

# **Drug Information Development**

**A Case Study**

**NEPAL**

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## Acronyms

|                |  |
|----------------|--|
| <b>AHFS</b>    | American Hospital Formulary System   |
| <b>CSFSP</b>   | Child Survival and Family Services Project                                 |
| <b>DALY</b>    | Disability adjusted life year  |
| <b>DDA</b>     | Department of Drug Administration  |
| <b>DINoN</b>   | Drug Information Network of Nepal  |
| <b>EBT</b>     | Electronic Book Technologies   |
| <b>EDL</b>     | Essential Drugs List   |
| <b>GDP</b>     | Gross domestic product   |
| <b>GTZ</b>     | Gesellschaft fur Technisches Zusammenheit (German government's aid agency) |
| <b>HDI</b>     | Human Development Index  |
| <b>HMG</b>     | His Majesty's Government   |
| <b>INRUD</b>   | International Network for the Rational Use of Drugs                        |
| <b>IOM</b>     | Institute of Medicine  |
| <b>ISO</b>     | International Standards Organization                                       |
| <b>JSI</b>     | John Snow, International   |
| <b>MOH</b>     | Ministry of Health   |
| <b>MSH</b>     | Management Sciences for Health   |
| <b>NCDA</b>    | Nepal Chemists and Druggists Association                                   |
| <b>NHRC</b>    | Nepal Health Research Council  |
| <b>NR</b>      | Nepali rupee   |
| <b>PHON</b>    | Pharmaceutical Horizons of Nepal   |
| <b>RECPHEC</b> | Resource Centre for Primary Health Care                                    |
| <b>RPM</b>     | Rational Pharmaceutical Management   |
| <b>SGML</b>    | Standard generalized mark-up language                                      |
| <b>SO</b>      | Strategic objective  |
| <b>STG</b>     | Standard treatment guidelines  |
| <b>TUTH</b>    | Tribhuvan University Teaching Hospital                                     |
| <b>UNDP</b>    | United National Development Program  |
| <b>USAID</b>   | United States Agency for International Development                         |
| <b>USP</b>     | United States Pharmacopeia   |
| <b>USP DI</b>  | United States Pharmacopeia Drug Information                                |

## Introduction

The appropriate, effective and fiscally responsible use of pharmaceutical products is an oft neglected issue in international health programs in developing countries which have focused on low-technology, low-cost interventions for family planning, maternal health, child survival, malnutrition, prevention of sexually transmitted infections and environmental health problems. However, regular availability and proper use of pharmaceuticals is key to the success of many of these interventions, e.g., malaria prophylaxis and treatment, DOTS, Vitamin A supplementation, and management of complications of pregnancy and delivery. A critical component of effective drug selection and use is up-to-date, unbiased information on indications, contra-indications, pharmacokinetics, precautions, side effects, drug interactions, storage, packaging and labeling.

In 1992, The United States Pharmacopeia (USP), began working in developing countries through the Rational Pharmaceutical Management Project (RPM), a cooperative agreement with the U.S. Agency for International Development. USP, established in 1820, is a voluntary, not-for-profit health care organization. USP is responsible for establishing legally recognized product quality standards for drugs available in the United States. Updated standards are published in the *United States Pharmacopeia* and the *National Formulary* every five years. USP also develops objective information on drugs and drug use; this is maintained through the USP DI® drug, nutritional, and therapeutic information database. The USP DI® includes clinically relevant, consensus-based information for health care professionals, patients and consumers. Information in the database is published annually in three volumes in partnership with Micromedex.

The RPM Project aimed to improve access to essential drugs, increase *rational drug use* and to increase local capacity to develop, package and disseminate unbiased, locally-specific drug information. *Rational drug use* is sometimes defined as getting the right drug to the right patient at the right time in the right dose at the right price. Misuse of drugs occurs in all countries, however, *rational drug use* as a health care strategy for USAID has come about in response to research findings that show certain irrational practices to be especially common and costly in developing countries. Such practices include:

- polypharmacy, or the unnecessary prescription of more than one drug for an illness
- the use of wrong or ineffective drugs
- underuse or incorrect use of effective drugs
- use of combination products which are often more costly and offer no advantage over single compounds
- common overuse of antimicrobials and injections.

Access to clinically relevant, up-to-date, user-specific, unbiased drug information is essential to improve the way medicines are used.

## **Background on Nepal and Needs Assessment**

Selection of countries was one of the most critical elements in the RPM project. RPM team members from USP and Management Sciences for Health (MSH) conducted studies of pharmaceutical and health indicators in six countries before choosing the 3 main RPM sites. Despite a series of development plans and assistance from international aid agencies, Nepal's economic growth has just barely kept pace with its expanding population. In FY1999, gross domestic product (GDP) per capita was less than \$225, making Nepal one of the poorest countries in the region. Several structural factors hinder the country's attempts at development such as (i) the difficult terrain of a mountainous, landlocked country; (ii) heavy dependence on subsistence agriculture; (iii) low levels of physical infrastructure and human capital; (iv) dependence on foreign assistance; and (v) inadequate institutional capacity for development management. While the country has been moving toward a more market-oriented economy since the early 1990s, frequent changes in government have hampered the implementation of policy reforms and delayed the implementation of development projects.

The social indicators for Nepal show little progress in reducing poverty and improving the socioeconomic status of low-income groups. Nepal ranks 144th among 174 countries in the United Nations Development Programme's (UNDP) 1997 human development index (HDI), published in 1999. While some improvement has been made over the past decade, the reduction in the total fertility rate from 6.3 in 1985 to 5.0 in 1996, and infant mortality rate from 152 per 1,000 live births in 1985 to 74 per 1,000 live births in 1997 are still high in comparison to countries of similar income level. While the adult literacy rate has increased at an average rate of about 1.0- percent per year in recent years, the vast majority of the adult population in rural areas is illiterate. About 71 percent of the population have access to safe water and only 20 percent of households have sanitary facilities. Poor water supply and sanitation and unhygienic living conditions, especially in rural villages and slums, remain among the major obstacles to improving the health status of the people. Child malnutrition is widespread at 47 percent, resulting in mental impairment, school dropout, loss of productivity, and lifelong disabilities such as blindness due to vitamin A deficiency.<sup>1</sup>

### **Illness and Death**

Infectious diseases, maternal and perinatal ailments, and nutritional deficiencies, termed "Group I disorders" by the World Bank, are the leading causes of illness and death in Nepal. Pneumonia and other bacterial diseases particularly tuberculosis, intestinal infections, bronchitis, and asthma are the leading causes of such deaths for both men and women. Deaths among women peak during the child-bearing ages (15-44) - with about 28 percent of deaths in this age group related to abortion and its associated complications. Sixty-three percent of pregnant women have anemia.<sup>2</sup> Children are particularly hard hit. Intestinal infectious diseases, other bacterial diseases, pneumonia and perinatal factors cause most deaths among children under age 5.

The wide disparity in health conditions and access to health care in Nepal is reflected in life expectancy statistics. In the Kathmandu district, the average life expectancy is 74.4 years; in the remote mountain district of Mugu in the Mid Western region, average life expectancy is just 37 years. Eighteen of the 20 districts in which life expectancy is less than 55 years are

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<sup>1</sup> Country Assistance Plan – Nepal. Asia Development Bank, Mar 30 1999.

<sup>2</sup> Pradhan et al., 1997; MOH and Macro International, 1997

located in the Mid Western and Far Western regions; 17 of these districts are inaccessible mountainous areas. For the country as a whole, life expectancy is 57 years for both men and women -- lower than in Bangladesh (57 for men, 59 for women) and India (71 for men, 75 for women).<sup>3</sup>

About 7.7 million *disability-adjusted life years* (DALYs ) are estimated to have been lost in Nepal in 1996. Compared with the global burden of disease estimates for other developing countries (1991), the burden in Nepal is high, especially for Group I disorders. Such disorders were responsible for five times as many lost DALYs as in China and 36 percent more than in India. The World Bank has recommended an increased focus on tuberculosis and other preventable communicable diseases that are becoming more of a threat such as HIV/AIDS and hepatitis B.

### **Pharmaceutical Use in Nepal**

Nearly 42% of the national health budget is spent on drugs (HMG 1997) and another three times that much is spent by international donors. Local manufacturing is increasing, but 80% of pharmaceutical products are imported, mostly from India. Although the number and prices of drugs on the local Nepal market are increasing, a 1993 RPM assessment found that drugs were only sporadically available at health posts and clinics around the country. Inappropriate prescribing practices were encountered frequently. Stories like the one below could be found in the national press.

#### **Family Planning Pill for Gastroenteritis**

MAKWANPUR- In what appears to be negligence and sheer lack of management open at Raksirang health center Ram Bahadur Praja gave pill meant for family planning to a woman suffering from gastroenteritis.

Says Mr. Praja, "It is not good to disappoint those who make it to the Center in the hope of living. There was no other medicine I therefore gave the pill, though it was for family planning."

Praja has been manning the Raksirang Health Center single handedly for the last five months. Constant practice has make him able to tell a family planning pill from other medicines.

-RSS

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<sup>3</sup> Nepal: Operational Issues and Prioritization of Resources in the Health Sector (Discussion Draft). World Bank 1998

RPM was particularly concerned with improving the way medicines are used. Documented examples of irrational drug use in Nepal have included the following (unless otherwise noted, data is from the Department of Drug Administration, MOH, HMG Nepal):

**Polypharmacy** – the dosing of multiple prescribed drugs. The average number of drugs per prescription in Nepal is about three. Combine this with the lack of patient information on how to properly take each drug and the result is pharmaceutical wastage. It has been estimated that 51.4% of drugs sold to patients in the country are wasted due to irrational prescribing.

**Expired drugs** - Drugs received at health posts from the government health system are frequently short-dated.

**Irrational combination drugs** - Over 43% of prescriptions contain combination drugs. Specific recommendations exist concerning the families of drugs to be combined in a single formulation. For example cough suppressants and expectorants should not be combined in a single formulation, in practice these combinations are often found.

**Antibiotic resistance** – Over 50% of all prescriptions contain at least one antibiotic. Most antibiotics are taken through self-medication and or prescribed by untrained primary health care workers: The theory appears to be “When in doubt prescribe antibiotics”. Doctors have been known to prescribe one antibiotic until a resistance is discovered and then change to a newer antibiotic. Following this practice, treatment of simple diseases soon will require the use of newer, less available and more expensive drugs. Many times the full course of an antimicrobial regimen is not dispensed. In one study, a full course of antibiotic treatment was received less than 25% of the time in retail shops.<sup>4</sup>

**Over-dependence on injections** – A 1997 study of health facilities in two districts found injections prescribed at 22% of encounters.<sup>5</sup>

**Vitamins/herbal remedies** - Over 42% of prescriptions include vitamins, perhaps unnecessarily adding to the cost of health care.

**Prescribing by brand name** - Survey results using drug utilization indicators have shown that the percentage of generic drugs prescribed is quite low (16.1% to 30.9 %).<sup>6</sup>

**Retail shops prescribing** -There are about 1400 practicing physicians and about 250 pharmacists in Nepal. Almost 50% of prescribing and about 80% of dispensing is done by private sector drug retailers of whom there were 12,000 in 1997 and over 20,000 in 1999. In addition to prescribing, retailers are often called upon to counsel customers on proper use of their medicines. When patients forget dosing instructions, they ask retailers who are more accessible than physicians and other formally trained health care providers.

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<sup>4</sup> Rational and Irrational Use at the Primary Health Care level in Rural Hilly Eastern Nepal. Dr. Kathy Holloway, British Nepal Medical Trust, 1997.

<sup>5</sup> Rapid Assessment Survey of Pharmaceutical Management and Utilization in Dhading and Siraha districts, Department of Drug Administration in cooperation with the Primary Health Care Project, GTZ-Kathmandu. 1997.

<sup>6</sup> Ibid.

Appropriate drug use is complicated by several other factors. There is a **remote rural population** in Nepal and there are few hospitals. The average travel time to a health facility in the mountain districts is almost 1.5 hours. The hospitals that do exist have poor or no pharmacies. **Poverty** is widespread and about 45 percent of the population, or more than 10 million people, live below the national poverty line of NRs4,400 (\$77) per capita per annum. The current **literacy** rate is 48 percent (66 percent for men and 30 percent for women). However, only 20 percent of the poor are literate compared to 60 percent of those in the higher-income groups. Poverty also heightens gender differences. While 32 percent of poor men are literate, the literacy rate of poor women is much lower at 9 percent.<sup>7</sup>

In one study done in 60 facilities in 8 hill districts and including over 2000 interviews, it was found that consumer demand for drugs in rural Nepal is high and not consistent with rational use. There is no sense of risk in taking drugs; patients want more drugs than they can get. In spite of low literacy rates and poor communications, nearly half the people surveyed knew the names of the drugs they wanted.<sup>8</sup>

### **Drug Information**

Other factors considered in the 1993 RPM assessment included the interest of local USAID missions in a pharmaceutical sector program; political stability and willingness of local authorities to participate in the project; availability of local counterparts; the readiness of local administrators to implement change; opportunities for collaboration with related development activities; and language issues.

The most important findings from the Nepal needs assessment in terms of drug information were:

- Unbiased, current drug references were not available in most clinical facilities, nor was such information available to officials and committees who develop drug lists and make procurement decisions. There were very few sources of objective (non-industry) drug information. The tertiary hospitals had libraries, but seldom had any outreach mechanisms to disseminate information, e.g., bulletins, newsletters, etc.
- A study covering five districts in Nepal revealed that 54% of clinical facility staff were not aware of the Essential Drug List (EDL) and 88% were not aware of the Standard Treatment Guidelines (STG's).
- Insufficient drug supplies at clinical facilities were contributing to such inappropriate behaviors as: prescribing and dispensing incomplete courses of treatment, and prescribing drugs by brand name for dispensing by retail pharmacies at higher prices.

USP assessed the drug information needs of key users – physicians, pharmacists, government administrators and consumers – and began to formulate a strategy to continuously meet those needs with current, unbiased information on pharmaceutical

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<sup>7</sup> Country Assistance Plan – Nepal. Asia Development Bank, Mar 30 1999.

<sup>8</sup> Rational and Irrational Use at the Primary Health Care Level in Rural Hilly Eastern Nepal. Kathy Holloway, M.D. British Nepal Medical Trust, 1997.

products available and used to address the major health issues in Nepal. This strategy included the following key components:

- 1) development of drug information centers in several appropriate institutions/organizations
- 2) provision of equipment and on-site training to drug information center staff
- 3) developing a local adaptation of the USP Drug Information Database (USP DI) for Nepal
- 4) small grants to some centers to conduct research or drug information dissemination activities
- 5) professional development opportunities for staff of local counterpart organizations
- 6) facilitation of a drug information network to increase dissemination
- 7) collaboration with USAID Nepal on mission health priorities
- 8) support for drug policy development

## **1. Drug Information Centers**

In the decade following World War II, relatively few drugs existed. Since the 1950s there has been an explosion in the number of drugs that have been released onto the international market. The newer drugs are generally more potent and selective, and formulations are becoming increasingly complex. In addition, a vast number of generic drugs have been marketed since patents have expired.

The literature on drugs has also expanded at a staggering rate and covers a wealth of information on comparative efficacy, mechanism of action, side effects, precautions and economic issues. The sources of information are diverse and include publications in the fields of pharmacy, medicine, pharmacology and general health media. The international pharmaceutical industry also produces a number of its own publications. In order to introduce a new drug into practice, the health professional needs to evaluate this information. A simple quick reference to a pharmacopoeia or a formulary is no longer sufficient. When drugs were few in number and generally of low potency, a quick reference to a general medical or pharmacy textbook could easily answer most questions. Now the rapid increase of information requires some mechanism to digest, evaluate and disseminate. This has led to the development of drug information services and centers internationally.

Drug information is an essential element in achieving national health goals, and should ideally be a part of comprehensive national drug policies and plans. Drug information centers (DICs) in general, are service units committed to providing drug information as it relates to therapies, pharmacoconomics, education, and research programs. A drug information center may provide unbiased information to health care professionals and/or patients and consumers. Many centers also provide workshops or other forms of training to enhance the skills of healthcare professionals. A drug information center is usually a unit located within and/or affiliated with a larger organization (i.e., a pharmaceutical association, etc.) or facility (i.e., a hospital). It should be staffed by people trained in library science and/or pharmacy, medicine, or pharmacology, or at least accustomed to using medical literature for basic research. The center should have specific hours of operation and adequate technological resources (i.e., computers, phone lines, faxes, etc.). The drug information center should have the latest pertinent publications and ideally publish a newsletter or other informational updates for its patrons. Successful drug information centers exist in the following developing countries: Indonesia (Penang, at the University), Zimbabwe (Ministry of Health?), South Africa (Cape Town Red Cross Hospital), Costa Rica (Poison Control Unit), and Venezuela.

The primary role of a DIC in a developing country is to give clear and definitive information on well-established essential drugs and promote their rational use. A secondary role would be to keep up-to-date with pharmacological and therapeutic literature and to disseminate relevant information, as it becomes available

### **Aims and objectives of drug information services**

A center's objectives could include one or many of the following:

- The provision of information to health professionals on specific problems related to the use of drugs in particular patients;
- The provision of information to officials in government agencies to optimize the decision making process;
- The preparation and development of guidelines and formularies;
- To improve patient compliance and to provide a guide to responsible self medication;
- To develop and participate in continuing education programs;
- To participate in undergraduate and graduate teaching programs;
- To develop educational activities regarding the appropriate use of drugs for patients in the community;
- To prepare and distribute material on drugs to health personnel in the form of a drug information bulletin and/or other media;
- To develop and participate in research programs.

The objectives and scope of the intended drug information service should be based on a realistic assessment of available resources, including funding and skilled staff.

Four organizations in Kathmandu were initially identified as potential sites for drug information centers:

- Department of Drug Administration (DDA), Ministry of Health
- Institute of Medicine (IOM), Tribhuvan University Teaching Hospital
- Resource Centre for Primary Health Care (RECPHEC), a local non-governmental organization
- Nepal Chemists and Druggists Association (NCDA), a professional association for retailers and wholesalers.

They were selected because they represent a mix of public and private sectors; they each have a specific constituency or target group that requires current drug information; they had space available and staff to work in a drug information center; and they were established

organizations likely to ensure the sustainability of their units. Also, they were very familiar with one another and agreed to refer calls/inquiries to other centers as appropriate.

A fifth organization, the Nepal Health Research Council, also expressed an interest in establishing a drug information center. USP attempted to facilitate this, but was never as successful with this group. NHRC is a relatively new, quasi-governmental body whose mission is to review and approve all proposals for medical and health research to be conducted in Nepal. They had plenty of available space, but insufficient staff to operate a center and were not firmly institutionalized within the government or another organization. They have remained peripherally involved with drug information development in Nepal.

## **2. Equipment and Training**

USP helped to equip the drug information centers with one of each: computer, telephone, fax machine, photocopier and necessary software. Selected reference books and periodicals appropriate to specific centers were also provided. Reference materials included:

### Journals:

- 1) New England Journal of Medicine
- 2) British Medical Journal
- 3) Lancet
- 4) International Pharmaceutical Abstracts
- 5) American Journal of Health Systems Pharmacists
- 6) Hansten and Horn Drug Interactions: Analysis & Management

### Books:

- 1) USP DI Vol. I & II
- 2) AHFS Drug Information
- 3) Goodman and Gilman's Pharmacological Basis
- 4) Harrison's Principles of Internal Medicine
- 5) Martindale: the Extra Pharmacopoeia
- 6) British National Formulary
- 7) Meyler's Side Effects of Drugs
- 8) Merck Manual
- 9) Merck Index
- 10) Drug Interactions
- 11) Handbook on Injectable Drugs
- 12) Parenteral & Enteral Nutrition
- 13) Basic Clinical Pharmacokinetics
- 14) Drugs Prescribed. in Renal Failure
- 15) Drugs in Pregnancy and Lactation
- 16) Dorlands Medical Dictionary
- 17) Drug Facts and Comparisons

In addition to standard Microsoft applications, the center which would be managing the adaptation of the USP DI database was provided Electronic Book Technology (EBT), a software package that complements SGML-formatted documents, e.g., the USP DI database.

(SGML is an international standard (ISO 8879) for electronic data transfer.) This package allows users to search and retrieve information from the USP DI database and to adapt the existing database by placing electronic notes into the document. These notes can be incorporated into the text through a conversion process. CD-ROMs featuring the newly integrated information can then be created. This technology has allowed counterparts to adapt the USP DI database to suit local conditions and practices.

### **3. Adaptation of the USP DI database**

The centerpiece of USP's early work in Nepal was the provision of the USP drug information database (USP DI) in electronic format for adaptation by a suitable counterpart institution(s). The counterpart was expected to assume a leadership role in the process of adapting the USP DI to meet local needs. This may include revising dosage forms and sizes available, rewording or adding indications and contra-indications, adding locally available brand names, etc. The Department of Drug Administration volunteered to coordinate revisions suggested by the other drug information centers and transfer them to USP. USP then integrated the revisions into a new CD ROM-based version of the DI. The first Nepal DI was released on CD ROM in September 1997 and an updated version was released in September 1998. The adapted database then served as a primary drug information source for the drug information centers. The centers referred to the database to respond to inquiries and drew from it to disseminate information on particular drugs via bulletins, newsletters, radio programs, posters and workshops. For example, in *DRUG & THERAPEUTICS NEWSLETTER*, Volume 5, Number 2, March-April 1992, the Institute of Medicine at TUTH advises readers against the use of Terfenadine and Astemizole based on potentially lethal side effects and cites drug interactions and contra-indications published in the USP DI, Vol. I, 18<sup>th</sup> edition and provides locally available brand names.

### **4. Grants to Local Organizations**

Studies presented at the 1998 *International Conference on Improving the Use of Medicines* in Chiang Mai, Thailand showed that providing drug information without implementation of awareness raising or educational activities had virtually no impact on primary care prescribing practices. In order to stimulate the use of drug information for education, outreach, and training activities, USP provided subagreements to local organizations in Nepal to implement such activities.

Pharmaceutical Horizons of Nepal (PHON), a research-focused non-governmental organization, investigated the extent of coverage of rational drug prescribing and drug use information in various academic and non-academic courses in nursing, medicine, pharmacy and public health offered at a variety of institutions in Nepal. Institutions investigated included Institute of Medicine at TUTH, Kathmandu University, B.P. Koirala Institute of Health Sciences, Council for Technical Education and Vocational Training, National Health Training Center of the MOH, and an orientation course for drug retailers and wholesalers run by the Dept. of Drug Administration, MOH. This study found very little discussion of the importance of following treatment guidelines developed by the MOH for various diseases. Conflicting information on pharmacology was also found when course content was reviewed among institutions.

A second subagreement to PHON supported research into the prescribing practices of qualified and unqualified prescribers at various levels of the health care system in Nepal. That study (1998) found that almost 20% of drugs prescribed were not indicated, were

ineffective, were needlessly expensive or harmful. Results of both studies were then used to guide further RPM activities in Nepal. For example, a later subagreement with the Institute of Medicine, TUTH supported the development and implementation of a training program for new physicians on rational therapeutics. This problem-oriented training included how to select the right drug (including cost considerations), drug use in pregnancy and lactation, pediatric and geriatric drug use, rational use of antibiotics, tuberculosis pharmacotherapy, and marketing and advertising of drugs in Nepal. After the initial implementation of the course in Kathmandu, it was repeated in Pokhara in collaboration with the regional hospital.

## **5. Professional Development**

Identifying talented individuals for professional development opportunities is a key strategy for improving implementation, increasing local capacity and leading to sustainability of drug information activities. USP provided a range of training and professional development opportunities for Nepal counterparts. These included:

- On-site training directly to representatives of the drug information centers. This focused on computers and database management.
- Workshops in drug information development and dissemination were organized at various locations in Nepal, first in Kathmandu and later in the cities of Biratnagar, Nepalgunj and Pokhara. Not only did these provide training opportunities for physicians and pharmacists attending, but leaders from the drug information centers and other institutions were invited to make presentations and lead sessions.
- Training at USP headquarters in Maryland. Key representatives from the drug information centers were invited to Rockville, Maryland for training with USP staff in drug information development and drug standards. During the same visit tours and discussions were arranged also at FDA and NIH.
- Sponsorship to attend and present papers at conferences of the International Pharmacists Federation.
- Sponsorship to participate in regional training programs of the International Network for the Rational Use of Drugs (INRUD).
- Support for memberships in professional organizations such as the Drug Information Association (DIA) and the International Society of Drug Bulletins (ISDB).

The opportunity to participate as a member of an international body and to make presentations on the uses of drug information to peer groups was one of most successful ways of sharing ownership of drug information objectives and projects. In Nepal, USP has virtually shifted leadership of the drug information program to local counterparts, ensuring that activities will not only continue, but grow - even when USP is no longer regularly involved.

## **6. Creating an information network – identifying target groups of information users, relationships among groups**

After the drug information centers were up and running it soon became apparent that the referral mechanisms would operate more smoothly and dissemination would increase if the centers were formally incorporated into a drug information network.

Since 1994, USP had built a relationship with the Department of Drug Administration, MOH. In 1995, His Majesty's Government of Nepal established a National Drug Policy; the new policy included an objective to improve the dissemination of accurate, unbiased drug information within the country. DDA, short of staff and underfunded, realized they could not achieve this objective alone. In fact, there was no single organization in Nepal with the expertise, resources and capacity to satisfactorily meet the drug information needs of a wide range of target groups. Thus, the Drug Information Network of Nepal (DINoN) was established on November 23, 1996.

DINoN's mission is to develop and disseminate information about the proper use of drugs, possible adverse reactions, contraindications, toxicity, drug standards and efficacy, precautions, and proper storage and handling to health care professionals in the public and private sectors, pharmacists, drug retailers, and consumers. A steering committee was created with representatives from the five founding organizations: Department of Drug Administration (DDA), Institute of Medicine (IOM), Resource Centre for Primary Health Care (RECPHEC), Nepal Chemists and Druggists Association (NCDA), and the Nepal Health Research Council (NHRC). The committee coordinates group activities and sets overall policies and goals while a working group manages daily operation of the centers and routine communications among the members. Each drug information center serves a particular constituency; DDA serves government administrators and the general public; IOM serves students and faculty at Tribhuvan University Teaching Hospital; RECPHEC serves consumers, NGOs and primary health care workers; NCDA serves pharmacist and drug sellers; and NHRC serves researchers. As network members, each center acts as a referral point for the other centers.

Partly due to the RPM project's relationship with DDA and partly due to USAID's traditional approach of working with government, DDA began to assume a coordinating role within DINON. This was not always effective. Occasionally other DINON members felt that DDA was assuming a role that could not be supported by their existing capacity and expertise. DDA was not the only focus of conflict within the fledgling network. Before roles of the individual members were clearly defined, and responsibilities sorted out between the steering committee and the working group, professional rivalry sometimes hindered progress. At the point that this case study was written, many controversies have been resolved; however, in hindsight, all parties involved perhaps should have developed the structure of the network more gradually, with more steps and opportunities for discussion and "buy-in". Allowing one member to assume the role of "coordinator" too early in the process could have been avoided with more detailed planning of the network design. When a similar network was facilitated later by RPM/USP in Russia, professional facilitators were brought in to lead the network members through an organizational development process that resulted in a clear understanding of objectives, roles and responsibilities.

## **7. Collaboration with USAID Nepal and other organizations**

Close communications with USAID Nepal allowed USP to understand the mission's strategic objectives (SO's) and to augment or enhance the activities of DINON to better support those goals. Broadly speaking, RPM/USP most directly supports USAID-Nepal's *Strategic Objective 2: Reduction in fertility and improvement in maternal and child health*. Better and more accessible information on pharmaceuticals and pharmaceutical products, including contraceptives, for the patient and consumer should lead to increased use of

family planning and maternal/child health services and improved quality of those services. USP identified how provision of high-quality drug information would support the SO and implemented specific activities with the support USAID Nepal, in addition to support provided by USAID Washington global programs.

Other organizations have collaborated with USP at various stages of the involvement in Nepal. Initial computer equipment for the drug information centers was provided through the bilaterally funded Child Survival and Family Services Project (CSFPSP) implemented by John Snow International (JSI). Regular communications between RPM and CSFPSP continued throughout the project and JSI provided computer maintenance and local logistical support to USP consultants in the early years of RPM. USP consultants regularly communicated with Management Sciences for Health, Nepal-based staff of WHO, CARE, United Hands to Nepal, other donor governments and United Missions to Nepal. Collaboration on training activities with these organizations was particularly successful.

In 1998, under SO 2, USAID-Nepal identified the following *Intermediate Result 2.4: Strengthened capacity and programs to control selected infectious diseases*. The mission planned to allocate eight percent of total program funds (over \$4.5 million) to this new IR over the next five years. With this new commitment, the mission has pledged to participate in USAID's worldwide strategic objective to reduce the threat of infectious diseases of major public health importance. USAID's global priorities are on antimicrobial resistance, tuberculosis, malaria and other infectious diseases and on surveillance and response systems.

Nepal was targeted for infectious disease prevention and control for a variety of reasons. There are many vector-borne diseases, substantial antimicrobial resistance and accelerating prevalence of tuberculosis. Increasing rice production and irrigation potentially will increase malaria and Japanese Encephalitis. High volume population movement among bordering countries increases the spread of diseases. Nepal also presents an opportunity for modeling programs that may lead to regional implementation. It is a landlocked country with epidemiology, ecology and culture similar to bordering nations. The government is flexible and open to innovative programs. Kathmandu is the headquarters for SAARC, enhancing its potential for a regional role. In addition, other donors, e.g., WHO/Nepal, SEARO, and GTZ, have expressed interest in collaborating. USP was asked to participate in efforts to increase the rational use of antimicrobial drugs.

Numerous studies in Nepal have documented poor antimicrobial prescribing practices (PHON, RPM, and BNMT). Antibiotic and antimalarial resistance has also been documented even in remote areas. USP conducted training workshops with DINON members and other interested parties to explain the problems of resistance and how poor prescribing has been linked to AMR. Information and communication activities were initiated with DINON to disseminate data about local resistance patterns and proper drug regimens. At the same time, the MOH was revising the national formulary to reflect resistance patterns and include second line drugs.

RECPHEC, a DINoN member, focused on consumer information. With support from RPM/USP, RECPHEC created, produced and disseminated posters for consumers on appropriate antimicrobial drug use. The posters were designed for the non- or semi-literate consumer. RECPHEC also developed and placed print media messages targeted to consumers on proper purchase, storage and use of antimicrobial drugs.

## 8. Support for drug policy development

USP focused technical and financial assistance on three areas of policy development: government support for the provision of unbiased drug information, licensing requirements for private sector drug retailers, and antibiotic drug use.

In 1995, His Majesty's Government of Nepal established a National Drug Policy. Policy development began by focussing on the local drug manufacturing industry and the goals were to make the country self-reliant in drug production and to ensure regular availability of safe, effective, high-quality drugs. USP encouraged the government to include a position on drug information. Under section 4.3.2, the policy states that the government will develop an efficient drug information system and states that non-governmental organizations will be encouraged to participate in information dissemination to the public.<sup>9</sup> In many ways, this is a remarkable position from which to start. Many government bodies in less developed nations are skeptical of and competitive with local NGOs; and, in fact, throughout project implementation, the government did not always embrace the non-governmental members of DINoN as equals. However, USP learned that by accepting a certain amount of political diversity and by providing tactful facilitation and clear objectives most of the distrust and disagreement could be resolved, or at least worked around.

The large role of the private sector in drug access and use in Nepal has been mentioned above. Most people receive antimicrobial drugs directly from a private drug seller or chemist, usually without a prescription. The DDA is planning to change the current training requirements for licensure as a chemist/drug seller from 72 hours to a two-year certificate program. This is a huge increase in commitment on the part of the retailers and will create a large gap in competency between the currently licensed drug sellers and graduates of the new program. The NCDA is in opposition to the proposed policy change. Both DDA and NCDA have agreed to support a field test of an RPM intervention to improve the dispensing of and patient counseling for antimicrobial drugs by licensed drug retailers. DDA has agreed in principle that the RPM/USP training intervention will be included in the new certificate program and may possibly be used to upgrade the skills of the existing licensees during the gap between discontinuation of the 72 hour program and graduation of the first class of certificate chemists.

During the 1999 regional drug information workshops implemented by USP and DINoN in Nepalgunj and Pokhara a paper was presented by the Senior Pharmacist of the DDA on the need for a national policy on antibiotic drug use. Inappropriate use of antibiotics is considered to be one of the major factors responsible for the development of bacterial resistance to antimicrobial drugs. After listening to the discussion at these workshops, USP supported the implementation of a national antimicrobial policy development workshop held in May 2000 in Dhulikhel. This has resulted in a draft National Antibiotic Policy (Appendix 2) especially noteworthy because it is a collaborative effort by public, private and academic sectors.

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<sup>9</sup> National Drug Policy 1995, His Majesty's Government (Nepal), Ministry of Health, Department of Drug Administration.

## Challenges

Some of the challenges of building capacity in drug information development in Nepal have been mentioned above. Some early challenges were resolved over time without USP intervention but with the steady **evolution of information technology**. In 1992 USP was just beginning to use electronic versions of the USP DI. The initial process of adapting the information for the local context involved a cumbersome system of data transfer between the counterpart and USP headquarters. Technological snafus slowed the adaptation process as did the limitations of providing training “on-line” via email or telephone. A **lack of available staff** for sufficient on-site training not only slowed the adaptation process, it fostered a waning of motivation and energy on the part of Nepal counterparts. Beginning in June 1995, USAID-Nepal mission funding allowed new infusions of USP technical assistance in the field, which stimulated renewed activity on the adaptation, new information product development and more enthusiasm for the drug information network.

Facilitating the network of DINoN was encumbered by **local personality conflicts**, both intra- and inter-organizational. This was unfortunate because it probably reduced the number of collaborative activities that might have occurred to promote rational drug use if all five organizations had been more willing to work together, such as joint training workshops and public education campaigns. As continued field support allowed USP to provide technical support more evenly across the DINoN membership, the cooperation has steadily, if gradually, improved. In 2000, each DINoN member still plays an important role in disseminating drug information and the members still are willing to act as referral points for each other. In the past two years, the DINoN members collaboratively, with USP support, implemented five major workshops including the workshop on a national antibiotic policy. In further testimony to a stronger collaboration, two new members recently have joined DINoN: United Hands to Nepal Poison Information Center and British Nepal Medical Trust.

**Skilled human resources and funding**, as mentioned earlier, are in short supply in Nepal. Only 58% of primary school age children were enrolled in school in 1980-85.<sup>10</sup> There are only about 1400 practicing physicians and fewer degreed pharmacists. A result of this thin layer of qualified people is that the same individuals are involved in every medicine-related program or initiative in the country. The same few research reports are cited in every health-related discussion. The few local experts are over-tasked by competing issues, donors and organizations. One solution is to make professional development, which has been discussed above, a program objective. Although it may be tempting to always send the most experienced and well-spoken host country nationals to international conferences and training programs, it is vitally important to provide training and presentation opportunities to the next layer of skilled people, the “up-and-coming” professionals, the more recent graduates. It may be a short-term remedy for a systemic problem within the country, but within the scope of RPM/USP’s mandate and resources it is not only justifiable but also essential.

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<sup>10</sup> Nepal Social Indicators, The World Bank in Nepal, [www.worldbank.org.np](http://www.worldbank.org.np)

**Institutional weakness**

## **Appendices**

### **1. Organizational chart of Ministry of Health**

## 2. National Antibiotic Policy – Final Draft

### National Antibiotic Policy 2000

#### 1. Preamble

In accordance with the objectives of the National Health Policy 1991, to fulfill the commitment of His Majesty's Government (HMG) of Nepal, to provide "health for all" and to improve and manage the prudent use of antibiotics by establishing co-ordination among human and veterinary health care professionals involved in prescribing and dispensing of antibiotics and consumers, it is proposed that a National Antibiotic Policy 2000 be promulgated for implementation.

#### 2. Definition

For the purpose of this policy,

- a. Antibiotic: The term antibiotic means any chemical substance produced by a microorganism or any semi-synthetic or synthetic product which has the capacity, in suitable concentration, to inhibit growth selectively or to destroy the microorganism through various mechanisms.
- b. Antibiotic resistance: The phenomenon where a microorganism which once responded to an antibiotic becomes less sensitive to the same antibiotic is known as antibiotic resistance.
- c. Health care workers: Health care workers are defined as those individuals involved in prescribing, dispensing, distributing, administering, and storing of antibiotics used in human and animal health care.

#### 3. Main Policy

To safeguard, maintain, and promote the health of humans and animals by preserving the efficacy of antibiotics through their prudent use, thereby, reducing the emergence of microbial resistance.

#### 4. Objectives

- a. To promote prudent use of antibiotics, thereby, reducing the emergence of antibiotic resistance.
- b. To establish an antibiotic resistance surveillance system in the country and take measures to minimize the development of antibiotic resistance.
- c. To discourage random and sub-therapeutic use of those antibiotics which are used for therapeutic purpose in humans and animals in animal feed as a growth promoter.

- d. To develop an appropriate system to administer, monitor and regularize the prudent use of antibiotics in humans and animals and in agriculture and other usage.
- e. To develop an effective system of training/education for all levels of manpower involved in the prescribing, dispensing, and administering of antibiotics and in increasing the awareness of consumers on the prudent use of antibiotics.
- f. To develop a standard set of codes and norms for rational and ethical promotion of antibiotics.
- g. To establish an antibiotic committee at all health institutions to develop and implement their own antibiotic guidelines.
- h. To establish an effective mechanism to enforce regulatory requirements for registration of antibiotics prior to use in humans, animals or in agriculture and other areas.
- i. To develop standard codes and norms for proper storage, ethical use, and maintenance of quality and efficacy.

## 5. Strategic guidelines

### 5.1 Restrictions on the use of antibiotics

- a. Antibiotics for human and animal use will be classified into 3 categories-- reserved, restricted, and semi-restricted .
- b. Antibiotics which are used for therapeutic purpose in humans and animals will not be allowed as a growth promoter or prophylactic agent in animal feed.
- c. Antibiotics will not be allowed to be dispensed without prescription or outside of nationally approved protocols.

### 5.2 Antibiotic guidelines

National antibiotic guidelines will be developed to assist individual health and veterinary institutions to formulate local antibiotic guidelines.

### 5.3 Laboratory facilities

HMG Nepal will facilitate health and veterinary institutions to develop facilities for anti-microbial resistance testing and detection of antibiotic residue in livestock products.

### 5.4 Prudent use of antibiotic

#### 5.4.1 Education and training

- a. To promote prudent use of antibiotics, health care workers who are eligible to prescribe drugs will be trained periodically at all levels and sectors.

- b. Curricula for training and education on prudent use of antibiotics will be developed and incorporated at all levels of prescriber's and dispenser's education.

#### 5.4.2 Awareness of prudent use of antibiotics

HMG Nepal will facilitate governmental, non-governmental and private institutions in the promotion of prudent use of antibiotics to health care professionals and the general public.

### 6. National antibiotic control committees

6.1 HMG will constitute a national antibiotic control committee comprised of concerned experts from human and animal health, agriculture, and other sectors including professional organizations and organizations involved in consumer rights and awareness.

6.2 HMG will constitute and regulate a national antibiotic therapeutic advisory committee (NATAC) comprised of concerned experts from relevant sectors.

### 7. Research and development

Research on prescribing, dispensing, and use of antibiotics and antibiotic resistance will be facilitated and a national antibiotic surveillance system will be established.

### 8. Technical cooperation

HMG will encourage the involvement of national and international agencies in technical cooperation on training, education, and research related to prudent use of antibiotics and harmonizing antibiotic policies between and amongst them.

### 9. Monitoring and Evaluation

The national antibiotic control committee will constitute subcommittees responsible for successful and effective implementation of the antibiotic policy as well as monitoring and supervision of its implementation.

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