CLINICAL RESEARCH

- Pharmacy practice research is vital to the future of the pharmacy profession. Having good evidence is paramount as we strive to improve patient outcomes, expand scopes of practice, and determines the safety and effectiveness (efficacy) of medications.
- To facilitate oncology and hematology pharmacists' participation in research it is highly recommended that pharmacists possess knowledge in the areas of epidemiology, statistical analysis, and research protocol development and the areas of:
    - Oncology literature and information retrieval systems
    - Study design and methodology
- The research question and study design must be of benefit to patients and interest to the oncology and hematology teams. Research may relate to everyday practice and include identifying evidence gaps for oncological and hematological conditions, implementing evidence-based practice in cancer care, evaluating novel cancer therapies, comparator studies of cancer therapies, and interventions directed at reducing patient admissions for supportive care and improving patient safety
    - Selective strengths and limitations of different study designs.
    - Statistical methods used for data analysis.
    - Clinical versus statistical significance.
    - Qualitative research in the area of pharmaceutical care of cancer patients (including patients and/or cares education and counseling).
    - Regulatory and ethical issues related to research in patients with cancer (including confidentiality, informed consent, and patient rights)

6.1.The Oncology Pharmacy practice research examples:

- Impact of clinical pharmacy services in terms of clinical improvement, patient satisfaction, and compliance in the clinic and the community.
- Evaluation of activity and tolerance of new anticancer agents in real-life studies.
- Patterns of use of supportive-care drugs (antibacterial agents, antifungal agents). Development and integration of measures of supportive care.
- Evaluation and analysis of off-label use of anticancer agents.
- Analysis of unexpected severe side-effects or low efficacy.
- Exploration of drug interactions (with food, beverages, concomitant drugs).

- Development and integration of therapeutic drug monitoring and pharmacogenomics in drug use optimization.
- Impact of body size on pharmacokinetic and clinical variability of anticancer agents.
- Pharmacoeconomic studies.

6.2.The role of oncology pharmacist in clinical trials and drug design and development process

- The pharmaceutical company, or any study sponsor, that supports the use of investigational drugs in health systems should receive reliable and valid data. The following recommendations will serve as a guide to the pharmaceutical industry or other study sponsors to ensure that investigational drug use is managed appropriately and that studies are conducted effectively, efficiently, and safely.
- Clinical trials involving new drugs are commonly classified into four phases. Each phase of the drug approval process is treated as a separate clinical trial. The drug-development process will normally proceed through all four phases over many years. If the drug successfully passes through Phases I, II, and III, it will usually be approved by the national regulatory authority for use in the general population. Phase IV is post-approval studies
- **Pharmacists' roles in clinical trials generally fall into one of two categories**:
- Drug storage, preparation, and record-keeping, frequently through an investigational drug service.
- Serving as a principal investigator or a sub-investigator, manager, or coordinator within a research team that may include other health care professionals, research sponsors, monitors, contract research organizations, institutional review boards (IRBs), and institutional administrators.

- Presentation of research at relevant conferences and seminars as referenced in Training and Education, such as those organized by SHPA, COSA, ASCO, and ISOPP is highly recommended.

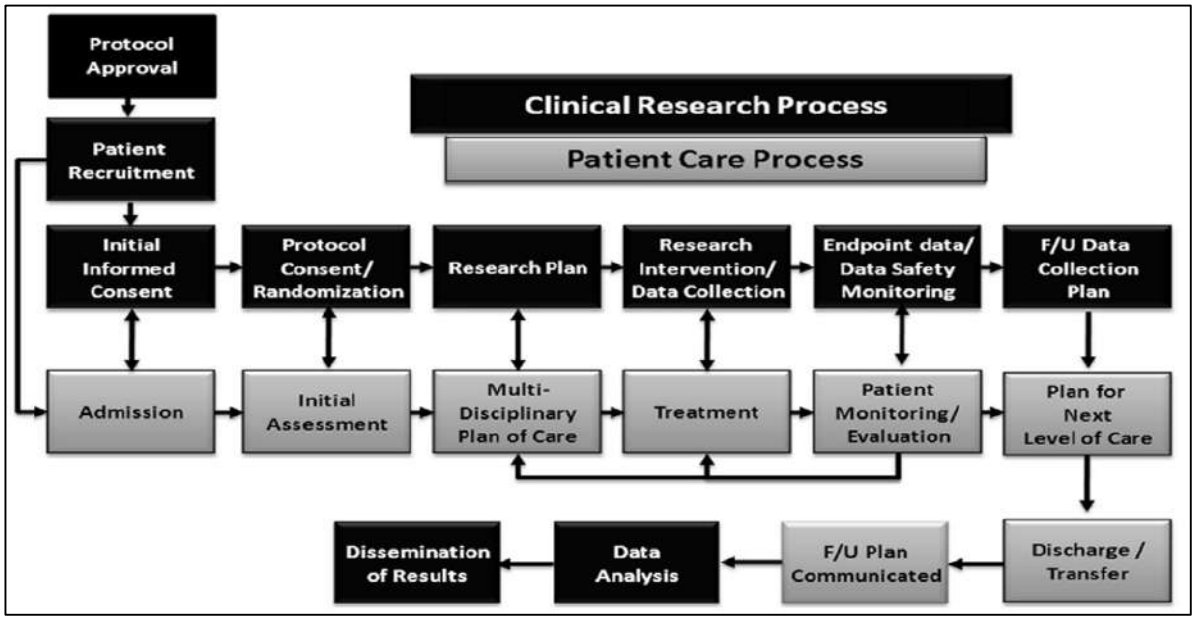


Figure (8) the process of integrating research and clinical care

6.3.Principles of Good Clinical Practice

Good Clinical Research Practice (GCP) is a process that incorporates established ethical and scientific quality standards for the design, conduct, recording, and reporting of clinical research involving the participation of human subjects**.**

The responsibility for GCP is shared by all of the parties involved, including sponsors, investigators and site staff, contract research organizations (CROs), ethics committees, regulatory authorities, and research subjects**.**

- Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
- The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over the interests of science and society.
- The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

- Clinical trials should be scientifically sound and described in a clear, detailed protocol.
- A trial should be conducted in compliance with the protocol that has received prior institutional review board/independent ethics committee approval/favorable opinion.
- The medical care is given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
- Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective tasks.
- Freely given informed consent should be obtained from every subject before clinical trial participation.
- All clinical trial information should be recorded, handled, and stored in a way that allows accurate reporting, interpretation, and verification.
- The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules by the applicable regulatory requirement(s).
- Investigational products should be manufactured, handled, and stored following applicable good manufacturing practices. They should be used by the approved protocol.
- Systems with procedures that assure the quality of every aspect of the trial should be implemented. **(***Clinical research & clinical trials chapter***)**

APPENDICIES

APPENDIX (1) FOLLOW UP CARD

Patient Name :		**male/female:**		
Hospital number :				
Age:	**Height :**		**Wt:**	**BSA:**
Diagnosis :		**Allergy :**		
Consultant name:				

Medical History	
Protocol Name: **Shifting to:**	
Current Medications	

Other comments need to consider:

Nephrotoxicity

Cardiotoxicity

Other:

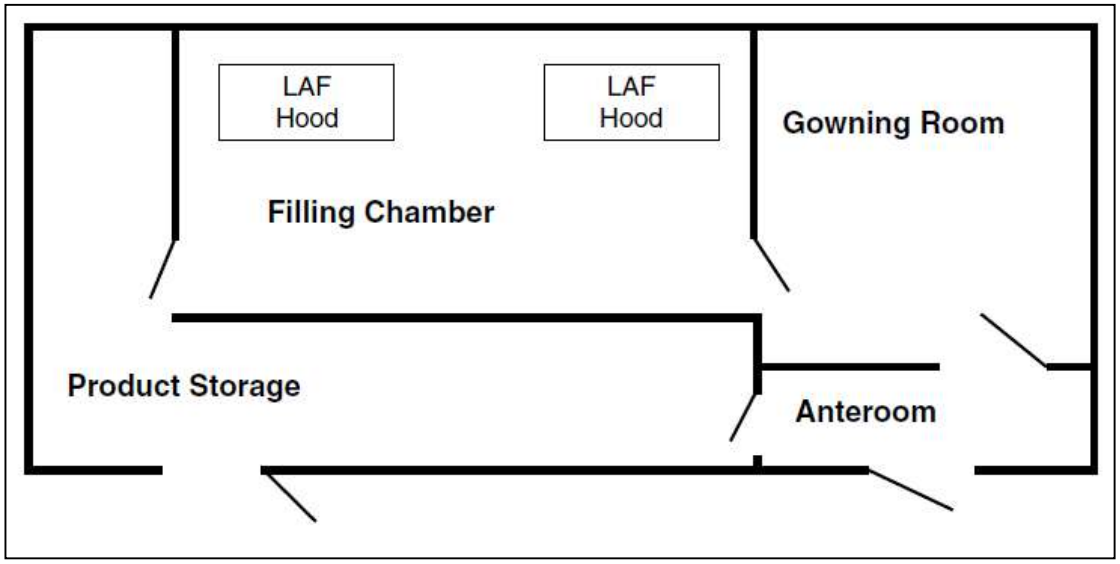
APPENDIX (2) ISO STANDARD 14644-1

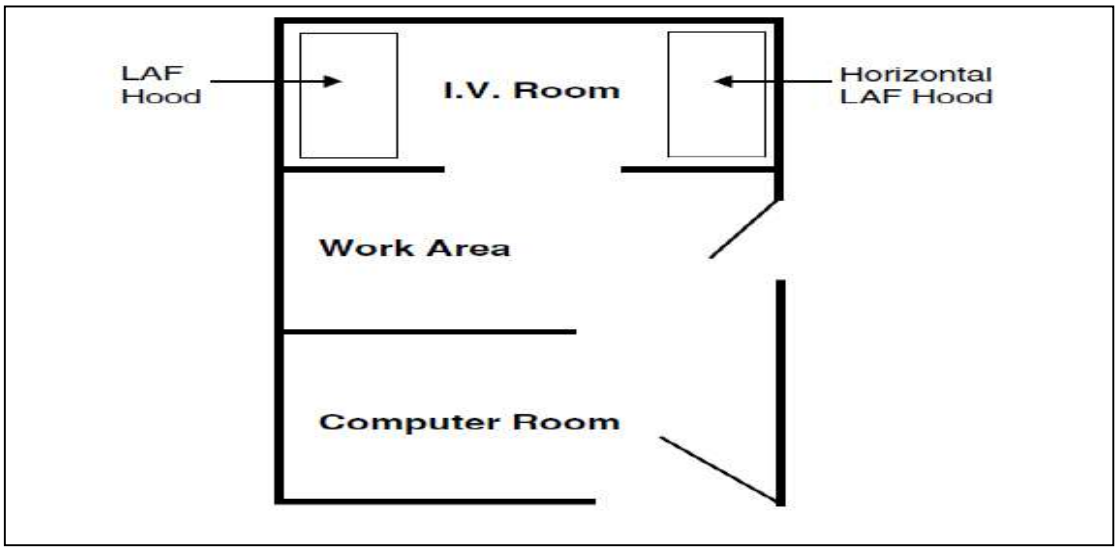
Sterile compounding facilities must be designed to minimize the risk of airborne contamination of the area in which sterile compounding occurs. Proper design and controls are required to minimize the risk of exposure of CSPs to airborne contaminants. The ISO standards for air quality in controlled environments are provided in the **Table.**

Classes of air cleanliness for airborne particulates in clean rooms and clean areas, according to ISO 14644-1

ISO Class	Particle Count /m^3
3	35.2
4	352
5	3520
6	35,200
7	352,000
8	3,520,000

APPENDIX (3) DESIGN AND RELATIONSHIP OF ROOMS





APPENDIX (4) SAMPLE DESIGN CRITERIA FOR CLEAN ROOM ISO-7(CLASS 10,000)

Sample Design Criteria for Cleanroom or Buffer Room- ISO Class 7 (Class 10,000)

SUGGESTED SPECIFICATIONS	
CEILINGS	• Drywall—epoxy painted • Clean room ceiling tile with anodized aluminum T-Bar grid
FLOORS	• Monolithic vinyl • Monolithic epoxy
WALLS	• Monolithic vinyl • FRP laminate panel • Tempered safety glass • Drywall—epoxy painted • Melamine panel
DOORS	• Stainless steel • Anodized aluminum • Epoxy painted metal door
LIGHT FIXTURES	• Standard construction recessed clean room fixture; RTV sealed to anodized aluminum T-Bar ceiling grid; acrylic lens with baked enamel finish
WINDOWS	• Tempered safety glass with no sills and stainless steel or anodized aluminum frames
AIR CHANGES	• An adequate number of air changes to properly condition the space with no less than 30 air changes per hour
AIR PRESSURE	• Anteroom must be negative to the compounding room and positive +0.02 wc to the general area
AIR FILTRATION	• IEST-RP-CC001 Type C HEPA filter with a 30% Efficiency ASHRAE* or better prefilter
PARTICULATE CONTROL	• ISO Class 7 per ISO 14644
TEMPERATURE	• 66˚F +/- 4˚F (these values are for employee comfort when properly garbed)
RELATIVE HUMIDITY	• 35 - 65 % RH (these ranges are optimized for employee comfort, suppression of microbial growth, and component functionality)

*The American Society of Heating, Refrigerating and Air-Conditioning Engineers, www.ashrae.org.

APPENDIX (5) BIOLOGICAL SAFETY CABINET CLASSIFICATIONS

Type		Minimum Inflow Velocity	Airflow Pattern	Radionuclides/ Hazardous Drugs	Product Protection
Class I		75 feet/minute	In at front; rear and top through HEPA filter	NO	**No**
Class II	**Type A1**	75 feet/minute	70% Recirculated through HEPA; exhaust through HEPA	NO	**Yes**
	Type A2	100 feet/minute	70% Recirculated through HEPA; exhaust through HEPA that can be ducted	Yes (Low levels/volatility) when ducted	**Yes**
	Type B1	100 feet/minute	30% Recirculated through HEPA; exhaust via HEPA and hard ducted	Yes (Low levels/volatility)	**Yes**
	Type B2	100 feet/minute	No recirculation; total exhaust via HEPA and hard ducted	YES	**Yes**
Class III		NA	Supply air inlets and exhaust through 2 HEPA filters	YES	**Yes**

APPENDIX (6)MINIMUM FREQUENCY FOR CLEANING AND DISINFECTING SURFACES AND APPLYING SPORICIDAL AGENTS

Site	Cleaning	Disinfecting	Applying Sporicidal
PEC(s) and equipment inside the PEC(s)	Equipment and all interior surfaces of the PEC daily and when surface contamination is known or suspected.	• Equipment and all interior surfaces of the PEC daily and when surface contamination is known or suspected. • Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, com- pounding must not be disrupted and the work surface of the PEC must be disinfected immediately after compounding.	Monthly
Removable work tray of the PEC	• Work surface of the tray daily • All surfaces and the area underneath the work tray monthly	• Work surface of the tray daily • All surfaces and the area underneath the work tray monthly	• Work surface of the tray monthly • All surfaces and the area under- neath the work tray monthly
Pass-through(s)	Daily	Daily	Monthly
Work surface(s) outside the PEC	Daily	Daily	Monthly
Floor(s)	Daily	Daily	Monthly
Wall(s), door(s), and door frame(s)	Weekly	Weekly	Monthly
Ceiling(s)c	Weekly	Weekly	Monthly
Storage shelving and bins	Weekly	Weekly	Monthly

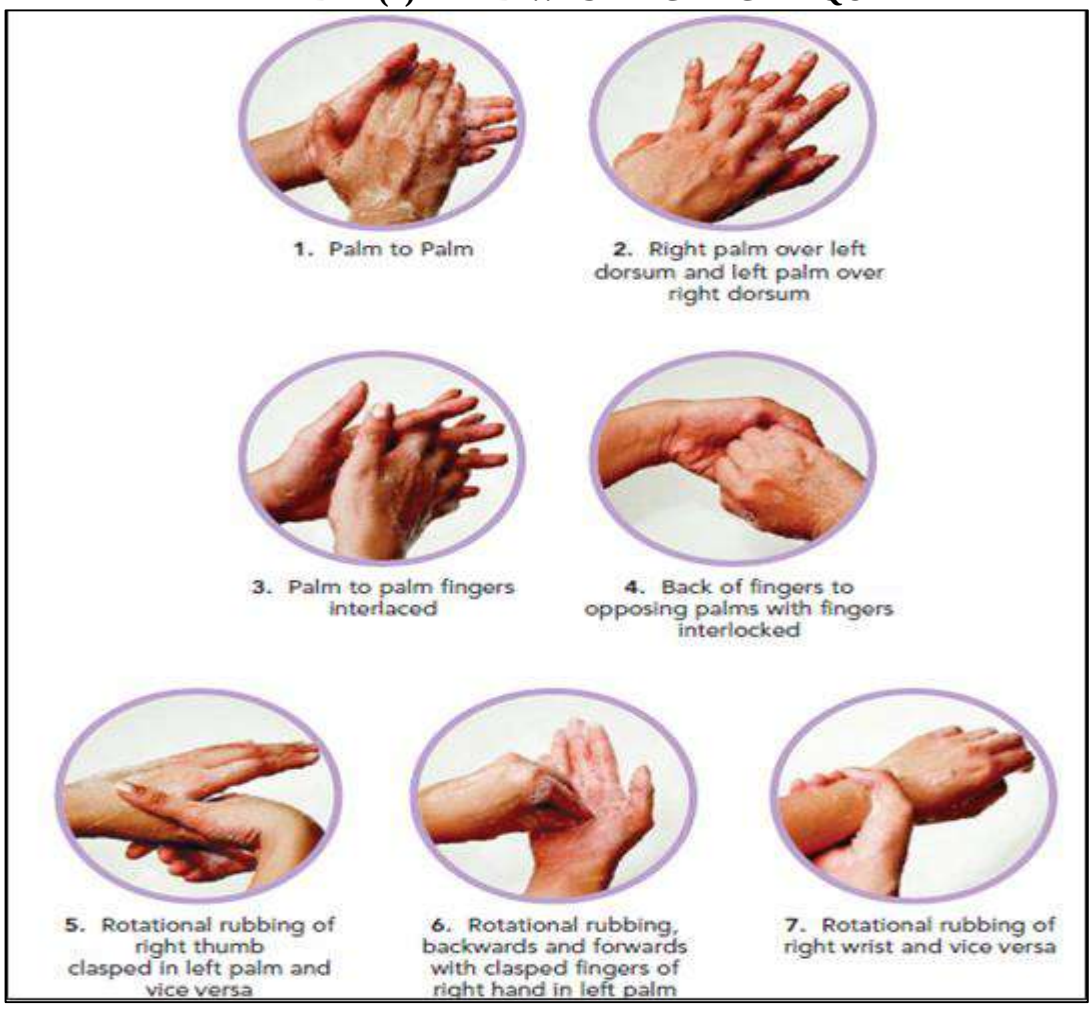
For surface that has been splashed

Apply Sterile water for injection or irrigation (for cleaning), followed by sterile 70% isopropyl alcohol (for disinfecting)

All surfaces and subfloor (Weekly at the end of a workday)

Apply Sterile water for injection or irrigation (for cleaning), followed by a sporicidal agent and then sterile 70% isopropyl alcohol (for disinfecting)**.**

APPENDIX (7) HAND WASHING TECHNIQUE



7-Step Technique:

i. Scrub palm to palm

ii. Right palm over left dorsum and left palm over right dorsum

iii. Palm to palm fingers interlaced

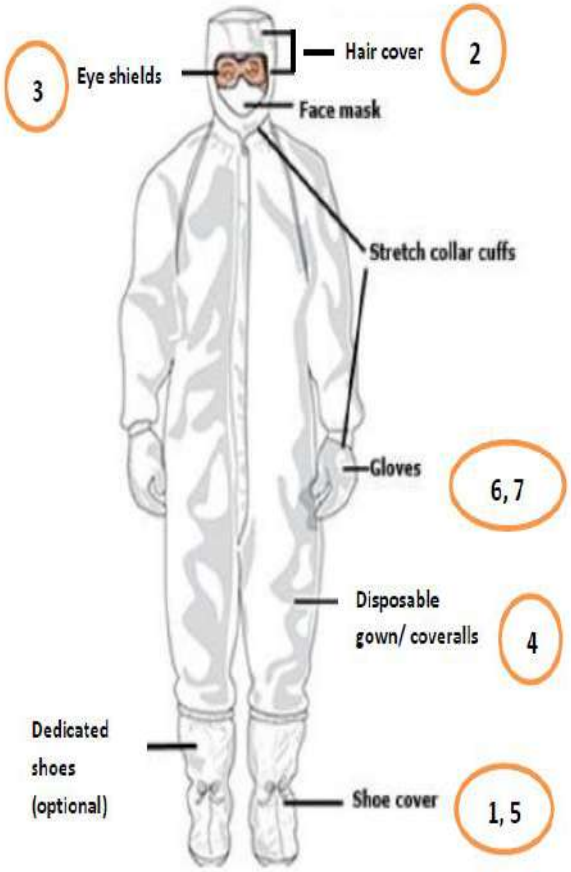
iv. Back of fingers to opposing palms with fingers interlocked

v. Rotational rubbing of right thumb clasped in left palm and vice versa

vi. Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa

vii. Rotational rubbing of right wrist and vice versa. Rinse and dry thoroughly.

APPENDIX (8) GOWNING ORDER

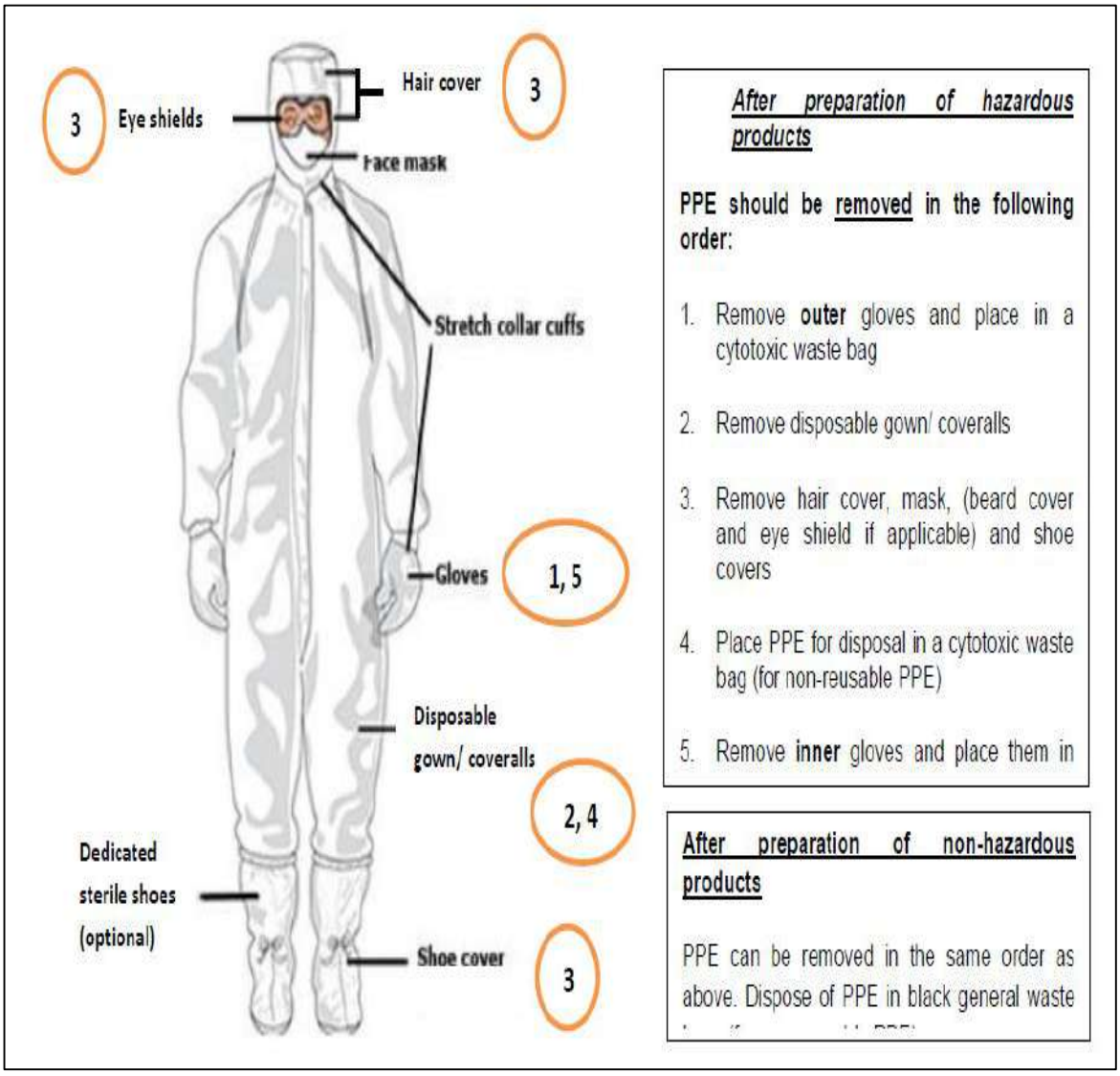


PPE should be donned in the following order:

1. Dedicated shoes or shoe covers
2. Hair cover
3. Face mask (beard cover and eye shields if required)
4. Non-shedding gown with a closed front, long sleeves and elastic or knit closed cuffs (Coveralls are only required for cleanroom procedures)
5. If handling hazardous drugs, a second pair of shoe covers should be donned.
6. Perform hand hygiene with antiseptic wash
7. Powder-free gloves

If handling hazardous drugs, second pair of gloves must be worn, with the outer pair extending over the cuff of the gown.

APPENDIX (9) DE-GOWNING ORDER



After preparation of hazardous products

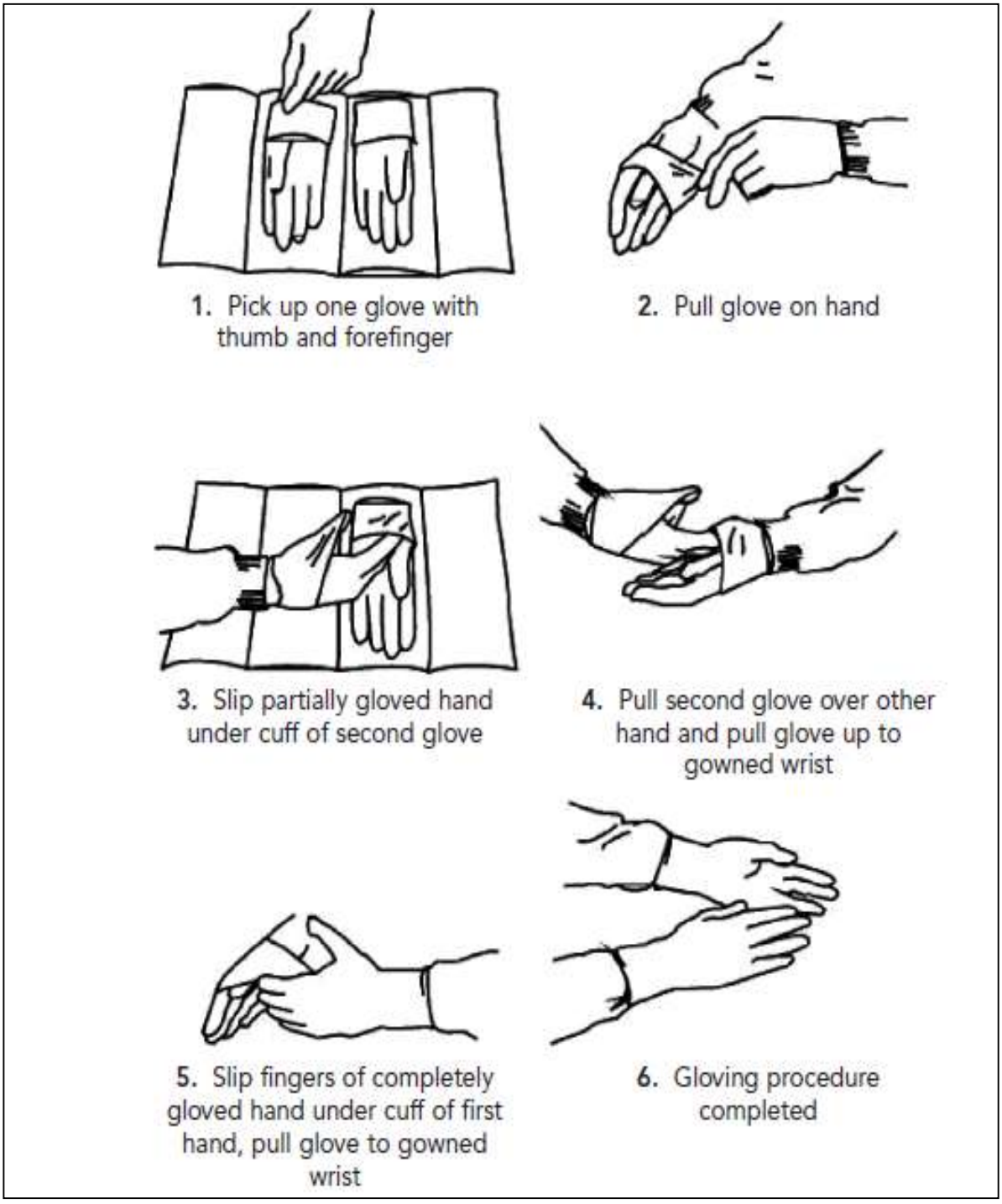
PPE should be removed in the following order:

1. Remove **outer** gloves and place in a cytotoxic waste bag
2. Remove disposable gown/ coveralls
3. Remove hair cover, mask, (beard cover and eye shield if applicable) and shoe covers
4. Place PPE for disposal in a cytotoxic waste bag (for non-reusable PPE)
5. Remove **inner** gloves and place them in

After preparation of non-hazardous products

PPE can be removed in the same order as above. Dispose of PPE in black general waste

APPENDIX (10) GLOVING TECHNIQUE



APPENDIX (11) SAVING EXCEL SHEET

M	L	K	J	I	H	G	F	E	D	C	B	A	
										السبت ١١/١/١١١١		التاريخ:	1
MESNA		Cyclophosphamide		Vincristine		Cytrabine		Adriamycin					2
الجرعة	الصرف	الجرعة	الصرف	الجرعة	الصرف	الجرعة	الصرف	الجرعة	الصرف	رقم الاخطار	رقم المستشفى	اسم المريض	3
						750	1000	30	50			فلان الفلاني	4
1800	2000	1750	2000	1.5	2			90	100			فلاني الفلان	5
2600	2800	2250	3000			1300	2000					فلان الفلان	6
						800	1000	70	100			فلاني الفلاني	7
													8
													9
													10
													11
4400	4800	4000	5000	1.5	2	2850	4000	190	250	Total			12
400		1000		0.5		1150		60		Saving			13
1		1		0.25		1.15		1.2		vials			14
1		1		0		1		1		closed vials			15

(Designed by Dr. Amany El-Zei

APPENDIX (12) THE ROLE OF ULTRAVIOLET RADIATION IN BSCS

- Ultraviolet radiation is a form of non-ionizing radiation, and biological effects from it vary with wavelength, photon energy, and duration of exposure. The 100-280 nm wavelength band is designated as UV-C, which is used for germicidal purposes.
- The sterilization/decontamination activity of UV lights is limited by a number of factors, including Penetration, Relative humidity, Temperature, air movement, Cleanliness, and UV age. For these reasons and other concerns, the National Sanitation Foundation (NSF) does not recommend the use of UV lights in BSCs.
- **If a UV lamp is used in your BSC,** UV lights must be turned off whenever the room is occupied; due to the short time for UV exposure can result in skin burns and severe eye damage.
- BSCs with UV lamps **MUST** be labeled with a UV Light Source Caution sticker. UV lamps are not recommended for decontamination unless they are properly maintained.

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