Review Article

Clinical Pharmacy Practice in Low and Middle-Income Countries; Special Focus on Nepal

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ABSTRACT

The paradigm shift of pharmacy practice from the conventional compounding and dispensing role towards more advanced patient-centered care has a positive impact on the health care system. Not only has it rendered safe, appropriate, and cost-effective drug therapy, but it has also optimized the therapeutic outcome. Though there is optimal growth of clinical pharmacy practice in the developed world, incorporating these new models into action has become a challenge for low-and middle-income countries (LMICs) like Nepal. Notably, the existing pharmacy curriculum is not updated to meet the current healthcare needs. Currently, the job opportunities are limited to manufacturing roles in pharmaceutical industries and as dispensers in the community and retail pharmacies. Pharmacists and pharmacy practice have to evolve with the latest trends in demographics, epidemiology, societal factors, economy, and technological advances. It is high time that the policy-making bodies prepare and implement guidelines for strengthening clinical pharmacy practice in LMICs. The clinical pharmacy practice assures the rationalization of therapeutic outcomes with proper protocols, effort from the pharmacists, sound academic background and related training, and professional attitudes. This review sought to explore and expand the role of clinical pharmacists in healthcare settings, particularly in LMICs like Nepal.

Keywords: Pharmacists, Developing Countries, Nepal, Professionalism, Patient-Centered Care

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INTRODUCTION

Pharmacy service is an indispensable part of a healthcare system. The pharmacists' traditional role has evolved from medication dispensing to the patient-oriented care. Besides maximizing therapeutic efficacy, this approach has also reduced medication use-related problems. This is why we can say that the pharmacists' participation in inpatient care has contributed to the rational use of medicines. The

American College of Clinical Pharmacy (ACCP) defines clinical pharmacy as a health science discipline that constitutes the application by pharmacists of scientific principles of pharmacology, toxicology, pharmacokinetics, and therapeutics to patient care. This concept is implemented in numerous developed countries such as the United States, demonstrating the paradigm shift of practice.² Concerning this, the clinical pharmacy is explained as promoting rational

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drug therapy where the competent pharmacists ensure drug use and hence disease management according to patients' social, psychological, and biological aspects for optimizing therapeutic outcomes.

Clinical pharmacy service has become inevitable for a complete health care system. The pharmaceutical care focused on the patients in a health care facility has gained momentum in today's world. Clinical pharmacists gain expertise through specialized education and training in the relevant field. A multidisciplinary team comprising physicians, nurses, other health care professionals, and clinical pharmacists can ally optimizing therapy. Pharmaceutical service is a vital component of health care settings, ensuring the availability of the right medicines to the right person at the right time.³

In low-and middle-income countries (LMICs) like Nepal, where a proper healthcare system is not fully established, clinical pharmacy is yet to be recognized and is in its infancy. Some government and private hospitals have hired pharmacists to work in clinical settings. The existing inadequacies in the pharmacy curriculum have not been able to provide necessary clinical exposure to the students. The job openings are restricted to pharmaceutical industries pharmacists perform manufacturing roles and in community and retail pharmacies where they play the role of dispensers. Whereas several previous studies have discussed the clinical pharmacy practice in many other countries, in the current review, we will explore and expand the role of clinical pharmacists in healthcare settings in LMICs, particularly in Nepal.

METHODOLOGY

Google Scholar, PubMed, ScienceDirect, and current affairs were electronically searched using specific keywords like "Clinical Pharmacy" and "Clinical Pharmacist" or "Pharmacy practice" and "Pharmaceutical Care" and "Nepal". Related experts in the field were also consulted. Papers published in the English language were included for the conduction of this narrative review.

PROFESSIONAL ACTIVITIES

Knowing the patients' medication history is a significant step in the medication reconciliation process for a pharmacist. It helps protect the patients from adverse drug events that might result from medication

discrepancies between different health care settings.⁴ Clinical pharmacists can assess medication adherence, efficacy, and safety of prescribed drugs, patient knowledge regarding medicines, adverse drug reactions (ADRs), drug interactions (DIs), and potential drug misuse or abuse. With a sound theoretical and practical background, they can interact with patients regarding current clinical conditions, different pharmacologic and non-pharmacologic approaches to disease management, and the use of medical devices if necessary. This mutual interaction patient adherence, which promotes improves therapeutic outcome and quality of life, and level of patient satisfaction. This intervention also increases patients' understanding of medicine use and the importance of lifestyle modification in chronic conditions.⁵ When clinical pharmacists take part in ward rounds, it can facilitate individualized drug therapy; understanding past medication history, current medical conditions, selection of appropriate treatments, and discharge planning will improve the patient care quality. 6,7 Participation of pharmacists in therapeutic drug monitoring (TDM) helps in pharmaceutical evaluation of drug use, improving the choice of drug use and cost-effectiveness.8 TDM is the measurement of specific drugs concentration in a patient's blood to ensure the safety and efficacy of that drug.9 To optimize therapy, pharmacists apply pharmacokinetics and biopharmaceutics principles to interpret basic pharmacology into clinical pharmacology pharmacotherapeutics.^{6,9} The selection of drug dosage regimens based on individualized drug therapy can improve clinical outcomes. Graabaek T et al. reported that clinical pharmacists' medication reviews at hospitals improve patient outcomes.¹⁰

Good knowledge of organic and inorganic chemistry enables pharmacists to understand unexpected interactions between drug-drug and drugfood.⁶ They can be involved in drug interactions surveillance programs to advise on interventions for managing any adverse events that could affect drug therapy. A significant number of morbidity and mortality occurs due to adverse events and ADRs related to drug use. Therefore, pharmacovigilance, which means studying the benefits and risks of drugs, can be another critical responsibility to be taken by clinical pharmacists.¹¹ Their involvement in detecting, evaluating, monitoring, and minimizing ADRs

enhances patient compliance to medicine use. It, in turn, reduces hospitalization due to adverse events, harm to the patient, and ultimately the cost of therapy. Pharmacovigilance programs address the problems of underreporting and over-reporting of adverse events related to drug use. Such programs will help develop interventions to prevent ADRs and adverse events management costs. 12,13

Clinical pharmacists support and participate in research activities to advance human health and health care by developing research questions; conducting or participating in clinical, translational, and health services research; contributing to the evolving literature in evidence-based pharmacotherapy; and/ or disseminating and applying research findings that influence the quality of patient care. 14,15 Their involvement in clinical trials and drug development processes can also justify their roles in research and development.¹⁶ They can identify, resolve, and prevent medication-related problems. As a member of the multidisciplinary healthcare team, clinical pharmacists can involve themselves in the prescription review, drug use evaluation, investigational use of new drugs, etc. Thus, conducting a well-designed drug utilization review (DUR) helps understand drug use problems and develop appropriate interventions.¹⁷ The formation of different hospital committees that include clinical pharmacists can contribute to developing plans and policies related to patient care. 18 They can be involved the formulary development process, management procedures, and Standard Treatment Guidelines (STGs) formulation. They can also be involved in ambulatory care services. The extended health service (EHS) practices, including telepharmacy health services, preventive health services, disaster management programs, health service outreach programs (HSO), chronic disease management programs, etc., can further strengthen the clinical pharmacy practice. 1,16,19,20

HISTORICAL ASPECT: WHERE DO CLINICAL PHARMACISTS STAND?

The clinical pharmacy concept originated in the 1960s, which led to rapid evolution in pharmacists' role from conventional duties to direct patient care. This gave a new perspective to patient-centered care and developed the concept of the pharmaceutical care model in 1990. The model emphasized the role of the pharmacists as

"the responsible provision of drug therapy to achieve definite outcomes that improve a patient's quality of life." This model supported inter-professional collaboration (IPC) and is widely adopted, enabling pharmacists to become an essential component of the multidisciplinary health care team to deliver effective and patient-centered care. 22

The USA first embraced the clinical pharmacy practice and has been gaining acceptance throughout the world lately. American Association of Colleges of Pharmacy (AACP) has approved Doctor of Pharmacy (PharmD) as an entry-level pharmacy degree and the only professional degree in pharmacy.²³ Lately, developing countries like Pakistan, India, Bangladesh, several countries in the Middle East, and Africa are adopting this new curriculum in pharmacy education to create a better academic background for clinical pharmacy practice.²⁴

Clinical pharmacists have a direct role in inpatient care in the United States. This involves the selection, modification, and monitoring of patientspecific drug therapy. The IPC with other healthcare providers is vital. The provision of satellite pharmacies has decentralized pharmacy practice and brought pharmacists and patients together; this partnership has ensured the need for pharmacists in inpatient care. "Standards of practice for Clinical Pharmacists" was developed by ACCP and has highlighted the roles and responsibilities of clinical pharmacists for rational drug therapy.¹⁵ Collaboration of clinical pharmacists with other members of the health care team in ward rounds has resulted in a lower incidence of ADRs related to prescribing. There was a reduction in medication errors resulting from an inappropriate duration of use which is common in the countries with high-income economies and LMICs. 14,25 Malaysian government has prepared and implemented guidelines focusing on ward pharmacy, pharmacotherapy ward rounds, and clinical pharmacokinetic services.²⁶ In Kuwait, clinical pharmacy is well perceived but has not been able to overcome the barriers; lack of firm policy, time constraints, and poor clinical skills of pharmacists.²⁷ A study conducted in Vietnam after the commencement of legal regulation of clinical pharmacy service found a majority of the clinical pharmacy services non patient-specific in drug information, ADR counseling, reporting, etc.²⁸ Pharmacists' professional identity, work environment, and external barriers are also

hindrances to the delivery of clinical pharmacy services. Non-pharmacy healthcare professionals consider pharmacists as an element of the supply chain. Common competencies like leadership, confidence are falling, which has been attributed to opposition from other medical staff. Adequate numbers of pharmacists and pharmacy technicians with proper career plans a firm policy are required.²⁹ In countries like India and Pakistan, significant numbers of pharmacy students graduate each year. However, not much has been achieved in the clinical field as most of them are employed by pharmaceutical manufacturers.³⁰ In developed countries, pharmacists are given a prescriptive authority in particular settings whereby they can contribute to the quality of drug therapy.³¹ In the USA, the ambulatory care pharmacy residency program provides pharmacy residents with elaborative pharmacy practice training and experience in different settings. Clinical pharmacists monitor and supervise the anticoagulation services, which has led to optimization of drug therapy with targeted International Normalized Ratio (INR).³² Clinical programs like pharmacists assisted pharmacy antimicrobial treatment has led to optimized antimicrobial treatment, which has led to a reduction in length of hospital stay, hospital mortality, and better pharmacoeconomic outcomes in many parts of the globe.33

Clinical pharmacy practice, in particular, clinical pharmacy services in LMICs, including South Asian countries, is lagging. The reason behind this is inadequate faculty with expertise in a relevant field, poor pharmacy practice setups, lack of awareness, lack of regulations from an authority, and diverse curriculums taught without appropriate scope and opportunities.³⁴ A significant number of preceptors based in hospitals are lacking. Successful and effective preceptors require adequate training and preparation, which again becomes a human resource issue. Hospital pharmacists are often thought of as suitable alternatives, but this also comes when the hospitals are overwhelmed with patients.35 In Malaysia, doctors are still involved in dispensing duties which are attributed to a lack of pharmacists.³⁶ EPS has been in practice in the developed part of the world. However, LMICs are yet to implement policies to incorporate pharmacy services and build a positive attitude towards EPS which could contribute to the quality of health if the

government and other agencies would support and facilitate it.³⁷ Distinct separation in dispensing roles is seldom seen as the pharmacists are not the sole dispenser of medicine. There is a lack of separate dispensing guidelines for pharmacists.³⁶

Clinical Pharmacy Status in Nepal

Pharmacists in Nepal are primarily employed in industries, government sectors, marketing, community, and academic settings. The involvement of pharmacists in a hospital setting is getting recognized lately for their contribution to health care delivery. Though the pharmacists are involved in community-based pharmacy services, the function is limited to a mere shopkeeper without any guidelines and regulations. With limited rights and privileges, most pharmacists working in hospital settings are reluctant to participate in clinical practice. Much needs to be done as they are included in drug procurement, storage, and inventory management functions. The appointment pharmacists in clinical roles is still a farfetched dream in Nepal. In this regard, in the context of Nepal, clinical pharmacy is yet to get recognition and is in its early stage of development. The job openings are limited to manufacturing roles in pharmaceutical industries and dispensers in the community and retail pharmacies. A handful of private hospital hires pharmacists to work in clinical settings.

The existing inadequacies in the pharmacy curriculum have not been able to provide necessary clinical exposure to the students. There is a need for timely evidence-based teaching-learning techniques to produce efficient clinical pharmacists and recognition by policy-making bodies. The need for clinical pharmacy practice is crucial for pharmacists to enroll and practice in clinical settings. Institute of Medicine (IOM), Tribhuvan University (TU) was the first to start the proficiency certificate level (PCL) pharmacy program in 1972. Kathmandu University (KU) commenced the Bachelor of Pharmacy (BPharm) program in 2000, which was a milestone for pharmacy education in Nepal. Subsequently, Master of Pharmacy (M.Pharm.) and Doctor of Philosophy (PhD) in pharmaceutical sciences began in KU in 2000 and 2004, respectively. Pokhara University and Purbanchal University included B. Pharm and M. Pharm courses in their academics. KU also started a post-baccalaureate

PharmD program in 2010 to produce graduate pharmacists specialized in direct patient care.³⁸

Experts have made efforts in relevant fields to implement and strengthen clinical pharmacy practice. Formation of Drug and Therapeutics Committee (DTC), hospital formulary committee, hospital procurement management pharmaceuticals and policies, pharmacovigilance, and drug information services are positive steps. Though insignificant, pharmacists in some government and private hospitals such as Shree Birendra Hospital, Norvic Hospital, Mediciti Hospital, Bharatpur Hospital, and Patan Hospital have started patient-centered services like patient counseling, solo ward rounds, drug information services, prescription writing consultations, and drug therapy management services.

In 2015, Hospital Pharmacy Service Guideline was prepared and published by the Department of Drug Administration (DDA), Ministry of Health and Population, Nepal, which states that every hospital should have its pharmacy. It also recommends the ADRs monitoring, hospital formulary development, and formation of DTC for better therapeutic outcomes. The guideline is the first kind to recommend the presence of at least one clinical pharmacist for the hospital with a capacity of more than 50 beds. ^{39,40} Implementation of this guideline could provide a concrete platform for aspiring pharmacists pursuing their careers in clinical pharmacy.

SWOT ANALYSIS

Strengths

Pharmacists in clinical settings are uniquely positioned to provide complete drug therapy management services owing to their academic and professional expertise. When pharmacists work in association with the other healthcare team, it will positively impact medication cost-effectiveness, appropriateness, pharmacovigilance, adherence to drug therapy, and ultimately to health-related quality of life (HRQoL) of patients. 41 Pharmacists are the first point of contact for healthcare needs in a community where they see their patients multiple times than physicians.⁴² Pharmacists in the community are the third largest healthcare professionals who can have a beneficial effect in managing chronic illness at the community level.⁴³ Pharmacists working in clinical settings can further

enhance the medication reconciliation process to tackle drug mis-adventuring.⁴

Weaknesses

The pharmacy profession is in transition with uncertainty and ambiguity. Inadequate pharmacy personnel with limited medical logistics without sufficient training are common barriers to delivering pharmacy care in LMICs.⁴⁴ Pharmacists are constantly under role stress. Pharmacists' physical and mental health has deteriorated due to changing roles and demands set forth. Unless respective regulators and policymakers address this, the future of the profession and the safety of the patient is at stake. 45 The pharmacy workforce varies significantly amongst countries based on population and economic indicators, so countries with lower economic indicators will have lesser pharmacists, which will further cause disproportionate access to medicines and medical expertise. 46 Although it is well-established fact that pharmacists' inclusion in the health care team has contributed to patient-centered care, the enthusiasm and effort to promote clinical pharmacy services is minimal.³ It is noteworthy that competent pharmacists are affluent, and their tendency to work in urban areas causes shortages of qualified pharmacists in rural areas where pharmacists could further strengthen the drug use process.³⁶ Professional organizations, regulators, and concerned authorities should come forward and be vocal in including pharmacists in clinical practice to achieve definite pharmaceutical outcomes for the patients.

Opportunities

An effective team is paramount as there is an increase in co-morbidities requiring specialized patient care. Much-needed patient-centered care is the need of the hour. This can be achieved by sharing the values and principles of each involved to form a cohesive team that delivers optimum care to the patient.²² Such a good healthcare team requires the inter-and intraprofessional collaboration of healthcare experts. Pharmacists' roles can further be expanded to other non-clinical yet significant ones to achieve desired therapeutic success like patient advocacy. Clinical and managerial roles are the two key positions that pharmacists can hold. Pharmacists with sound backgrounds in drug costing can be an asset for the cost-effective management of therapy. This is of particular importance in LMICs, where medical costs are out of the pocket expenditure. Another chance for pharmacists is to use their knowledge base and involve in different phases of clinical trials, including post-marketing surveillance studies. A spontaneous reporting system widely used can be fortified by pharmacists. As a spontaneous reporting system, a pharmacovigilance system can be reinforced conducting unhindered as under-reporting is a common problem.

Threats

Pharmacists' inclusion in the core healthcare teams is a big challenge, particularly in LMICs. Standardized orientation and practice in clinical settings like residency programs are seldom conducted, further exposing the vulnerabilities of pharmacists. Possession of an adequate knowledge base in basic pharmacology and therapeutics may be insufficient for optimal delivery of pharmaceutical care in a patient-focused approach. An inadequate workforce with minimal exposure in such work areas may increase the workload on aspiring pharmacists and decrease their efficiency. Accepting the norms and values as clinical personnel is yet another challenge as they are often not considered healthcare specialists.

CONCLUSION

Much of the developed world has witnessed the optimal growth of pharmacy practice towards patient-centered services and thereby promoting rational drug use. The LMICs are far from reaping the benefits of the expertise of pharmacists. As demographics, epidemiology, societal factors, economy, and technological advances keep on changing, pharmacists and pharmacy practice have to evolve to suit themselves with the need. For implementation, proper continuation. strengthening of clinical pharmacy practice, the policybodies, including leading making pharmacy organizations and all concerned stakeholders, should step up their efforts in this part of the world. Thus, clinical pharmacy practice is not an option but rather an important obligation to be fulfilled to render safe, effective, and cost-effective drug therapy. Muchneeded individualized pharmacy services can be catered through clinical services given by pharmacists at community, hospital, and other clinical settings. Clinical pharmacy services can fulfill the caring void that has been created due to inadequate interprofessional collaboration. It can facilitate ethical access to drug therapy at an affordable cost and optimum quality.

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