

Editorial

Using medicines rationally: Why are we still struggling?

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To ensure the rational use of medicines (RUM), patients must receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements and at the lowest possible cost to them and their communities. The importance of right information regarding using the medicines is also emphasized [1]. RUM has been emphasized for over five decades. However, recent studies show that over half of all medicines may not be used rationally. In South Asia, a study among outpatient department pharmacies of government hospitals in Sri Lanka showed the major contributors to irrational prescribing and inappropriate use of medicines were polypharmacy and over-prescription of

antibiotics [2]. A study in the Department of Medicine at a tertiary care teaching hospital in Nepal found that average number of medicines per prescription was 2.55, drugs prescribed by generic name were 57.5%, antibiotics were 9.7% and injections were 0.6%. Drugs prescribed from the Essential Drug List of Nepal was 65.8% [3]. A study among different levels of healthcare in Nepal found drugs are prescribed with generic names in most health facilities but only half of the patients are dispensed complete prescribed medicines and most lack complete knowledge regarding medicine use. Similarly, some of the drugs were found to be substandard in the Nepalese market. There were also large variations in price among different brands of the same generic [4]. In this editorial, factors hindering rational use of medicines will be analysed and discussed.

Pharmaceutical industry, pharmaceutical promotion and RUM

There are several factors that hinder RUM. The pharmaceutical industry is among the most profitable ones on the planet. Companies have nearly limitless resources to promote their medicines. Organizations promoting RUM operate with much more limited budgets. This basic imbalance creates challenges. Pharmaceutical companies are for profit entities and would like to get the maximum return on investment. They also have social responsibilities in ensuring appropriate medicines for illness. The industry continues to use a variety of techniques to influence the prescribing and use of medicines. Among these are free medical samples, gifts, journals, and direct marketing. However, many health professionals underestimate the effects of pharmaceutical promotion on their professional practice and believe that they

are not personally influenced by promotion [5]. The industry would like doctors to prescribe newer, patented, more expensive medicines where an older, less expensive one may still be effective. This may be seen in the case of newer more expensive members of an existing medicine family with minimal advantages over an existing medicine. This is often seen with cardiovascular, and metabolic medicines and with antibiotics. Over the last several decades, the pharmaceutical industry has played an important role in addressing public health challenges [6]. Many medicines have been developed by the industry. In Nepal being socially and environmentally responsible was not only good for society but also excellent for increasing and preserving shareholder value and corporate image of pharmaceutical companies [7].

Companies may carry out small modifications to a molecule to extend the patent protection. This is termed '*evergreening*'. The purpose is to delay the generic competition by extending the length of the exclusivity period beyond the legitimate patent term without any considerable improvement in therapeutic benefits of an already patented medicine [8]. There is also the question of '*reserve*' antibiotics. These are new molecules that are held in reserve for infections that do not respond to existing antibiotics. The question of who will pay for a medicine that may not be used often is an important one. Humanity has the resources to do this, as is evident by the billions spent on keeping nuclear weapons in reserve, but it is another matter whether the political and the administrative will exists in the case of medicines.

The industry remains the major and sometimes the only sponsor of conferences in Nepal. They also sponsor physicians to attend conferences. Clear rules of engagement

between the industry, conference organizers and physicians should be considered to reduce possible conflicts of interest [9]. In Pakistan, the pharmaceutical industry was the largest sponsor for physicians to attend educational events. The type of expenses paid for attending the educational events included meals, accommodations, airfare, registration fees, taxi fare, and participation fees. The authors concluded that educational events are being used as a promotional tool for pharmaceutical products in Pakistan [10].

'Snakes' and rational use of medicines

Irrational prescribing, polypharmacy, and aggressive promotion act as "snakes" hindering healthcare progress and RUM. Combating these challenges necessitates robust educational initiatives, institutional support, and updated treatment guidelines [11]. Pharmaceutical representatives are paid according to the amount and the value of medicines they can push in their territory. Using a newer, more expensive medicines where an existing one is effective can lead to greater profits but can also create several problems including, antimicrobial resistance. Humans may need to be able to think beyond current profits and look at the longer-term effects of their actions to avoid catastrophe. A study published in 2016 mentions most companies were seeking to achieve short-term profitability instead of trying to find ways to ensure the long-term sustainability. Investing in environmental technology is costly with no quick payback and though the situation is changing companies may be reluctant to invest in costly technologies [12]. Organizations must meet changing societal demands, adapt their long-term strategies and incorporate environmental and social aspects into their product offerings and decision-making. However, at the same time

companies must satisfy short-term profitability interests and demands from shareholders [13].

In Nepal, shortage of essential medicines continues to be a problem especially in remote and rural areas. Companies and distributors may focus on manufacturing or importing medicines that may bring higher revenue and greater profits, and hence low-cost lifesaving medicines may not be manufactured at all or may be done in inadequate quantities. Imports still account for over 50% of medicines (different sources mention between 50 to 80%) and the capacity of domestic manufacturers should be expanded. Financial incentives by manufacturers and distributors have frequently led to questionable practices such as promotion of marginally effective medications at premium prices, manipulation of clinical trial data, and systemic underinvestment in areas/diseases of significant public health need but limited profit potential [14].

Cost of medicines

The issue of medicine cost requires careful scrutiny. Patent protection has been strengthened in recent decades, and many new medicines are extremely expensive. What is a reasonable return on investment and how to ensure that medicines are accessible to those who require them are important questions. Most expenditure on medicines is out-of-pocket in developing nations. The paucity of rigorous studies on the effectiveness of pharmaceutical pricing and purchasing strategies makes it especially difficult for policy makers in these countries to decide on a course of action. Many policy options for medicine pricing and purchasing have been found to be effective, but they also

have attendant risks to be considered [15]. A study in 30 developing nations published in 2009, found that the average public sector availability of generic medicines ranged from 29.4% to 54.4%. Median government procurement prices for 15 generic medicines were 1.11 times the corresponding international reference prices, although purchasing efficiency ranged from 0.09 to 5.37 times international reference prices. Low procurement prices did not always translate into low patient prices. The authors concluded that treatments for acute and chronic illness were largely unaffordable in many countries [16].

In Nepal, treating selected non communicable diseases with medicines was generally affordable, with 1 month of treatment costing no more than a day's wage of the lowest paid unskilled government worker. The authors mentioned that the lower availability of these medicines in the public sector limits the effectiveness of the government's policy of providing free health services at public facilities [17].

Unfortunately, medical students are not often taught about the cost of medicines and to carry out a basic cost-effectiveness analysis and compare different medicines and other products. Students and doctors are unaware of the cost of medicines they frequently prescribe [18]. Personal drug selection includes the criteria of cost, but again this does not get the attention it requires. Medicines are a finite and valuable resource, and cost should be considered in the selection process.

Prescribing indicators

The WHO/INRUD prescribing indicators are a simple, practical resource to analyze the rational use of medicines in a health facility.

Studies have shown that the average number of medicines prescribed is high, most medicines are prescribed using brand name, injections are also commonly prescribed, and the average cost remain high. A study in two government zonal hospitals of province 1 found an average of 3.45 drugs per consultation. About 30.2% of prescriptions encountered contain at least one antibiotic, whereas injectables were prescribed in 1.8%. Only 3.9% of total medicines were prescribed using generic name and only 31.7% of drugs prescribed were from the essential medicine list of Nepal [19].

A recent systematic review of studies using prescribing indicators in Nepal found that the standards for WHO core prescribing indicators were not met, and problems included overuse of antibiotics, underuse of essential medicines, and minimal generic prescribing. The authors suggested targeted interventions, including prescriber education, policy reforms, enhanced monitoring, and regular prescription audits [20].

Medical students should learn about these indicators and their importance in analysing medicine use. They should also be knowledgeable about understanding and responding to pharmaceutical promotion. Medicines should be prescribed using generic names, oral preparations should be preferred and where suitable, older, well-tested, and cheaper medicines should be used. These topics should be taught by pharmacologists during the Basic Science years and reinforced during clinical training and continuing professional education. Gaps in knowledge about RUM have been noted among medical students [21], and there is a need for more education on this topic [22]. Several other challenges exist.

Substandard and falsified medicines

An important one is of substandard and falsified medicines. Identifying these medicines and taking them out of the medicine supply chain should be a matter of priority. In Nepal these medicines represent an under-documented yet critical threat, and impact disproportionately marginalized communities [23]. Information sources for patients should be available in different languages and simple videos on the topic of use of medicines should be created. Patient counselling by pharmacists should be strengthened.

Labelling of medicines

Proper labelling of medicines is important. A study found that majority of medicines studied did not meet the regulatory standards of primary labelling of Nepalese pharmaceutical products [24].

Interactions between complementary and allopathic medicines

In Nepal, many patients also take different complementary and alternative medicines (CAM) along with allopathic medicines. Information about their use may not be volunteered by patients and should be specifically enquired into. These medicines can interact with allopathic medicines, [25] and a database of these interactions should be created. Drug interactions can occur at the pharmaceutical, pharmacodynamic, or pharmacokinetic level. In Nepal as ayurvedic and herbal remedies are widely used, medicines containing St John's Wort (*Hypericum perforatum*), ginkgo (*Ginkgo biloba*), kava (*Piper methysticum*), digitalis (*Digitalis purpurea*), willow (*Salix alba*) can have the most interactions with individual medications. Warfarin, insulin, aspirin,

digoxin, and ticlopidine had the greatest number of reported interactions with CAM preparations in the literature [26].

ADR reporting in the country

Reporting of adverse drug reactions (ADRs) is another challenge. The number of ADR reports in the country is still low, and there is a lack of information on ADRs experienced by the genetically diverse Nepalese population. A study among healthcare professionals in a tertiary care hospital found that the reasons mentioned for not reporting ADRs were that ADR reporting was not widely promoted by relevant authorities, followed by not knowing where and how to report ADRs [27]. A recent systematic review found that while health professionals recognise the importance of reporting ADRs, they often lack a sufficient understanding of pharmacovigilance processes and demonstrate suboptimal reporting behaviour. Factors contributing to these gaps include inadequate training, unavailability of ADR reporting forms, and limited awareness of the procedures required for effective reporting [28].

Priority action areas to strengthen RUM

These challenges should be addressed on three fronts: education, regulation and access. Among the steps are:

- Strengthen prescriber education on essential medicines, generic prescribing, cost-effectiveness, and WHO prescribing indicators, starting in undergraduate training, continued during postgraduate training and reinforced in clinical practice.
- Enforce conflict-of-interest rules for industry sponsorship, gifts, and educational events so prescribing

decisions are less influenced by promotion.

- Improve access to reliable treatment guidelines, antibiotic susceptibility data, ADR reporting systems, and drug-interaction resources for CAM and allopathic medicines.
- Expand pharmacist-led counselling in simple language and local languages, with short videos and patient leaflets to improve adherence and safe use.
- Strengthen regulation and surveillance of substandard/falsified medicines, especially in remote areas, while supporting domestic production of essential low-cost medicines. The recent shift toward a federal governance structure and adoption of primary healthcare approach present Nepal with ample opportunities to further the nation's existing health sector initiatives and outcomes and strengthen the healthcare system [29]. Electronic prescribing is now being adopted and the problem of bad handwriting and medication errors due to mis interpretation may be lower. Information on diagnosis, recommended medicines, the correct route and dose, and the cost of treatment can be available in the system. If combined with a proper medication management system, e-prescribing can support RUM, though medium-term studies will be required.

These fundamental challenges have been inadequately addressed and may be responsible for irrational medicine use in the country. A recent preprint mentions irrational medicine use in Nepal as a systemic

challenge. This is driven mainly by structural constraints, including weak regulatory enforcement, limited diagnostic capacity, patient expectations, sociocultural norms, and commercial pressures [30]. Cooperation between regulators, the domestic pharmaceutical industry, importers and distributors, healthcare professionals, patients and civil society is required to address this issue and preserve the power of medicines.

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