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# SCENARIO OF CLINICAL PHARMACIST IN PATIENT COUNSELLING IN INDIA

**Asim Mohamed P.*** **and Amit Ranjan**

Department of Pharmacy Practice, Jamia Salafiya Pharmacy College, Malappuram, India – 673637.

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***Corresponding Author**
**Asim Mohamed P.**
Department of Pharmacy Practice, Jamia Salafiya Pharmacy College, Malappuram, India – 673637.

## ABSTRACT

The referred articles showed that, almost all retail as well as hospital pharmacists were practicing patient counselling, it was not up to the mark due to lack of infrastructure, awareness and of knowledge. To prevail over these issues, concerted efforts by the government authorities, pharmacists and academicians are needed. The gap can be filled with regularly organized content updating training programs for clinical pharmacists, introduction of new subject related to patient counselling in syllabus at diploma as well as undergraduate level. This will help to mobilize pharmacists to use modern techniques and social media for counselling.

**KEYWORDS:** Clinical Pharmacist, patient counselling, Pharmacist.

## INTRODUCTION

Throughout the world, over the past four decades there has been a consolidated effort to shift the concept of pharmacy practice from its earlier focus on medicine supply to patient care. An important responsibility of contemporary pharmacy practice is to ensure appropriate and safe drug therapy which is cost effective and socially committed.[1] Presently the situation has changed in a way that the pharmacy profession has moved from behind the counter to explore their excellence in the field of pharmaceutical care. The pharmaceutical care implies all pharmacy activities aimed at promoting right use of medicines by patient in the right manner.[2] Patient counselling is one of the most important tools for better pharmaceutical care. Knowledgeable patient's exhibit increased compliance with drug regimens, resulting in improved therapeutic outcomes. In 1996 first separate patient counselling centres was established in the Govt. Medical College Hospital, Trivandrum, attached to the community

pharmacy services of the department of Pharmacy Practice. In 1997, counselling centre with separate cabins and library facilities working on the clock basis was established. Patient counselling is defined as providing medication information orally or in written form to the patient or their representative on the direction of use, advice on side effects, precaution, storage, diet and life style modification.[2] It should be interactive in nature.

In 1990s Omnibus Budget Reconciliation Act specified some guidelines that pharmacist should follow while counselling patient: Name and description of the medication, dosage form and route of administration, special precautions for the preparation, administration or use of medication by the patient, common severe side effects, adverse effects, interactions and contraindications that may be encountered, technique for self-monitoring therapy, proper storage of the medication, prescription re-fills information, any action that should be taken in the event of a missed dose.[3] The information is usually given verbally, may be supplemented with written materials. Good communication skills and knowledge are needed to gain the patient's confidence and motivate the patient to adhere to the recommended regimen. But still there is no satisfactory counselling by the pharmacist in pharmacies and hospitals with very few evidences of separate counselling cabins. Pharmacist should have knowledge and skills to provide effective and accurate patient education and counselling. To obtain and sharing information with patient, effective open-ended questioning and active listening are essential skills. A separate room or space that ensures privacy and confidential communication with the patient that allows counselling and education to be conducted. Patient education and counselling usually occurs at the time prescriptions are dispensed but may also be provided as the separate service. Counselling concerning use of 'Generic medicines' is today's need. In Indian set up nobody will do the things unless there is strict act to implement regulations to provide compulsory patient counselling and pharmaceutical care by qualified personnel. So, legal assistance is specifically important by enacting a law by the parliament. In Maharashtra, the Pharmacy Council also took steps to popularized the counselling activities in the community set up with initiation of 'Patient Counselling Course' for pharmacist and recently focusing it to an academic curriculum of the diploma in pharmacy.[4]

## PROBLEMS AND ISSUES OF CURRENT SCENARIO

India is a developing country, facing significant drug related problems due to poly pharmacy. Compared to developed countries, patient compliance is not satisfactory in India. Survey investigations revealed pharmacist facing patient, system and provider-based barriers while

working as health care professionals. busy pharmacies, lack of time, non-availability of suitable infrastructure and lack of knowledge, sources, absence of training in skills like communication and interview, poor patient perception.[18, 19]

## PATIENT COUNSELLING

Patient counselling is defined as providing medication information orally or in written form to the patients or their representatives on directions of use, advice on side effects, precautions, storage, diet and life style modifications.[22] Patient compliance is defined as the adherence of a patient towards the prescriber's instructions.

Objectives of patient counselling[23, 24, 25]

1. Patient should recognize the importance of medication for his wellbeing.
2. A working relationship for continuous interaction and consultation should be established.
3. Patient understanding of strategies to deal with medication side effects and drug interactions should be improved.
4. Patient becomes an informed, efficient and active participant in disease treatment and self care management.
5. The pharmacist should be perceived as a professional who offers pharmaceutical care.
6. Drug interactions and adverse drug reactions should be prevented.

- Therapeutic drug monitoring of drug with narrow therapeutic index
- Drug information service
- Patient Service
- Improving patient compliance collecting past medical history.

## CLINICAL PHARMACIST IN INDIA

In lieu of the fact that without adequate supervision, the assurance of quality of any system is not possible; clinical pharmacy has emerged as one of the latest and unmapped discipline of pharmacy in the 21$^{st}$ century. The existence of clinical pharmacists in medical rounds could support physicians in optimizing pharmacotherapy. This novel profession in India extends its diversions to good manufacturing practices, procurement/preparation/distribution of medication, reporting ADRs/ ADEs and on the whole to a very promising aspect of patient healthcare service. The state of clinical pharmacy in India is in the transformational state showing serious positive promising changes in the past couple of years. Even hospitals have started distinguishing the importance of clinical pharmacy and have taken initiatives for

making it possible although at a budding stage. The clinical pharmacy branch of pharmacy is surely attaining new heights in regard to patient care services which have certainly increased the services and satisfaction to the patients.

Clinical pharmacy has emerged as one of the latest branches of pharmacy in 21$^{st}$ Century. It is where pharmacists deal with various aspects of patient care, dispensing of drugs and advising patients on the safe and rational use of drugs. It can also be explained as a part of pharmacy in which the clinical pharmacist provides patient care that optimizes the use of medication and promotes health, wellness, and disease prevention. To elaborate the story, we can say that clinical pharmacy is to use drug control and the effective application of the knowledge. Professional skills and ethics assure the optimal safety in the distribution and use of medicine. The purpose of the Professional Education in Clinical Pharmacy and Public Health is to qualify each pharmacologist (expert in pharmaceuticals) to practice clinical pharmacy at a higher and more professional level. Hence, ensures the patient's maximum well-being during the drug therapy.

Clinical pharmacy describes the new role of the 21$^{st}$ Century's pharmacists. It doesn't restrict the role of a pharmacist merely to good manufacture practices, easy procurement, proper preparation, distribution and control of drug products. In addition, it also comprises functions necessary to discharge a particular set of social responsibilities related to proper therapeutic use of drugs in the aspects like prescribing, dispensing and administrating drugs, documenting professional services, direct patient involvement, Reviewing drug use, Education, Consultation and Counselling. The aim of clinical pharmacy practice is to ensure the patient's maximum well-being and to play a meaningful role in the safe and rational use of the drugs. These goals are to enable the physician do a better job of prescribing and monitor the drug therapy for patient. Further, to help the medical and para-medical staff to enable effective drug therapy. Clinical pharmacy practice also deals with proper maintenance of the documentation regarding the medication incidents effectively to maximize the patient's compliance in drug use process.

## HEALTH CARE TEAM AND A CLINICAL PHARMACIST

There are certain laid roles and responsibilities of a clinical pharmacist in a health care team that consists of several medical and para-medical professionals. These responsibilities should be executed by the clinical pharmacist with immense care. The clinical pharmacist should interact with the patients and maintain their complete and exhaustible medical history. The

clinical pharmacist should also do proper documentation of the hypersensitivities or allergy to certain drugs, food habits, drug dependence or intoxications to certain chemical substances, side effects of some drugs, incorrect drug administration, etc about the patient.[7] The prescribed drugs may interact with certain OTC drugs; therefore, after receiving the prescription the clinical pharmacist should check the patient's medical history for drug related interactions and patient's habits. This helps in effective and accurate medical therapy.

In the selection of a proper drug product/generic formulation (depending on the bio-availability and equivalence of such products) the clinical pharmacist can help the physician. Clinical pharmacist can help in monitoring of drug therapy to ensure safety and efficacy. Monitoring of the drug therapy is very important particularly for those drugs that have narrow therapeutic index or administered chronically.[8] Various pharmacokinetic parameters can also be checked by the clinical pharmacist based on: plasma concentration of drug, enzymes and measurement of glucose quantity in blood, etc.

Patients with kidney impairment or hepatic disorders are more prone to adverse drug reactions. Clinical pharmacist can help in detection, prevention and reporting of adverse drug reactions. He may advice the physician for alternate drug therapy for the concerned patients. Clinical pharmacists may play a major role in designing health and drug policies, and assist as a source of information for the health care professionals and to the public. The drug management greatly relies on the clinical pharmacist to check the selection, requirement, procurement, distribution and use of the drugs. Also, Research and development in the field of biological availability of active ingredients requires active participation by the clinical pharmacists. The clinical pharmacist can help in executing clinical trials and based on standard principles and bio-statistical evaluation. A clinical pharmacist is an expert to provide detailed information to the health professionals and the general public. Effective selection, utilization and retrieval of drug literature by the clinical pharmacist can enable in the proper understanding of the facts by the medical team. He can also abstract information from periodic bulletins, newsletters or other pharmacy literature.

## SCOPE OF CLINICAL PHARMACY IN INDIA

In hospitals the services regarding clinical pharmacy are of considerable value because the concerned clinical pharmacist serves as a guide to the physician for safe and rational use of drugs.[9] He also assists to achieve economy in the hospital by planning safe drug policies, suggestive means of reduction of waste, by preventing misuse or pilferage of drugs. In

addition to it the preparation of preventing forecasting future drug requirements of the hospital, based upon their drug utilization patterns. Therefore, scope of clinical pharmacy covers areas to foster innovation, improve public health and provide a knowledge exchange. Clinical pharmacist enables rational drug use by providing correct drug information including the proper utilization of the drugs utilized as drug therapy, along with all the precautions to be taken as indicated or asked by the pharmacist or the physician.[10] It discourages any irrational or reckless use of drugs and also, concerns with the procurement of the drugs into the market from the industry and their channelization to the patient for use. Clinical pharmacy also deals with ensuring safety and efficacy of the drugs after marketing. Safety can be evaluated by means of non-experimental research, whereas evaluation of efficacy in a variety of settings representing normal medical practice generally requires experiments, randomized and blinded. National or International markets are flooded with tens of drug combinations, low therapeutic value products or duplicate brand names.[11] Thus, under this study it is clarified how to choose the correct drug for administration or treatment.

## PATIENT SAFETY: THE KEY ROLE OF THE CLINICAL PHARMACIST

A surprising 30 percent of drug prescriptions are never filled and up to 50 percent are not continued as prescribed, especially after the first six months. National patient safety awareness week (March 13-19, 2016) provides an opportunity to highlight the unique role of clinical pharmacists in improving patient safety by ensuring that patients understand how to take their medication as prescribed. By improving patients', medication adherence, clinical pharmacists help prevent adverse drug events (ADEs) that are the result of patients not taking medication as prescribed.

Over the past 20 years, clinical pharmacists have developed patient safety strategies and have played a leading role in their implementation. The clinical pharmacist's role is to make sure patients understand and adhere to their medication regimen with respect to timing, dosage, and frequency during the prescribed length of time. In addition, the clinical pharmacist prevents ADEs by providing drug information in plain language to the patient at key transition times, such as hospital admission and, discharge, as well as during the patient's entire stay. The clinical pharmacist assures that the patient is taking their medications as prescribed, monitors for adverse effects and lack of adherence, and helps with early identification of issues that may compromise patient safety.

For example, clinical pharmacists reduce the rate of drug-related problems when patients are admitted to the hospital through medication reconciliation by developing a complete list of medications that a patient is taking. Clinical pharmacists also present medication information and assess patient understanding when the patient is discharged.

By working with patients both as they are admitted and discharged and applying the principles of health literacy to ensure that patients understand how to take their medications, clinical pharmacists detect and resolve potential issues that could lead to ADEs and help build a foundation for patient safety.

One patient safety strategy that clinical pharmacists use is the "simple plan" which focuses on communication skills, cultural sensitivity, and patient-centred care.

- S – Simplify the regimen (e.g., adjust the timing, dosage, or frequency of medication to make it easier to follow)
- I – Impart knowledge (e.g., distribute written information about the medication and/or health condition)
- M – Modify patient beliefs and behaviours (e.g., assess benefits and barriers to adherence)
- P – Provide communication and trust (e.g., actively listen to the patient)
- L – Leave the bias (e.g., tailor the education to the patient's level of understanding)
- E – Evaluate adherence (e.g., follow up with patients to make sure they are taking their medication)

**PROBLEMS FACED BY PHARM D DEGREE HOLDERS IN INDIA**

The scenario of students who have done the Pharm D (Doctor of Pharmacy) course can be observed here in a nutshell. This course was introduced in 2008 by Pharmacy Council of India (PCI). It is a Pre-PhD post-graduate doctoral programme similar to Doctor of Medicine (MD) for doctors and Doctor of Dental Sciences (DDS) for dentists. This course is divided into two programmes. First is the Pharm.D (Regular) course which has a duration of six years for students taking admission after completing their 10+2 or D.Pharm (Diploma of Pharmacy). Another programme is known as Pharm.D (Post Baccalaureate) which has a duration of three years. It is for those students who have graduated in B.Pharm (Bachelor of Pharmacy) which is a four years course. So, a pharmacy student would spend seven pivotal years of their life in getting the two degrees.

India introduced pharm d course because,

1. India is a big country, with a large population, old and poor infrastructure, facing major healthcare-related issues especially when it comes to safe and rationale drug (medicine) use by common people as well as by healthcare professionals. People nowadays suffer from multiple diseases and seek treatments from multiple sources. This puts their health in even more danger.

2. The doctors, on the other hand, have to treat these patients, prescribe them medicines. More often than not, the information related to these medicines is provided to the doctors by medical representatives of multinational companies who want to increase their sales. This is risky because the information provided by these medical representatives might not be authentic or fact-based, because everyone claims that their medicines are safer and cheaper to use.

3. The doctors are very busy all the time because of a large number of patients that they have to treat. Due to this, they don't have time to extensively counsel the patients regarding their ailments. As a result, patients don't understand the importance of taking medicines on time and sticking to the medical advice of the doctor, and this again leads to the deterioration of their health.

4. So to combat these issues, it was decided that there is a need of a healthcare professional who can provide evidence-based information to the doctors by participating in ward rounds and ensure the best treatment is received by the patients, counselling the patients about their disease and medicines and ensure safe and rationale drug use. Hence, this course was introduced, to train professionals who would be known as 'Clinical Pharmacists'.

**The Issues**

The issues started to appear when the government introduced the course but forgot to create a cadre for the post of 'Clinical Pharmacist'. In the absence of these designations, students are rendered jobless. Then they look for job opportunities in the private sector where they are offered starting salaries of a mere □ 15,000-16,000. The problem becomes worse when they have to compete with other pharmacy students who have completed their B.Pharm or M.Pharm, who haven't received theoretical knowledge or practical training to work as Clinical Pharmacists.

There are 233 colleges approved by the PCI to run the Pharm.D programme. They have produced an overall of 20,000 graduates, and approximately 9,000 more are graduating each

year. These colleges charge up to  2,50,000 per year for this course. One can understand the pain and sorrow of these students after investing an exorbitant amount of money and time, gaining knowledge and being unable to utilise it in the right place.

The government, the Pharmacy Council of India or Health Ministry? The answer is hard to find. But when asked about this issue PCI said they are working on it, the Health minister said that graduates are eligible to work as a Pharmacist while being silent on the issue of creating the post for Clinical Pharmacists in the government sector.

It is very disheartening to see the results of such a far-sighted Pharm d course. Both the government and PCI have failed to display the zeal necessary to salvage this important course that can help to address present and future health care issues. Now it is up to professional bodies and the government, whether they want to step in and do something about it or let these unfortunate souls curse their decision of joining a profession which they cannot practice even after holding a Dr. prefix before their names.

A Doctor of Pharmacy (PharmD) is a health professional who is qualified to practice the rational use of medication (right drug, at right dose, at right time, in right route of administration, at right cost), especially for effective treatment outcomes and medication safety. PharmDs are well trained to address various drug related problems as well as economic issues related to drug use. The Pharmacy Council of India (PCI) had introduced a very expensive six-year course after 10+2 (where fees are collected during the final year of Internship as well), in the year 2008, with the approval of ministry of health & family welfare under Pharmacy Act 1948, section 10. The course was introduced with the Pharm.D gazette 2008 guidelines and also approved as master's qualification by UGC under section 22(3) of 1956 UGC ACT. According to the Pharm.D gazette 2008 guidelines, the student who completes Pharm.D, also awarded as doctoral degree by the government. This course is a specialized program in which students are exposed to pharmacology for 2 years, pharmacotherapy for all the medical conditions over a period of 3 years & clinical toxicology through a bed side training setup. This course meets the criteria so as to provide better health care to the large patient population. Though Pharm.D students passing out, they were left orphaned by the pharmacy council. The Main objective of the course is to provide rational therapy to the patients which reflects a reduction in medical expenditures and the disease burden on patient by preventing the drug related issues like side effects or adverse drug reactions or any adverse drug events.

Though it has been passed over 6 years from the introduction of this course, neither the central government nor state government has created any specific cadre to the profession. There are 1160 pass-outs for the 2013-14 all over India and this number is piled up to 2480 students for the year 2014-15 and these number are expected to increase tremendously, as the PCI continues to approve new colleges every year. The number of colleges has increased from 29, in 2008-09, to 191 institutions by the year 2014-15 and the expected to increase for next academic year. Presently, PharmDs who passed out, till to date, don't have any provision to practice the profession and the government has not initiated any necessary steps for the recruitment of such highly qualified professionals in the health sector to improve mortality and morbidity rate due to drugs, particularly in India. Thus, everyone who completed Pharm D are turning into unemployed youth.

Medical tourism is more alarming these days which would generate direct and indirect employment as well as contributes to the growth of Indian economy, a proven fact with Singapore. For medical Tourism to happen, all health facilities are to be accredited to global certification under JCI (joint commission international) accreditation, whose provisions make it compulsory to accommodate clinical pharmacists as the integral healthcare provider of a healthcare team, and which promote concept of rational treatment and the evidence based medicine in real practice. In fact, there are 42 JCI accredited hospitals whose standards don't exist in any government hospitals. Even "the top most hospitals" like All India institute of medical sciences (AIIMS), Jawaharlal institute of medical sciences and research and etc., haven't recruited a single clinical pharmacist even after 7 years of course introduction. Is this due to lack of awareness or outright ignorance.

## CONCLUSION

The referred articles showed that, almost all retail as well as hospital pharmacists were practicing patient counselling, it was not up to the mark due to lack of infrastructure, awareness and of knowledge. To prevail over these issues, concerted efforts by the government authorities, pharmacists and academicians are needed. The gap can be filled with regularly organized content updating training programs for clinical pharmacists, introduction of new subject related to patient counselling in syllabus at diploma as well as undergraduate level. This will help to mobilize pharmacists to use modern techniques and social media for counselling.

Pharmacist involvement in patient care has reduced number of hospital admissions and emergency department visit and improved health status of patients and their quality of life. It was found that almost all pharmacists were providing patient counselling services without any charges while only 1.6% respondent were not providing any counselling services. This indicates that most of respondents were aware regarding importance of counselling and practices it with positive attitude.

It is very disheartening to see the results of such a far-sighted Pharm d course. Both the government and PCI have failed to display the zeal necessary to salvage this important course that can help to address present and future health care issues. Now it is up to professional bodies and the government, whether they want to step in and do something about it or let these unfortunate souls curse their decision of joining a profession which they cannot practice even after holding a Dr. prefix before their names.

PharmD graduates should be recruited in government programs under the state & central health Programs organized by rural health mission (NRHM), other several national health programmes.

Indian PharmD has to be developed as a program to promote research and evidence-based practice culture.

Government has to adopt and implement certain guide lines for practicing pharmacists including dress codes, good dispensing practices and other ethical professional aspects. Our community pharmacies need to be standardized with the support of accreditation process.

Pharmacy Act 1948 and Drugs and Cosmetics Act 1940 as the rules framed are seven decade old so need to be update.

Under pharmacy Act 1948 sec 42 only registered pharmacists must dispense the drugs.

Inspection process should not permit for un- ethical practices.
Surprise inspections have to be arranged by the Universities, State Pharmacy Clinical Councils and State Governments.

The current Pharm.D specific Regulations give very little focus for employability of the graduates coming out of the Universities and schools/colleges of Pharmacy.

The Pharm.D graduates have to be specialized in disciplines like Nephrology and Urology, Psychiatry, Neurology, Oncology, Dermatology, Paediatrics, Endocrinology/ Diabetology etc.

Students have to pay fees only for PharmD 1st year to Pharm.D 5th year and given stipend during the 6th year (internship) of the course.

Government should develop research fellowship schemes for pharmacy practice students.

Government must recruit PharmD graduates as clinical pharmacist, physician assistant, drug information specialist and patient counsellor posts in all primary, secondary and tertiary care hospitals according to the bed size.

Unless the above measures are taken, the practices like introduction of new courses would go in vain. PharmDs, are not being hired at hospitals. Hundreds of PharmDs are now unemployed.

This is a matter vital to both public health and the increasing number of qualified professionals being led to unemployment.

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