

## **What's standing in the way of Clinical Pharmacy in India: Understanding History, Development and Issues plaguing it**

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**Abstract:** India's great cultural diversity is reflected in its healthcare system and it is also a country with significant drug-use problems. The major contributor in combating these problems can be the clinical pharmacists. In this article we tried to shed some light on questions such as how India accomplished the task of introducing the clinical pharmacy, how this is similar to the paradigm shift that took place in western countries, what are the current issues plaguing it, what lessons can be learned from the past experiences which can be implemented in India to pave the way for rise of clinical pharmacists as an effective member of healthcare team in Indian healthcare system.

**Keywords:** Clinical Pharmacist, Clinical Pharmacy, Pharm.D, Pharmacy Practice, Doctor of Pharmacy

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### **I. INTRODUCTION**

India's great cultural diversity is reflected in its healthcare system. A wide array of health care providers including allopathic, ayurvedic, unani, siddha and homoeopathic practitioners can be found throughout the country.[1] India is also a country with significant drug-use problems. Irrational and unnecessary prescribing is common and antibiotic resistance is widespread and a major health issue as well.[2] The major contributor in combating these drug related problems can be the "Pharmacists" who are the most accessible health care professionals to the community as compared to the doctors who are usually preoccupied with large number of patients because of the large population and low ratio between the doctor and the patient. According to National Health Profile 2018 (NHP), India has only one allopathic government doctor for every 11,082 residents, 11 times more than the WHO recommended doctor-population ratio of 1:1000.[3] There are about 0.5 million pharmacists registered with various official bodies in the different states.[4] This is according to old data published in 2007, these numbers can be much higher at present. According to the annual report of Pharmacy Council of India (PCI) there are 1073 approved colleges running B.Pharm course with an admission capacity of 75,861 annually.[5] also there are 233 colleges running the Pharm.D (Doctor of Pharmacy) course. The Pharm.D course of India was meant to produce Clinical Pharmacists who specializes in Clinical Pharmacy Services which help in addressing the complex issues such as longer duration of hospital stay, high cost of treatment, drug related problems, unbiased information and management of pharmacotherapy of patients suffering from multiple co-morbidities, safe and rational drug use, pharmacotherapy in special populations and dose adjustment in renal and hepatic failure which are plaguing the Indian healthcare system through "Pharmaceutical Care".[6] Yet the clinical pharmacy in India is in its infancy stage.[7] To understand the current scenario we have to take a look on how India accomplished this task of introducing the clinical pharmacy, how this is similar to the paradigm shift that took place in development of clinical pharmacy, what are the current issues plaguing it, what lessons can be learned from the past experiences which can be implemented in India to pave the way for rise of clinical pharmacists as an effective member of healthcare team in Indian healthcare system.

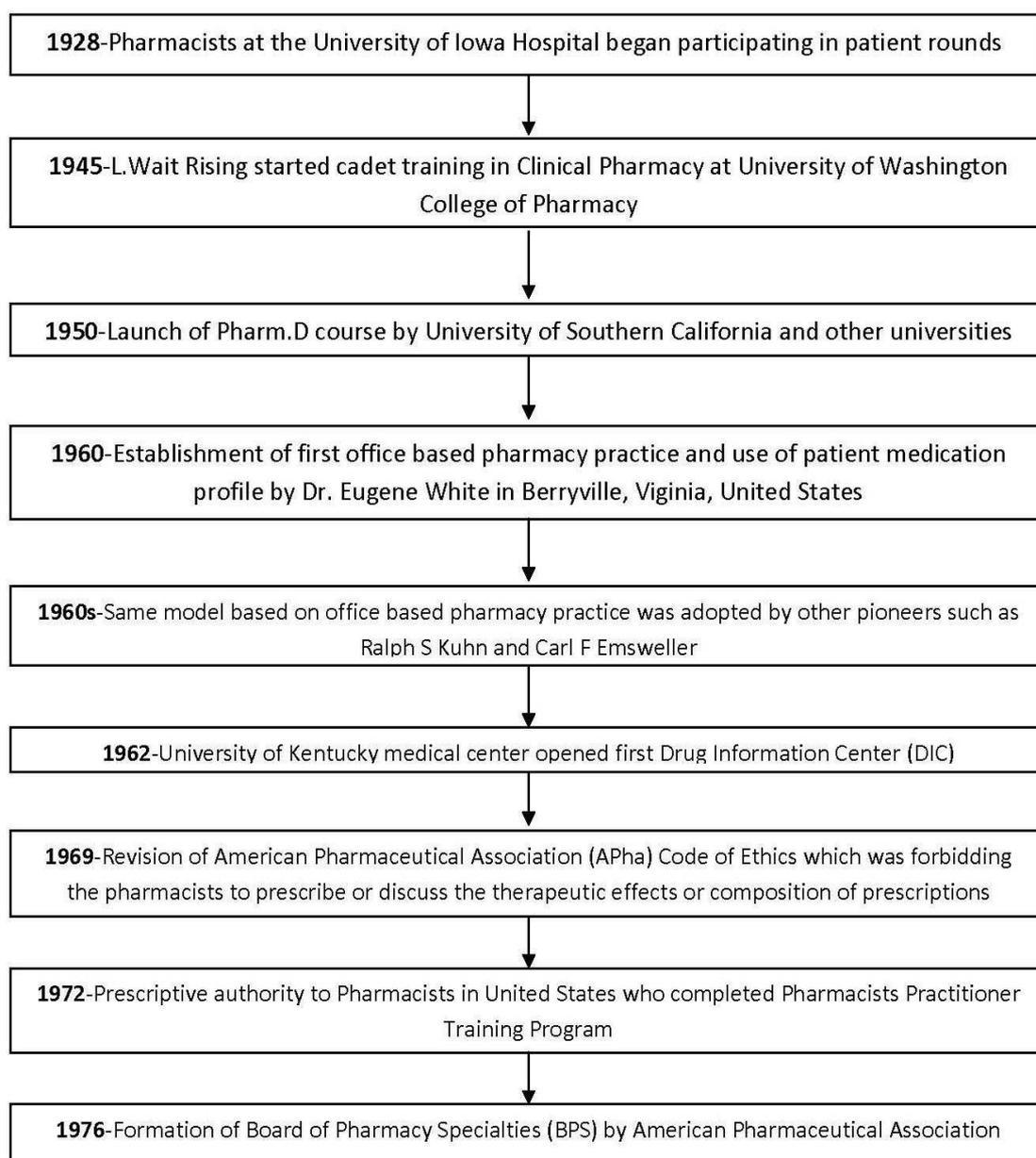
## **II. HISTORY AND DEVELOPMENT OF CLINICAL PHARMACY:**

The Clinical pharmacy has emerged as one of the latest branches of pharmacy in 21st Century.[8] However this journey was not easy, many barriers, restrictions was overcome with the optimism and persistent efforts of many pioneers who started with nothing. It all begin with when pharmacists at the University of Iowa hospital began participating in 1928.[9] Later efforts were made by Professor L.Wait Rising [10] at the University of Washington College of Pharmacy, who compared training in clinical pharmacy with cadet training through his research program in teaching pharmacy students utilizing some of the numerous professional prescription in Seattle in 1945-46.[11] Professor Heber .W. Youngken Jr at University of Washington wrote an article entitled "The Washington Experiment - Clinical Pharmacy" which brought to the notice of the world pharmacists about the Prof. L.Wait Rising's experiment which bring forth a storm of protest from American Association of College of Pharmacy (AACP) and the American Council in Pharmaceutical education.[10] Next major milestone came in year 1950 when the University of Southern California started to offer Pharm.D course to cater the educational needs of modern pharmacy practice, this lead to other universities follow the same pathway.[12]

Another major contribution in the history and development of clinical pharmacy is credited to Dr. Eugene White, who established the first office based pharmacy practice in Berryville, Virginia, United States in 1960 and for the first time used individual patient medication profile and devoted his entire life to this newly founded practice. In other words based on his devotion and achievements that bought a Hugh change in the practice of pharmacy and image of pharmacist which was lost after vanishing of apothecary due to industrialization[11], he can also be credited as "Father of Clinical Pharmacy or Pharmacy Practice". Later this same model of office based pharmacy practice was adopted by other practitioners such as Ralph S Kuhn[13] and Carl F Emswiller[14]. The idea of involving the pharmacist in the decision-making process of optimal patient care originated within the drug information concept.[15] In year 1962, the University of Kentucky medical center opened the First Drug Information Center.[9,15] This concept generated enormous enthusiasm in the pharmacy profession and sooner drug information centers began to sprung up everywhere.[15]

The highest barrier standing in the development of clinical pharmacy was Code of Ethics of American Pharmaceutical Association (APhA) which restricted the pharmacists to prescribe or discuss the therapeutic effects or composition of prescriptions. This barrier fell in August 1969 with the revision of the American Pharmaceutical Association Code of Ethics, which opened the doors for extensive development of clinical pharmacy.[11] There was another problem existed in this domain that there was absence of standard definition of clinical pharmacy, however the American Pharmaceutical Association (APhA) and the National Association of Boards of Pharmacy tried to define clinical pharmacy which was widely viewed as being patient oriented but was difficult to define because its meaning changed according to the ongoing developments of pharmacy practice.[16–18] Later in 1972, prescribing authority was granted to pharmacists in Indian Health Service who completed Pharmacist Practitioner Training Program.[9]

In 1976, formation of Board of Pharmacy Specialties (BPS) by APhA facilitated the way for further developing skills of a clinical pharmacist in a certain specialty.[19] Also in 1989, the term "Pharmaceutical care" was coined by Hepler and Strand. Pharmaceutical care comprises of responsible provision of drug therapy for the purpose of achieving positive outcomes that improve a patient's quality of life.[20] This helped in defining the Pharmacist's Intervention in management of pharmacotherapy and made the clinical pharmacist a valuable member of healthcare team. Later on the many other domains were added in clinical pharmacy from Therapeutic Drug Monitoring (TDM) to Anti-microbial Stewardship (AMS).[9,21] Major milestones in history and development of Clinical Pharmacy are shown in figure 1



**Figure 1: Major milestones in history and development of Clinical Pharmacy**

### **III. DEVELOPMENT OF CLINICAL PHARMACY IN INDIA**

India was latecomer in clinical pharmacy as compared to their western counterparts. The journey of introduction of clinical pharmacy in pharmacy education began when Dr. B.D. Miglani, the father of Indian Hospital Pharmacy and a living giant of pharmacy practice in the India through his efforts helped in starting the first postgraduate course in Hospital and Clinical Pharmacy in Delhi College of Pharmacy ( now known as DPSRU) in 1984.

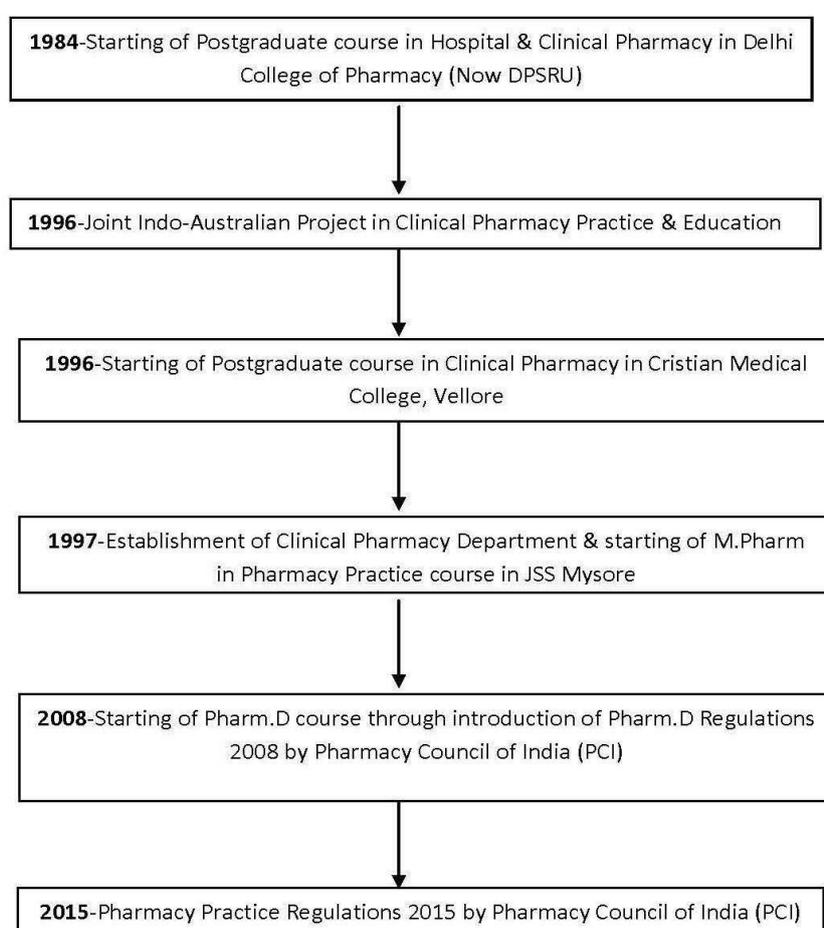
In 1996 CMC Vellore started a postgraduate diploma course in Clinical Pharmacy and in the next year (1997) the J.S.S Hospital & College of Pharmacy Mysore started a postgraduate programme (M.Pharm) in Pharmacy Practice giving special importance to Clinical Pharmacy under the joint Indo-Australian project in clinical pharmacy practice and education lead to cooperation between the Repatriation General Hospital (RGH) in South Australia and the JSS Colleges of Pharmacy in India. As part of this program four Indian pharmacists spent nine to twelve months at RGH received clinical pharmacy training, and one pharmacist from RGH spent six months in India assisting with development of clinical pharmacy. This resulted in the establishment of Departments of Clinical Pharmacy at two hospitals and postgraduate courses in clinical pharmacy practice.[1,7,15,20,22–25]

The first effort to introduce Pharm.D in India was initiated in Trivandrum Government Medical College in 1999 when the syllabus and regulations framed by Department of Hospital and Clinical Pharmacy of the Medical College with the help of some American Universities got approved by the Board of Studies and the Faculty of Medicine of the University of Kerala. However the program could not be started.[26]

In 2002 the Foreign Pharmacy Graduation Equivalency Committee (FPGEC) in USA mandated a 5 year pharmacy graduation program to be eligible to take their Foreign Pharmacy Graduation Equivalency Examination (FPGEE). Indian pharmacy graduates with 4 year B.Pharm degree were not permitted to appear for the North American Pharmacist Licensure Examination (NAPLEX) as a prequalification for practice of pharmacy. It was in that context the Indian authorities started thinking seriously about the introduction of Pharm.D in India.[27]

The Pharm.D program in India was introduced in 2008 by Pharmacy Council of India (PCI) under the legal framework of Pharm.D Regulation 2008.[28] It is an Pre-PhD post graduate doctoral program which is divided in to two programs. First is Pharm.D (Regular) course which has duration of 6 years for students taking admission after completing their 10+2 or D.Pharm. The course is divided in two Phases. Phase I – consisting of First, Second, Third, Fourth and Fifth academic year. Phase II – consisting of internship or residency training during sixth year involving posting in specialty units. Another program is known as Pharm.D (Post Baccalaureate) which has duration of 3 years and divided in two Phases. Phase I – consisting of First, Second academic year. Phase II – consisting of internship or residency training during third year involving posting in specialty units.) This course is for those students who are graduated in B.Pharm[6,28].

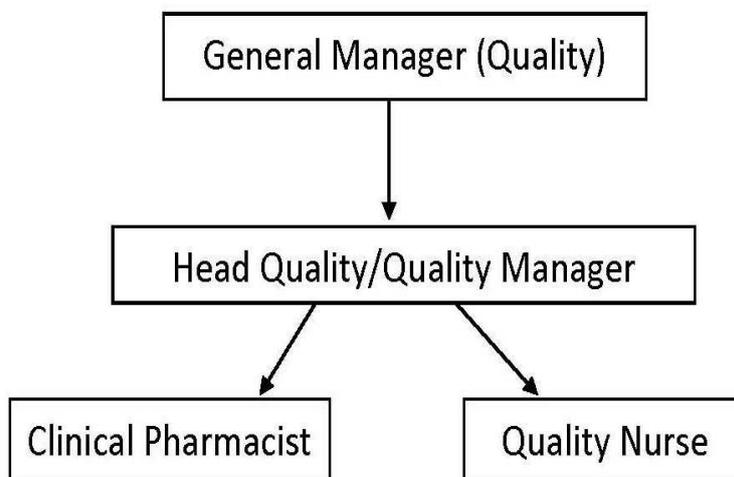
Another major breakthrough in development of clinical pharmacy in India was introduction of Pharmacy Practice Regulations 2015 by Pharmacy Council of India.[29] These regulations were meant to pave the way in improvement of pharmacy practice in India and it also clearly defined the roles, responsibilities, code of ethics, standard procedures as well as the qualifications required to hold various designations of pharmacists. The major milestones in development of Clinical Pharmacy in India are shown in figure 2.



**Figure 2: Major milestones in development of Clinical Pharmacy in India**

#### IV. CLINICAL PHARMACISTS IN INDIAN HOSPITALS:

Unfortunately there is no such post of clinical pharmacist in government hospitals.[6] Only those private hospitals employ clinical pharmacist which are accredited with National Accreditation Board for Hospitals and Healthcare Providers (NABH) and Joint Commission International (JCI). These clinical pharmacist works in Quality Department headed by Quality manager holding BDS/MBBS degree with PG Diploma in healthcare management or MHA or MBA, here the clinical pharmacist is responsible for assessment and reporting of certain parameters necessary for accreditation. The Hierarchy of quality department is shown in figure 3.



**Figure 3: Hierarchy of quality department in which clinical pharmacists work in India**

Qualification of clinical pharmacist in Indian private hospitals:

1. B.Pharm
2. M.Pharm (Any specialty)
3. Pharm.D/Pharm.D (Post Baccalaureate)

Most of the private hospitals in India are NABH approved and a majority of the roles and responsibilities of clinical pharmacist fall under chapter three of accreditation standards which is known as Management of Medication (MOM).[30] Contents of this chapter are shown in table 1.

**Table 1: Summary of accreditation standards that falls under chapter three of NABH**

MOM 1:	Documented policies and procedures guide the organization of pharmacy services and usage of medication
MOM 2:	There is a hospital formulary.
MOM 3:	Documented policies and procedures guide the storage of medication.
MOM 4:	Documented policies and procedures guide the safe and rational prescription of medications.
MOM 5:	Documented policies and procedures guide the safe dispensing of medications.
MOM 6:	There are documented policies and procedures for medication administration
MOM 7:	Patients are monitored after medication administration.
MOM 8:	Near misses, medication errors and adverse drug events are reported and analysed.
MOM 9:	Documented procedures guide the use of narcotic drugs and psychotropic substances.
MOM 10:	Documented policies and procedures guide the usage of chemotherapeutic agents
MOM 11:	Documented policies and procedures govern usage of radioactive drugs.
MOM 12:	Documented policies and procedures guide the use of implantable prosthesis and medical devices.
MOM 13:	Documented policies and procedures guide the use of medical supplies and consumables

#### 4.1 Roles and Responsibilities of clinical pharmacist in private hospitals

1. Performing audits such as Narcotic audit, High alert medication, Refrigerator medication audit, Look Alike Sound Alike (LASA), Prescription audit, Crash cart audit, Ambulance medication kit audit and present the analysis.
2. Carrying out Pharmacovigilance activities.

3. Carrying out Root Cause Analysis (RCA) of Medication errors
4. Carrying out the Antimicrobial Stewardship (AMS) program.
5. Ensuring compliance of MOM (Management of Medication) as per NABH requirement.
6. Coordinating with Pharmacy and Therapeutics Committee and Infection Control Committee.

#### **4.2 Issues and challenges in development of clinical pharmacy in India**

**Lack of representation among professional bodies:** There are many associations which represent the pharmacy profession in India. These are:

- a. Indian Pharmacy Graduates Association (IPGA)
- b. The Indian Hospital Pharmacist's Association (IHPA)
- c. The Indian Pharmaceutical Association (IPA)
- d. Indian Pharmacist Association (IPA)
- e. Doctor of Pharmacy Association (DPA)

Barring the DPA which is mainly composed of Pharm.D graduates which had raised its voice for the creation of separate cadre of clinical pharmacists in government hospitals in the past through holding protests in various states such as Telangana and Andhra Pradesh,[31] however this association is mainly active in the southern part of the country due to the large number of Pharm.D colleges in South India. The remaining associations do not have clinical pharmacy division in their composition nevertheless they do have hospital pharmacy division, but they only represent pharmacists who are working in hospital pharmacy. The Accreditation board NABH which comes under the authority of Quality Council of India does not have even a single representative of any pharmaceutical association which represents the clinical pharmacists or PCI which regulates the pharmacy profession in India. This lack of representation of the clinical pharmacists among professional bodies act as a barrier in the development of clinical pharmacy in the country.

**Lack of support from the Government:** One of the major driving force behind the development of clinical pharmacy in west was Congressional Comprehensive Health Manpower Training Act of 1971 (Public Law 92-157), which provided federal support only to colleges that “increased emphasis on and training in clinical pharmacy.”[11,32]. In absence of such driving force from the government acts as an hindrance for further advancement of clinical pharmacy in India. There are only four government colleges that are running Pharm.D course in the country that shows the level of commitment by the government towards the clinical pharmacy. Lack of job opportunities in government hospitals forces the Pharm.D graduates to work in non-core fields such as medical coding, medical writing.[6,19,33,34]

**Underutilization:** The term 'Clinical' implies practice in presence of patient whether they are at home or hospital and Clinical Pharmacy is a health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention.[35] Absence of any interaction with the patient or Physician to provide pharmaceutical care threatens the whole concept of clinical pharmacy here. The clinical pharmacists employed in private hospitals work merely as an auditor not as a part of the health care team. They are grossly underutilized. The roles and responsibilities taken by them are not even close to the roles and responsibilities undertaken by their western counterparts. Some of the essential component of the clinical pharmacy services is Providing Drug Information/Poison Information, Providing Pharmaceutical Care, Attending ward rounds, Carrying out Therapeutic Drug Monitoring (TDM), Taking Medication History Interview, Conducting Patient Counseling, Medication Chart Review, Carrying out Dosage adjustment in special populations as well as in the Renal and Hepatic Impairments, Carrying out the Medication Therapy Management (MTM) and much more.[6,9,11,20,21,36–40] These services are just the tip of the iceberg which are meant to be provided by the clinical pharmacists.

**Under-qualification for the job:** The majority of clinical pharmacist recruited by the private hospitals are B.Pharm or M.Pharm in Pharmacology or even Pharmaceutics who are under-qualified for the job and they don't undergo training of clinical pharmacy as part of their curriculum. This under-qualification not just act as professional incompetency, but also hinders employment opportunities of Pharm.D graduates who holds the qualification and training necessary to carry out the role of clinical pharmacist.

#### **V. HOW INDIA CAN BRIDGE THE DIVIDE BETWEEN NEED AND ACCEPTANCE OF CLINICAL PHARMACISTS IN THE HEALTH CARE SYSTEM**

1. Universities can offer placing clinical faculty at the hospital to provide clinical services free of cost and also use it as a way to teach students experientially as part of their training.
2. Placing clinical pharmacist in DOTS centers to provide counseling to the patients and ensuring medication adherence..
3. Utilizing the services of clinical pharmacists in vaccination and immunization programs can also be a good starting.

4. Recruiting and posting clinical pharmacists in rural areas where there is a shortage of doctors to provide medical treatment of minor ailments.
5. There are very few Drug/Poison information centers in India such as in AIIMS, New Delhi. The clinical pharmacists can be employed in these on position of Drug Information Pharmacists. This was a way clinical pharmacy was introduced in the US.

The scenario of clinical pharmacy in India is very similar to the scenario faced by the pioneers 50 years ago in west as Francke echoed Dr. Eugene White's disappointment in 1969: It was the narrow provincialism of pharmaceutical educators themselves, which held back the development of the concept for more than a quarter of a century.[41] As clinical pharmacists have precise knowledge about therapeutics and regular interaction with prescribers help them to bridge the gap between patients and physicians. The association of clinical pharmacist and clinician can provide a strong base for quality assured patient care.[40] There is plenty of evidence supporting this statement.[1,7,12,19,22,23,25,33,37–40,42–46] The health and economic outcomes of clinical pharmacy are chiefly relevant in India, which is a country with significant health and medication use problems.

## VI. CONCLUSION

It is very disheartening that having initiated a far-sighted advancement of clinical pharmacy in India both the government and PCI failed to display the zeal necessary to salvage this endeavor of utmost importance that can help to address the present and future health care issues. Now it is up to professional bodies and government to learn from the past experiences of the west or repeat the same mistakes made by them if that happens then India will remain a large, over-populated third world nation plagued with major health issues-maybe even with the world's third largest GDP.

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