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REVIEW

Framing Objective Criteria For Selection Of Medicines In A Nepalese Teaching Hospital: Initial Experiences

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Inefficient and irrational use of medicines is a widespread problem at all levels of health care. [1] Per capita wastage from inefficiencies and irrational use tends to be greatest in hospitals. This is particularly worrisome, since resources are scarce and prescribers in the communities often copy hospital prescribers. Many of these sources of wastage could be reduced if some simple principles of drug management and use are followed. However, it is difficult to implement these principles because staff from many different disciplines is involved in different aspects of drug management and use. Often, there is no forum for these different disciplines to work together in developing and implementing appropriate drug policies.

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Irrational Use of Medicines and Its Impact

Medically inappropriate, ineffective and economically inefficient use of pharmaceuticals is commonly observed in the health care system throughout the world, especially in developing countries like Nepal. However, various forms of irrational prescribing often remain unnoticed by those who are involved in the health sector decision making or in the delivery of health services. The need for promoting the rational use of drugs in the health care system is not only because of the financial reasons with which policy makers and managers are usually most concerned, but also because the appropriate use of medicines is necessary for achieving a high quality of health and medical care for patients and the community [2]. The impact of irrational use of medicines may be seen in various forms, like in the reduction in the quality of drug therapy, leading to increased

morbidity and mortality. Waste of resources leading to the reduced availability of other vital drugs and increased costs, increased risk of unwanted effects such as drug reactions and the emergence of drug resistance, is noted. Patients may come to believe that there is “a pill for every ill”. This may lead to an apparent increased demand for drugs [3].

The Medicine and Therapeutics Committee

In hospital settings, a Medicine and Therapeutics committee (MTC) provides a forum to bring together all the relevant people to work jointly to improve health care delivery. A MTC may be regarded as a tool for promoting more efficient and rational use of medicines. In many developed countries, a well-functioning MTC has been shown to be one of the most effective committees in hospitals, which is able to address drug use problems [1]. The purpose of the Committee is to take a number of initiatives for the safe, effective and economical use of drugs in the hospital [4], [5].

A MTC can significantly improve drug use and reduce costs in hospitals and other health care facilities by providing advice on all aspects of drug management and by developing drug policies. It also helps by

evaluating and selecting drugs for the hospital formulary and develops and implements standard treatment guidelines. Assessing drug use to identify problems and conducting interventions to improve drug use is another strategy of the MTC. It also helps to manage adverse drug reactions and possible medication errors [5].

Medicine Use Problems in Nepal

The major medicine use problems in Nepal are polypharmacy and misuse of antibiotics. Self-medication is a common practice in Nepal [6]. Use of vitamins and tonics, irrational fixed dose combinations and unethical and aggressive drug promotion are other common practices [3]. These problems may pose a significant clinical risk and have a great economic impact. In a hospital or a regional setting, a MTC can solve different drug use problems by establishing procedures for developing, implementing and updating a formulary list and by using only registered drugs. This is being done in one of the Nepalese hospitals i.e., Patan hospital. A structured drug order form has been successfully used in Patan hospital to manage drug use, especially antibiotics. Such a form has specific medicines printed together with the specific indications for which they may be used and the doses and the dosing intervals. Prescribers must select one of the choices offered on the structured order form for their patient, considering various patient and medicine characteristics and thus may be guided to prescribe in the most cost-effective way [1]. Another method for solution of drug use problems can be, establishing procedures for developing and revising the hospital formulary based on the treatments of choice and this is being done at our hospital [7].

MTC at KIST Medical College

KIST Medical College is a tertiary care hospital and a new medical school in Lalitpur, Kathmandu, Nepal. It plans to admit medical, dental, nursing, and pharmacy students. The hospital started functioning in January 2008 and the initial steps towards formation of the Medicine and Therapeutics Committee (MTC) were taken. In the first week of February 2008, the hospital Medicine

and Therapeutics Committee (MTC) started functioning. The MTC has members from all the clinical departments. The Chairman is the clinical coordinator from the department of Medicine. The member secretary is the Pharmacy program coordinator and the overall in charge of the pharmacy. Members from various areas, like microbiologist, dental coordinator, hospital director and matron were also selected. Besides these, the in charges of the medication counseling center, drug information services and the pharmacovigilance officer are also members. At present, the MTC operates via four different sub-committees which are assigned with a particular type of work, like drug utilization, formulary, pharmacovigilance and antimicrobial subcommittees. All the members meet frequently to improve the services. The MTC has finalized a medicine list for the hospital and a procedure for selecting medicines on the basis of efficacy, safety, cost and convenience. MTCs are a key recommendation for promoting the more rational use of medicines [7]. The MTC has gone in for both educational and managerial interventions to improve medicine use. The hospital pharmacy is run under the guidance and support of the MTC [8].

The Nepalese Pharmaceutical Situation

In Nepal, there are 40 pharmaceutical companies producing medicines, meeting 40% of the total country's demand and the remaining 60% of the medicines are being supplied by multinational companies [9]. Among the Nepalese companies, only 10 are Good Manufacturing Practice (GMP) certified. There are many advantages in using medicines produced by Nepalese companies. There will be less chance of circulation of fake medicines from outside suppliers for international brands. Nepalese companies can be encouraged to add production capacity to meet the demand of the country, which in turn may help the growth and development of the industry and the country's economy.

GMP implies that the manufacturing company uses proper manufacturing techniques to produce the drug and the drug will satisfy a minimum standard of quality. GMP covers all

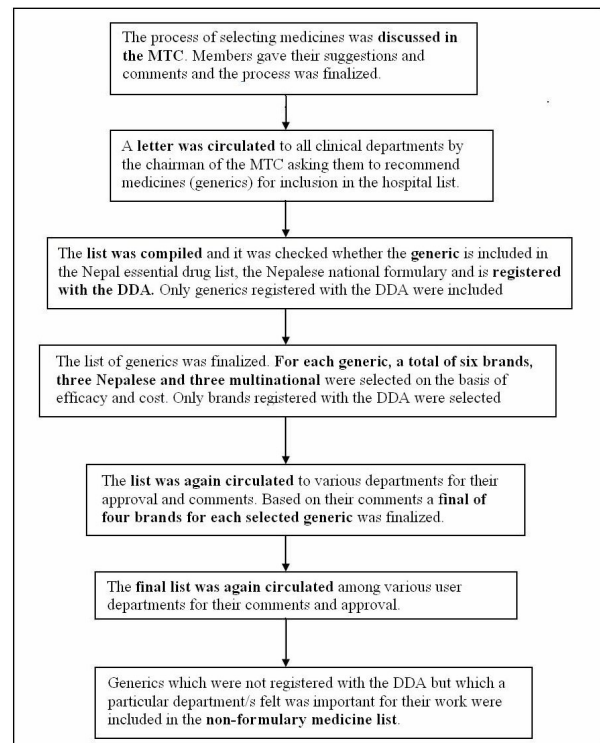
aspects of the manufacturing process: defined manufacturing process; validated critical manufacturing steps; suitable premises, storage, transport; qualified and trained production and quality control personnel; adequate laboratory facilities; approved written procedures and instructions; records to show that all steps of the defined procedures have been undertaken; full traceability of a product through batch records and distribution records; and systems for recall and investigation of complaints [10].

Selecting Medicines for the Hospital Medicines List

The MTC of KIST Medical College has recommended that for a particular generic, three brands from among the national pharmaceutical companies and three brands from among the multinational pharmaceutical companies will be considered. Common dosage forms and strengths available in the market were selected. Other dosage forms were selected based on the recommendations of the user departments.

Initially, the clinical departments were asked by the pharmacy to provide the name of the drug to be used in the department (using generic names). From this list of six, a maximum of four brands (two Nepalese and two international) were finally selected. A list of medicines where bioavailability would be affected by the formulation has been finalized and the MTC has decided to go in for reputed brands for these medicines. The criteria for selection are registration of the brand with the national drug regulatory authority (Department of Drug Administration (DDA)), possession of Good Manufacturing Practice (GMP) certification by the company and cost. For efficacy, we went by available descriptions in the literature. A limitation was that we did not have the means to directly compare the efficacy of various brands. The DDA while registering a brand considers pharmacokinetics, pharmacodynamics and stability data. The list was then again circulated among all the departments of KIST Medical College for the final selection of four brands. Further additions and deletions are

done in MTC meetings using objective criteria. The list was then submitted to the Pharmacy Procurement Committee for procurement. [Table/Fig 1] schematically depicts the process of selecting medicines for the hospital medicines list. We are hoping that our pharmacovigilance program will help us to obtain data on the safety of medicines in our patients.



(Table/Fig 1) Flow chart illustrating the process of selecting medicines for the hospital medicine list at KIST Medical College

Brand Selection, an Example

We are illustrating the process of selecting generic names and brands for the hospital medicine list using the example of ciprofloxacin. Ciprofloxacin has been mentioned in the Nepal Essential Medicines list and the Nepalese National Formulary. Also, a number of clinical departments had recommended this generic for inclusion in the hospital medicine list. This medicine was also mentioned in the national drug regulatory authority's list. Then, we checked for the various brands of ciprofloxacin registered with the DDA and compared the prices of all the available registered brands. Finally, we chose two Nepalese brands and two international

brands of ciprofloxacin having the least cost but of good quality. We only chose brands from companies having GMP certification.

After selecting the brands, equal amounts of the selected brands are procured. It is recommended that clinicians prescribe by generic names and if clinicians prescribe brands which are not stocked in the hospital pharmacy, they would be automatically substituted by a stocked brand. To ensure the supply of good quality medicines, they are procured only from authorized distributors who are prequalified, using defined criteria.

Advantages of Limiting Brands

The advantages of limiting the number of brands in the hospital pharmacy are, lesser probability of medication errors and less space required to store the drugs which can aid in the procurement of other needed medicines. The most important one is, buying bulk quantities of a limited number of brands, which will be cheaper for the hospital management and the patient. KIST Medical College had decided to use objective criteria for selecting medicines for the hospital medicine list right from the very beginning. So, it was not possible for us to do a before and after comparison of the impact of this particular procedure.

The Hospital Medicine List

The development and updating of the medicine list is necessary to promote the safe, effective and economic use of medicines in the hospital. The list can also promote drug safety and reduce the risk of medication errors [6]. The medicine list consists of 329 generics with 1316 brands. The pharmacy procures approximately equal quantities of the selected brands. Besides these selected medicines, some more medicines were added on the request of the prescribers, which were not listed in the National Drug Regulatory Authority (Department of Drug Administration (DDA) list for their convenience. These brands which were not being registered with the DDA were termed as non-formulary drugs and about 69 generics were added as a separate list of non-formulary

medicines while making the hospital medicine list. The brands for these non-formulary generics were chosen by the prescribers from different clinical departments. Some of the non-formulary medicines are ayurvedic preparations and all the 69 generics are available in the market.

Adding or deleting medicines to the list

Medicines are added or deleted after thorough discussion in the MTC meeting, based on recommendations from user departments. The MTC has developed a form for recommending medicines for inclusion, based on the methods described in the Practical Guide to Drug and Therapeutics Committees [1]. The advantages of the proposed medicine over medicines from the same class which are already present in the hospital medicine list and the cost of the medicines are among the different information sought. The MTC also plays an active role in controlling irrational combinations and has banned the use of the fixed dose combination of ampicillin and cloxacillin. As Ampicillin and cloxacillin are two antibiotics acting through the same mechanism, they cannot be combined in order to avoid unnecessary drug use.

Advantages of the Hospital Medicine List

The list aims to promote the rational use of medicines and ensure the availability of good quality medicines and economic brands. This will result in better economic outcomes and patient's health. The list will facilitate the identification of priorities for medicine supply and minimize the number of products. This selection will promote the rational use of medicines with consensus on the treatment of first choice. Prescribers will become more familiar with limited treatments and they will acquire more knowledge in principles of good prescribing. Resources can be spent more effectively. The list will also help in the preparation of the hospital formulary and in developing standard treatment guidelines for common disease conditions.

Limitations

The limitations are the selection of limited brands and the exclusion of the costlier but 'renowned' brands, which might sometimes interfere with the laity and the physician's strong belief towards the particular brand. In this list, we have not discussed the procurement of drugs which are not available in Nepal. Non-availability of the most recent and updated list from the DDA was a problem.

Lesson for Other Hospitals

This process of selecting medicines for the hospital medicines list will be of interest to other hospitals. The importance of selection criteria for different medicines, including medicines with a narrow therapeutic index, the process of finalizing the selected medicines and the issue of procurement for the hospital pharmacy, are important issues. There are only a few hospitals in Nepal who have developed their own medicine list and hospital formulary. Besides this, the non-formulary medicine list and its selection and procurement would be also of interest for other hospitals.

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