Evolving Role of Clinical Pharmacologists in Indian Accredited Hospitals

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Abstract

Over the past decade, the health-care sector in India has made significant progress. It is presently one of India's largest sectors, in terms of revenue and employment, and is continuing to expand rapidly. The huge pool of trained medical professionals in the country and the availability of high-quality medical services at affordable costs have given India the advantage over its peers in the rest of the world. Presence of world-class hospitals and skilled medical professionals has strengthened India's position as a preferred destination for medical tourism. Improving patient safety, medication management, infection prevention and control, quality performance and improvement, and environment of care are the primary objectives of hospitals. The hospitals involved in medical tourism are voluntarily seeking accreditation of their patient safety and service quality standards from accrediting bodies nationally and internationally. In India, the National Accreditation Board for Hospitals and Healthcare Providers (NABH) is the constituent board of Quality Council of India, which has been set up to establish and operate accreditation program for health-care organizations. The accreditation program requires complete compliance to safe medication practices as a part of the management of medications in the hospital. This review discusses the evolving role expected to be performed by clinical pharmacologists as the primary custodian of medication management and medication safety process. As more hospitals in India aspire to become NABH accredited, it is expected that the role of clinical pharmacologists will be understood better and would be required to ensure proper and safe medication management system.

Keywords: Clinical pharmacologist, Indian hospitals, medication safety, National Accreditation Board for Hospitals and Healthcare Providers

Introduction

Over the past decade, the health-care sector in India has made significant progress. It is presently one of India's largest sectors, in terms of revenue and employment, and is continuing to expand rapidly. Health administration in India is governed by the Ministry of Health and Family Welfare. The central administration provides co-ordination and direction to a network of state health ministries for actual implementation.

The government has made several landmark moves including the National Rural Health Mission, 2005, Rashtriya Swasthya Bima Yojana, 2008, and the Clinical Establishments Act (Registration and Regulation Act, 2010). The private sector has grown across the value chain. Hospitals have emerged as stand-alone corporate entities, as have diagnostics providers. Health insurance and device and equipment manufacturers are being incorporated into the system. Pharmaceutical players too have continued to grow. Collaboration between the government and private sectors has emerged stronger.[1]

Health-care revenue in India is expected to increase from USD 72 billion in 2011 to USD 280 billion by 2020. Expenditure has expanded at a compound annual growth rate (CAGR) of 12% over 2012–2015. Rising incomes, greater health awareness, lifestyle diseases, and increasing insurance penetration are some of the major factors driving the growth of the sector.[2]

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Rising Medical Tourism

Presence of world-class hospitals and skilled medical professionals has strengthened India's position as a preferred destination for medical tourism.

The growth in the health-care sector is underscored by the cost advantage that India provides to the patients from developed countries. Notably, India also attracts medical tourists from developing nations due to lack of advanced medical facilities in many developing countries. During 2008–2020, the health-care sector is expected to record a CAGR of 16.5%. The total health-care industry in India is expected to earn USD 160 billion by 2017 and USD 280 billion by 2020.[2] The major service offerings that attract medical tourists from European nations and the Middle East to India include yoga, meditation, Ayurveda, allopathy, and other traditional systems of medicines.

The main reasons for the growing popularity in medical tourism in India are: (a) the long waiting lists in the developed countries, (b) the low cost of medical treatments in India than the other developed countries; in India, complicated surgical procedures are being done at one-tenth of the cost as compared to the procedures in the developed countries, (c) the affordable international airfares and favorable exchange rates, (d) the Internet; with the development of communications, new companies have emerged who act as intermediaries between international patients and hospital networks, giving patients easy access to information, prices, and options, and (e) the state-of-the-art technology, specialist doctors, nurses, and para-medical staffs that have been adopted by the big hospitals and diagnostics centers in India. In India, the medical education system also caters to the ever-increasing demand for the delivery of quality health-care services all over the country.[3]

Quality Commitment

Improving patient and medication safety, infection prevention and control, performance quality, and environment of care are the primary reasons for which the hospitals and medical facilities involved in medical tourism worldwide voluntarily seek Joint Commission International (JCI) accreditation.

In India, the Quality Council of India (QCI), an organization of the Government of India, has set up National Accreditation Board for Hospitals and Healthcare Providers (NABH). In an NABH-accredited hospital, there is strong focus on patient rights and benefits, patient safety, control and prevention of infections in hospitals, and practicing good patient-care protocols such as special care for vulnerable groups, i.e., critically ill patients for achieving better and controlled clinical outcome.[4]

Accreditation in Health-care Services

National Accreditation Board for Hospitals and Healthcare Providers

The NABH is a constituent board of QCI, set up to establish and operate accreditation program for health-care organizations. The board although being supported by all stakeholders, including industry, consumers, and government, has been authorized with full functional autonomy in its operation.

The NABH provides accreditation to hospitals in a nondiscriminatory manner regardless of their ownership and degree of independence. As per the latest information, a total of 526 health-care organizations have NABH accreditation.[5] The International Society for Quality in Healthcare (ISQua) is an international body which approves accreditation bodies in the area of health care as a mark of equivalence of accreditation program of member countries.[6] The current NABH hospital standards (4th edition standards released in December 2015) have been accredited by the ISQua. The approval of ISQua authenticates that NABH standards agree with the global benchmarks. The hospitals accredited by the NABH have international recognition which provides boost to medical tourism. The NABH is the founder member of the Asian Society for Quality in Healthcare registered in Malaysia and also a member of the International Steering Committee of WHO Collaborating Centre for Patient Safety as a nominee of ISQua Accreditation Council.[6]

Joint Commission International

The JCI is the oldest and largest standard-setting and accrediting body in health care based in the United States. This accrediting body was founded in 1994 by the Joint Commission. The ISQua ensures that the standards, training, and procedures used by the JCI as a health-care accreditor meet the highest international standards for accreditation entities. Through international accreditation, consultation, publications, and education programs, the JCI extends the Joint Commission's mission worldwide by helping the health-care organizations to improve the quality of patient care and to enhance patient safety. India received the first JCI accreditation in health-care sector in June 2005. As per the latest information, there are 36 JCI-accredited hospitals in India.[7] The JCI operations describe that all member health-care organizations are subject to a 3-year accreditation cycle and a survey of laboratories is conducted every 2 years. Organizations maintaining compliance with almost all the applicable standards are bestowed with the JCI accreditation.

Clinical Pharmacology and the Clinical Pharmacologist

Clinical pharmacology is the study of effects of drugs in humans.[8] This covers not only pharmacokinetics, but also pharmacodynamics, exploration of mechanism of action and effects.

Hospital functions of clinical pharmacologists vary from country to country and can sometimes overlap with clinical pharmacy. They could include the management of a pharmacokinetics (therapeutic drug monitoring) laboratory or toxicology unit to undertake patient dose management and poison management or counseling respectively. Clinical

pharmacologists may also be involved in hospital activities such as formularies or clinical research.[9]

Role of the Clinical Pharmacologist in the Health-care System

It was Sir William Osler who in 1891 stated that "A desire to take medicine is perhaps, the great feature which distinguishes man from other animals."[10] Clinical pharmacology has become indispensable for the development of new treatments as well as for the proper understanding and practice of contemporary medicine. Today's clinical pharmacologist fulfills a number of roles in the current health-care system, which is closely linked to monitoring medicinal usages [Table 1].[11]

Management of medication usage and medication safety process

As per the standards of both NABH and JCI, medication management requires the services of a clinical pharmacologist whose job responsibilities include the following:

- Convener of the drugs and therapeutics committee who formulates policies and procedures to guide the organization about pharmacy services and usage of medication
- Facilitate the formulation of hospital formulary
- Facilitate the development of policies and procedures for storage of medication
- Formulate policies and procedures for prescription of medications and guide the safe dispensing of medications
- Formulate policies and procedures regarding the use of implantable prosthesis
- Generate defined procedures for medication administration
- Development of pharmacovigilance system: adverse drug event reporting, management, and monitoring
- Medication error detection and mitigation system

Table 1: Role of the Clinical Pharmacologist in an Accreditated Indian Hospital

1. Medication Management System
a) Convenor of Pharmacy & Therapeutics Committee
b) Formulary Development
c) Advice on Inventory Management
d) Drug InformationServices
2. Medication Safety
a) ADR Reporting System Development/Pharmacovigilance
b) Medication Error Detection and Mitigation Advice
c) Protocol Development for Safe IV Infusion Services
d) Safe Chemotherapy Preparation and Practice Advice
e) Advice on Safe Use of Narcotic & Psychotropic Drugs
f) Development of Standard Treatment Guidelines in Collaboration with Different Clinical Departments including Antibiotic policy
3. Clinical Research
a) Advice on Clinical Trial Study Design
b) Advice on Research Ethics
c) Mentoring of Clinical Research Coordinators
d) Role of Basic Medical Scientist in IEC

- Formulate policies and procedures regarding the use of narcotic drugs and psychotropic substances
- Formulate policies and procedures regarding the usage of chemotherapeutic agents and radioactive drugs
- Implement evidence-based therapeutics through prescription audits
- Play pivotal role in the formulation of hospital antibiotic policy along with clinical microbiologist and head of critical care medicine
- Drug utilization studies
- Facilitate the development of quality indicators in relation to safe medication usage and pharmacy.

Medication management system

Medication management includes safe, effective, and appropriate drug therapy to patients prescribed by physicians and approved by a clinical pharmacologist. Patient care is ensured by the various staffs of pharmacy, which needs to be monitored by a clinical pharmacologist. He/she has a very active role in the development of formulary which is an official list of drugs and consumables which are available within a pharmacy. This list needs development by collective inputs from pharmacy-in-charge, clinical pharmacologist, consultants of various clinical departments, and the medical administration team. The committee which oversees the development of formulary consists of the members mentioned above and is known as the pharmacy therapeutics or drugs and therapeutics committee. The clinical pharmacologist functions as a convener of this committee and manages the entire process of development and updating of the formulary list.

Prescription audit

Clinical pharmacologists are expected to lead the prescription audit services within the hospital. The NABH-accredited hospitals have to monitor certain quality indicators every month which describe the quality of prescribing services in the hospital. Some of the quality indicators are: number of illegible prescriptions, number of medication orders with error-prone abbreviations, and number of prescription errors. Once the audit has been conducted with an adequate sample size, appropriate corrective and preventive actions have to be offered by the clinical pharmacologist. The utility of these actions can be assessed by conducting more prescription audit in days to come.

Medication safety services

Management of adverse drug reactions

Adverse drug reactions (ADRs) are a major medical problem, accounting for 3%–10% of general practitioner consultations, hospital admissions, and excess hospital days.[12,13] They result in the death of several thousand patients each year[14,15] and can represent up to 15%–20% of a hospital's budget.[13,15] Through the involvement of clinical pharmacologists in hospitals, further prevention of ADRs can be achieved by the selection of drugs that are not only cost-effective but also safer. The clinical pharmacologist participates in the process of ADR management as soon as the physician contacts the department of clinical

pharmacology for its opinion. The issue can range from a request for an advice regarding drug administration, or the choice of a drug in specific situations, to a call for assistance in managing complex clinical problems where the treating physician suspects that a drug interaction is involved. The solution can also range from being merely informative to a more comprehensive approach in the management of the case, including suggesting diagnostic or therapeutic procedures. Such advice can be completely neutral, based on the literature or knowledge of ongoing problems or it can be part of a more proactive approach, with the clinical pharmacologist taking part actively in the resolution of the drug-related problem. There may also be a preventive approach, when the prescriber approaches the clinical pharmacologist with a question concerning prescribing choice.

The clinical pharmacologist has a unique insight into the possible mechanism of the putative adverse reaction, the underlying or concomitant diseases, and the possibility of drug–drug, drug–food, or drug–disease interactions. The interaction will, therefore, be more fruitful, with the clinical pharmacologist being able to give sound advice to the prescriber and, at the same time, improving the quality of the data on individual cases, such as suggesting laboratory tests or the order of drug withdrawal, or an experimental approach to solve more complex problems. Knowledge of ongoing problems through participation in regulatory processes or advisory committees may also help to identify suspect drugs, as the physician may not be aware of the suspect because the risk is not yet well known. Having early access to such information can also help solve problems related to drug withdrawals, which are often attributed to a newly introduced substituted drug. For example, a cause of seizures in hospitalized elderly patients is withdrawal of benzodiazepines that the patients were not always aware they were taking, at admission.[9]

It is also necessary for the clinical pharmacologist to have the knowledge of ongoing regulatory processes, in addition to having access to the published literature.

Minimization of medication errors

Majority of medication errors occur, not as a result of callous attitude on the part of health-care providers, but as a result of the complexity of the medication use cycle. A number of definitions exist for a medication error. One definition proposed by the National Coordinating Council for Medication Error Reporting and Prevention is "any preventable event that can cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer."[16] According to this definition, medication errors also include prescribing errors, which may be defined as the incorrect drug selection for a patient and can include the dose, quantity, and indication, or prescription of a contraindicated drug.

The incidence of medication errors varies between 2% and 14% among patients admitted to hospital, with between 1% and 2% of patients in the USA being harmed as a result of medication errors, the majority of which are due to poor prescribing.[11]

The methods of avoiding medication errors depend on many factors, and it is essential to adopt a supportive safety culture to improve the rate of reporting of medication errors, thereby allowing further investigation of these cases. The clinical pharmacologist has a specialized insight into the many causes of medication errors, particularly in the field of prescribing, and therefore has a definitive role in averting these types of preventable patient injury.

Clinical Research Services

The clinical pharmacologist can play an active role in the development and facilitation of clinical trial services within the hospital. He/she can take part in the feasibilities of the clinical trials being offered to various clinical colleagues and become the point of contact for the sponsor. Clinical pharmacologists can be the nodal person in establishing the clinical research unit in a hospital setup which can provide complete technical and logistical support for the conduction of clinical trials. The institutional ethics committee in India requires a basic medical scientist as a mandatory component of quorum which should preferably be a pharmacologist.[17] Hence, the clinical pharmacologist plays a vital role in deliberating clinical trial designs in ethics committee meetings within the hospital. The NABH has launched the Ethics Committee Clinical Trial Accreditation program in 2015 which is expected to be embraced by the ethics committees of the NABH-accredited hospitals in India.

Clinical Pharmacologist's Role and Accreditation Body Stand

The accreditation bodies currently do not clearly define the role. The NABH guidebook does not clearly define this role or discusses qualification of the individual as who can function as a clinical pharmacologist in the hospital. The JCI 6th edition standards book mentions that there should be qualified individuals directly supervising the activities of pharmacy or pharmaceutical practices in hospitals where medication is organized internally. The expectation is that the standards of medication of management chapter should be properly implemented in order to successfully satisfy the NABH or JCI assessment requirement and achieve NABH/JCI accreditation. Currently, the hospitals which are accredited with the JCI have majorly employed MD Pharmacology doctors for overseeing the medication management system. The authors strongly believe that a doctor with specialization in MD Pharmacology/DM Clinical Pharmacology is the best candidate to implement the NABH medication management standards because many of these standards require dedicated and exhaustive training of medical pharmacology domain along with extensive hands-on patient handling experience which the pharmacy candidates (Bachelor of Pharmacy or Master of Pharmacy or PharmD) lack due to their less patient-centric curriculum. The medication management expert doctors can help implement generic prescription policy of the hospital by regularly undertaking prescription audit and communication

with the prescribers. The current NABH or JCI standards have not defined the role of clinical pharmacologist in therapeutic drug monitoring, pharmacogenetic testing, and pediatric or geriatric drug prescribing. These are key medication safety areas where specific guidelines are required to be developed by these accrediting bodies. The NABH and JCI hospital accreditation standards get revised and updated every 3 years (NABH standards were last revised in December 2015). There is a strong possibility that the future standards on medication management would define the role and area of work of clinical pharmacologist in a much more comprehensive manner. The authors expect that awareness created among the MD Pharmacology postgraduate students about this role would motivate them to apply for these roles in already accredited or seeking accreditation hospitals to improve medication management standards.

The Road Ahead

Therapeutics today is so diverse that its instruction must be carried out by people knowledgeable in each of the disease areas. It is expected that a clinical pharmacologist can maintain a focus on all aspects of this content and keep trying for its inclusion in the setups of modern Indian accredited hospitals. They have to provide unbiased advice on the most cost-effective and rational use of medicines in the society in order to improve patient outcome. With the ever-spiraling number of adverse effects of drugs, prescribing errors, patients' expectations concerning drug safety, and the need for appropriate new drug appraisal, clinical pharmacologists will play a very important role in educating new prescribers and patients about their medicines, thus helping clinicians deal with individual patient problems. Development of better therapeutics and the progress of medicine in this country rely on the development of clinical pharmacology in the hospitals. The need of the hour is to develop it as an independent discipline by realizing its direct and immense contribution to the overall patient outcomes and patient safety.

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Conflicts of interests

There are no conflicts of interest.

References

1. India Healthcare: Inspiring Possibilities, Challenging Journey, A McKinsey & Company report, Prepared for Confederation of Indian Industry (CII), December 2012.
2. Available from: https://www.ibef.org/industry/healthcare-india.aspx. [Last updated on 2018 Jun 01; Last accessed on 2018 Aug 22].
3. Suthin K, Assenov I, Tirasatayapitak A. Medical Tourism: Can Supply Keep up with the Demand. Proceedings, APac-CHRIE & Asia Pacific Tourism Association Joint Conference. Beijing, China; 23-27 May, 2007.
4. A study of problems and challenges faced by medical tourists visiting India. Study by Indian Institute of Tourism and Travel Management (IITTM) and Commissioned by Ministry of Tourism, Government of India; 2011. Available from: http://www.tourism.gov.in/sites/default/files/Other/Med.pdf. [Last accessed on 2018 Aug 22].
5. Available from: http://www.nabh.co/frmviewaccreditedhosp.aspx. [Last updated on 2017 Apr 29; Last accessed on 2018 May 03].
6. Quality Council of India, National Accreditation Board for Hospitals and Healthcare providers. Available from: http://www.nabh.co/. [Last accessed on 2018 Aug 22].
7. Available from: http://www.jointcommissioninternational.org/about-JCI/JCI-Accredited Organizations/India/latest/. [Last accessed on 2018 Jun 09].
8. Wang RI. The definition and scope of clinical pharmacology. JAMA 1980;243:1901-2.
9. Moore N. The role of the clinical pharmacologist in the management of adverse drug reactions. Drug Saf 2001;24:1-7.
10. Osler W. Recent advances in medicine. Science 1891;17:170-1.
11. Williams D. Monitoring medicines use: The role of the clinical pharmacologist. Br J Clin Pharmacol 2012;74:685-90.
12. Dormann H, Muth-Selbach U, Krebs S, Criegee-Rieck M, Tegeder I, Schneider HT, *et al.* Incidence and costs of adverse drug reactions during hospitalisation: Computerised monitoring versus stimulated spontaneous reporting. Drug Saf 2000;22:161-8.
13. Moore N, Lecointre D, Noblet C, Mabille M. Frequency and cost of serious adverse drug reactions in a department of general medicine. Br J Clin Pharmacol 1998;45:301-8.
14. Tramèr MR, Moore RA, Reynolds DJ, McQuay HJ. Quantitative estimation of rare adverse events which follow a biological progression: A new model applied to chronic NSAID use. Pain 2000;85:169-82.
15. White TJ, Arakelian A, Rho JP. Counting the costs of drug-related adverse events. Pharmacoeconomics 1999;15:445-58.
16. Medication Error Definition. National Coordinating Council for Medication Error Reporting and Prevention; 2018. Available from: http://www.nccmerp.org/about-medication-errors. [Last accessed on 2018 Aug 22].
17. Sanmukhani J, Tripathi CB. Ethics in clinical research: The Indian perspective. Indian J Pharm Sci 2011;73:125-30.