

**Revised Workplan**

**September 16, 1999- September 15, 2000**

**CA # HRN-A-00-92-00052**

**RPM/USP CORE PROGRAM WORKPLAN**  
**HRN-A-00-92-00052**  
**September 16, 1999- September 15, 2000**

**Objective**

**1 To increase the acceptance of oral polio vaccine (OPV) in developing countries**

Despite the success of EPI programs there is still considerable resistance to the use of OPV in developing countries, particularly in Africa. Last year, USAID's Polio Eradication Program requested USP to develop an enhanced therapeutic monograph on polio which would address superstitions that exist about the vaccine, in addition to the regular components of a USP monograph. In addition, USP has updated its drug monograph on OPV and USP's Advice to the Patient. All three monographs have been translated into French, Portuguese, Russian and Arabic and 2000 copies in each language have been printed. USP is disseminating the monographs through WHO, UNICEF, Rotary International, and other organizations. In addition, the monographs in all five languages will be available on USP's website.

<b>FY 98 funds remaining</b>	<b>\$ 15,000</b>	
<b>FY 99 funds obligated</b>	<b><u>\$100,000</u></b>	
<b>Total funds available</b>	<b>\$115,000</b>	<b>(Polio)</b>

**2 To support the work of USP's International Health Advisory Panel**

Several projects of the Panel are ongoing but can be completed by the end of RPM. A questionnaire developed by the Information Development and Access Working Group was sent to over 300 drug information centers around the world to collect information about what makes a DIC successful. 122 have been returned and a draft paper with preliminary analysis of the data has been written and sent to all 122 participating DICs for comment. The paper will be revised based upon the feedback and submitted to the journal of the International Federation of Pharmacists. The data will also be disseminated as part of a document containing a case study of the RPM/USP experience in Nepal.

The Patient/Consumer Education Working Group has developed guidelines for evaluating consumer education materials and programs. The guidelines have been finalized by the USP panels and will be published after a period of public review.

A meeting of the Panel will be scheduled during FY 2000 to review the past five years of USP's international work and make recommendations for the new Panel to be appointed in June 2000.

<b>FY 98 funds remaining</b>	<b>\$ 25,000</b>	
<b>FY 99 funds obligated</b>	<b><u>\$-0-</u></b>	
<b>Total funds available</b>	<b>\$ 25,000</b>	<b>(CS)</b>

### **3 To support USAID's new Strategic Objective for Infectious Diseases**

In line with the focus areas outlined in the ID strategy, and USP's particular expertise in drug information and information materials development, two multiyear activities will be completed and two new activities have been identified for FY 2000. In addition to the activities listed below, one USP staffperson will attend a global strategy development workshop to be conducted by WHO, \$2,000 has been allocated for this purpose.

#### **A Improving patient counseling and dispensing skills of private drug retailers**

**Objective** To reduce the spread of resistance to antimicrobial drugs used to treat the most common infectious diseases in Nepal (tuberculosis, malaria, STI's, pneumonia, diarrheal diseases, and kala-azar) by improving the skills of the major provider of antimicrobial drugs private retailers.

**Rationale** Most people in Nepal receive antimicrobial drugs directly from a private drug seller or chemist, usually without a prescription. Through USP's experience in Nepal, it has been observed that training requirements to become a licensed drug seller are minimal and no "refresher" training is required. Studies have shown that 68% of retailers in Nepal have no qualifications to sell drugs, let alone to prescribe. In one study, a therapeutically appropriate full course of antibiotic treatment was received less than 25% of the time in retail shops. Using Nepal Infectious Diseases funding, RPM/USP has researched the antimicrobial drug knowledge and consumer counseling practices of licensed private sector drug sellers in Nepal in cooperation with the Nepal Chemists and Druggists Association (NCDA). Based on the results of this research the RPM project is developing a training intervention to improve patient counseling and dispensing of antimicrobial drugs used to treat the most common infectious diseases in Nepal. It is anticipated that the training intervention will become institutionalized as a part of the new legal requirements for becoming a licensed drug retailer currently being enacted by the Dept. of Drug Administration, HMG-Nepal and later rolled out to reach the majority of drug sellers in the country.

**Progress to date** Research has been done with the private sector retailers on the dispensing of and patient counseling for antimicrobials during FY 99 using funds from the 1998 allocation of ID money. The Manoff Group was contracted to develop a research plan, manage data collection and analysis and present findings and recommendations for an appropriate intervention. Manoff has worked in collaboration with New Era, a local Nepali research group. The research results will inform the design and development of training and reference materials. For example, simple and easy-to-use reference materials on appropriate packaging and labeling may be indicated. In addition, support for drug retailers' encouraging clients to follow a full course of antibiotic treatment, instead of taking the medicine just until they feel better, may be appropriate.

**Planned for FY 2000** The training intervention is being developed and field-tested in collaboration with RPM/MSH. Nepal ID and core funds will be used to evaluate the field test and revise the intervention and materials for Nepal. The group of drug sellers who go through the field-test training will be compared to a group of untrained drug sellers three to six months after the training. At the end of the field test, measures such as decreased AM drug sales, changes to

more appropriate products, increases in repeat customers, improved patient/consumer counseling, will be used to evaluate impact. At this point, a rollout implementation phase could be planned. The DDA has already agreed, in principle, to include the training in the new requirements for drug retailer licensing being established now in Nepal.

<b>FY 98 core funds remaining</b>	<b>\$ 12,458</b>	
<b>FY 99 core funds obligated</b>	<b>\$ 20,000</b>	
<b>FY 99 Nepal field support</b>	<b>\$ 80,000</b>	
<b>Total funds available</b>	<b>\$112,458</b>	<b>(ID)</b>

**B State of the Art Technical Review of Antimicrobial Drug Information**

**Objective** A series of country-specific analyses of the quality of drug information sources and recommendations for modifications or additional information sources required by each country to help reduce antimicrobial resistance.

**Rationale** In order to determine what, if any, drug information needs to be created for specific countries or regions to help eliminate practices which lead to antimicrobial resistance and to provide guidance to international bodies attempting to develop drug information for developing countries as part of broader health programs, RPM/USP has been conducting a review of the most accessible and widely-used AM drug information available in six countries: Nepal, Russia, Mozambique, Peru, Ghana and Zambia.

**Progress to date** Local consultants in all six countries have collected data and papers analyzing the results have been drafted for four countries. A summary paper comparing findings and making recommendations to RPM is currently being prepared.

**Planned for FY 2000** The summary paper and the country analyses will be provided to USP's International Health Advisory Panel for further input and a request for recommendations. Results of the review will be disseminated through WHO, USAID, FIP, INRUD and other international networks and organizations.

<b>FY 98 core funds remaining</b>	<b>\$ 9,408</b>	
<b>FY 99 core funds obligated</b>	<b>\$ -0-</b>	
<b>Total funds available</b>	<b>\$ 9,408</b>	<b>(ID)</b>

**C Improving knowledge of primary care physicians and medical students to enhance rational prescribing of antimicrobials through the use of established drug information centers and networks**

**Objective** To develop and evaluate prototype programs and materials for primary care physicians and medical students that would improve access to and understanding of information relating to the appropriate prescribing of antimicrobial agents.

**Rationale** It is generally accepted that the misuse of antimicrobial drugs, resulting in part from a lack of appropriate drug use information, contributes to antimicrobial resistance. Based on the state of the art technical review of antimicrobial drug information in Russia, Nepal,

Peru, and Ghana, USP has found that, in general, physicians lack concise up-to-date information on the use of antimicrobials, especially information on basic use, pharmacokinetics, pediatric and geriatric use, drug interactions, and treatment of side effects. In addition, more information is needed on appropriate perioperative infection prophylaxis, recommendations for adjustment of treatment regimens, e.g., parenteral to oral therapy, as the patient improves, and practical comparisons among antimicrobial agents, in particular within families of drugs. This review also found that there is very little drug information included in disease-specific standard treatment guidelines and that these guidelines tend to be poorly disseminated within countries.

**Description of the activity** The activities will build on the Russian translation/adaptation of the USP DI database and the establishment of the 12-member All-Russia Drug Information Network (ARDIN) and the Moldavian Association DRUGS. USP will work with members of ARDIN and the Moldavian Association DRUGS in the development of strategies for improving access to unbiased information about antimicrobial agents and in the creation of a training module for educating practitioners and students about their appropriate use. Concurrently, USP will work with PHARMEDINFO to publish a subset of the translated/adapted USP DI antimicrobial information monographs as an inexpensive reference for clinicians. The information will be condensed from the full monographs included in the Russian USP DI translation/adaptation. PHARMEDINFO will publish up to 20,000 copies of the handbook (depending on costs) and make them available for use in the training initiatives. Local and regional ARDIN members will coordinate use and evaluation of the teaching modules in their respective areas. After appropriate evaluation and revision, through a "training-the-trainers" approach, ARDIN members and the Association DRUGS will work to involve other information centers and institutions in Russia, Moldova, and potentially other NIS countries in effectively using the training module in their respective populations.

<b>FY 98 core funds remaining</b>	<b>\$ -0-</b>	
<b>FY 99 core funds obligated</b>	<b>\$ 68,000</b>	
<b>Total funds available</b>	<b>\$ 68,000</b>	<b>(ID)</b>

**D Technical Paper on Fixed-dose-combination (FDC) Drug Products**

**Objectives** 1) To identify and analyze the issues surrounding use of FDCs 2) To establish a generic protocol for issues that need to be addressed in the development of FDC products 3) To examine the pros and cons of FDC products proposed for malaria therapy and make recommendations for what needs to be considered in developing optimal combinations and ensuring appropriate use

**Rationale** Although fixed-dose combination (FDC) drug products are generally discouraged in rational drug use strategies, there may be a place in therapy for such combinations when a patient must take multiple medicines and compliance is essential (e.g., treatment of tuberculosis or malaria). Combination drug therapy trials will soon be starting in several African countries to look at the efficacy of artemisinin derivatives in conjunction with other drugs for the treatment of malaria. Pending acceptable outcomes of these trials, the question of need and appropriateness of FDC therapy will have to be addressed. With many issues impacting the decision to accept FDCs (e.g., need for compliance, manufacturing standards, optimal dosing regimens, potential adverse reactions), RPM/USP believes it is necessary to identify and analyze the relevant issues and make this information available to procurement

offices, manufacturers, essential drugs programs, health ministries, and other concerned parties before decisions on registration and production are made. Only in this way can a responsible plan of action be developed to ensure that safe, needed, high-quality products with proven therapeutic advantages are produced and distributed.

**Description of the activity** This activity would focus on collecting available FDC information and experiences (by literature and policy review and through interviews with key individuals who are knowledgeable about FDCs), analyzing the issues presented, identifying the pertinent areas of concern, and subjecting the draft report to the scrutiny of experts and other interested parties. As part of the information/experience collection, selected FDCs on the market will be used as case studies/examples, policies of regulatory agencies and manufacturers will be explored, and research relating to the effect of FDCs on patient compliance/adherence will be reviewed. A group of experts will be asked to serve as a reviewing body, with opportunity for public review and comment. The process will be open and transparent. Most of the discussions will take place via mail, telephone, and e-mail, with one face-to-face meeting of the individuals serving on the reviewing body scheduled towards the end of the deliberation period. The final draft document will be published for the review and comment of all interested parties.

<b>FY 98 core funds remaining</b>	<b>\$ -0-</b>	
<b>FY 99 core funds obligated</b>	<b><u>\$ 60,000</u></b>	
<b>Total funds available</b>	<b>\$ 60,000</b>	<b>(ID)</b>

**4 To provide up-to-date unbiased drug information to the Cost Estimate Strategy being developed by RPM/MSH for a minimum reproductive health services package that should be provided by government health services**

USP staff will develop condensed monographs for all the drugs included in the CES basic minimum package for reproductive health services. A prototype format for the monographs has been agreed to between USP and MSH, the first five monographs will be completed by September 30, 1999. At this time, MSH will review them with an advisory group. The remaining monographs will be completed taking into consideration any feedback received on the first five.

<b>FY 98 core funds remaining</b>	<b>\$ 20,000</b>	
<b>FY 99 core funds obligated</b>	<b><u>\$ 30,000</u></b>	
<b>Total funds available</b>	<b>\$ 50,000</b>	<b>(RH)</b>

**5 To raise awareness of the role of drug information in promoting rational drug use through the dissemination of RPM case studies**

USP will document the results of work in Nepal and Russia and disseminate these case studies through a variety of information networks, publications and selected international conferences including the Global Health Council, the American Public Health Association and the International Federation of Pharmacists

<b>FY 98 core funds remaining</b>	<b>\$ 20,000</b>	
<b>FY 99 core funds obligated</b>	<b><u>\$ 10,000</u></b>	
<b>Total funds available</b>	<b>\$ 30,000</b>	<b>(CS)</b>

**6 To improve financial and logistics management of RPM/USP**

USP will engage an additional part-time person to provide administrative back up to all activities to be carried out under the RPM cooperative agreement

<b>FY 98 core funds remaining</b>	<b>\$ 20,000</b>	
<b>FY 99 core funds obligated</b>	<b><u>\$ 10,000</u></b>	
<b>Total funds available</b>	<b>\$ 30,000</b>	<b>(CS)</b>

**7 To complete the remaining 7 monographs for drugs included in the WHO essential drugs list but not currently in the USP DI®**

Forty-seven monographs have been completed since the beginning of RPM. With the completion of this objective, all drugs on WHO's most recent Model List of Essential Drugs will have full monographs included in the USP DI®

<b>FY 98 core funds remaining</b>	<b>\$ 9,818</b>	
<b>FY 99 core funds obligated</b>	<b><u>\$ 10,000</u></b>	
<b>Total funds available</b>	<b>\$ 19,818</b>	<b>(CS)</b>

**CORE BUDGET SUMMARY**

	<b>Polio/CS</b>	<b>ID</b>	<b>RH</b>	<b>TOTAL</b>
Remaining 1998 core funds	\$ 89,818	\$ 21,866	\$20,000	<b>\$131,684</b>
1999 core funds committed	<u>\$130,000</u>	<u>\$150,000</u>	<u>\$30,000</u>	<u><b>\$310,000</b></u>
<b>TOTAL FY 2000 Budget</b>	<b>\$219,818</b>	<b>\$171,866</b>	<b>\$50,000</b>	<b>\$441,684</b>

**Program for the Prevention and Control of Selected Infectious Diseases in Nepal  
Anti-microbial resistance surveillance and rational drug use component**

**Revised 9/15/99**

**Workplan for RPM/USP in Nepal  
10/99 - 9/00**

**Objectives**

**1 Raise awareness of antimicrobial drug resistance and the importance of high-quality information on antimicrobials outside of Kathmandu**

Information dissemination within Kathmandu through the Drug Information Network of Nepal (DINoN) has been steadily increasing and has begun to reach beyond the capital city through mechanisms including newsletters, drug information bulletins, workshops and newspaper articles. RPM/USP will continue to support and encourage an expansion of information dissemination efforts by the network and individual members. The following activities will be supported during the RPM extension period through subagreements with RPM/USP:

RECPHEC will (1) evaluate the Rational Drug Use workshops/campaign, which they have conducted in six locations over the past two years of the RPM project. One of the stated goals for these workshops was "to encourage participants to initiate actions to minimize irrational use of drugs." The evaluation will identify actions initiated, for example: Did schoolteachers use workshop materials in their classes? Did journalists publish articles on drug information/rational drug use?

RECPHEC will also (2) create, produce and disseminate two new posters for consumers on antimicrobial drug use and 20 patient information leaflets on commonly used antimicrobial drugs with the appropriate pictograms or other illustration for the non- or semi-literate consumer. RECPHEC may use USP pictograms adapted under Objective #4, or RECPHEC may create original pictograms. The leaflets should be tested in two districts to see if they are understandable by consumers before they are printed in a large quantity.

RECPHEC will also (3) develop and place six print media messages targeted to consumers on proper purchase, storage and/or use of antimicrobial drugs.

DDA will implement a national antimicrobial policy development workshop. Inappropriate use of antimicrobials is considered to be one of the major factors responsible for the development of bacterial resistance to antimicrobial drugs. Other factors include availability of drugs without a prescription, poor quality of antimicrobial drugs, and unavailability of up to date drug information, drug substitution, cost constraints, non-compliance, and use of drugs in food-producing animals.

<b>FY 98 Funding remaining</b>	<b>\$15,097</b>
<b>FY 99 Funds</b>	<b><u>\$25,000</u></b>
<b>Total committed as of 9/14/99</b>	<b>\$40,097</b>

**2 Field test and evaluate the intervention for drug sellers on proper dispensing of and patient counseling for antimicrobial drugs which will be developed in FY00 and plan "roll-out" of intervention**

RPM/USP has contracted the Manoff Group to develop and test this intervention. Data has been collected on the dispensing of and patient counseling for antimicrobial drugs by licensed drug retailers in Nepal. In collaboration with RPM/MSH, a workshop will be held in Kathmandu to disseminate the results of the data analysis. Following that, Manoff will lead a working group through a 4-5 day intervention development session. The NCDA, a DINoN member, has agreed to facilitate the field testing of the intervention by Manoff. At the end of the field test, measures such as decreased AM drug sales, changes to more appropriate products, increases in repeat customers, and improved patient/consumer counseling, will be used to evaluate impact. The group of drug sellers who go through the field-test training will be compared to a group of untrained drug sellers three months after the training.

A monitoring system will be established to assess the improvement in patient counseling practices of the trained drug sellers as the intervention is rolled out to more participants. 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. DDA has agreed in principle that the RPM/USP training intervention will be included in 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.

<b>FY 98 Field support remaining</b>	<b>-0-</b>
<b>FY 98 Core remaining</b>	<b>\$12,458</b>
<b>FY 99 Field support</b>	<b>\$ 80,000</b>
<b>FY 99 Core</b>	<b>\$ 20,000</b>
	<hr/>
<b>Total committed as of 9/14/99</b>	<b>\$112,458</b>

**3 Strengthen institutional capacity of existing DINoN members to develop and disseminate unbiased information on antimicrobial drugs and their proper use to their target audiences**

In response to USAID's evaluation of the drug information component of RPM in Nepal, a training needs assessment was conducted of each drug information center in the Drug Information Network of Nepal (DINoN) in January, 1998. Weaknesses were identified in the centers' ability to develop, manage and disseminate unbiased information on drugs to their various constituencies, i.e., physicians, drug sellers, government administrators and primary health care workers. In response to this assessment, a draft manual has been developed that addresses all aspects of operating a successful drug information center including how to access the appropriate information, how to evaluate the literature, development of information products, dissemination of information, and documentation of the center's activities. The manual will be tested through training sessions with individual DINoN members.

A brochure highlighting the services available through DINoN will be published and widely disseminated in order to increase awareness of the drug information centers and how to access

them Also, advertisements will be placed in the major media sources encouraging use of the DIC services

Additionally, drug and medical information resources will be updated and equipment required for materials development and dissemination will be upgraded Partial support may be given to several drug information centers outside of Kathmandu (Nepalgunj and Biratnagar DDA offices, BPK Memorial Hospital) which would also support objective #1, the extension of drug information services outside of Kathmandu

<b>FY 98 funds remaining</b>	<b>\$25,000</b>
<b>FY 99 funds</b>	<b><u>-0-</u></b>
<b>Total funds available as of 9/14/99</b>	<b>\$25,000</b>

#### **4 Adapt USP pictograms for antimicrobial drug patient information for Nepal**

USP pictograms have been adapted for use specifically with antimicrobial drugs by Rhodes University, South Africa RPM/USP will borrow the Rhodes model and adapt the pictograms for Nepal in collaboration with two DINoN members, Resource Centre for Primary Health Care and NCDA Both of these organizations have already begun to adapt a small sample of the pictograms for use by community health workers and drug retailers RECPHEC and NCDA will also be able to test the adapted pictograms through their constituencies and members

<b>FY 98 funds</b>	<b>\$-0-</b>
<b>FY 99 funds</b>	<b><u>\$ 40,000</u></b>
<b>Total funds committed as of 9/14/99</b>	<b>\$40,000</b>

#### **5 Continue adaptation of USP DI database**

The second Nepal Drug Information Database was released on CD ROM in September 1998 This product is a result of collaborative work of the DINoN members in adapting the USP Drug Information Database for Nepal Brand names, dosage forms, dosage sizes and localized indications specific to Nepal are being added to the USP DI to make it more relevant and user-friendly in Nepal Computer programmers and electronic product development staff at USP will continue to integrate the Nepal adaptations into the database and produce updated CD ROMs for Nepal

<b>FY 98 funds remaining</b>	<b>\$12,000</b>
<b>FY 99 funds</b>	<b><u>-0-</u></b>
<b>Total funds available as of 9/14/99</b>	<b>\$12,000</b>

RPM/USP Nepal Budget Summary

FY 98 remaining field support as of 9/15/1999	\$ 52,097
FY 98 core ID funds remaining	\$ 12,458
FY 99 Field support committed	\$ 145,000
FY 99 core ID funds committed	<u>\$ 20,000</u>
<b>Total Estimated budget for FY 2000 equals</b>	<b>\$ 229,555</b>

**Revised Workplan for RPM/USP Mozambique  
September 15, 1999 – September 15, 2000**

As a result of discussions among USP, USAID-Maputo, DF-Ministry of Health and USAID-Washington, the items below were agreed upon for the remainder of the RPM project, i e , until September 15, 2000

- 1 RPM/USP will develop a manual of monographs for selected drugs contained in the Mozambique National Formulary for a specific target group, e g , physicians' assistants, to be determined in cooperation with the DF The format for the monographs needs to be developed with and agreed to by someone representing the Ministry of Health The monographs will be condensed from the full USP monographs If possible, monographs from GUIAMED will be used in the manual

Estimated budget \$77,470

- 2 A recent study by WHO found that 25-30% of drugs imported by Kenya and Zimbabwe are counterfeit, Mozambique probably has a similar proportion of imports that are either counterfeit or substandard USP will assist the Government of Mozambique to identify their priorities for drug quality control lab services RPM/USP would help the GOM to do an assessment of services available in Mozambique and southern Africa, determine the feasibility of accessing existing services or creating new laboratory capacity and will present options for the development/strengthening of Mozambique quality control services USP will identify appropriate technical expertise to complete this assessment

Estimated budget \$39,370

- 3 USP will provide guidance to the Dept of Pharmaceuticals on developing standards for packaging of drugs to be imported and/or repackaged and distributed in Mozambique USP is responsible for establishing standards for medicine and health care technologies We also maintain the relevance of such standards in manufacturing processes, packaging technology and distribution procedures Based on the results of the assessment conducted under #2, training can be provided in establishing packaging needs for the climate and storage conditions available in Mozambique

Estimated budget \$30,640

- 4 USP will continue with the six months Workplan (Mar-Sept 1999) presented in the last trip report It is our current understanding that, the drug information center being developed by the Faculty of Medicine will be responsible for developing drug information and responding to inquiries The center at the National Institute of Health will have dissemination of information as it's primary function For example, a bulletin developed by the Faculty of Medicine would be disseminated through the National

Institute of Health Based upon the success of that six months plan, support for both centers and a drug information bulletin would be extended through June 2000

Estimated budget \$ 31,950

RPM/USP will monitor the following indicators to measure results

**Access to health services** The number of drug information materials published and disseminated by drug information centers at the FAS and the INS will be monitored on a monthly basis These materials will include the promotional pamphlet already developed by the FAS center, the drug bulletin and the formulary manual

**Demand for health services** The number of inquiries received by the drug information center at the FAS will be monitored on a monthly basis beginning in September 2000

FY 98 Field support remaining \$ 18,630

**FY 99 Field support committed** \$160,800

**Total Mozambique budget for FY 2000** \$179,430