Essential Drugs Concept : its application in Nepal

B.B. Thapa[1] **G.B. Bhuju**[4]

R.R. Prasad[2] **V. Rajbhandari**[5]

B.M. Shrestha[3]

Abstract

Essential drugs are those that satisfy the healthcare needs of the majority of the population; they should therefore be available at all times in adequate amount and in the appropriate dosage forms. Various factors need to be considered for the selection of such drugs, though the model list published by WHO serves as valuable guidelines. National List of Essential Drugs, Nepal (EDL) was published in 1986, which was first revised in 1992 and then in 1997. Implementation of it helps to provide health care to a large population in relatively less resources. We have made an effort in this paper to analyze the situation after implementing EDL in Nepal and suggest the ways and means for more effective implementation so that the goal of 'health for all' could be achieved.

Keywords: Essential drugs; Nepal.

Introduction

"Do not hasten to use the 400 new drugs coming on the market each year particularly if that are variant of standard drugs with which you have already had experience.

Wait, Wait, Wait, and then Wait.

Let the other fellow poison his patients or learn that the drug is worthless. In the course of months or years the truth will be known and the drug may or may not be discarded. If a truly valuable 'miracle drug' appears, the whole world will probably acclaim it within months."

Lawson Wilkins, 1962

Drug has been defined as "any substance or product that is used or intended to be used to modify or explore physiological systems or pathological states for the benefit of the recipient". It is needless to say drug is an important component of health care, both to prevent as well as to treat diseases. The consumers' demand of drug is straightforward, that it be effective, reasonably safe, available and affordable. In many developing countries, we see the paradox of the shortage of essential drugs for the most common diseases existing side by side an over-use of non-essential and even spurious drugs. There are a variety of pharmaceutical products under different names in the private retail pharmacies, where most essential common drugs may have limited availability. Due to lack of appropriate drug information, there is a very limited possibility for the rural population to buy quality medicines in the private pharmacies when the public sector stock is insufficient. Hence it is very important that a concept be introduced to identify the most essential drugs needed for the healthcare needs of the majority of the population and effort be made to make these drugs available to every corner of the country at all times. The scarce financial resource of the health facilities should be utilized to procure such drugs and if resource is not sufficient to last for the whole year, the patient should have access to such drugs in local retail pharmacy. To achieve the goals, WHO introduced essential drug concept1 in 1977. In Nepal it was adopted2 in 1986 after which a lot of progress has been made though there is still a lot more to be done.

WHO's Concept of Essential Drugs

The World Health Organization defines essential drugs as "those that satisfy the health care needs of the

majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms."3

The choice of such drugs depends on many factors, such as the pattern of prevalent diseases, treatment facilities, training and experience of the available personnel, financial resources and genetic, demographic, and environmental factors. Only those drugs should be selected for which sound and adequate data on efficacy and safety are available from clinical studies and for which evidence of performance in general use in a variety of medical settings has been obtained. Each selected drug must be available in a form in which adequate quality, including bioavailability, can be assured; its stability under the anticipated conditions of storage and use must be established. Where two or more drugs appear to be approximately similar the selection between them should be made on the basis of a careful evaluation of their relative efficacy, safety, quality, price, and availability. In cost comparison between drugs, the cost of the total treatment, not just the unit cost of the drug, must be considered. The choice of the essential drugs may also be influenced by other factors like comparative pharmacokinetic properties and availability of the manufacturing facilities.

Most essential drugs should be formulated as single compounds. Fixed-ratio combination products are acceptable only when the dosage of each ingredient meets the requirements of a defined population group and when the combination has a proven advantage over single compound administered separately in terms of therapeutic effect, safety or compliance. Dosage forms and strengths should also be included in the list. The main purpose of selecting dosage forms and strengths is to minimize the number of preparations. Dosage forms are selected on the basis of their general utility and their wide availability internationally. However, other factors like cost, pharmacokinetics, bioavailability, stability under ambient climatic conditions, availability of the excipients and established local preference, should be considered.

Assuring people's access to essential drugs is based on the following criteria:

- Safety
- Efficacy
- Quality
- Affordability
- Accessibility
- Relevant to prevalent diseases
- Appropriateness to the capability of health workers at different levels of health care
- Benefit/risk ratio

The essential drugs programme is intended to extend the accessibility of the most necessary drugs to population whose basic health needs could not be met by the existing supply system. So the selection of drugs depends on the health needs and on the structure and development of the health services of each country. WHO first published the model list of essential drugs in 1977, which is periodically revised and updated. At present it is revised every two years. But due to great differences between countries, the preparation of a drug list of uniform, general applicability is not feasible or possible. Each country has the direct responsibility of evaluating and adopting a list of essential drugs according to its own policy in the field of health, where WHO's model list serves a valuable guideline. The list of essential drugs should be drawn up locally, and periodically updated, with the advice of experts in public health, medicine, pharmacology, pharmacy and drug management. During revision changing priorities for public health action and epidemiological condition as well as progress in pharmacological and pharmaceutical knowledge should also be taken into account.3

The concept of essential drugs has been disseminated and promoted extensively at the country level by WHO's Action Programme on Essential Drugs as well as by bilateral agencies. Most national lists of essential drugs are stratified to reflect requirements at different levels within
the health care infrastructure. Typically,
a very short list has been compiled for community health workers while the most comprehensive lists have been reserved for large urban and regional hospitals.

Implementation of EDL in Nepal

The main events for the introduction of essential drug concept were in the following order in Nepal: promulgation of Drug Act in 1978; first publication of National List of Essential Drugs (EDL) in 1986; adoption of National Drug Policy4 in 1995; and publication of Nepalese National Formulary5 in 1997. As these events are not in logical sequence, the country had to face many setbacks for the implementation of essential drugs concept. The National Drug Policy has clearly mentioned to use the essential drug list at all levels of health facilities including central and referral hospitals and manage the procurement, storage and distribution system accordingly. It also aims at producing 80% of the essential drug formulation within the country by 2005.

Nepal, like many countries, developed its own essential drugs list2 in 1986, based on WHO's model list. This was first revised in 1992 and then in 1997 and will in future be revised every three to five years.

The first list of essential drugs included 245 drugs, but dosage forms were not included in it. A short list of drugs for health post and still shorter list for primary treatment level were also included. The first revision in 19926 further included list for district level, and sub-health post level. There were deletion of 15 drugs (Table I) and addition of 30 drugs (Table II) thus making the total number of drugs to 256, of which 231 are in the main list and 25 are in the complimentary list. There were only 20 drugs in the complimentary list in 1986.7

The drugs in the main list are the drugs that satisfy the health care needs of the majority of the population whereas the complimentary drugs are for treating rare disorders or when drugs in the main list cannot be made available or becomes ineffective or inappropriate for a given individual.

Table I: First revision: Drugs deleted

Ampicillin
Bephenium
Bisacodyl
Chlorthalidone
Codeine
Desferrioxamine
Dimercaprol
Dehydroemetine
Gluteraldehyde
Haloperidol
Ipecacuanha
Nalorphine
Reserpine
Sulphadimidine
Typhoid Vaccine

Table II: First revision: Drugs added

Albumin Human
Amoxicillin
Beclomethasone
Bismuth Iodoform Paraffin
Cisplatin
Clove Oil
Cytarabine
Enalapril
Formaldehyde
Fludrocortisone
Ketoconazole
Levodopa+Carbidopa
Lysol
Mianserin
Naloxone
Nifedipine
Penicillamine
Pentamidine
Phenol
Piroxicam
Polygeline
Praziquantel
Prilocaine
Protamine zinc sulphate
Selenium sulphide
Sodium Cromoglycate
Sodium Nitroprusside
Sulphasalazine
Tamoxifen
Tetanus human immunoglubulin

The total number of drugs included in the second revision 19978 is 262, of which 233 are the main drugs and 29 complimentary drugs under various therapeutic groups. There is deletion of 22 drugs (Table III) and addition of 28 new drugs (Table IV) under therapeutic groups from the previous revision of 1992. A deletion is made when some other better drug is available preferably in cheaper price. But the deletion does not mean that the drug cannot be marketed in Nepal.

The number of drugs for various levels of health facilities included in the second revision are: for district level 177, health post level 88, sub-health post level 50, and primary treatment level 18.

Table III: Second revision: Drugs deleted

Chromic acidPiroxicam
Vasopressin
Imipramine
Immunoglobulin, human normal
Indomethacin
Phenoxymethylpenicillin
Neomycin
Trimethoprim
Propranolol
Methyl Salicylate
Sulphur
Magnesium Hydroxide
Mianserin
Hepatitis B Immunoglobulin
Gallamine
Prilocaine
Ethosuximide
Praziquantel
Nalidixic Acid
Cytarabine
Belladonna Dry extract

Table IV: Second revision: Drugs added

Acetic acid
Compressed Air
Diclofenac Sodium
Albendazole
Ciprofloxacin
Cefotaxime
Doxycycline
Mefloquine
Mitomycin
Melphalan
Omeprazole
Leucovorin Calcium
(Folinic Acid)
Atenolol
Procarbazine

Hyoscine butylbromide
Japanese B Encephalitis Vaccine
Zinc Sulphate
Zinc Oxide
Isoxsuprine HCl
Thioridazine
Alprazolam
Chlordiazepoxide
Disulfiram
Isoflurane
Desmopressin
Lomustine
Tetracaine

The essential drugs concept discourages the combination products. Fixed ratio combination products are acceptable only if the combination has proven advantage over single compounds administered separately in terms of therapeutic effect, safety and compliance. Only the following combination drugs are recognized in the Essential Drug list 1997 for oral use.

Norethisterone + Ethinyloestradiol

Thiacetazone + Isoniazid

Ferrous Salt + Folic Acid

Sulphamethaxazole + Trimethoprim

Levodopa + Carbidopa

Sulfadoxine + Pyrimethamine

Revision of the essential drug list is a continuing process and evaluation of a drug for inclusion in the list or deletion from it is done regularly. Working groups comprising medical experts and pharmacists are selected by the Department of Drug Administration to undertake the initial work on specific therapeutic categories. The draft prepared by the group is reviewed by Drug Advisory Committee, chaired by Health Secretary and then forwarded to the Drug Consultative Council chaired by Minister of Health, prior to government approval. The approved list of essential drugs is the basis for procurement and distribution of drugs in the public sector health facilities in Nepal. HMG/Nepal has constituted a five member committee under the convenorship of a Special Secretary at the Ministry of Health to monitor if drugs procured by HMG conforms to the EDL.

Impact of EDL in Nepal

Consumption of modern drugs is increasing day by day due to increase in health facilities, growing awareness in the general public and increased accessibility due to construction of roads. The consumption of drugs in 1979 was estimated to be worth Rs. 11.5 million9, which increased rapidly and arrived to a figure of Rs. 1,532 millions in 1992. The present estimated consumption for the year 1997 is Rs. 3,360 million and the annual growth rate is 28.5%.18 The survey on quantification of drugs done by DDA10 showed that the vitamins and hormones occupy the highest market share followed by antibiotics. In antibiotic, ampicillin was the top most selling product. The major proportion of sale takes place through retail pharmacy. The findings clearly show the misuse of drug and overuse of less needed hormones and

vitamins.

Some of the recent studies show that the essential drugs are widely prescribed more in health facilities than in private practice. DDA's study on 'Drug Prescribing habits in Private Practice in Kathmandu Municipality area'11 shows an average number of drug per prescription to be 2.6; drug prescribed in generic name is 5%; drugs prescribed from EDL 32.4% and prescription containing combination products to be 43%. Another study in the health post and sub-health post of nine Terai districts12 shows an average number of drugs per prescription is 2.1; drugs prescribed by generic name is 50%; drugs prescribed from EDL is 85% and prescription containing one or more antibiotics is 55%. There is a different situation in Zonal hospitals.13 A study carried out in three zonal hospitals shows that the drugs prescribed by generic name is 5%, drugs from EDL is 42% and percentage of encounter receiving antibiotics is 49%. Since none of these hospitals dispensed drugs, and has to be bought from private retail pharmacy, implementation of essential drug list seems to be only in health posts and sub-health posts.

The list of drugs needed for basic needs health programme in 1988 contained 60 drugs out of which 48 are from EDL.14 A recent study jointly carried out by the DDA and GTZ/PHCP shows that 80% of drugs prescribed in District hospital, Health Post and Sub-health of Dhading and Siraha, are from the EDL.15 The same study shows that Essential Drug List and Standard Treatment Schedule are not available in the health facilities.

The target of National Drug Policy is to manufacture 80% of the essential drug formulations in the country. In 1993, seventeen national industries manufactured 66 essential drugs.16 At present 21 industries are manufacturing 75 essential drugs17 which is only 28.2% of the total essential drugs. So, a great effort is needed to achieve the goal. Production capacity of National industries are not fully utilized and more industries are coming up rapidly; the goal can be changed into reality.18

Foreign currency to import raw materials for production of essential drugs in Nepal is available at a preferential rate of exchange.7 Similarly, priority has been given to the registration of essential drugs whether locally produced or imported.7 With the recommendation of WHO mission on essential drugs to Nepal, 199319, Drug Information Network of Nepal (DINoN) has been established with the technical and financial support from USAID through RPM/USP to provide unbiased, accurate and prompt drug information to a wide range of audience including prescribers, medical students, pharmacists, consumers, manufacturers, drug traders, paramedical staff and researchers. Information includes indication, adverse reaction, contraindica-tion, interactions, dosing details, special precautions including drug use in pregnancy and lactation, drug poisoning, availability, storage, cost, pharmacokinetics, and drug regulation of all drugs including essential drugs available in the local market of Nepal.20 It is hoped that awareness will be generated to all especially to the prescribers, so that the concept of essential drugs will be promoted.

Discussion

We have to realise the fact that the drugs are becoming less affordable to the common public. Providing free medicine has become an unsuccessful mission whereas on the other hand, people cannot afford to buy full course of medicine. So to achieve the goal, successful implementation of essential drug is the only means to bring down the cost of medicine. The survey results have indicated that the essential drugs are more often prescribed, if drugs are available in health facilities. Since the resource is limited, providing the drug throughout the year is not possible. On the other hand, it has been seen that the people are willing to pay whatever they can. So partial cost recovery scheme should be implemented so that the funds that is recovered can be used to buy fresh stock of drugs. Prescribing habit should be promoted to follow 'Standard Treatment Schedule'21 so that the drugs prescribed will be from EDL, though it may be bought from private retail pharmacy. Since, prescribers at lower level health facilities have a tendency of copying the prescription of referral hospitals, rational prescribing should be practised at the central and referral hospitals also. Prescribing at the health post similar to that in zonal hospital is one of the examples of such a case. Providing cheaper, but effective drugs rather than the newer drugs that have arrived in the market recently, is one of the aims of EDL. However, it does not restrict the use of life saving newer drugs, alternative for which may not be available.

Generation of awareness is another area to work. NGO's like Pharmaceutical Horizon of Nepal (PHON) and Resource Centre for Primary Health Care (RECPHEC) and many others are working in this area. PHON has conducted Medicine Awareness Training (MAT) for School teachers22 and Journalists23 and the evaluation shows a significant change in the knowledge about proper use of drugs.

The DDA has recently published Nepalese National Formulary (NNF)5 which provides information on drugs and formulation. It also gives information about essential drugs and rational prescribing.

Awareness could also be generated by introducing it in curricula of the academic institutions. A recent study shows that the concept of essential drugs is introduced in the curricula of two out of seven undergraduate academic course of medical and pharmacy school run by different universities, whereas three out of three at certificate level course run by the same schools and two out of the three vocational course approved by the government contained the concept of essential drugs.24 So the curricula should be revised and uniformity be maintained at different levels of education.

Providing adequate health care in a country like Nepal is not an easy task, but it can be achieved by the co-operation of all concerned persons and institutions and by effective implementation of EDL and National Health Policy supplemented by National Drug Policy.

Acknowledgement

We are grateful to Dr. Asfaq Sheak, Chief Drug Administrator, DDA, for his permission and valuable suggestion for publishing this article.

References

1. World Health Organization, Geneva, First report of the Expert Committee on the selection of Essential Drugs. WHO Technical Report Series No. 615, 1977.

2. Department of Drug Administration, HMG/Nepal. National List of Essential Drugs Nepal, 1986.

3. World Health Organization, Geneva. The use of essential drugs. WHO Technical Report series no. 796, 1990.

4. Department of Drug Administration, HMG/Nepal National Drug Policy 1995.

5. Department of Drug Administration, HMG/Nepal, Nepalese National Formulary, 1997.

6. Department of Drug Administration, HMG/Nepal. National List of Essential Drugs Nepal, First Revision, 1992.

7. Shrestha BM: Developing and Using an essential drugs list in Nepal, Essential Drug Monitor, No. 17, 1994, Geneva, World Health Organization.

8. Department of Drug Administration, HMG/Nepal. National List of Essential Drugs Nepal, Second Revision, 1997.

9. Sheak A, Thapa BB. The Potentiality and Condition of Nepalese Drug Market. *J. Nepal. Pharm. Assoc*, 1980; **8**: 25-29.

10. A Quantification of Essential Drug Requirements: A Consumption Study 1992, Dept. of Drug Administration, HMG/Nepal and WHO.

11. A study on Prescribing Habit of Private Practitioners of Kathmandu Municipality Area, Dept. of Drug Administration/WHO 1994.

12. INRUD/Nepal, Aug 1995, Intervention Test of Training and Supervision on Prescribing Practices.

13. Kafle KK, Shrestha BM, Bhuju GB, Dangi Chhetri GB, Humagain BR: Prescribing Practices in Tertiary care of Nepal; INRUD News Vol. 7, No. 1 March 1997.

14. Basic Needs Health Program, 1988, Ministry of Health quoted in: Bajracharya PP, Joshi DD. Consumption Pattern of Essential Drugs. *J. Nepal Pharm Assoc* 1989; **16**: 61-71.

15. Strengthening Drug Management at District Level: Rapid Assessment of Pharmaceutical Management and Utilization in Dhading and Siraha: Dept. of Drug Administration/GTZ/PHCP, June, 1997.

16. Thapa BB, Prasad RR, Shrestha BM, Bhuju GB, Shrestha NP, Poudel AN, Nepalese Pharmaceutical Guide 1993. Associated Pharmatech Consultancy Kathmandu March 1993.

17. Thapa BB, Prasad RR, Shrestha BM, Bhuju GB, Shrestha NP. Nepalese Pharmaceutical Guide Second edition. Associated Pharmatech Consultancy Kathmandu February 1997.

18. Sheak A. Background Information on drug use activities in Nepal. Proceedings of the Regional Drug Information Workshop, Biratnagar, Nepal, 1998 DDA/USP. pp 9-14.

19. WHO Essential Drug Mission 1-21 August, 1993, Drug Bulletin of Nepal (DBN) Vol. 4, No. 1, January 1994.

20. Joshi MP, Shrestha BM, Shrestha PP, Shrestha CK, Housley D, Johnson KW. Drug Information Network of Nepal: An innovative Approach to the Provision of Information, INRUD News 1996; **6** (2):16-17.

21. Department of Drug Administration, HMG/Nepal, Standard Drug Treatment Schedule 1987, First Revision 1993, Second Revision in Press.

22. An Impact Study Report of Medicine Awareness Training (MAT) for School Teachers, Pharmaceutical Horizon of Nepal (PHON), Kathmandu, July 1996.

23. An Impact Study Report of Training/Workshop on Proper Use of Drug fro Journalists, Pharmaceutical Horizon of Nepal (PHON), Kathmandu, August 1996.

24. Assessment of Drug Information and Rational Prescribing in Medical and Pharmaceutical Curricula; Pharmaceutical Horizon of Nepal (PHON)/ USAID/ USP, Nov. 1997.