Research in Pharmacy and Health Sciences

Doctor of Pharmacy: A New Born and Emerging Course in India

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ABSTRACT

The intention behind this review work is to enable every single individual around the India thoroughly understand the emerging field in Indian pharmacy i.e., Pharm.D, newly introduced in 2008 by the Pharmacy Council of India. It gives a doctorate degree after five years of graduation and one year internship in a hospital. Clinical pharmacy denotes the practice of pharmacy beside the bed side of the patient. The Doctor of Pharmacy (Pharm.D) degree, is a professional doctor degree in pharmacy and is a global program in pharmacy education. As the practice of pharmacy evolves, requiring more clinically oriented healthcare providers, Doctor of Pharmacy (PharmD) programs expand their training to more hospital sites to expose students to the provision of safe, effective, and economic drug therapy to patients.

Received: 18-08- 2015 Revised: 21-09-2015 Accepted: 27-10-2015 *Correspondence to: Mr. Sai Krishna G. Email:sknanu06@gmail.com

Review Article

Funding: The authors have no support or funding to report.

Competing Interests: The authors have declared that no competing interests exist.

Keywords: Pharmacy Council of India, Clinical pharmacy, Doctor of Pharmacy, economic drug therapy.

INTRODUCTION

The word pharmacy originated from the Greek word "PHARMAKON". It was in 9th century the profession of pharmacy started acquiring shape. However in the 19th century it completely sorted out from medicine and started developing as a separate profession [1]. This happened only when the role of pharmacist as a compounder of medicines were identified and differentiated from physician whose role was accepted as the therapist. The practice in those times was restricted to compounding, dispensing medication and manufacturing medicaments in bulk lots not for general sale. The 19th century witnessed various milestones being set in the field of pharmacy [1].

The Pharm.D course (6 year doctoral degree program in pharmacy) was introduced by the Pharmacy Council of India in 2008 aimed at improving patient care and providing pharmacy education programs. It is a pre-PhD, post- graduate program. It lays emphasis on all pharmacy practice components namely Pharmacotherapeutics, Clinical Pharmacy, Community Pharmacy, Clinical Research, Regulatory formulation development and Quality Control [2].

In traditional hospital practice most of the drug therapy decision making falls on the physician. However studies shown that physicians some times makes error in the prescribing drugs [3]. While most errors are preventable. The pharmacists can provide clinical pharmacy services such as medication history interview, participation in wards rounds and meetings, provision of drugs/poison information, prevention with assessment and management of drug interactions, adverse drug reaction management (ADR), medication order review, therapeutic drug monitoring (TDM), selection of drug therapy, patient medication counselling, with community services etc. In hospital, Pharm.D candidates may give better services than pharmacy graduates because the Pharm.D candidates are exposed to various Pharmaceutical care services during their practical training, which enables them to be a competent professional in implementing effective patient care [4].

The main objective of PharmD program is to maximize the clinical effects of medicines, i.e., using the most effective treatment for each type of patient; minimizing the risk of treatment-induced adverse events, i.e., monitoring the therapy course and the patient's compliance with therapy trying to provide the best treatment alternative for the greatest number of patients [2].

Earlier the profession and practice of pharmacy was more towards product oriented which has slowly shifting to patient oriented approach. A clinical role for pharmacists has developed in response to the societal need to improve the use of medicines.India also faces several problems associated with medicines use. The path for continuous growth of the pharmacy profession obviously requires expansion, resurfacing and modernization. This justifies the need for new pharmacy programme and curriculum that can produce the manpower required for the new roles. Thus, the launch of the Doctor of Pharmacy (PharmD) programme in India is a pioneering course which is a welcome development [5].

Present evolution of pharmacist roles are following the wider use of quality systems to address errors in prescribing and drug administration and improved documentation of care; widening of prescribing roles; increased patient education and higher patient expectations; patient-centred research; development of primary care and improved accessibility to pharmaceutical advice; integration of pharmacists' public health roles in strategies to address prevention and management of disease [2,5].

The extension of clinical training of pharmacists became formalized through the Doctor of Pharmacy (PharmD) programme. Pharm D's attend ward rounds with doctors and are involved in selecting and managing the pharmacotherapy of their patients, to produce optimal outcomes from their treatments [2,5].

GENESIS AND DEVELOPMENT OF PHARM D PROGRAM IN ASIA

Pharm D is a multidisciplinary and multifunctional programme. It aims at producing pharmacists with better clinical skills who can provide pharmaceutical care to people. The doctor of pharmacy (Pharm D) program was introduced in Asia to mould up students with the knowledge and skills with conventional learning methods including clinical simulations and training. The introduction of Pharm D in various countries in Middle East and Asia including India will enable them to give more emphasis to patient care and spend considerable time in the community or in the hospital pharmacy. This kind of knowledge and skill development prepares the graduates to practice confidently in the hospital and community setting [6].

COURSE STRUCTURE AND ADMISSION CRITERIA IN INDIA

Pharm. D course shall be six academic years full time with each academic year spread over a period of 200 working days. The first to fourth year are academic years whereasfifth and sixth years involving posting in various units in the hospital.

The minimum qualification for admission is:

i. 10+2 examination with physics and chemistry as compulsory subjects along with Mathematics or Biology.

ii. A pass in D. Pharm course from an institution approved by Pharmacy Council of India under section 12 of the Pharmacy Act.

• Pharm. D (Post Baccalaureate) course shall be three academic years, each year spread over a period of 200 working days. This course shall be started from fourth year and continued up to sixth year which is as same as Pharm.D.

The minimum qualification for admission to:

• A pass in B.Pharm from an institution approved by pharmacy council of India under section 12 of the Pharmacy Act.

• Number of admission in each academic session are in the following:

Pharm. D: 30 students

Pharm. D (Post Baccalaureate): 10 students

• Under the regulations, which institutions running B.Pharm approved under section 12 of the pharmacy Act, will only be permitted to run Pharm.D and Pharm.D (P.B) program will be permitted only in those institutions which are permitted to run Pharm.D.

• The first year include the subjects (theory and practical): Human Anatomy and Physiology, Pharmaceutics, Medicinal Biochemistry, Pharmaceutical Organic Chemistry, Pharmaceutical Inorganic Chemistry, Remedial Mathematics and Biology.

• The second year subjects are Pathophysiology, Pharmacology –I and Community Pharmacy and coursesinclude the subjects (theory and practical): PharmaceuticalMicrobiology, Pharmacognosy and Pytopharmaceuticals, Pharmacotherapeutics-I.

• The third year subjects are Pharmaceutical Jurisprudence and courses include the subjects (theory and practical): Pharmacology-II, Pharmaceutical Analysis, Pharmacotherapeutics- II, Medicinal Chemistry, and Pharmaceutical Formulations.

• The fourth year subjects are Biostatistics and Research Methodology and Clinical Toxicology and courses include the subjects (theory and practical): Pharmacotherapeutics- III, Hospital Pharmacy, Clinical Pharmacy, Biopharmaceutics and Pharmacokinetics.

• The fifth year subjects are Clinical Research, Pharmacoepidemiology and Pharmacoeconomics, Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring.The clerkship also include the course which the students attending ward rounds on daily basis.

• The sixth year consists of internshipor residency training including postings in specialty units. Students shouldindependently provide the clinical pharmacy services to the allotted wards.

i. Six months in general medicine departments.

ii. Two months each in three other specialty departments (Surgery, Pediatrics, Gynecology and Obstetrics, Psychiatry, Skin and VD, Orthopedics).

• Examination: The examination shall be of written and practical (including oral nature). Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination [6].

PHARM. D REGULATION 2008

The regulations framed under section 10 of the Pharmacy Act, 1948 which is approved by the Government of India, Ministry of Health and notified by the Pharmacy Council of India. In exercise of the powers conferred of section 10 of the Pharmacy Act, 1948 (8 of 1948), the pharmacy council of India, with the approval of the central government hereby makes some regulations such as:

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• Pharm. D shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the pharmacy Act, 1948 [6].

OBJECTIVE OF PHARM D GRADUATES

1. To provide pharmaceutical care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, socio-cultural, economic and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social, or behavioral or administrative, and clinical sciences that may impart therapeutic outcomes.

2. To manage and use resources of health care system, in co-operation with patients, prescribers and other health care providers and administrative and supportive personnels, to promote health; to provide, assess, and coordinate safe, accurate, and time sensitive medication distribution; and to improve therapeutic outcomes of medication use.

3. To promote health improvement, wellness, and disease prevention in co-operation with patients, communities, atrisk population and other members of an inter-professional team of health care providers.

4. To demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.

5. To develop leadership qualities to function effectively as a member of health care team organized to deliver the health and family welfare services in existing socioeconomic, political and cultural environment.

6. To communicate effectively with patients and the community [7-9].

ACTIVITIES OF PHARM D STUDENTS IN HOSPITAL

Drug Information Services

Pharmacists provide information regarding diseases, drugs and poison related queries for clinicians, nurses, pharmacists, medical students and other healthcare professionals. The center receives queries via a drug information request form, or through telephone calls or by direct visits to the DIC,ward rounds, internet or by e-mail. After receiving the query, the pharmacists has to categorise the ultimate question whether is related to drug therapy, dosage, administration, pharmacokinetic, pharmacodynamic, ADR, drug interaction, indication, or pregnancy and lactation. Then he has to develop search strategy and conduct search referring to drug information sources available in the center. These sources include primary (journals, bulletin, newsletters etc), secondary (Micromedex, electronic therapeutic guideline (eTG) etc.) and tertiary sources (Martindale, AHFS, BNF etc.) [10].

Pharmacovigilance Activities

The pharmacists also run a peripheral Pharmacovigilance center in the hospital. The center focuses on monitoring the Adverse Drug Reactions (ADRs) occurring in the hospital. Pharmacists use to identify ADRs during ward rounds, at the time of follow up or get informed by the other health care professionals. He also detects ADR by Identifying and monitoring patients who are most susceptible to ADR, through routine drug therapy monitoring, by assessing the patients who have had previous history of adverse drug reaction to a drug. After detection of ADR the pharmacists carry out the causality, severity and preventability assessments for the ADRs as per the Naranjo's algorithm, Modified Hartwig and Siegel Scale and Modified Schumock and Thornton scale respectively [11].

Patient Counseling Services

Providing counseling to the patients is another important activity of the pharmacists. The pharmacists make the patient understand about his disease condition, symptoms, further complication if not treated. The name and description of the medication, dosage form, route of administration, duration of therapy, special directions, selfmonitoring technique, refill information, actions are to be taken in the case of missed doses and storage techniques. The patient is also advised about life style modification which is beneficial to improve his condition. After counseling, pharmacists document the consultation by completing the medication counseling documentation form [12].

Participation in ward rounds

As a member of the health care team, it is important for clinical pharmacists to attend ward rounds. He visits ward rounds and participates in the discussion with other health care professionals daily. During ward rounds pharmacist provides drug information which is directed by physician or other health care professionals, detects any ADR, and gives update about drugs and counseling to the in-patients. The presence of pharmacist in ward rounds influences the prescription at the time of decision making [12].

Pharmaceutical care services

Pharmacist collect the data and makes the Subjective Objective Assessment Plan (SOAP). While subjective findings include the chief complaints of patient Objective findings include laboratory data, medical and medication history, social history, physical findings, previous allergy. Thus assessment is related to desired outcomes and end points, drug related problems and to find out whether current therapy is relevant to standard therapy or not .In planning therapeutic selection the Pharmacist has to follow Monitoring parameters (therapeutic and toxicity) such as patient's past medical history, allergy status, other health complications etc [13].

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Medication history interview

Medication history interview is done to obtain information and aspects of drug use that may assist in overall care of the patient. The pharmacist interviews the patient about demography (Name, age, sex), occupation, previous disease, medication history, allergies, Social history (Smoker, alcoholic, tobacco), surgery, diet and present history and documents it appropriately.

Prescription order review

Pharmacists review the prescription during ward rounds or after completion of ward rounds. While reviewing prescription order, Pharmacists check medication duplication, interactions or incompatibilities along with these things. They ensure things like: cost effectiveness for drugs, ensuring that all necessary medications are ordered. After reviewing the prescription, if the Pharmacist finds any problem during ward rounds he will discuss thethings with the doctor immediately.

Drug Interaction services

Pharmacist regularly monitors for potential drug interactions while reviewing patient drug therapy, particularly in the patients with multiple drug therapy, multiple disease state, especially pediatrics and geriatrics patients. If any drug interaction is suspected with adverse event this has to be discussed with doctors. So the pharmacist has to search about drug interaction in the Micromedex, drug interactions text book and other sources. Once the interaction is identified the pharmacist gives the information about the severity of drug interaction and its clinical management to doctors and documents it appropriately. So that recurrence of the same interactions in future can be prevented.

Pharmacist's Intervention services

Pharmacists do interventions either during ward rounds or while assessing the patient profile forms. This intervention may or may not be accepted by the physician. These interventions are documented. These documents are required to analyze the clinical pharmacy services.

Adverse Events Following Immunisation (AEFI) reporting services

The World Health Organization (WHO) defines an AEFI as a medical incident that takes place after an immunisation, causes concern, and believed to be caused by immunisation. Pharm Ds play a major role in identifying and reporting AEFI.

Poisons Information Service

It is the Poison Information Services provided by the Health care Pharmacist to the public on prevention, early diagnosis and treatment of poisoning and hazard management.

Patient referral documentation services

Primary health care centers need to maintain a close relationship between all the levels of a health system. In the primary health care hospitals physician's refer the patients to clinical Pharmacist for ADR detection & management, patient counseling, selection of drug therapy etc [14].

THE RESPONSIBILITIES OF AN PHARM.D'S MAY INCLUDE

- To provide expert advice
- Patient medication history interview
- Medication order review
- Patient counseling regarding safe and rational use of drug
- ✤ Adverse drug reaction monitoring
- Drug interaction monitoring
- Therapeutic drug monitoring
- Attending ward rounds
- Providing drug information
- Liaising with other departments
- Developing and maintaining professional guidelines
- Educating medical and nursing staff, students and others
- Demonstrating and aquiring leadership qualities
- Carrying out research.

CAREER OPPORTUNITIES OF PHARM D GRADUATES

1. Clinical Research

Clinical research is a branch of medical science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.

2. Pharmacovigilance

It is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines.

3. Research and Development

The phrase research and development refers to the "creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications".

4. Medical Writing

This is the activity of producing scientific documentation by a specialized writer. The medical writer typically is not one of the scientists or doctors who performed the research. A medical writer, working with doctors, scientists, and other subject matter experts, creates documents that effectively and clearly describe research results, product use and other medical information. The medical writer also makes sure the documents comply with regulatory, journal, or other guidelines in terms of content, format and structure.

5. Product Managers

A product manager investigates, selects, and develops products for an organization, performing the activities of product management.

6. Regulatory affairs

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals and medical devices.

7. Community Pharmacy

It is a community-based pharmacy. The main responsibilities of a community pharmacy include appropriate procurement, storage, dispensing, and documentation of medicines.

8. Geriatric Pharmacy

Geriatrics is a sub-specialty of internal medicine and family medicine that focuses on health care of elderly people. It aims to promote health by preventing and treating diseases and disabilities in older adults.

9. Home Health Care

Home Care, is health care or supportive care provided in the patient's home by healthcare professionals. Often, the term home health care is used to distinguish non-medical care or custodial care, which is provided by persons who are not nurses, doctors, or other licensed medical personnel, as opposed to home health care that is provided by licensed personnel.

10. Hospital Pharmacy

A hospital pharmacy is concerned with pharmacy service to all types of hospital and differs considerably from a community pharmacy. Some pharmacists in hospital pharmacies may have more complex clinical medication management issues whereas pharmacists in community pharmacies often have more complex business and customer relations issues.

11. Managed Care

The term managed care is used in the United States to describe a variety of techniques intended to reduce the cost of providing health benefits and improve the quality of care ("managed care techniques") for organizations that use those techniques or provide them as services to other organizations ("managed care organization" or "MCO").

12. Pharmacoeconomics

Pharmacoeconomics refers to the scientific discipline that compares the value of one pharmaceutical drug or drug therapy to another. It is a sub-discipline of Health economics. A pharmacoeconomic study evaluates the cost (expressed in monetary terms) and effects (expressed in terms of monetary value, efficacy or enhanced quality of life) of a pharmaceutical product.

13. Others

Governmental agencies, Medical representatives/Business managers/Marketing executives, Academics, Correspondents and Trainers etc [15].

SUGGESTIONS FOR YOUNG PHARM D GRADUATES TO BECOME SUCCESSFUL LEADERS

1. Self confidence and believe in own capabilities.

2. Think high and have only positive thoughts and can automatically go high.

3. Have interaction with the lecturers which excel your carrier.

4. Make a network of innovators and a network of users.

5. Attend international conferences.

6. Utilize libraries and laboratories.

7. Attend seminars, refresher programs, work shop and training programs continuously in collaboration with industries.

8. Development of writing skills as well as communication skills.

9. Work hard and have a dream for the future. From the dream have a good vision and the vision comes to a reality.

By this way, one can improve and update the knowledge to face global challenges.

ROLE AND IMPORTANCE OF PHARMDs IN WARD ROUNDS

The pharmacy profession and the practice of pharmacy have evolved over the years and, at present; the pharmacist is expected to play a vital role in the care and management of the patient in all settings [16]. Thus, the field of clinical pharmacy has come to an age as a pharmacy specialty in order to bridge the gap between the pharmacist as a custodian of medicine and the clinical (ward-based) health professionals, such as nurses and physicians. The practice of clinical pharmacy enables pharmacists to participate as part of the team at the interface with the patient and allows them to influence clinical care decisions to the benefit of the patient through proper pharmaceutical care. Hospital ward rounds are one way to ensure quality pharmaceutical care, where the Pharm.D graduates work together to improve aspects such as quality assurance, safety, effective administration of medicines, promotion of the rational use of medicines, public education and the monitoring of adverse drug effects [17]. Ward rounds improve patientprovider communication, with better patient outcomes and more cost-effective expenditure on pharmaceutical products. For instance, the presence of a pharmacist on a

post-take ward round was shown to improve the accuracy of drug history documentation, reduce prescribing costs and decrease the potential risk to patients in hospital [18].

Traditionally, the pharmacist has undertaken a number of roles on the wards, such as the management of pharmaceutical stock and the provision of information on drug use and storage but with less involvement in actual patient care decisions and pharmaceutical care. It is thought that greater involvement of pharmacists in ward rounds helps reduce problems such as prescribing errors. There have been many changes to the training and practice of pharmacy worldwide since 1960s, including the introduction of clinical pharmacy training as a specialty in the profession [19]. There is thus increasing demand for pharmaceutical care requires that pharmacists be well versed in the actual care of patients, beyond their primary role as custodians of pharmaceutical products.

The profession of pharmacy in India is not just the "change from D. Pharm to Pharm.D" but change in quality pharmaceutical education to meet the challenges and the needs of the nation in the 21st century [20]. The implementation of the Pharm.D program must largely emphasize pharmaceutical care encompassing areas of patient care such as hospital and clinical pharmacy.

BENEFITS OF PHARMDs OVER PHYSICIANS

Pharm Ds are having enough capability in improving medication adherence through patient counselling because of many reasons:

- Physicians having insufficient time to counsel the patient.
- Unfamiliarity of few physicians with the native / local language.
- Inability of the patients to understand the terminologies used by the physician.
- Fear of patients in asking physicians to clarify their doubts regarding their disease condition and about the drugs being prescribed.
- Misunderstanding or improper understanding of patient's mentality by physicians due to lack of time [20].

Future Pharm.D degree competency licensing examination

While the PCI provides a uniform Pharm.D program syllabus for all pharmacy institutions in India to follow, the methods for evaluating competency of Pharm.D graduates differs across institutions. Amongst these institutions very few provide their students with a strong learning infrastructure and have their own hospitals to provide hands-on clinical training. So India needs a national level Pharm.D degree competency licensing examination which will enable all Pharm.D program graduates to practice pharmacy in India.

Hence, a national level licensing examination would serve as the NAPLEX equivalent in India, which means that any foreign Pharm.D program graduate who decides to practice in India would be required to pass this examination [21].

CONCLUSION

The current era of globalization has witnessed evolution in the professions of the health sector, especially in pharmacy. Whereas previously the pharmacist worldwide was seen as responsible primarily for manufacturing and supplying medicines, today the pharmacist's role has evolved towards a clinical orientation. The profession is still under continuous transition. With change in the health demands, pharmacists have a further role to play in patient care.

The presence of Pharm D graduates in the ward rounds as a member of the patient care team in the hospital associated with substancially lower rate of ADR's caused by prescribing errors. The activities and research carried out by the PharmD students in India will achieve the objective of providing-adverse effect free- medical facilities in India to equal with advanced countries like the U.S.A. where the Pharmacist occupies the most prominent place in the decision-making of prescription.

As the PharmD is mostly patient-centered curriculum, therefore, patients will be benefited the most. The patients would be able to know all the information about their disease, drugs and lifestyle modifications for the disease in future which would definitely increase prognosis of the patients. The clinical pharmacy services would also minimize the work-load of physicians from their busy schedule as well as it would decrease the load on the Indian health-care system. As a summary, it can be expected that the Pharmacists, i.e., PharmD would play a major role in Indian health care system in future. This course will give an opportunity to pharmacists to work more prominently in Indian health care system.

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Cite this article as: Krishna SG. Doctor of Pharmacy: A New Born and Emerging Course in India. Res Pharm Health Sci. 2015;1(1):35-41.