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Editorial

Challenges to rational prescribing and use of essential medicines in India

The concept of essential medicines was introduced in 1977 with the publication of the World Health Organization's (WHO) *Model List of Essential Medicines*. These medicines are intended to satisfy the priority health care needs of the population. They are selected with regard to public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and at a price the individual and the community can afford.[1] The WHO advises countries to adapt the essential medicines list according to their priority health care needs. The model list of WHO serves as a guide for the development of a national list of essential medicines (NLEM). An essential medicines list can serve as a model for procurement, local licensing and manufacturing, and the rational use of good-quality medicines, especially within the public sector. It also helps in allocating limited resources effectively and in a cost-effective manner.[1,2]

By the turn of the 20th century, 156 countries had adapted a NLEM.[2] Like many other developing countries, India too has prepared a NLEM that aims at addressing the prevailing diseases of the nation and lists the commonly used medicines at primary, secondary and tertiary healthcare levels. The first NLEM for India was prepared in 1996 and subsequently revised in 2003. The latest revision of the NLEM comprising of 348 medicines was released in June 2011. The update was carried out after a series of core committee meetings and expert committee workshops starting since September 2009. Inputs from 87 experts (comprising of clinicians from various disciplines, pharmacologists, pharmacists, and drug regulators) along with appropriate literature based evidence were used during the revision. The process also took into account two important national reference documents, the Indian Pharmacopeia 2010 that provided standards of identity, purity and strength of the medicines and the National Formulary of India, 2010 that provided critical information for rational use of the medicines. In addition, the NLEM incorporated all the medicines used in various existing national health programs of India. Despite the efforts, some noticeable irregularities in the updated list have been criticized, suggesting a scope for improvement in subsequent revisions.[3]

Many states have also developed their own list of essential medicines based on the NLEM. Tamil Nadu was the first state to develop its own essential medicines list as early as 1994. The state government of Delhi too has developed its own list. However, many of the lists are not updated regularly.[1] A hospital formulary can also be based on the NLEM or the state essential medicines list. It is not compulsory that all the medicines used in the hospital should be in the hospital formulary.[1,4] There is evidence to show that that clinical guidelines and lists of essential medicines, when properly developed, introduced, and supported, improve prescribing quality and lead to better health outcomes. However, there are two major challenges to the optimal use of essential medicines in our country namely inappropriate/irrational prescriptions by physicians and limited availability of essential medicines within the healthcare facilities.

Appropriate selection and use of medicines is a basic requirement for rational medicine practice. However, the WHO has estimated that half of all medicines are inappropriately prescribed and used, suggesting that it is a universal problem and not limited to developing countries like India alone. Often the problem of irrational prescribing has its origins in the way medical students are taught during their formative years. Prescribing is a complex task that requires diagnostic skills, knowledge of medicines, communication skills, an understanding of the principles of clinical pharmacology, appreciation of risk and uncertainty, and critical judgment. It is an important skill which needs to be continuously supervised, assessed and refined.[5]

In the current Indian medical education system, the undergraduate student is introduced to pharmacology during the second year. In a typical curriculum, great emphasis is put on acquisition of theoretical knowledge about mechanism of drugs, their potential uses and adverse effects. The practical aspects of selecting a drug appropriate to a clinical condition, based on patient characteristics and available evidence is rarely conveyed to the students. Moreover, in medical colleges where rational prescribing is taught using problem based learning, the cases discussed are mostly hypothetical and too simple in nature to be of major relevance in influencing the decision making capabilities of the student.[6] A good alternative is to encourage students to follow real patients admitted in the hospital, and discuss the treatment with an interdisciplinary faculty comprising of pharmacologists and clinicians. The emphasis in such discussions should centre on whether standard treatment guidelines and essential medicines were employed during the case management. Concepts such as reduction in 'factual burden', horizontal and vertical integration

between clinical and non-clinical disciplines for development of content, delivery and assessment of clinical pharmacology curriculum are not entirely new and have been described since 1993 by the UK General Medical Council in its publication *Tomorrow's Doctors*.[5]

Practicing physicians often tend to prescribe irrationally, favoring complicated treatment regimens, newer medicines and polypharmacy.[5] The uptake of new medicines especially newer generation antibiotics is particularly striking. Between 2005 and 2009, the sales of antibiotics increased by 40% with cephalosporins leading the with 60% increase in sales.[6] Additionally, there is disproportionate increase in the empiric use of piperacillin tazobactum and third generation cephalosporins in the intensive care setting.[7] Microbiological resistance has increased significantly and currently high levels of resistance to even newer antibiotics like fluoroquinolones is observed.[6] Poor diagnostic facilities, high patient volume, shorter decision times, greater patient expectations, low levels of training and supervision, and absence of hospital formularies, standard treatment guidelines and concrete medicine use policies facilitate such practices. The problem is further compounded by low acceptance of NLEM, aggressive marketing strategies adopted by pharmaceutical companies to push newer drugs and fixed dose combinations and easy availability of medicines without prescription. Such practice drives up the cost of treatment and increases the chances of adverse drug reactions, drug resistance and ultimately lowers the compliance with therapy. A survey carried out among 504 clinicians in six medical colleges in North India revealed that while majority were aware about essential medicines, only 25 % actually prescribed them. Around 83% of the respondents depended on medical representatives for information on new medicines.[8]

While the problems are easy to identify, the solutions are not straight forward. Awareness about rational prescribing may ameliorate such practices but cannot abolish it. Proper implementation of policies like encouraging prescribing of personal drugs (P-drugs) sourced from a hospital formulary or from the NLEM, restricting the use of newer antibiotics to specialty care facilities, and rotating between classes of antibiotics, coupled with regular antibiotic resistance surveillance and medicine use audits may be useful in increasing the accountability of the prescriber. It would be worthwhile if efforts are directed towards creating independent and unbiased sources of medicine related information to promote evidence based practice. Furthermore, implementing continuing medical education as a mandatory licensure requirement would also be helpful. Stringent measures like those initiated by the state government of Orissa, including recovery of the cost of medicines from the prescriber if the prescription is found to be irrational can also act as a possible deterrent.[9]

Recently, certain regulatory measures have been proposed to curb the practice of irrational prescribing and prevent the growing menace of antibiotic resistance. An amendment to the Drugs & Cosmetics Rules 1945 termed as Schedule HX has been proposed. It would have two parts. Part A of Schedule HX lists 16 medicines useful in life threatening conditions including meropenem, imipenem, ertapenem, linezolid and cefpirome that would be sold directly by drug manufacturers to tertiary care hospitals. Part B of Schedule HX includes 75 medicines like gentamicin, amikacin, oxacilin, cefalexin, cefaclor and cefdinir that would be sold under prescription only. The policy also entails a prescription audit. Prescribers will have to provide two copies of prescriptions to every patient. One copy will have to be kept for two years by the chemists while the other one will be audited by office of the drugs controller general (India).[10] Another initiative, the National Pharmaceuticals Pricing Policy, 2012 has been formulated to ensure availability of essential medicines at reasonable prices. All strengths and dosages of medicines specified in the NLEM 2011 will be under price control and based on market based pricing. Ceiling Prices (CP) of an essential medicine will be computed as the simple average price of all brands that medicine having market share of 1% or more. Manufacturers will be free to fix any price for their products equal to or below CP.[11] However, the actual impact of these proposed regulations can be ascertained only when they are stringently implemented and supervised.

Prescribing generic medicines rather than branded products especially in publicly funded healthcare facilities can also help in reducing in healthcare costs. A survey pointed out that only 15% of clinicians prescribe in generic form.[8] A possible reason could be that the quality of generic medicines is considered to be inferior to their branded counterparts. It is paradoxical that while India offers high quality, low-cost generics to the world its own population does not have access to good quality generics of essential medicines. In view of this, in April 2008, the Department of Pharmaceuticals, Government of India launched a campaign to open drug stores called Jan Aushadhi stores to provide quality generic medicines at lower prices. However, due to low awareness and limited number of such stores, the overall impact has been very limited.[12]

The second major impediment to use of essential medicines is its low availability within health care facilities. A six-state survey carried out in 2004-2005, revealed that the median availability of a basket of 27 essential medicines in the public sector outlets was 0-30 %.[12] Similar conditions were also reported in a cross-sectional study carried out in 3 primary health centers, 3 additional primary health centers and 6 sub-centers in Darbhanga in Bihar.[13] These data suggest that unless procurement and delivery systems of essential medicines are strengthened, mere presence of a NLEM will largely be futile.

While there are many challenges to rational prescribing and use of essential medicines, none is insurmountable. Inculcating a culture of rational use of medicines in current and future prescribers and implementation of seamless procurement, distribution and storage mechanisms for essential medicines at all healthcare levels can ensure equitable distribution of healthcare resources to our patient population.

Biswa Mohan Padhy
Department of Pharmacology, Vardhman Mahavir Medical College & Safdarjung Hospital,
New Delhi-110029, India.
Email: drbisu7@gmail.com

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