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A Review on Scope Importance and Future Needs of Clinical Pharmacy Practice in India

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A B S T R A C T

It is a branch of pharmacy where the pharmacist provides patient care with opimum use of medications cure treatment prevention of the disease. Area of the pharmacy concern with the science and practice of rational use of the drugs. Pharmacy practice is to improve public health through ensuring safe, effective, and appropriate use of medications. Contemporary pharmacy practice reflects an evolving paradigm from one in which the pharmacist primarily supervises medication distribution and counsels patients, to a more expanded and team-based clinical role acivities to providing patient care, medication therapy management, adverse drug reactions management, ward round particiration, drug interactions identity, therapeutic drug monitoring, drug information and poison information services, drug policies, medication chart writing drug health improvement, drug evaluation and utilisation, disease prevention acivities and pharmacovigilense, clinical research, teaching, conducting awreness[1] programes in rural areas regarding disease prevention and management. the pharmacy council of India initiated M.Pharm in Pharmacy Practice In JSS College of Pharmacy, Mysore in 1995 with the support of Australian educational societies fullfledged teaching as well as clinical case based learning.

Keywords: Adverse effects, TDM, Ward Rounds, Disease, Pharmacovigilence

A R T I C L E I N F O

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1. Introduction

Clinical pharmacy is defined as that area of pharmacy concerned with the science and practice of rational medication use. Clinical Pharmacy includes all the services performed by pharmacists practising in hospitals, community pharmacies, nursing homes, home-based care services, clinics and any other setting where medicines are prescribed and used. The term "clinical" does not necessarily imply an activity implemented in a hospital setting.

Goals of pharmacy practice

To Promote the correct and appropriate use of medicinal products and devices.

These activities aim at:

a. Maximising the clinical effect of medicines
b. Minimising the risk of treatment-induced adverse events
c. Minimising the expenditures for pharmacological treatments.

Clinical Pharmacy Requirements

a. Before the prescription
b. Clinical trials
c. Formularies
d. Drug information
e. Drug-Related Policies

During the prescription

a. Counselling activity
b. Clinical pharmacists can influence the attitudes and priorities of prescribers in their choice of correct treatments.
c. The clinical pharmacist monitors, detects and prevents

Medication related problems

a. The clinical pharmacist pays special attention to the dosage of drugs which need therapeutic monitoring [2].
b. Community pharmacists can also make prescription decisions directly, when over the counter drugs are counselled.

After the prescription

a. Counselling
b. Preparation of personalised formulation
c. Drug use evaluation
d. Outcome research
e. Pharmacoeconomic studies
f. The earliest traditional systems of medicine practiced in India have been Ayurveda and Siddha. The Unani Greco- Arabic medical system came from West Asia. The colonial period brought the new western system of medicine and paved the way to emerge pharmacy houses in India.
g. The origin of pharmacy institutions in India dates back to 1899 in Madras for training of pharmacists followed by the state medical faculty of Bengal in 1928. Prof. M.L. Schroff, father of pharmacy educa-tion in India, started UG program in pharmacy at BHU in the year 1932, later, Andhra University in 1937, Madras University in 1938, Bombay University in 1943, Punjab University in 1944 and L.M. College in 1947 started degree programme.
h. The statutory regulation of pharmacy institutions in India was established with the enactment of the Pharmacy Act 1948, and The Pharmacy Council of India was established in the year 1949 and the first education regulations (ER) framed in 1953, which were subsequently amended in 1972, 1981 and 1991.
i. The PCI regulates the pharmacy education and profession in India At present there are more than 1500 institutions offering various pharmacy programmes of Diploma, UG, PG and Pharm.D with an annual intake of more than 1,00,000 students. The syllabus is more industry oriented and mainly focused to cater the needs of the Pharmaceutical Industry.
j. The Pharmacists with UG and PG qualification preferred working in Industry rather than Community Pharmacy due to lucrative job opportunities and most of the commu-nity pharmacists engaged are Diploma holders in India[3]. The patent regime triggered the growth of Indian Pharma Industry as innovative Industry. The availability of vast technical pool, skilled manpow-er, well-established state of art manufacturing plants, made Indian Pharma Industry as global Pharma destination.
k. The universities or in a university department. Students holding a B.Pharm degree can earn an M.Pharm degree in 2 years, of which the second year is devoted to research leading to a dissertation in any pharmaceutical discipline, for instance pharmaceutics, pharmacology, pharmaceutical chemistry, or pharmacognosy. Recently, MPharm programs on industrial pharmacy, quality assurance, and pharmaceutical biotechnology have been intro-duced.
l. To train the graduate pharmacist to provide clinical-oriented services, the MPharm program in pharmacy practice was introduced at Jagadguru Sri Shivaratreeswara (JSS) College of pharmacy at Mysore in 1996 and at Ooty in 1997.
m. There are 6 National Institutes of Pharmaceutical Education and Research (NIPERs) in India offering MS (Pharm), MTech (Pharm), and higher-level degrees.
n. The NIPERs were created with the vision of providing excellence in pharmacy and pharmacy-related education. Students with an MPharm degree in any discipline can work toward a PhD with an addition-al minimum 3 years of study and research.
o. The Pharm.D program constitutes 6 years of full-time study. The PharmD (post-baccalaureate) program is a 3-year program. The Pharm.D program was introduced in 2008 with the aim of producing pharmacists who had undergone

p. extensive training in practice sites and could provide pharmaceutical care to patients.[4]

Clinical Pharmacy Practice areas

a. Ambulatory care
b. Critical care
c. Drug Information
d. Geriatrics and long –term care
e. Internal medicine and subspecialties
f. Cardiology
g. Endocrinology
h. Gastroenterology
i. Infectious disease
j. Neurology
k. Nephrology
l. Obstetrics and gynecology
m. Pulmonary disease
n. Psychiatry
o. Rheumatology
p. Nuclear pharmacy
q. Nutrition
r. Pediatrics
s. Pharmacokinetics
t. Surgery

How to Pursue a Profession in Clinical Pharmacy in Abroad

i. Pharm.D
ii. Master Degree in clinical Pharmacy Practice
iii. Residency with 3 years of training in Government hospitals

Clinical pharmacy practice offering colleges in india

- JSS college of pharmacy Mysore.
- JSS college of Pharmacy.ooty
- SRM University, Chennai.
- Andra university, vizag.
- Annamalai University, Chennai
- Amity University, Kerala
- Dr.M.G.R.University, Chennai.
- KLE University.Bangalore.
- MANIPAL University, Manipal.
- Nirma university, Gujarat
- Al-Ameen college of Pharmacy, Bangalore
- Ratnam institute of Pharmacy, .Nellore.
- Rao's college of Pharmacy, Nellore
- RIPER, Anantapur
- Sri Venkateswara college of Pharmacy, Chittoor.
- Sri Padmavathi School of Pharmacy, Tirupati
- Vagdevi College of Pharmacy, warangal.

Clinical Pharmacist Roles

a. Medication history investigation.
b. Adverse drug reactions Management
c. Drug information services
d. Poison information services
e. Pharmaceutical care
f. Patient counselling
g. Therapeutic drug monitoring
h. Ward Round Participation
i. Patient referrel services[5]
j. Drug interactions management
k. Drug chart Writing
l. Drug policies writing
m. Inventory control methods
n. Response to drug querys
o. Drug chart writing
p. Clinical Lab Investigations

Basic components of Clinical Pharmacy practice

- Prescribing of drugs
- Administering of Drugs
- Documentation of drugs
- Review of the drugs
- Communication
- Counselling
- Consultations
- Prevent the Medications errors

2. Scope of Clinical Pharmacy Practice

The changing scenario in societal requirement and more emphasis on health care system indicates clear shift in the science based pharmacy education to practice based. With successful implementation of PG programmes in Hospital Pharmacy and Pharma-cy Practice in selected institutions, the Policy makers and Pharmacy educators in India proposed the introduction of Pharm.D programme (5 yrs of training and 1 yr internship). As a major break-through in the history of Pharmacy education in India, The Pharm.D regulations u/s 10 of the Pharmacy Act 1948, have been notified in the Gazette of India on10thMay, 2008 with an aim to equip the future pharmacist of India with skills of not only dispensing medicines but also to serve as counselor of medicines with focus towards patients and prescriber of drugs.[6]

Steps involved in scope of pharmacy practice

- Drug information
- Drug selection
- Drug utilisation
- Drug administration
- Drug distribution
- Drug evaluation
- Medication Therapy management
- Formal education
- Teaching
- Research
- Disease state management

Clinical Pharmacy requirements

- Knowledge of drugs
- Knowledge of disease
- Knowledge of Non drug therapy
- Knowledge of better therapeutic Knowledge
- Drug information skills
- Communication skills
- Physical assessment skills
- Patient monitoring skills

Medication Related problems

- Untreated indications.
- Improper drug selection.
- Subtherapeutic dosage.
- Medication Failure to receive
- Medication Overdosage.
- Adverse drug reactions.
- Drug interactions.
- Medication use without indication.

Information sources

- Medication records
- Patient
- Family members
- Health care team
- Responsibilities of clinical pharmacist
- Design of dosage forms
- Recommendation of drugs
- Adjust of the drugs
- Communication
- Counselling
- Consultation
- Collaboration with departments of hospitals
- Design of research

Medical Records investigations

a. Admission Information
b. Initial history
c. physical examination
d. Progress notes
e. Consultations
f. Nursing notes
g. Laboratory data
h. Diagnostic Procedures
i. Radiology
j. Surgery
k. Orders
l. Medication administration orders
m. Consent forms

Responsibilities of clinical Pharmacist

- Designing patient-specific drug dosage regimens
- Recommending or scheduling measurements of drug concentrations in biological fluids
- Monitoring and adjusting dosage regimens
- Evaluating unusual patient responses to drug therapy for possible pharmacokinetic and pharmacologic explanations.
- Communicating patient-specific drug therapy information to physicians, nurses, and other clinical practitioners and to patients orally and in writing, and including documentation of this in the patient's health record[7].
- Educating pharmacists, physicians, nurses, and other clinical practitioners about pharmacokinetic principles and appropriate indications for clinical pharmacokinetic monitoring, including the cost-effective use of drug concentration measurements.
- Developing quality assurance programs for documenting improved patient outcomes and economic benefits
- Promoting collaborative relationships with other individuals and departments involved in drug therapy

Pharmacists with specialized education, training, orexperience may have the opportunity to assume the following additional responsibilities:

a. Designing and conducting research
b. Developing and applying computer programs and point-of-care information systems to enhance the accuracy and sophistication of pharmacokinetic modeling and applications to pharmaceutical care.
c. Serving as an expert consultant to pharmacists with a general background in clinical pharmacokinetic monitoring[8].

Role of the Pharmacist in Pharmaceutical Care

Direct responsibility for patient outcomes and medication management

a. Improve patient compliance with therapy (both pharmacologic and non-pharmacologic)
b. Decrease medication errors by enhancing communication
c. Monitor disease state status
d. Reduce probability of extended care
e. Manage costs by intervention

Standards of Pharmacy practice

- Promote consistency and uniformity in the practice of pharmacy
- Continuous quality improvement
- Assess quality of care provided
- Assess competency of practitioners

Vision for Pharmacy Practice

- The scope of pharmacy practice should be defined by national practice standards
- Competency based licensing criteria are the first steps in standardization
- Scope of practice must align with the expectations for standards of care[9]

Patient counselling

Stages in patient counseling:

a. Introduction.
b. Content.
c. Process.
d. Conclusion.

Introduction:

- Review the patient record prior to counseling.
- Conduct an appropriate patient counseling introduction by self and patient.
- Explain the purpose of counseling session.
- Obtain pertinent initial drug related information. E.g.: drug allergies, and other medications.
- Warn the patient about taking other medications including OTC drugs, herbals, or botanical drugs and alcohol which could inhibit or interact into the prescribed medication.
- Asses the patient understandings of reason for therapy.[10]
- Assess any actual or problems of importance to the patient.

Counseling contents item:

a. Discuss the name and indication of the medication.
b. Explain the dosage regimen including duration of therapy when appropriate.
c. Assist the patient in developing a plan to incorporate the medication regimen into his/her daily routine.
d. Explain how long it will take for the drug to show its effect.
e. Discuss storage and refilling information.
f. Emphasize the benefits of completing the medication as prescribed.
g. Discuss the potential side effect.

h. Discuss how to prevent or manage the side effects of the drug.
i. Discuss the precautions.
j. Discuss the significant drug-drug, drug-food, and drug-disease interaction.
k. Explain precisely what to do if the patient misses the dose.
l. Explore the potential potential problems of the patient.

Barriers to patient counseling:

The barriers that come in the way of conducting patient counseling are:

- Environment
- A busy pharmacy
- Lack of privacy
- Noise
- Physical barrier
- Patient factors
- Physical disabilities
- Comprehensive difficulties
- Illiteracy
- The pharmacist
- Time

Adverse drug reactions

Definition

Response to a drug that is *noxious and unintended* and that occurs at doses used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiologic function.{11}

Classification

Onset of event:

a. Acute within 60 minutes
b. Sub-acute 1 to 24 hours
c. Latent > 2 days

Classification – Severity

Severity of reaction:

- Mild;bothersome but requires no change in therapy
- Moderate; requires change in therapy, additional treatment, hospitalization
- Severe; disabling o r life-threatening

Classification

Type A

a. Extension of pharmacologic effect
b. Often predictable and dose dependent
c. Responsible for at least two-thirds of adrs
d. E.g: Propranolol And Heart Block, Anticholinergics And Dry Mouth

Type B

a. Idiosyncratic or immunologic reactions
b. Rare and unpredictable
c. E.g: Chloramphenicol and Aplastic Anemia

Type C

a. Associated with long-term use
b. Involves dose accumulation
c. E.g: phenacetin and interstitial nephritis or antimalarials and ocular toxicity[12]

Type D

Delayed Effects (dose independent)
Carcinogenicity (e.g., immunosuppressants)
Teratogenicity (e.g., fetal hydantoin syndrome)

Common Causes of ADRs

- Antibiotics
- Antineoplastics*
- Anticoagulants
- Cardiovascular drugs*
- Hypoglycemics
- Antihypertensives
- NSAID/Analgesics
- Diagnostic agents
- CNS drugs*
- Account for 69% of fatal ADRs

ADR Detection

Subjective report

Patient Complaint

Objective report:

a. Direct observation of event
b. Abnormal findings
c. physical exam
d. laboratory test
e. diagnostic procedure

Medication order screening

- Abrupt medication discontinuation
- Abrupt dosage reduction
- Orders for "trigger" substances
- Orders for special tests or serum drug concentrations
- Spontaneous reporting
- Medication utilization review
- Computerized screening
- Chart review and concurrent audits

ADR Detection in Clinical Trials

Methods

a. Standard laboratory tests
b. Diagnostic tests[13}
c. Complete history and physical
d. Adverse drug event questionnaire
e. Extensive checklist of symptoms categorized by body system
f. Review-of-systems approach
g. Qualitative and quantitative

Appropriate triage: Acute (ER, ICU, Poison Control)

Detailed Description of Event

a. History of present illness
b. Signs / Symptoms: PQRSTA
c. Provoking or palliative factors
d. Quality (character or intensity)
e. Response to treatment, Radiation, Reports in literature
f. Severity / extent, Site (location)[15]
g. Temporal relationship (onset, duration, frequency)
h. Associated signs and symptoms

Pertinent Patient/Disease Factors

Demographics

a. Age, Race, Ethnicity, Gender, Height, Weight
b. Medical history and physical exam
c. Concurrent conditions or special circumstances
d. E.g., Dehydration, Autoimmune Condition, Hiv Infection, Pregnancy, Dialysis, Breast Feeding

e. Recent procedures or surgeries and any resultant complications
f. E.g: contrast material, radiation treatment, hypotension, shock, renal insufficiency
g. End-organ function
h. Review of systems
i. Laboratory tests and diagnostics
j. Social history
k. tobacco, alcohol, substance abuse, physical activity, environmental or occupational hazards or exposures
l. Pertinent family history[16]
m. Nutritional status
n. special diets, malnutrition, weight loss

Pertinent Medication Factors

Medication history

- Prescription medications
- Non-prescription medications
- Alternative and investigational therapies
- Medication use within previous 6 months
- Allergies or intolerances
- History of medication reactions
- Adherence to prescribed regimens
- Cumulative mediation dosages

Medication

Indication, dose, diluent, volume

Administration

Route, method, site, schedule, rate, duration

Formulation

Pharmaceutical excipients

E.g: colorings, flavorings, preservatives

Other components

a. E.g: DEHP, latex
b. Pharmacology
c. Pharmacokinetics (ADME)
d. Pharmacodynamics
e. Adverse effect profiles
f. Interactions
g. Drug-drug
h. Drug-nutrient
i. Drug-lab test interference

Cross-allergenicity or cross-reactivity

Causality Assessment

- Prior reports of reaction
- Temporal relationship
- De-challenge
- Re-challenge
- Dose-response relationship
- Alternative etiologies
- Objective confirmation
- Past history of reaction to same or similar medication

Examples of causality algorithms

a. Kramer
b. Naranjo and Jones
c. Causality outcomes
d. Highly probable
e. Probable
f. Possible
g. Doubtful

Management Options

a. Discontinue the offending agent if:
b. It can be safely stopped
c. The event is life-threatening or intolerable
d. There is a reasonable alternative
e. Continuing the Medication will further exacerbate the Patient's Condition
f. Continue the medication (modified as needed) if:
g. It is medically necessary
h. There is no reasonable alternative
i. The problem is mild and will resolve with time.
j. Discontinue non-essential medications
k. Administer appropriate treatment

E.g: atropine, benztropine, dextrose, antihistamines, epinephrine, naloxone, phenytoin, phytonadione, protamine, sodium polystyrene sulfonate, digibind, flumazenil, corticosteroids, glucagon

Provide supportive care

E.g: hydration, glucocorticoids, warm / cold compresses, analgesics or antipruritics

Consider rechallenge or desensitization

Management options: Follow-up and Re-evaluation

- Patient's progress
- Course of event
- Delayed reactions
- Response to treatment
- Specific monitoring parameters

Documentation and Reporting

a. Medical record
b. Description
c. Management
d. Outcome

Reporting responsibility

a. The Government of India has initiated the National Pharmacovigilance Programme. The Central Drugs Standard Control Organization (CDSCO) is coordinating this country-wide programme. It has established 2 zonal centres, 5 regional centres and 28 peripheral centres for monitoring Adverse Drug Reaction (ADR) in India. (jipmer.edu)
b. Pharmaceutical manufacturer
c. Publishing in the medical literature

What to report

a. Report adverse experiences with medications
b. Report serious adverse reactions. A reaction is serious when the patient outcome is:
c. death
d. Life-threatening (real risk of dying)
e. Hospitalization (initial or prolonged)
f. Disability (significant, persistent or permanent)
g. Congenital anomaly
h. Required intervention to prevent permanent impairment or damage

Report even if:

You're not certain the product caused adverse reaction

You don't have all the details although point nos. 1, 5, 6, 7, 8, 11 and16 in the ADR form are essentially required.

Who can report

Any health care professional (Doctors including Dentists, Nurses and Pharmacists).

What happens to the information submitted

a. Information provided in this form is handled in strict confidence. Regional Pharmacovigilance Center will do the causality analysis and forward this form to the Zonal Pharmacovigilance Centre. The data is statistically analysed and forwarded to Central drug standard control organization (CDSCO). Ministry of Health & Family Welfare, Govt. of India, New Delhi. Finally the report will be deposited in the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center, Sweden.
b. Data is periodically reviewed by the National Pharmacovigilance Advisory Committee constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with responsibility to review the data and suggest any interventions that may be required.

Confidentiality

The patient's identity is held in strict confidence and protected to the fullest extent. Program staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction [17].

Components of an ADR Report

a. Product name and manufacturer
b. Patient demographics
c. Description of adverse event and outcome
d. Date of onset
e. Drug start and stop dates/times
f. Dose, frequency, and method
g. Relevant lab test results or other objective evidence
h. De-challenge and re-challenge information
i. Confounding variables

Pharmaceutical care

The principal goal of pharmaceutical care is to achieve positive outcomes from the use of medication that improves patients' quality of life.

These outcomes include:

a. Cure of a disease
b. Elimination or reduction of symptoms
c. Arresting or slowing a disease process
d. Prevention of disease
e. Diagnosis of disease
f. Desired alterations in physiological processes,
g. All with minimum risk to patients.

Pharmacy Practice Sites

a. Community Pharmacy
b. Hospital Pharmacy
c. Clinical Pharmacy
d. Long-term Care Facilities
e. Academia
f. Pharmaceutical Industry
g. Government
h. Armed services
i. Mail order/Internet pharmacy

Therapeutic drug monitoring (TDM)

Why request TDM

- Noncompliance
- Inappropriate dosage
- Poor bioavailability
- Drug interaction
- Kidney and liver disese
- Altered protien binding
- Fever
- Cytokines
- Genetically determined fast or slow metabolizers
- Criteria for TDM

Assay methods

a. Narrow therapeutic range
b. Poor relationship between dose and serum drug concentrations (SDC)
c. Non-linear pharmacokinetics
d. Good relationship between serum SDC and therapeutic/toxic effects
e. Factors affecting tdm
f. Disease states: renal, liver, cardiac, thyroid
g. Habits: diet, smoking, drinking
h. Pregnancy, age, weight
i. Non-compliance
j. Electrolyte balance : Digoxin vs K+ & Ca++
k. Drug interactions
l. Plasma protein binding
m. Bioavailability
n. Sampling time

Ward round participation

Participation the medical round with medical students along with the doctors

a. Professor round
b. Teaching round
c. Resident round
d. Pre round

Medication Chart Review

a. It is a fundamental responsibility of a pharmacist to ensure the appropriateness of medication orders.
b. It serves as starting point for other clinical pharmacy activities (medication counselling, TDM, DI, and ADR).
c. Organising information according to medical problems (example disease) helps breakdown a complex situation into its individual parts

Clinical Review*:*

Clinical review is one of the integral components of medication review and should preferably be performed on a daily basis. It is the review of the patients' progress for the purpose of assessing the therapeutic outcome. The therapeutic goal for the specific disease should be clearly identified before the review.

Goals:

The primary aims of the clinical review are to:

a. Assess the response to drug treatment.
b. Evaluate the safety of the treatment regimen.
c. Assess the progress of the disease and the need for any change in therapy.

d. Assess the need for monitoring, if any.
e. Assess the convenience of therapy(to improve compliance).

Role of Pharmacist in the Management Of ADR

- Monitoring the patients who are at greater risk of developing ADR's
- Monitoring the patients who are prescribed with drugs highly susceptible to cause adr
- Assessing and documenting the patient's previous allergic status
- Assessing the patient's drug therapy for its appropriateness
- Assessing possible drug interactions in case of multiple therapies
- Assessing health care professionals in detection and assessment of ADR's
- Encouraging/ stimulating healthcare professionals in reporting on ADR
- Documentation of suspected reported reactions for future reference
- Follow up of patients to assess the outcome of the reaction and management
- Obtaining feedback about the reported reaction
- Educating healthcare professionals about the importance of an ADR
- Educating patients

Drug use evaluatiion (DUE)

Drug udrug uslevel). Ibe necestructura drug review use evaluatise that will hIf therapy iessary to ored so that i(indication(DUR) andion (DUE**)** help ensures deemed to optimize drug

The goals of a DUE meets standards to promote the standards of care. A n optimal Additional medication objectives therapy a may include and ensure the:

a. Creatinng guidelines (criteria)for appropriate drug utilization
b. Evaluating the efffectiveness of medicatiion therapy
c. Enhancing responsibility/acccountability in the mediicine use process
d. Controlling the medicine cost.[17]

3. Conclusion

Pharmacy practice is a case oriented learning in abroad well established better accepted by the community. But in India under developing, pharmacy practice provides patient care and safety to the patient. The new evolutions in health care and pharmacy practice are presenting many new opportunities for pharmacists to perform functions and provide services to the community and lack of awareness it was back in India. We are hope that in coming days it was better accepted by the communities in India and create disease less society.[18]

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