

Development of Clinical Pharmacology in India: Perspective of a Young Researcher

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The credit for the founding of the discipline of clinical pharmacology goes to Dr. Louis Lasagna, who in 1954 started the division of clinical pharmacology at the Johns Hopkins University School of Medicine, one of the oldest in the world.¹ It was his vision, mission and creative thinking which has successfully pushed this discipline to the international front, and now is recognized as an integral part of any drug development program worldwide both in industry and academia. He was a deep thinker, and his suggestions on the need for randomized controlled clinical trials, with if necessary a placebo, along with proper statistical consideration right from the beginning of the trials, inclusion and exclusion criteria etc. continue to be applicable in contemporary clinical research. His brain child has now grown into a mature discipline after almost six decades of efforts across the world.²

When Dr. Lasagna was busy shaping the discipline of clinical pharmacology in the USA, at the same time in India, Professor U.K. Sheth started the first department of clinical pharmacology at Seth G. S. Medical College and King Edward Memorial Hospital, Mumbai, in 1960. This work was carried forward by eminent pharmacologists like Dr. Ranjit Roy Choudhary, Dr. Ashok Vaidya, Dr. A. S. Naniwadekar, and others. Since then, the discipline has taken many turns and twists, and has slowly but steadily progressed and contributed to the development of various new drugs, drug regimens, rational drug use, and clinical trials and research in the country. Clinical pharmacologists have made major contributions to discovery, development, regulation, and utilization of medicines and in teaching rational therapeutics to current and future medical professionals, combining laboratory research, desk work and hands-on clinical consultation.^{3–6} There has been a transformation in the role of the clinical pharmacologist, with a demand especially in developing countries for their contribution to public health.^{7–9}

Today, clinical pharmacologists and other professionals who have training in clinical pharmacology can

influence national and international policy, practice, and education. Clinical pharmacology is also a critical component of the National Institute of Health (NIH) roadmap and the Food and Drug Administration (FDA) critical path initiative to meet the growing needs of public and private sector.⁴ The world health assembly has recently focused on developing R&D agreements between nations, developing partnership alliances among academia, public sector, private firms, and philanthropic institutions to research, develop or deliver drugs, vaccines and diagnostics for neglected diseases with open innovation and cost sharing mechanisms.¹⁰ For these ventures to succeed in a country like India, there is need to strengthen academic institutions in smaller towns, where problems of neglected diseases and neglected communities are experienced.

With the majority of people (69.35%) in India living in villages, the government of India has initiated various programs like the National Rural Health Mission (NRHM), Rogi Kalyan Samiti (RKS), and Village Health Sanitation and Nutrition Committees.¹¹ There is also increasing commitment from industry to rural areas. But all of this has not been enough to achieve the millennium development goals¹² of reducing maternal and infant mortality. There is also a concern over development of antimicrobial resistance which is largely due to overuse,

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misuse, and irrational use of medicines. Adverse reactions to drugs, ethics in clinical research, and personalized medicine are subjects of media attention.

The 12th 5-year plan subcommittee for AYUSH (Ayurveda, Unani, Siddha, and Homeopathy) research and industry envisages programs for basic and clinical research, and observational and epidemiological studies. Capacity building for these activities is also envisaged.¹³ Clinical pharmacologists can contribute to development, access, and affordability of medicines to the poor and those at risk of contracting rare diseases, achieve millennium development goals, and contribute to antimicrobial oversight. However, there are shortcomings in the current system. We put forth strengths and deficiencies in the current systems, especially from a perspective of young researchers, and suggest a way forward for the development of this discipline in one of the most promising and upcoming countries.

Strengths and Deficiencies

Medical Colleges

In India there are 335 medical colleges with graduate programs, 188 offering postgraduate degree courses in pharmacology to medical graduates and six offering super speciality courses in clinical pharmacology. These courses are regulated by the Medical Council of India (MCI) which specifies the minimum requirements. Pharmacology and clinical pharmacology are taught in the 2nd year of the undergraduate program. Clinical pharmacology is expected to be taught in the 3rd, 4th, and 5th years, through the integrated program, however in practice that is rarely achieved. There is not much attention to research methodology. In postgraduate programs for clinical subjects, although a research thesis is compulsory, the focus is on learning clinical skills and there is not much attention to research. Only recently has the MCI made training in research methodology mandatory.¹⁴ An infrastructure in medical colleges and teaching hospitals is available, and pharmacology departments have equipment required for experimental pharmacology. Now, with a restriction on animal experimentation, postgraduate students are taking up clinical work for their research. However, as most of the teachers are not trained in clinical pharmacology, the quality of research and research training is not adequate.

Pharmacy Colleges

Pharmacists represent the third largest healthcare professional group in the world. The majority of pharmacists practice in hospitals, community pharmacies, and at other medical facilities. A smaller number is employed in the pharmaceutical industry. For example, in South East Asia, 20% are in hospitals, and 53% in community.¹⁵

Pharmacy education in India has been industry and product oriented. Pharmacy education initially was a combination of pharmaceutical chemistry, analytical chemistry, and pharmacology, preparing graduates to work as specialists in production, quality control, and standardization of drugs for a pharmaceutical company. Bachelor in pharmacy (B. Pharm) and diploma in pharmacy (D. Pharm) courses in subsequent years introduced hospital and clinical pharmacy and the emphasis was on practical training. Masters in pharmacy and clinical pharmacy degree programs were started in 1996 for training pharmacy students in patient oriented service, but did not attract many students.¹⁶

The clinical pharmacy concept was introduced in USA in 1920–1940, and the Pharm D program was introduced in 1955. The FPGEC (Foreign Pharmacy Graduation Equivalency Committee) in the US mandates 5 years of a pharmacy graduation program to be eligible for the FPGEC examination. In India, a Pharm D program has been started in 27 colleges. Only about 15% of Indian pharmacy colleges are situated in healthcare campuses attached to a medical college or hospital. The Pharm D syllabus includes regular pharmacy and subjects like therapeutics and clinical pharmacy.¹⁷ It emphasizes clinical and patient-oriented aspects of the profession, but still overemphasizes basic sciences while subjects like health policy are being overlooked. The pharmacy practice course does provide training for pharmacy in the community, hospital, and clinical pharmacy areas, including patient activities, drug committees, pharmacy drugs and therapeutics committees, hospital formulary, infection control committees, and the institutional review board.¹⁸ However, the faculty is not trained in clinical pharmacology. A minimum of equipment is oriented to experimental pharmacology, and pharmacy equipment for training in clinical pharmacology, clinical research, and drug development is not yet a focus.

Alternative Systems of Medicine Colleges

Students of alternative systems of medicine learn in colleges and hospitals of their speciality, such as Ayurveda, Homeopathy, Unani, regulated by their respective councils and Ministry of AYUSH (Ayurveda, Unani, Siddha, and Homeopathy). There are approximately 0.6 million AYUSH practitioners, and every year about 29,000 students are trained in the country. Faculty and infrastructure are suitable for training in the practice of Ayurveda and homeopathy.¹⁹ There also exists regional disparity in the location of the colleges across the country.

Way Forward

The clinical pharmacologist's contribution to drug development and access to safe and effective drugs and policies at local,

national and international levels can be achieved by faculty development, continuing professional development programs, infrastructure development at teaching institutions, and collaborations.

Training

Continuing professional development programs are needed for doctors to be trained as well-informed prescribers, astute evaluators of information on new drugs, accredited investigators for clinical trials, innovative clinical researchers to identify local needs for research and clinical trials, and finally as leaders contributing to policy making. Few such programs exist and need to be made available to physicians in smaller towns, in private practice as well as in public sectors, academia, and industry. Faculty, students, and regulatory staff need to be exposed to regulatory requirements and ethics of research, and realities of healthcare needs in remote rural settings.

Faculty from colleges for pharmacy, especially those in small cities, should have the opportunity to upgrade their knowledge in drug discovery and development process in the laboratory as well as in the healthcare setting. This would require public private partnerships, national and international access, and associations with expertise. Centers of excellence in India and developed countries could provide fellowship programs with a special emphasis on hands-on experience. Funding could be provided by government or private trusts. The Department of Health Research, government of India, has recently announced fellowships and programs for training in various subjects including clinical trials, ethics, and good clinical practice. The Indian Council of Medical Research, government of India, has started specialist training programs in clinical pharmacology (PK/PD, outcomes research, pharmacovigilance and antibiotic oversight).

Infrastructure

A laboratory infrastructure for training and research is mandatory for colleges as per various council regulations such as the pharmacy and medical councils of India. Postgraduate students are required to conduct research projects. Various government departments provide grants in aid for infrastructure upgrades, and international agencies provide grants for specific topics such as HIV/AIDS and malaria. However, these are one-time grants, and often continuity is lost once the project is over and the student finishes the dissertation. Institutions, faculty, and students should be provided with funding opportunities to continue promising research work which is providing solutions to local problems with applications and scalability to other countries.

Collaborations

Students often work in isolation in their departments and cities. Dr. A.P.J. Abdul Kalam, former president of India,

has described five accomplishments of mind: mastery over one discipline, expertise in interdisciplinary work, finding new solutions to problems, ability to understand others views, and ethical behavior. Such qualities would be extremely useful for a clinical pharmacologist. Collaborations across disciplines and across countries will help in the development of clinical pharmacology. Collaboration with industry is crucial for exchange of ideas and expertise. Suitable job opportunities will also be created through this link. The Indian Council of Medical Research, government of India, has called for proposals for multidisciplinary consortium of excellence.

Recently, the South Asian Chapter of the American College of Clinical Pharmacology (extension of the American College of Clinical Pharmacology, USA) has been started in Mumbai. This could be further strengthened to be a common platform for scientific meetings and interactions for all those who are involved in drug development programs.

In conclusion, there is a great demand for the discipline to contribute to public health. Young researchers find current training and infrastructure in medical, pharmacy and alternative systems of medicine to be inadequate to prepare them for the challenges and opportunities. Greater emphasis on practical training and collaborations, especially for colleges in smaller towns, is needed. Associations like the South Asian Chapter of the American College of Clinical Pharmacology have contributed greatly to inspiring and training young researchers and should be strengthened further. As stated by Henry Ford: coming together is beginning, staying together is progress, and working together is success. There is a need to come together and join hands with the government, academic, and industry sectors for development of clinical pharmacology to provide guidance and direction to students especially in smaller towns.

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