Evolution of Medical Informatics in the Pharmaceutical Industry in India

**ABSTRACT**

Objective: Medical informatics (MI) has emerged as an important field in the pharmaceutical sector recently. In the developed countries, it is a distinct department with clearly defined roles and responsibilities. However, in India, medical affairs (MA) and MI are mostly merged and their distinct roles are yet to be clearly defined. This article focuses on the evolving role of MI in the Indian pharmaceutical industry.

Methods: Challenges faced by MI in Indian pharmaceutical sector were formulated based on literature search done in the databases including PUBMED, MEDLINE, and survey reports of the pharmaceutical and consultant service companies.

Results: Data collection reports that MI is a subset of MA. MIPs, thus serve a lynchpin, collaborating with the MA and the commercial teams like sales and marketing.

Conclusion: The role and future of MIPs in India is promising, their key offerings in core areas of MA need to be understood and recognized.

Introduction

Medical informatics (MI) strengthens medico marketing with strategic scientific inputs and has established a niche for itself in the pharmaceutical and healthcare industry. In the pharmaceutical industry, MI focuses on the optimal use of drug information for problem solving, and decision making with safe and ethical scientific promotion (Sarbadhikari, 2005). Though MI is a segregated and distinguished department in the pharmaceutical industry in the West, however, it is still in its infancy in India. This article focuses on the evolving role of MI within their organizations, the interactions of MI with other departments, and key challenges faced by medical informatics professionals (MIPs).

Methodology

Extensive literature search was conducted in the bibliographic databases including PubMed, Medline, the Cochrane library and the Google Scholar for the articles related to Medical informatics. Literature from books such as International medical informatics association (IMIA) yearbook of Medical Informatics, latest survey reports of few outsourcing medical affair companies such as Campbell alliance, Best practices LLC and ISR reports and pharmaceutical companies such as Bayer, Indigene etc was also studied. Authors, being the part of MA team of Wockhardt, also shared their experiences to describe the roles and responsibilities of MIPs.

Medical Informatics: History

The first paper on MI was published in the journal “Science” by Ledley and Lusted in 1959. But, MI became an increasingly recognized discipline first in 1970, with the digitization of medical files, now known as electronic health records (EHRs) (D’Avolio, Farwell, & Fiore, 2010; Paul, Chatterjee, & Ghosh, 2012). Then, it was introduced as a discipline in education in the late seventies, first in the USA, later in the Europe and as it gained popularity, it developed in the Eastern countries (Mihalas, et al., 2014). MI was most appropriately defined by Shortliffe and Perrault in 1990 as “the rapidly advancing scientific field that deals with the storage, retrieval, and optimal use of biomedical information, data, and knowledge for problem solving and decision making” (Shortliffe, Perreault, Wiederhold, & Fagan).

In India, MI was first recognized in 1993 by the Indian Association for Medical Informatics (IAMI). The IAMI was conceptualized by Prof (Dr.) Nanduri Gajanana Rao and its first registered office was at the Nizam’s Institute of Medical Sciences (NIMS), Department of Clinical Pharmacology, Hyderabad (“Indian Association for Medical Informatics IAMI- Its History, Formation, Objectives & Activities. Available at: http://iami.org.in/IAMI%20history/Brief_history_of_IAMI.pdf. Accessed on 8 Nov 2016.”). MI is often used to describe a broad range of intertwined disciplines including: health informatics, health care, clinical informatics, biomedical informatics, information science and computer science. Since the 19th century, MI has evolved in its progressive pathway; some of the milestones of which are presented in Figure 1 (a and b).

MI Conferences, Events, and Seminars (Global)

The increasing number of conferences and events implicitly indicate the growth and acceptance of MI. Some important global conferences are:

MI Conferences, Events, and Seminars (India)

a) The Indian Association for Medical Informatics (IAMI) (http://www.iami.org.in/) is a professional scientific Indian association established in 1993 with an aim to promote information technology in the fields of healthcare, bioscience, and medicine in India. Indian Conference on Medical Informatics and Telemedicine is an annual initiative taken up by the Indian Institute of Technology, Kharagpur, India.

b) Asia Pacific Association for Medical Informatics (APAMI) was launched by the International Medical Informatics Association (IMIA) in October 1993. They held their eighth conference at New Delhi, India in 2014.

MI in India

In India, the Association for Medical Informatics (IAMI) was first developed in 1983 at Amsterdam. IAMi is held every two years on the roles and applications of informatics in medicine, health and allied fields in various states of India. The first conference was organized at Hyderabad in 1995. The journal “Indian Journal of Medical Informatics” was started in May 2004 (“Indian Association for Medical Informatics IAMI- Its History, Formation, Objectives & Activities. Available at: http://iami.org.in/ IAMIs 20th History/ Brief_history_of_IAMI.pdf. Accessed on 8 Nov 2016.”).

Other organizations like Medical Computer Society of India (MCSI) and National Institute of Medical Informatics (NIMI) and web portals (www.indmedica.com and www.medindia.net) also offer useful MI services. MI is an emerging field in India and is playing a key role with respect to presenting information and assisting quality scientific promotion.

Structure and Functions of MI

Definitions of MI are not the same in global countries and India, and thus the roles of MIPS also differ. As per the vast literature available in informatics research and practical experience shared by pharmaceutical and healthcare experts, the terms Medical Affairs (MA) and MI are being used interchangeably in both pharmaceutical and the healthcare sectors. Despite the fact that both MA and MI are associated with MAs, the MIPS have different roles and responsibilities. In Western countries, like USA and other global territories, MI is a separate wing in any pharmaceutical industry. The role of MI is distinct from MA, Research and Development (R&D) and the sales team.

MA: Over the past 25 years, the continued regulatory pressure has put a greater onus of commercial activities on the medical expertise, most often to MA groups (“Pharmaceutical Drug Manufacturers, Medical Science Liaison. Avaliable at: URL: www.pharmaceutical-drug-manufacturers.com/articles/medical-science-liaison,” 2011; Werling & Carnell). The prime role of MA department is to interact and build bridges with physicians and other health care professionals (HCPs) at various levels in the clinical practice. The MA can partner with the national and international key opinion leaders (KOLS) to host a variety of scientific meetings like advisory boards, Continuing Medical Education (CME), round table meetings (RTMs), departmental meetings, registries and panel discussions etc. They also provide scientific and medical information to hospital consultants, KOLS, regulatory agencies and answer queries relating to the value and correct usage of the products. MA team is also responsible for clinical trial protocols and study linked training for the researchers and site personnel. They also follow up with the HCP for results and perhaps publish the results of the study which could be leveraged by the sales and marketing teams (“A blog on MedicalAffairsRoleinPharmaceuticalCompanies by Worksure MedPharma. Available at URL: http://medtechq.ning.com/profiles/blogs/medicalaffairsroleinpharmaceuticalcompanies. Last accessed on 8 Nov 2016 “, 2013). MA department plays an important role in new product launches. According to the research by Best Practices, LLC, choosing capable talent and building the right field-based medical team competencies are critical for creating a successful function of MA. Hence, the positions of the Strategic Medical Affairs (SMAV) Medical Science Liaison (MSL) have gained importance in the recent past. SMA has been a frequent position in many organizations. The whole objective is to get close to the HCP and build a bond with them. In most of the Western countries, pharmaceutical companies rely heavily on outsourcing for developing and deploying MA teams. These outsourced MA teams are involved in brand management and product leadership, competitive and business intelligence, customer service, clinical operations, market research, analytics and forecasting, marketing management, product launch, sales and supply chain in brand management and product leadership, competitive and business intelligence, customer service, clinical operations, market research, analytics and forecasting, marketing management, product launch, sales and supply chain. Though some companies like Eli Lilly, Merck and many others have their own in-house teams to regulate functions of MA (“Medical Affairs Role in Ensuring Excellence in Product Launch. Company’s report: Best Practices, LLC Strategic Benchmarking Research. Available at URL: http://www.best-in-class.com/bestpdomrep.nsf/products/medical-affairs-launch-excellence?OpenDocument. Last accessed on 15 Nov 2016,” 2016).

MI: MIPS may not necessarily be from clinical backgrounds or have training in MI, although certain experience is definitely useful. They are usually from a pharmaceutical background well versed with clinical pharmacology most usually post-graduate in pharmacy (M. Pharm) (Silverstein, 2000). They are technically competent individuals who can contribute effectively in this domain. Some of them have a prior experience of MA, which helps a lot (Wolin, Ayers, & Chan, 2001).

Roles and Responsibilities of MIPS in Indian Pharmaceutical Industry

As per our own in-house MI department, we have defined the roles and responsibilities of the MIPS (Figure 2).

Figure 2: Types of Job Responsibilities (percentage) in MI

1) Literature support and Information Exchange: The pharmaceutical sector is an information-intensive industry. Data integration and management at all stages of the drug product cycle; from discovery to real-world use after regulatory approval, is a fundamental requirement to allow companies to derive maximum benefit from the scientific trends (AT Kearney, 2015; Cattell, Chilukuri, & Levy, 2013). MI team plays a significant role in creating and maintaining the medical information with respect to its disease and management (Gupta, 2013). The practice of evidence based medicines (EBM) means integrating individual clinical expertise with the best available external clinical evidence from systematic research. The aim is to build clinical decisions
that maximize bene t: risk and bene t cost ratios to the patients. The practice of EBM is greatly facilitated by the availability of evidence summaries in the form of systematic reviews. Cochrane is the most authoritative and biggest online library of systematic reviews and Journals. MIPs play significant role to participate actively in development of EBM (Prasad, 2012).

a) Strategic scientific promotion: Different products require different scientific emphasis. MI strategically supports the required scientific promotion. There are various scientific inputs like preparing features and benefits of important flagship brands, scientific compendiums which collate and compile major clinical trials of a molecule together. Sometimes, a direct comparative analysis between two or more competitor molecules which maybe of the same class are also undertaken with key knockout points. These inputs could be used strategically for promotion to a HCP with a substantial impact and key outcomes like satisfying a possible existing query of the HCP and may even win prescription and sales over a competitor brand. Additionally, MI keeps an eye on the future of the therapies chalking out the various potential new drugs which are in early phase clinical trials and creates a ready repository of the same. MIP creates a repository of the pipeline molecules for various therapeutic areas thus giving MA a scope of looking into the future of the therapeutic area that can benefit the organization and expand the therapy portfolio. This data could also possibly be shared with the business development and the marketing teams.

b) Medical Updates: MIP scans all possible recent updates in disease and treatment especially those pertinent to the organization or maybe the brand in focus. Daily or weekly updates are sent out to both the MA team and the marketing teams. The marketing can then help the sales force use these updates for effective in-clinic discussion or even use it themselves for preparation of promotional inputs or sales pieces. Updates to external customers such as HCPs helps cater to their need of staying scientifically abreast and also helps to create a good scientific image of the organization. The ICMR (Indian Council of Medical Research)–NIC Centre for Biomedical Information has developed “IndMED” database covering the bibliographic details from 75 peer reviewed biomedical journals. A second database of on-line full text covering various essential parameters like pharmacodynamics and pharmacokinetics along with efficacy and safety. This information is both critical and important in ascertaining whether a particular product is a suitable candidate to be launched and would be helpful for the MA, marketing and strategic business teams (Chauhan, Moin, Pandey, Mittal, & Bajaj, 2013; Sarbadhikari, 2005).

These databases help to save time, increase efficiency and improve the overall quality of evidence.

a) New Product Evaluation: MIP also plays a very important role in evaluating new products to provide an adequate rationale for a particular product and helping find its place in therapy. As per the need, the evaluation is either preliminary or comprehensive covering various essential parameters like pharmacodynamics and pharmacokinetics along with efficacy and safety. This information is both critical and important in ascertaining whether a particular product is a suitable candidate to be launched and would be helpful for the MA, marketing and strategic business teams (Chauhan, Moin, Pandey, Mittal, & Bajaj, 2013; Sarbadhikari, 2005).

b) Handling Medical Queries: During pre and post launch, MI receive queries from HCPs. Within a time span of three working days, the MI ensures a suitable response to all the medical queries. An up to date list of all the queries answered is then maintained which also helps in answering a similar kind of query later. More than 50% of the work time of MIPs is engaged in literature search and maintaining medical information repositories which includes solving medical inquiries of both internal and external customers, providing literature support for advisory boards, scientific meetings, maintaining databases, and providing suggestions for new products launches (Crowley-Nowick & Smith, 2013). This function is a core responsibility of the MIP, thus, releasing the MA to focus on other important activities and increasing productivity for both functions. MI experts are key resources within MA for both medical science liaison (MSL) and the commercial teams.

Table 1: List of Useful Databases for Exploring Medical and Scientific Literature

<table>
<thead>
<tr>
<th>Database</th>
<th>Application</th>
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<tbody>
<tr>
<td>Springer</td>
<td>Springer has a collection of 3,500 journals apart from articles, chapters, conference papers etc. Journals and books on biomedical and medical sciences including the very recent addition of the distinguished ‘Nature basket’. There wouldn’t be better reviews out there on disease and therapy apart from Nature. Containing journals with impact factors close to 50, other most authoritative evidence is of high quality. The highlight of this database lies in very popular ADIS reviews and the Nature reviews.</td>
</tr>
<tr>
<td>Nature</td>
<td></td>
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<tr>
<td>Adis</td>
<td>It is an extremely helpful resource to study clinical trial evidence of available molecules giving a detailed drug profile and also look at possible molecules in the pipeline with development status, history and current data of ongoing trials worldwide, updated on a weekly basis. The distinguishing feature is the list of filters available to choose necessary information along with the variety of searches on the home page. The required data can then be exported in the Microsoft (MS) Excel, comma-separated values (CSV) and Bizint Formats.</td>
</tr>
<tr>
<td>Insight</td>
<td></td>
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<tr>
<td>Science Direct</td>
<td>A gamut of medical content with almost 4000 peer reviewed journals and therapy areas like dentistry, hospital medicine, pharmacology and toxicology and pharmaceutical sciences. Scopus which belongs to Science Direct is a comprehensive solution for medical evaluations, trends in drug discovery/ research and recent updates making it another helpful database which needs to be subscribed to separately.</td>
</tr>
<tr>
<td>Microme dex</td>
<td>It provides high-quality drug prescribing information available from 80 countries. It provides comprehensive ongoing reviews and recommendations obtained from various medical journals.</td>
</tr>
<tr>
<td>Cilite</td>
<td>It gives a concise summary of the developmental details of a product and its regulatory status across various markets in the world. It is helpful for evaluating new products, checking the reach of drug molecules along with the phase of research the molecule is in.</td>
</tr>
<tr>
<td>Up to Date</td>
<td>An evidence based, peer-reviewed information electronic clinical resource tool for physicians and patients. It provides access to over 10,000 topics in over 22 specialties. It is a constantly updated ready reckoner which is very useful in having a holistic picture for a disease and its management.</td>
</tr>
<tr>
<td>PubMed</td>
<td>A widely used renowned database comprising of more than 26 million literature from Medline, life science journals and online books.</td>
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1) Medical communications and publications: MI teams also work in medical writing and publications. The MI works with agencies on publications constantly, to ensure quality. Some Western organizations have separate publication planning teams which direct and plan publications. Approximately, 30% of the work time of MI involves working as medical writers. A publication planning team directs and plans for all drug related publications such as abstracts, posters, and manuscripts. The journals preferred for publication are PubMed indexed with a high impact factor. (Crowley-Nowick & Smith, 2013). MI team also plays an important role in addressing typical concerns about commercial drug products, including safety, efficacy, dosage, administration and pertinent supporting literature.
2) Review of promotional material: Medical review (MR) is another important activity performed by MIPs. They play a crucial role in reviewing the promotional material developed by the marketing team. The type of promotional material reviewed is slide presentations, websites, patient-focused materials, sales pieces, and in addition, there are other promotional material like visual aids (VA), LBL, posters, scientific booklets, and standees etc. Besides this, MIPs have numerous responsibilities that can range from reviewing pieces to conference kits. They are responsible for ensuring scientific accuracy, relevance, and completeness of clinical data; ensuring that claims are adequately supported by valid scientific references and current approved labeling. To ensure that promotional materials and activities comply with guidelines of ethical promotion, Uniform Code of Pharmaceutical Marketing Practices (UCPMP), pharmaceutical companies usually establish promotional review committees (PRCs), which are cross-functional groups that also take into account legal considerations and medical accuracy. Reviews may be time-consuming and may require a significant time investment to validate scientific information. It has been approximated that MI has about 10% job responsibility in reviewing promotional material (Bonk, Kothari, Andrikanich, & Yang, 2012; Tiwari, 2006).

3) Training: Every pharmaceutical company requires a dedicated training team to deliver various trainings to their employees, which includes understanding of internal standard operating procedures (SOPs), training on new features of a database, new databases, data presentations, group discussions for the MA and marketing teams, and sometimes a sales training program. The training team should have trainers who have the right set of skills to impart the customized trainings to all as per their requirements. MIPs being professionally qualified, having pharmaceutical background and with rich experience of serving pharmaceutical and healthcare industry can be suitable candidates for delivering trainings. The percentage responsibility of MIPs role is estimated as 10%. (Bonk, et al., 2012).

Challenges being faced by MIPs

A successful product launch in today’s competitive and regulated marketplace is highly dependent on the science-driven decision making. In such a scenario, MIPs play an important role, beginning right from the pre-launch phase and extending well beyond the launch date. After drug approval, when a new product faces a competitive environment and medical fraternity begins to incorporate it into their therapeutic programs, each initiative has to be well planned and carefully coordinated to maximize the amount of exposure, recognition, and buzz for a new drug product. During this phase, MI team has to cope up with the growing internal and external challenges “(Medical Affairs Role Functions. Available at URL: https://www.isrreports.com/wp-content/uploads/2014/07/ISR-Medical-Affairs-Benchmarking-Preview-0714.pdf. Last accessed on 12 Dec 2016,” 2014).

In India, most companies recruit candidates as MI Project manager, MI researcher or Research assistant, Medical database administrator etc., as they fit the candidature perfectly. Interpersonal skills are equally important as the job profile needs to have an interaction with the other teams. In order for the industry to display its scientific strength and the importance thereof, it would be helpful to create new positions for MI. This will be a statement of recognition.

Discussion

The importance of scientific promotion has been well recognized by both the industry and the medical fraternity. There is a lot of information available in medical databases (Medline, PubMed, Cochrane reviews etc.). However, integration of unbiased data and analysis of the evidence-based data from an efficacy and safety window needs a comprehensive evaluation. MI is a known entity among many multinational corporation (MNCs) abroad (USA, UK, EC, Canada and Japan) and India can soon adopt this global trend.

Some Indian MNCs have begun creating space for this department which will play a key role both in the present and the future. The primary role of MI departments would be integral to communicate timely, accurate, unbiased, EBM information to the existing cross functions in the organization like regulatory, MA, marketing and business development as well as HCPs and consumers, ensuring appropriate use of company products and therapy portfolio expansion. Therefore, many pharmaceutical sectors such as pharmacovigilance, drug regulatory affairs, clinical trials and drugs promotion; their sales and marketing need MI support (AT Kearney, 2015). It is good for us to know that the contribution of MI to the industry is growing globally with the growth curve demonstrating an upward trend. As per one of the survey report in 2008, only 26% global companies participated in MI services (“Global Medical Affairs: 26% of Pharmaceutical Companies Employ Global Teams, PR Newswire. Available at URL: www.prnewswire.com/news-releases/globalmedical-affairs-26-of-pharmaceutical-companies-employ-global-teams-53119937,” 2008). A survey analysis (2014-15) by the USA based MA organization has reported that 24% of life sciences companies globally including US, 38% each in non-US and others (Canada, West Europe and Nordic) have active MI organizations and the pace of change is expected to increase even more as we approach 2020 “(Medical Affairs Role in Ensuring Excellence in Product Launch. Company’s report: Best Practices, LLC Strategic Benchmarking Research. Available at URL: http://www.best-in-class.com/bestp/ domrep.nlm/products/medical-affairs-launch-excellence?Open Document. Last accessed on 15 Nov 2016,” 2016).

Challenges and Strategies to Overcome Them

1) Lack of demarcation of roles and responsibilities: Roles and responsibilities of MIPs are still not very clear in most of the pharmaceutical companies. There has been a shift in the functional roles between MA and MIP. MIPs deal not only with technical queries but also build bridges with a KOL. These are some of the overlaps with the role and responsibilities of the MA. Therefore, a pharmaceutical company must carefully define the roles of MIPs and communicate the same to other stakeholders. This will ensure better focus and concentration for MA and other departments(Tyson & Doyle, 2013)

2) Limited turn around time for deliverables: Arriving at a clinical decision is not all that easy and involves exhaustive work at first accumulating evidence and then analyzing and providing a fair unbiased conclusion. This is usually a laborious process which requires a substantial investment of time. Owing to the shortage of manpower in these roles, sometimes quality could be compromised. To overcome this, one needs to add to the manpower, prioritize the projects, and be more efficient. A SOP that defines timelines for various projects can also be tabulated to ensure smooth cross function operations.

3) Resource constraints: It is vital for the MI to work with quality databases to deliver quality scientific evidence for quicker responses. Quality databases need quality investment. In order to be resourceful, the MI needs good resources. Resources also help keep up with the recent updates and the wave of clinical evidence. Owing to a great competition, time is of great essence in maximizing their contribution to the marketing, medical teams and also the HCPs. As per the Industry Standard Research (ISR) report released from a top 25 company said, “We want people who have at least spent a year or two in a medical decision making capacity since they will be faced with medical and ethical decisions regularly” “(ISR Report: Benchmarking the Pharma Industrys Medical Affairs Functions. Available at URL: https://www.isrreports.com/wp-content/uploads/2014/07/ISR-Medical-Affairs-Benchmarking-Preview-0714.pdf. Last accessed on 12 Dec 2016,” 2014).
The technical contribution of the MI colleagues cannot be overlooked nor underestimated in times of cut throat competition. This rather than being a well-rounded technician is the current need of the pharmaceutical industry. This will also build on the scientific thrust that the industry is edging towards.

To streamline this, most of the pharmaceutical companies have been outsourcing the MI role to medical agencies. This helps them to reduce the workload of the MA team, there is lesser duplication of efforts. Also it provides scalability; well defined pathways to take on additional product responsibilities and gives internal team satisfaction and increased productivity by refocusing efforts on cross functional initiatives. An in-house MI team would at any given day understand the processes, needs, and focus of the organization better than a medical agency. They would emphasize for a certain kind of required quality in all their inputs. This would save a lot of time and resources for the organization.

In India, growth curve in MI is gradual. MIPs have an essential role to play with their huge sphere of influence. In the coming decades, there will be a high scope of job opportunities for MIPs in both health and pharmaceutical sector. The encouraging sign is that Indian organizations are recognizing the importance of it and are following the prototype of medical teams set up by the MNCs which of course include the MI as an integral function.

As per 2015 McKinsey Company’s report, it has been forecasted that the definition of “medical value” will be much broader by 2020 and will expand with the increase in types of healthcare stakeholders who demand a demonstration of value. A pharmaceutical company’s engagement with KOLs will significantly transform under an intense public scrutiny and demands for greater medical information to be exchanged. It shall widen the scope of MIPs in the pharmaceutical industry (Evers, et al., 2015). Subsequently, there will be a rise in the demand of MIPs in hospitals and health care systems, pharmaceutical companies, outsourcing companies for medical writing, medical transcription; and the growth could be in the type of exchanging information as well. These might include new data, particularly real-world evidence and patient-generated data (e.g., genomic information), which in the past were often disconnected data points that now need to be considered in the context of broader information sets (e.g., safety data) (Evers, et al., 2015).

MI is a lynchpin for other teams to rely upon especially MA. It acts as a credible link with external stake-holders and plays a progressive more crucial role in communicating the product or service information to HCPs and regulatory bodies. Thus, MI helps in establishing appropriate positioning for new products and leverages the latest information for future. Globally, change in the pharmaceutical industry has clearly defined the role of MIPs in MA and MI, giving them more responsibility than ever. MIPs provide all kinds of tools and services to manage internal and external information, their key areas of literature support and training delivery are the major contributions to support any pharmaceutical industry. However, in India, their key offerings and value additions in the core areas of MI need to be recognized and embraced by the pharmaceutical companies. Neuer roles and versatile job profiles of MIPs offer a bright future for MIPs in India.

Conflict of Interest
None of the authors have any conflicts of interest to declare. No funding was received.

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