

HEALTH
INFORMATION
DESIGNS, INC.

PN-PAW-529
154-3733

ESSENTIAL DRUGS
COMPONENT

LAC REGIONAL PROJECT

"TECHNOLOGY DEVELOPMENT and TRANSFER IN HEALTH"

December 3, 1984

Contract# LAC-0000-C-00-4078-00

Project# 598-0000

Project Title: LAC Regional Health Project
Development and Support

Prepared for: LAC/DR/HN

Prepared by: Aida A. LeRoy
M. Lee Morse

A. Current Status of Essential Drugs in the Region

Pharmaceuticals have assumed an increasingly important role in the management of many diseases. Rational use of medications provides an efficacious and cost-effective means of treating illness. In many cases, rational ambulatory use of medications can obviate the need for costly hospitalization. Formerly devastating diseases, such as pneumonia, tuberculosis and diarrheal disease can now be treated with medications thus avoiding the necessity of costly hospitalization. Many diseases (such as polio or measles) can be prevented altogether by use of vaccines.

Although up to 40 percent of health care budgets in developing countries are being spent on drugs, the majority of the population does not have access to many of the essential drugs needed to treat prevalent diseases. Frequently, the limited funds available are ill-spent on ineffective, duplicative, unacceptably dangerous drugs or wasted on nonessential drugs which are used inappropriately. Additionally, numerous studies have demonstrated that drugs have the capacity to not only cure, but to harm as well. This paradox of drugs is acutely experienced in developing countries because such a significant proportion of the health care budget is spent on drugs and access to drugs is a symbol of health care to the patient. When drugs are not available, the patient does not get well, is often given an inappropriate substitute, and he/she becomes disgruntled with the entire health care delivery system. On the other hand, if the drugs that are available are

irrationally used, therapeutic failures and drug induced illness add significant burdens to the already overburdened health system. There are numerous examples of irrational drug use/management in developing countries. Some examples particularly serve to underscore the importance of developing mechanisms to improve the delivery of essential drugs. For example, in one country, a patient was given chloroquine to treat a fever and cough when penicillin was not available. In other countries, expensive and potentially dangerous tricyclic antidepressant drops are used for the treatment of school phobia in children while in the same country insulin or mebendazole is unavailable. Thousands of vials of antibiotics reach their expiration date while sitting in customs awaiting port-clearing, because payment is not made to the supplier. Suppliers default on their contractual commitments and essential drugs must be obtained locally at private sector prices. Limited funds are also wasted due to inadequate inventory control, inadequate storage, stock mismanagement, and inappropriate prescribing and use of drugs at all health care levels.

Developing countries have begun to demonstrate an awareness of the need to rationalize drug use in their health care programs and have begun to implement measures aimed at increasing efficiency and effectiveness of therapy.

These measures include:

- 1) Development of essential drug formularies based on prevalent morbidities, utilizing criteria of efficacy, safety, and cost.
- 2) Development of therapeutic prescribing information and standards of care.
- 3) Improvement of inventory control systems
- 4) Establishment of management information systems
- 5) Improvement of procurement systems
- 6) Implementation of "Level of Use" standards
- 7) Development of quality control procedures

These efforts have been undertaken with the assistance of the World Health Organization, UNIDO, development banks, FDA, international manufacturing associations and AID. These groups have provided or funded technical assistance, equipment acquisition, training, production and procurement of drugs, warehouse construction, etc. Although each organization has different objectives and orientation, there are always overlapping spheres of impact. Unfortunately, there is frequently a lack of coordination and a resultant duplication or contradictory goals of programs.

B. Major Constraints to Improving Essential Drug Supply

The major constraints to improving essential drug supply exclusive of funding are traditionally addressed by seven categories.

<u>PROBLEM</u>	<u>SOLUTION</u>
1. Selection	<p>Develop an essential drug formulary which contains drugs of choice for the treatment of prevalent morbidities, avoiding therapeutic duplication, unacceptably dangerous drugs, or drugs of unproven efficacy.</p> <p>Create an Essential Drug Formulary Committee with broad representation of medical specialities, health care program administration, and pharmacy.</p> <p>Establish criteria and procedures for periodic objective evaluation of drugs proposed for addition to the essential drug formulary.</p>

1. Selection (cont'd)

Development of therapeutic information to accompany each drug included on the essential drug formulary to provide a basis for appropriate prescribing of the drugs.

Development of "level of use" standards for each drug on the essential drug formulary so that drugs requiring sophisticated monitoring techniques are restricted to use in health care installations staffed by appropriately trained personnel.

2. Procurement

Development of a method for measuring actual drug consumption to be used for procurement estimates.

Identify and implement vendor performance incentives.

Development of procurement criteria for vendor selection.

Development of order tracking procedures.

Development of detailed pharmaceutical product specifications.

Establish a procurement schedule for monthly, quarterly, semi-annual and annual purchasing.

Improve training of procurement specialists.

Development of information network on regional drug prices and vendors.

3. Inventory Control

Develop and implement a "simplified" inventory management system utilizing a manual approach initially with transferability to a computerized process.

Develop a critical drug locator system for locating and transferring supplies from one pharmacy or warehouse to another.

Develop minimum quantity standards for reordering for each health facility level.

Improve training of personnel responsible for inventory control.

3. Inventory Control
(cont'd)

Create a utilization driven inventory distribution program.

4. Quality Control

Develop procedures for selecting samples and testing products arriving at the central warehouse.

Develop a list of select drugs requiring strict quality control analysis.

Improve quality control facilities.

Improve quality control personnel capabilities through training.

Organize quality control scheduling for routine testing.

Support regional quality control facilities.

Develop subregional product defect inspection program.

Coordinate resources for quality control testing to minimize duplication.

5. Warehousing

Develop model "space planned" warehouse for efficient and secure storage and retrieval of medical supplies (pharmaceuticals).

Improve training for warehouse personnel.

Develop procedures that provide information for product tracking throughout warehouse.

Implement procedures to improve efficiency of order filling and handling of backorders.

Develop security programs/systems to minimize warehouse related theft and pilferage.

6. Distribution

Develop procedures for establishing delivery routes and scheduling.

Develop a plan for securing the transport of drugs.

Improve training of distribution personnel.

Improve procedures for dispensing drugs.

6. Distribution (cont'd)

Develop security programs/systems to minimize distribution related theft and pilferage ..

Evaluate feasibility of transfer of transportation tasks to private transport companies.

Evaluate feasibility of transfer of dispensing functions to the private sector pharmacies.

7. Use

Develop a system for collecting patient specific information on morbidities treated and drugs dispensed.

Develop a program for monitoring patients for rationality of pharmaceutical care and notifying prescribers of patients exhibiting a high risk potential for drug induced illness.

Develop patient drug education posters and brochures.

7. Use (cont'd)

Develop pharmacist based pharmaceutical use counseling programs.

..
Develop training programs in drug epidemiology and drug monitoring.

C. LAC Bureau Strategy with Regard to Essential Drugs

LAC Bureau has identified essential drugs as a priority component of its health program. The objective of LAC's strategy on essential drugs is to promote the availability and rational use of essential drugs in the Region. Essential drugs are defined as those drugs necessary for the treatment of the prevalent conditions/morbidities affecting the population. The rational use of essential drugs promotes the basic objective of AID's health programs as stated in the Health Policy, that is "to help developing countries become self-sufficient in providing broad access to cost-effective preventive and curative health services directed at the primary causes of morbidity and mortality". LAC Bureau recognizes the cost benefit of being able to successfully treat a patient with drugs on an ambulatory basis.

In order to promote the availability and rational use of essential drugs, LAC sees the increase of both bilateral and regional support for technical assistance and training for each of the seven areas affecting essential drug supply (selection, procurement, inventory control, quality control, warehousing, distribution and use).

These areas require specific in country technical assistance and regional training. The technical assistance must be action oriented rather than diagnostic or theoretical. Reports generated must be brief, and easily read and identify step by step tasks to be implemented with short to medium term impact. The technical assistance should be performed by professionals experienced in pharmaceutical logistics and sensitive to the particular constraints facing Latin American developing countries.

The training component of this initiative will utilize a two phase format incorporating a follow-up training experience for each trainee. The programs must be designed with practical exercises rather than extensive didactic presentations. Professional graphic and audiovisual techniques should be employed to maximize effectiveness of training. Regional centers, with demonstrated exemplary practices relevant to the training course subject should ideally serve as the training site, thereby maximizing the non-classroom opportunities for interactive education and hands-on experience. And finally, these training programs should be restricted in size, providing maximum trainee/faculty contact. The faculty for the training programs should be professionals from the region with support as needed from international experts.

D. Regional Activities to be Funded in Essential Drugs

In order to effect short and medium term improvements in the supply of essential drugs in the region AID/LAC will fund in-country technical assistance activities for, at a minimum, the following tasks:

- Analysis of existing essential drug formularies
- Development of objective criteria and procedures for the selection of drugs for the formulary
- Establishment of "level of use" standards for each drug
- Development of unbiased drug information for the essential drug formulary
- Design of methodology to calculate actual drug consumption statistics

- Development of drug supplier performance incentives
- Development of procurement criteria and detailed product specifications
- Development of an order tracking system
- Identification of reasonable procurement scheduling
- Design of manual or computerized inventory management system
- Design of system for locating and transferring critical supplies
- Development of minimum quantity standards for reordering drugs
- Development of sampling procedures for quality control to be carried out at the central warehouse down to the primary health care level
- Identify list of drugs that require strict quality control
- Facilitate arrangements between quality control laboratory and MOH, SS for routine quality control
- Coordinate resources for quality control among all health sectors to minimize duplication
- Organize warehouse
- Design a product tracking system for the warehouse
- Improve accuracy and efficiency of order filling
- Establish efficient delivery routes and scheduling
- Improve security of drugs during transport
- Develop dispensing procedures and standards for packaging
- Develop system for collecting patient specific information on drugs and morbidities
- Develop patient drug monitoring program and prescriber notification/education
- Design patient drug information posters and brochures
- Design a pharmacist drug counseling program

Regional training programs will be funded to provide training in the following areas:

- Drug selection
- Drug procurement
- Inventory control
- Quality control
- Warehousing
- Distribution/Dispensing
- Utilization

The training component of this initiative utilizes a two phased format. Trainees will attend a basic training program which will build on and reinforce the fundamentals of the course's topic. An advanced training program will be conducted a year later for the basic course trainees to strengthen skills learned previously and solve problems encountered while putting new skills into practice. Successful graduation from the course (award of certification) will require attendance at both basic and advanced/follow-up courses.

Each of the seven major topic areas will have one or more subtopic training programs. This approach fosters the concept of specialization within each of the major pharmaceutical logistics areas, thus minimizing the dependence lessor developed countries have on "one-man" operations. In light of the relatively high turn-over rates experienced at this level in the public sector, long range stability of the pharmaceutical program management can be strengthened by the experienced specialized staff that remain when attrition occurs. Summarized as follows are the major topic and corresponding subtopic training programs and their anticipated durations.

SELECTION 2 weeks

PROCUREMENT

Projecting Requirements 1 week
Procurement Process 1 week
Order Tracking 1 week
Vendor Management
(Negotiations with Pharmaceutical Suppliers) 1 week

INVENTORY CONTROL/WAREHOUSING

Central Facility Management Principles 2 weeks
Local Facility Management Principles 2 weeks
Utilization-driven System Design 1 week

QUALITY CONTROL

Laboratory Planning 1 week
Basis Drug Testing Principles 2 weeks
Advanced Drug Assaying Principles 2 weeks

DISTRIBUTION

Developing Delivery Routing/Schedules 1 week
Pharmaceutical Security Procedures
in the Distribution Cycle 1 week
Dispensing Principles and Practices 1 week

USE

Developing Morbidity Data Collection Schemes 1 week
Developing Drug Use Data Collection Schemes 1 week
Designing Drug Monitoring Programs 1 week
Developing National Adverse Drug Reaction
Reporting Programs 1 week
Principals in Drug Epidemiology
(physician only-option) 1 week

Several studies have demonstrated that significant price and product availability variation can occur among neighboring countries within a region. Although pharmaceutical manufacturers and suppliers assume a "what the market will bear" attitude with respect to product availability and pricing, armed with current procurement data from recently awarded contracts within the region, negotiators can secure lower prices and better terms for their pharmaceutical procurements. Thus, establishing a regional pharmaceutical vendor/pricing information network which would provide current data on procurements and suppliers within the region creates a stronger and more informed procurement process. Participating procurement offices would provide copies of successfully negotiated vendor contracts to a central coding and data entry facility. Quarterly, this information would be added to the network data base, copied onto diskettes and forwarded back to each participating procurement office. Pre-programmed micro-computers on-site would permit the data base to be interrogated on the basis on a number of variables (product name, therapeutic class, vendor, price, return goods policy, dating, etc)

A key requirement of a successful pharmaceutical logistics program is the rational selection, and ultimate use of the pharmaceutical products. Moreover, as many pharmaceuticals share the capacity to induce illness (adverse effects), the recognition of these risks must be attendant to the prescribing/dispensing process. To assist in the development and on-going awareness of the requirements for rational drug use, and to maintain an adequate consciousness relative to adverse effects AID/LAC will provide funding for the purchase of unbiased drug therapy/dispensing information resources for several sites within each

participating country. This support would be in three major categories: reference textbooks, journals and newsletters and microfiche libraries. Although the reference textbooks provide a useful theoretical foundation, monthly journals, newsletters and microfiche libraries represent current therapeutic awareness, and relevancy to the clinical issues confronting the health practitioner.

A number of important political constraints often exist in LDCs which impede the full optimization of the pharmaceutical logistics program. Often these constraints reflect historical infrastructure requirements, employment issues, and special interest considerations. However, notwithstanding these obstacles, AID should begin to fund certain activities which address alternatives which maybe available to LDCs to further improve the pharmaceutical component of the health care systems of their countries.

Among the most difficult of these areas is the possible transference of certain historically government managed functions to the private sector. Although in some LDCs, this concept is neither practical nor feasible, in others, the cost benefits and managerial efficiencies of a limited transfer of certain functions should be thoroughly explored. Thus AID may fund two feasibility studies which examine the short and long term impacts (both government and private sector) of transferring two functional areas, transportation and dispensing, to the private sector. These two areas, in particular, present the greatest potential of yielding desirable public/private sector outcomes due to the significant involvement of private industry in transport/shipping technology and the proliferation of community pharmacies throughout LDCs.

Developed countries have begun to recognize significant economies due to the shifting from trade name to generic pharmaceuticals. However, this shifting has not been without its political/medical concerns regarding the "quality" of the generic product. Governmental regulators and the medical profession have increasingly turned to sophisticated pharmaceutical testing procedures to assure the consumer (the patient) that the economies realizable from generic drugs are not at the expense of the quality of their care. Not surprisingly, the early negative experience of the developed countries regarding the quality of generic products, and the antigeneric marketing efforts of the major multinational pharmaceutical manufacturers have resulted in skepticism and fear among health care practitioners in LDCs. These fears and misgivings can only be adequately resolved by strengthening the pharmaceutical quality control programs within the region. Thus, AID may fund the modernization and increased technical capacity of existing quality assurance laboratories in selected countries. Armed with the ability to monitor for strict adherence to product specification standards, generic prescribing and an overall increase in the therapeutic effectiveness of pharmaceuticals will significantly improve the pharmaceutical component of the health care system in LDCs.

Pharmaceutical losses due to spoilage, theft and expiration remain significant problems confronting the pharmaceutical systems of LDCs. Effective warehouse design and management procedures address directly these problems, and provide non-political remedial opportunities which can be implemented readily. Because the design and space planning

component of pharmaceutical warehousing is so important, and involves architectural skills apart from the traditional pharmaceutical expertise, AID/LAC may fund the design of a "model" pharmaceutical warehouse which incorporates the latest structural technologies available to LDCs and the space planning skills required to efficiently handle the constant inflow and outflow of perishable and expensive pharmaceuticals. This activity will involve an existing warehouse structure, to which exterior and interior structural modifications will be made. Pharmaceutical logistics managers, warehousing personnel and architectural consultants will be able to use the model warehouse to develop strategies for transferring the relevant technologies to other countries in the region.

The issues of irrational pharmaceutical use, and subsequent therapeutic failure and/or drug-induced illness remain increasing liabilities to the overburdened health care systems of developing countries. Given that one can optimize the selection, procurement, warehousing and distribution components of the pharmaceutical supply systems, prescribing the wrong pharmaceutical, or taking a pharmaceutical incorrectly often result in outcomes which are antithetical to the expressed objectives of the health care systems in which the pharmaceuticals are being provided. Thus AID/LAC must begin to focus attention on the "end-point distribution" (patient) issues which share an importance equal to if not greater than the sum total of the other components of the pharmaceutical supply system. Through the acquisition of mini-computers and existing drug monitoring software packages, AID could begin to support the collection of patient-specific pharmaceutical use and morbidity experience data to

provide the foundation upon which the focus on irrational therapeutic selection/utilization and iatrogenic complications can evolve. The iterative process of recognition and feedback through drug monitoring systems will ultimately yield a rationality of pharmaceutical care resulting in an improved quality of life within a responsible allocation of resources.

ILLUSTRATIVE BUDGET FOR ESSENTIAL DRUGS PROGRAM

	<u>YEAR 1</u>	<u>YEAR 2</u>	<u>YEAR 3</u>	<u>YEAR 4</u>	<u>TOTAL</u>
Technical Assistance	\$100,000	\$218,400	\$218,400	\$100,000	\$ 636,800
Training	\$225,000	\$472,800	\$425,000	\$225,000	\$1,347,800
Pharmaceutical Information	\$ 13,400	\$ 10,600	\$ 10,600	\$ 10,600	\$ 45,200
Vendor/Pricing Information Network	\$ <u>82,450</u>	\$ <u>18,250</u>	\$ <u>18,250</u>	\$ <u>18,250</u>	\$ <u>137,200</u>
TOTAL	\$420,850	\$720,050	\$672,250	\$353,850	\$2,167,000

21

ESSENTIAL DRUGS COMPONENT
 TRAINING BUDGET
 (Budget Period: 4 years)
 Regional Centers

DIRECT LABOR

Professional Consultants	148 wks x \$1000/wk x 2 Faculty	\$280,000	
Graphic Support	38 programs x \$2000/program	\$ 76,000	
Audio/Visual Support	38 programs x \$1000/program	\$ 38,000	
Secretarial Support	28 wks x \$400/wk	\$ 11,200	<u>\$405,200</u>

TRAVEL/PER DIEM

Faculty

Travel	114 trips x 2 Faculty x \$700	\$159,600	
Per Diem	144 wks x 2 Faculty x \$500	\$ 72,000	
Ground Transportation	144 wks x 2 Faculty x \$50	\$ 14,400	

Trainees

Travel	114 trips x 5 Trainee/class x \$500	\$285,000	
Per Diem	144 wks x 5 Trainee/class x \$500	\$360,000	<u>\$891,000</u>

OTHER DIRECT COSTS

Materials/Printing	114 courses x \$200 course	\$22,800	
Postage/Freight	114 courses x \$100 course	\$14,400	
Audio/Visual Rental	114 courses x \$100 course	\$14,400	<u>\$ 51,600</u>

TOTAL TRAINING Budget \$1,347,800

Assumptions

- 19 basic courses and 19 follow-up advanced courses
 (Total 38 training programs)
- 72 weeks of actual training
- 76 weeks (38 courses x 2 week/course) faculty preparation

ESSENTIAL DRUGS COMPONENT
TECHNICAL ASSISTANCE BUDGET
(Budget Period 4 years)
In-Country

DIRECT LABOR

Professional Consultants	80 wks x 4 countries x \$1,000 wk	
Secretarial Support	4 wks x 4 countries x \$400 wk	<u>\$326,400</u>

TRAVEL/PER DIEM

Airfare	160 trips x \$700 trip	\$112,000	
Ground Transportation	320 wks x \$50 day	\$ 16,000	
Food/Lodging	320 wks x \$500 wk	\$160,000	<u>\$288,000</u>

OTHER DIRECT COSTS

Phones	320 wks x \$50 wk	\$ 16,000	
Postage/Freight	320 wks x \$20 wk	\$ 6,400	<u>\$ 22,400</u>

TOTAL TA Budget \$636,800

(\$39,800 per country year)

Assumptions

- 20 weeks TA per year per country
- Average stay per TA assignment: 2 weeks
- Four (4) countries requesting TA

ESSENTIAL DRUGS COMPONENT
 REGIONAL PHARMACEUTICAL VENDOR/PRICING INFORMATION NETWORK
 Budget Period: 4 years
 (Five Countries)

DIRECT LABOR (burdened by contractor overhead/fringe)

Systems Analyst	200 hrs x \$50/hr	\$10,000	
Programmer	100 hrs x \$50/hr	\$ 4,000	
Data Entry	100 hrs x \$20/hr	\$ 8,000	
Computer Operator	50 hrs x \$20/hr	\$ 4,000	\$ <u>26,000</u>

COMPUTER COSTS

Host Computer Processing	100 hrs @ \$100 x 4 yrs	\$40,000	
Micro-Computer (1 per country)	\$10,000 x 5 countries	\$50,000	
Maintenance	\$1,000 yr x 5 countries x 4	\$20,000	\$ <u>110,000</u>

OTHER DIRECT COSTS

Diskettes	\$4 diskette x 40 disk/yr x 5 countries x 4 yrs	\$800	
Postage/Freight	\$25 shipping x 4 shippings/yr x 4 yr	\$400	\$ <u>1,200</u>

TOTAL, Pharmaceutical Vendor/Drug Information Network \$137,200

\$6,860 per country per year

24

ESSENTIAL DRUGS COMPONENT
 PHARMACEUTICAL INFORMATION SUPPORT BUDGET
 (Budget Period: 4 year)
 Four Sites in Each of Five Countries

REFERENCE MATERIALS - TEXT

Martindales Extrapharmacopia	\$80 x 20 sites	\$1,600	
AMA Drug Evaluations	\$60 x 20	\$1,200	
United States Pharmacopia	\$50 x 20	\$1,000	
Pharmacologic Basis of Therapeutics	\$50 x 20	\$1,000	
US Drug Information	\$50 x 20	\$1,000	\$ <u>5,800</u>

REFERENCE MATERIALS - JOURNALS

American Hospital Formulary Service	\$120 x 20 x 4 yr	\$9,600	
Medical Letter	\$70 x 20 x 4	\$5,600	
Clinalert	\$70 x 20 x 4	\$5,600	
Hospital Formulary	\$50 x 20 x 4	\$4,000	
Facts & Comparisons	\$70 x 20 x 4	\$5,600	\$ <u>30,400</u>

REFERENCE MATERIALS - MICROFICHE

Adverse Drug Reaction Index	\$100 x 20 x 4 yr	\$8,000	
Microfiche Reader	\$500 x 20	\$1,000	\$ <u>9,000</u>

TOTAL Reference Material Budget \$2,260 per site

25

ESSENTIAL DRUGS COMPONENT
OPTIONAL PHARMACEUTICAL LOGISTICS PROGRAM ENHANCEMENTS
(Budget Period: 4 years)

OPTION A - Feasibility Study for the Transfer of Public Pharmaceutical Transportation to the Private Sector	\$ <u>80,000</u>
OPTION B - Feasibility Study for the Transfer of Public Pharmaceutical Dispensing Functions to the Private Sector	\$ <u>100,000</u>
OPTION C - Enhance the Equipment and Reagent Stocks of the Existing Food/Drug Quality Control Laboratories	<u>\$1,000,000</u>
OPTION D - Design and Structural Modifications to Existing Pharmaceutical Warehousing Facilities	\$ <u>200,000</u>
OPTION E - Equipment Acquisition (Mini-computer) and Software Development to Support a Computerized Pharmaceutical Logistics and Monitoring System	\$ <u>800,000</u>
TOTAL OPTIONAL PROGRAM ENHANCEMENTS	<u>\$2,180,000</u>

2/2