PHARMACY SERVICES IN RURAL MEXICO

A Randomized Controlled Trial of Augmented Pharmaceutical Services in Rural Mexico

By

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A Thesis

Submitted to the School of Graduate Studies

in Partial Fulfilment of the Requirements

for the Degree

Master of Science (Medical Sciences)

McMaster University

1981

PHARMACY SERVICES IN RURAL MEXICO

MASTER OF SCIENCE (1981) McMASTER UNIVERSITY
(Medical Sciences) Hamilton, Ontario
(Design Measurement and Evaluation)
(Health Care Research Methods)

TITLE: Pharmacy Services in Rural Mexico: A Randomized Controlled Trial of Augmented Pharmaceutical Services in Rural Mexico

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SUPERVISOR: Professor R.S. Roberts, M. Tech.

NUMBER OF PAGES: xi, 197

ABSTRACT

This thesis intends to study the effects of introducing a pharmacy-service-package in three health districts of the State of Tlaxcala, Mexico. Each district consists of several villages with rural health centres. They have small variation in size and their total economy and natural resources are almost equal. Districts have some features in common, none of them have experienced the "intervention" and all have the same health care system.

The investigative method followed consists of randomly allocated intervention and then surveying the districts at two points in time, noting the changes that occur in the interim. Thus it basically requires two sets of observations, one for what might be called the before period (from 1977-1981), the other for what might be called the after period (1982-1983).

These districts have already been studied by the University of Mexico. From this survey and auxilliary resources, enough information has been assembled that will be used to determine the initial health care conditions of the districts in the base line period. The investigation of the follow-up and terminal period are the author's responsibility. This work will consist of the designing of a study to collect comparable data and the designing of the analysis to provide evidence of the most important changes that will take place during the study.

Chapter One contains an overview of Mexico. Chapter Two des-

cribes the current health care system in Mexican rural areas with emphasis on pharmaceutical services. A review of the literature is presented in Chapter Three. In an attempt to establish some basis for the design of a study, existent data is presented in Chapter Four. In this chapter also a proposed protocol presents the design of a definitive study to analyse the effects of pharmacy services in those districts.

ACKNOWLEDGEMENTS

The author wishes to express her deep gratitude to Professor Robin Roberts, thesis supervisor, who has provided essential direction throughout this work and whose help and encouragement were of utmost importance in having this thesis done. His consistent availability and assistance were appreciated. Dr. Christel Woodward for her valuable guidance. Dr. Peter Tugwell whose experience has been very helpful in the conception of this thesis. Dr. Jack Sibley for his help and advice in the development of indicator conditions.

I have appreciated the time and continued support of Dr. Gary Anderson, my faculty advisor and fourth reader of this work.

Dr. José Laguna, Dr. José Rodriguez and Dr. José Narro were the principal investigators of the two research projects from which data were extracted as a base of this proposal. As sponsors of my coming to Canada, they are gratefully thanked for their encouragement and valuable help. I also wish to thank so many people from the U.N.A.M., in Mexico and McMaster University (D.C.E.&B.) in Canada that I cannot mention all of them; to each of you a very sincere "thank you".

Mrs. Linda Teiml for her patient and careful preparation of this thesis. She has done a neat work of the manuscript.

To my father's and grandmother's memory.

To my mother.

To Edith, Jorge, Luz Maria, Juan and the little ones in the family ... for their patience and understanding me ... I am grateful.

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CHAPTER 1

Background Information of Mexico

1.1 Geographic and Socio-Demographic Considerations

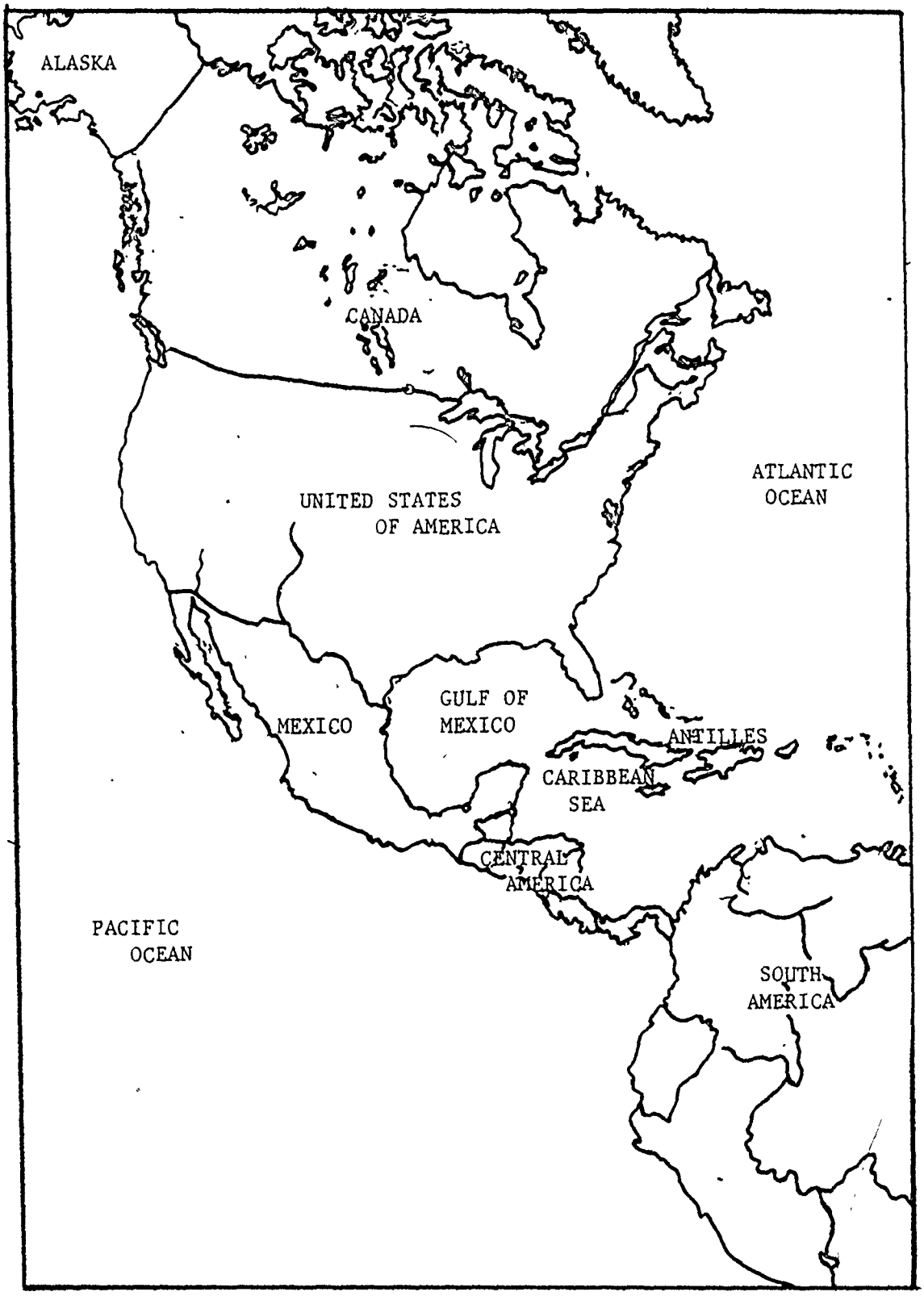
1.1.1 Geography

Mexico is one of the three North American countries covering an area of 1,972,547 square kilometers (760,373 square miles)[1]. It is bounded on the north by the United States of America; on the south-east by the Central American Republics of Guatemala and British Honduras; on the west and south-west by the Pacific Ocean; on the east by the Gulf of Mexico and the Caribbean. (Figure 1.1).

Mexico is traversed by large mountain chains ranging in altitude from about 3,000 feet near the American border to 8,000 and 9,000 feet around Mexico City. The Central chain that contains the highest peaks in the country, divides the northern and southern region. In the west the Sierra Madre Occidental (the longest mountain chain) seals off the Peninsula of Baja California and the State of Sonora from the north central plains of Mexico. In the south the Sierra Madre Occidental forms a barrier between the costal plain of the Gulf of Mexico and the interior highlands.

The country has several important rivers. The larger and more navigable rivers (in short distances) flow into the Gulf of Mexico. The shorter and less navigable flow into the Pacific Ocean. The interior of the country contains a few rivers as well as some lakes.

Figure 1.1



Source: Atlas de la Enc. Britanica - Spanish Edition

1.1.2 Climate

Mexico is considered a tropical country, although parts have a temperate climate. The country's temperature and rainfall depend more on variations in altitude than on geographic position. However there are the usual four North American seasons. The seacostal regions of Mexico as well as the lower altitudes of the interior are often very hot, except during the Winter season. Here variations in temperature are 100°F (38°C) in Summer to 75°F - 88°F (24-31°C) in Winter. In Northern Mexico, Summer temperatures reach up to 104°F (40°C) and drop in Winter to 21°F (-6 °C). Central regions are considered as the temperate area where the altitude is 4,000 to 6,000 feet and temperature ranges from 60°F (16°C) to 70°F (21°C). The cool zone above 6,000 feet has a mean temperature of 58°F (14°C) to 60°F (16°C)[1].

In general, the high central plateau on which Mexico City is located and the central states are Spring-like year-round, a bit cooler in the Winter and a little warmer in the Summer. The coastline is generally tropical in climate.

Rainfall ranges from very few drops a year in Northern Mexico to an annual precipitation of 16.4 feet in the south. Throughout the country there is a rainy season from May to October.

1.1.3 Demography

Mexico has a wide range of blended races. The bulk of the nation's population consist of mestizes (the end product of the Indian mixed with European stock, almost wholly of Spanish origin).

The population is divided into 3.2% Indians, 5.4% mestizo-

Indian, 30.6% mestizo, 60.2% mestizo-white and 0.6% white[2]. The population's density is 27.3 inhabitants per square kilometer irregularly distributed. Mexico City and the cities located around it are the most populated areas.

In 1970[3], 41% of the people lived in towns with a population under 2,500 whilst 59% lived in towns over 2,500 inhabitants. There are 91,000 towns with populations under 2,500. Considering sex, 51.6% are females and 48.4% are males (1978). The age distribution is as follows: in 1970, 46.22% were under 15 years and 13.50% over 45 years (Figure 1.2). The populations estimated at mid 1979 was 69,381,000[4].

The life expectancy, in 1976, was 63 years for males and 65.4 years for females. The annual birth rate in 1975 was 40/1000 and the country's growth rate in 1978 was 2.9% (in 1975 = 3.3%). The annual crude death rate in 1975 was 7.25/1000; the infant mortality rate during that year was 48.9/1000 in the cities and up to 104/1000 in the rural areas[5]. (Table 1.1).

1.1.4 Language

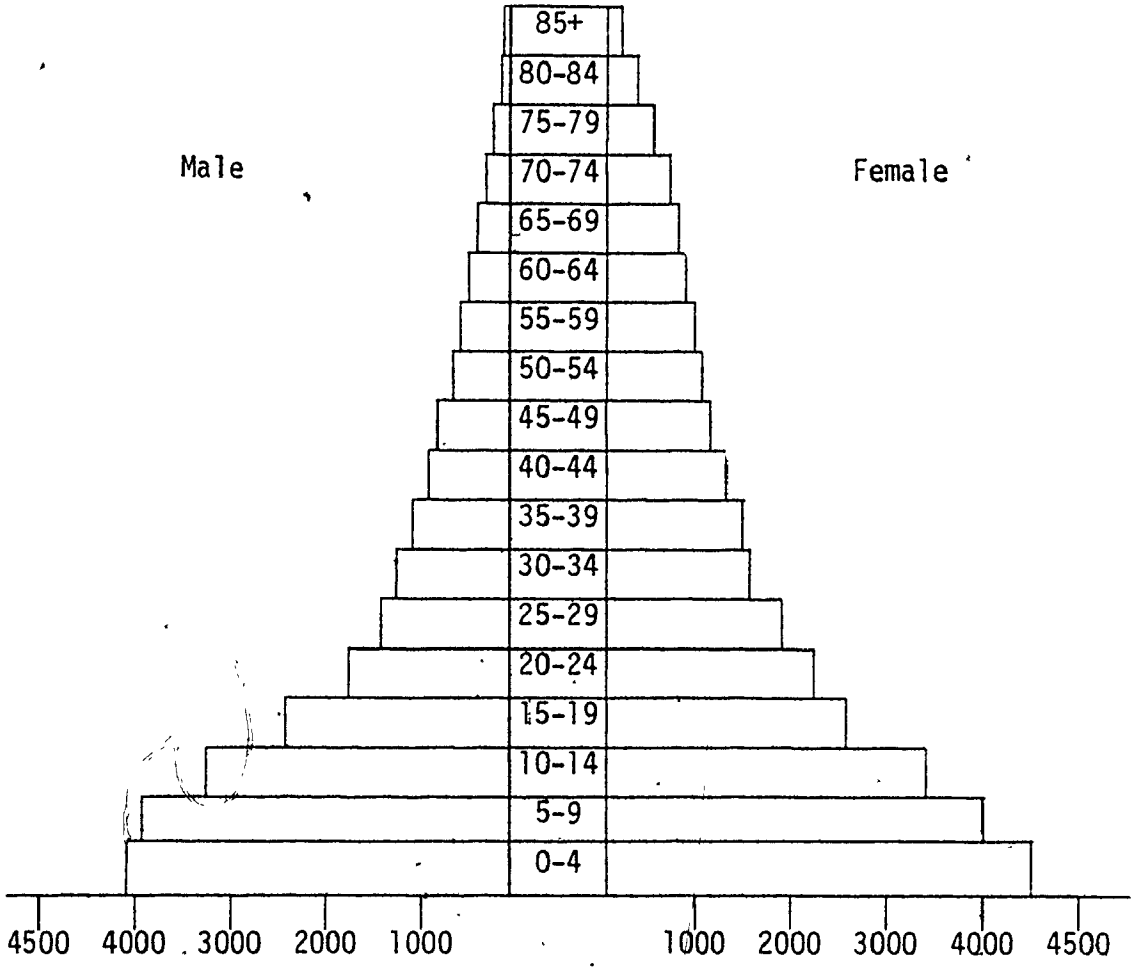
Spanish is the official language of Mexico and it is spoken by 96% of the population[1]. There are also 125 Indian languages, 90 Of them still in use today. Almost 1 million Indians speak only one of these languages. Another 1 1/2 million speak both Spanish and an Indian language[2].

1.1.5 Education

According to the census of 1970, 86% of the population, 14

Figure 1.2

The Population Pyramid of Mexico for 1970
(in thousands)



Source: La Salud Desigual en Mexico - D. Lopez Acuña, Ed. Siglo XXI, Mexico. P. 31

Table 1.1

Demographic Figures of Mexico

Indicator	1975					
	Mexico	Canada	U.S.A.	Cuba	Venezuela	Nicaragua
Estimated Population of Mid-June	58,544,505	22,831,000	213,540,000	9,332,000	11,993,000	2,155,000
Crude Birth Rate/1000	40.0	15.7	14.8	20.7	36.6	39.4
Crude Death Rate/1000	7.24	4.2	4.4	4.5	6.5	6.0
Adjusted Death Rate	7.4	-	-	-	6.5	-
Life Expectancy in Years (at Birth)	65.0	73	73	72	65	53
Growth Rate/100	3.3	.84	.59	1.53	2.96	-
Infant Mortality Rate/1000	48.9	14	16.1	27.3	49.0	110.0
Maternal Mortality (1973)	11.7	1.1	1.5	5.5	9.3	9.4
Fecundity Rate/1000 Women (age 15-44 years)	225.9*	70.1	69.2	122.3	170.6	189.4

* 1973

Source: W.H.O. - World Health Statistics Annual - Vital Statistics, 1977
General Direction of Statistics, SIC, Mexico, 1975

of age and older, are literate. Ninety percent of children aged 5-14 years were in primary schools and 65% of the children aged 15-19 years were in secondary schools. The population in colleges and universities is 7%. There are 38 government universities and 110 private colleges or institutes; both figures include 56 medical schools.

1.1.6 Political Administration

Mexico is officially named *Estados Unidos Mexicanos*. It is a Republic, composed of 31 states and one capital - Distrito Federal - or Mexico City. Each state or province is divided into districts (4-10) according to its size. Districts are sub-divided into municipalities and these are composed of towns and villages. The average population of a district is 100,000. Most states and districts are named after main towns which are usually also the most accessible cities.

The basic unit of local government is the municipality. It is represented by a Municipal President. Districts are represented by deputies or delegates and states by Govenors. Mexico's government is then made up of Legislative, Executive and Judicial branches. The President runs the country and he is the key figure in both political and economical life. According to the Constitution, Presidents can not be re-elected.

1.1.7 Economy

Primarily, Mexico is an agricultural and mining country. Although its industries and commerce have been developing rapidly since the Revolution in 1910.

Over 60% of the working population is engaged in farming. The chief products are corn, coffee, cotton, sugar, henequen, beans, potatoes, tomatoes and several fruits. Cattle raising is one of the main income sources in Northern Mexico. In mining, the country possesses vast mineral resources. Mexico is one of the world's foremost producers of silver. It also has an important income from its production of chemicals, pulp and paper, and petroleum. However, tourism still remains Mexico's largest industry.(2)

1.2 Health Care System

1.2.1 Organization

The Mexican health care system is very peculiar and offers a wide range of models of medical care. It can be said that the main scheme corresponds to public assistance*. It includes rudimentary health care services and public heatlh offered by the *Secretaria de Salubridad y Asistencia* (S.S.A.) or Secretary of Health and Assistance, which is equivalent to the Ministry of Health and Welfare. In addition to the S.S.A., there are medical services offered by governmental agencies with an insurance - like coverage and multiple semi-dependent social-insurance agencies. There are also private practices whose consumers are mainly high-income families. In addition, there is still the widespread practice of traditional medicine (traditional healers, midwives, witch doctors, and so on).

In order to simplify the scheme, it can be said(6) that there are three groups: Public Assistance, Social Insurance and Private Medicine. In the first group, whose postulate is "the health is a citizen's

* Equivalent to public subsidy of minimal health care needs.

right provided by the government", there are governmental institutions such as S.S.A.; D.F.F. (Federal District Department); D.I.F. (Comprehensive Development for the Family); I.N.I (National Indigenist Institute). In this group there are also dependencies with a mixed patronage such as the National Institute of Cardiology; National Institute of Nutritional Diseases; Mexican Hospital for Children and so on. All the above institutions provide medical care on a fee-for service basis. Those fees are really small and do not cover the true value of the services received.

In the second group, statatl (governmental) and para-statal social insurance institutions are based on the premise that "the prestation of services as a guild right" are the I.M.S.S. (Mexican Institute of Social Insurance) for the worker population; I.S.S.S.T.E. (Institute of Social Insurance Service for Government Workers) for the bureaucracy, P.E.M.E.X. (medical Services for Oil Workers); C.F.E. (Federal Comission of Electricity); E.N.M. (National Railroad Services); S.H.C.P. (National Revenue Office); S.M. (Mexican Navy); I.S.S.F.A.M. (Mexican Army Social Insurance). The financing of all those services is provided by the state and the agency of employees (if the case as in I.M.S.S.), contributions plus a premium from the employee.

Finally, the third group, the private medical services are constituted of professionals working in a team or individually, either on their own, or enrolled in an insurance company.

The accessibility of health services and the type of health services received is irregularly distributed among social classes. It

can be said that there are three groups: the first composed by the high upper class and upper middle class who can afford private and sophisticated medicine either in the country or abroad. The second group is composed of the worker class and their families covered by the social-insurance regimen. The third group is formed by the under or unemployed population, eventual workers, peasants and indigents who can not afford private services nor are eligible for any of the social insurance institutions. This population is theoretically covered by public assistance (group one above). In 1976, only 35% of the 62 million had access to social insurance services. The remaining 40 million were theoretically covered by the S.S.A. whose capacity could only cover 15-18 million(5). Using these statistics - it can be argued that 20-25 million Mexicans do not have access to health care services.

Availability of health care is also affected by the geographic and administrative distribution of the resources since Mexico, as most of the countries in the world, centralizes its resources in big cities that are easily accessible. Most of the health services are located in the capital, Mexico City. This causes a scarcity of resources in rural areas where only 2,600 towns out of 47,653, have medical care services for public assistance (S.S.A.) distributed in 1,593 centres (Community Health Care Centre, here after called type 'C' Centres) and 1,217 health houses(6). In 1971, there were 1,412 general hospitals; 377 specialized hospitals; 448 clinics; 126 aid posts and 216 medical offices. The other insurance institutions had approximately 500 units, sometimes located in the same towns where S.S.A. has health centres or

houses. More than 90,000 communities did not have medical units.

In terms of human resources, in 1975, there were eight physicians per 10,000 population; 4.6 nurses per 10,000; 8.2 nursing auxilliaries per 10,000 and a physician-nurse ratio of 2.1. This is the inverse of the proportion recommended by W.H.O. Due to the concentration of human resources in urban areas, 65% of the population has only 20% of the medical resources and 26% of nursing assistants. In private and social insurance institutes, the ratio of physicians per inhabitants is 2/1000 and 1.3/1000 whilst in public assistance is 0.5/1000. Tables 1.2 and 1.3 summarize the main features of health care resources.

The national expenditure in the health sector has been 7% of the G.N.P. for the last 30 years[7]. This expenditure includes education and welfare and only 45 to 47% is for health (public assistance and social insurance) distributed as follows: 38% is allocated to the I.M.S.S.; 15.4% to I.S.S.S.T.E. and 6.7% to S.S.A. (see Table 1.4) and the remaining institutions. The S.S.A., covers three times as much population as the other institutions do, receives only a third to a fifth of the resources of what others receive (Table 1.5 shows the coverage per institution). In general terms, 2.9% of the total expenditures in health was allocated to medical care in 1979.

1.2.2 Health Status

As a consequence of this health care system, the arbitrary allocation of resources and, despite the investments from the government in the health sector, Mexico is still considered as a developing coun-

Table 1.2

Medical and Para-Medical Personnel in Mexican Institutions in 1971

Institution	%							
	Physicians	Nurses	Specialized Nurses	Assistant Nurse	Assistants & Technicians in D_x and R_x	Administrative	Others	Total
Social Insurance System	53.6	52.5	43.9	48.2	81.2	50.7	51.2	53.2
Public Assistance	22.2	20.3	19.6	26.4	8.4	16.8	22.7	21,8
Private	15.4	19.1	25.2	15.8	5.3	25.8	16.6	16.2
Others	8.8	8.1	11.3	9.6	5.1	6.7	9.5	8.8

Source: Salud Desigual en Mexico, Lopez Acuña D.

Table 1.3

Distribution of Medical Units According to Institutions in Mexico
1971

Institution	Hospitalization Units		Outpatient Units					Total
	General Hospitals %	Specialized Hospitals %	Health Centres %	Clinics %	Aid Posts %	Medical Offices %	Others %	
Social Insurance	27.0	4.0	0	87.0	74.0	71.8	93.5	40.2
Public Assistance	36.4	14.0	100.0	0.0	0.0	0.0	0.0	39.4
Private	27.0	75.6	0.0	11.2	0.0	16.2	1.2	14.9
Others*	9.6	6.4	0.0	1.8	26.0	12.0	3.3	5.5
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

*Includes Civil Units, Red Cross and so on.

Source: D.G.E., Estadisticas Hospitalarias, 1971, Series V, No. 1, SIC, 1975.

Table 1.4

Allocation of the Public Expenditure in Health According to Institution
Mexico
1976-1979

Year	IMSS %	ISSSTE %	SSA %	Total Expenditure In Medical Care %
1976	28	11.8	5.4	45.2
1977	28.3	11.8	6.3	46.4
1978	26.3	13.8	6.4	46.5
1979	25.3	13.3	6.2*	44.8

Source: Jose Lopez Portillo; Sequndo Informe Presidencial, Anexo 1, 1978
Daniel Lopez Acuña: Salud Desigual en Mexico

* Estimations from previous years

Table 1.5

Medical Coverage for Social Insurance Institutions
Mexico
1970-78

Year	Medical Institution				Population Without Coverage %	Total
	IMSS %	ISSSTE %	Others %	Total %		
1970	20.52	2.79	1.97	25.78	74.72	100.00 (48,225,238)
1976	26.68	6.29	2.71	35.68	64.32	100.00
1978	20.00	4.80	1.50	26.30	73.70	100.00

Source: Statistical Annuals, Anuarios Estadisticos DGE/SIC 1970-1978.

try. Its health and other related problems are typical of these countries: high level of communicable diseases, rapid population growth, a wide gap between rural and urban development, high infant mortality rates and high percentage of people with nutritional problems. In general, many of the prevalent diseases in Mexico can be prevented only improving environmental conditions. These consisted of acute and chronic respiratory diseases, gastro-intestinal infections and infestations, nutritional deficiency diseases and accidents. Table 1.6 shows the 20 main causes of general mortality; and Table 1.7 compares some Mexican figures of general mortality to other countries' figures for the same causes of mortality.

In 1975, 40% of the deaths occurred in people under 15 years of age, and of these 43% occurred in children under 5 years of age. This means that the general mortality has a high component of death in early stages of life (see Table 1.8).

Infant mortality, although decreasing, remains still as an important public health problem. In 1960, the infant mortality rate was 74.2% which had dropped to 48.9% in 1975. However, according to the age, fetal mortality rate was 12.0% in 1975; hebdomadal mortality was 12.5%, and perinatal mortality was 24.6%. This can be explained by the risk to environmental hazards suffered by the new born[4].

According to the National Census of 1970, 20% of the total population never ate meat nor eggs; 70% never ate fish; 23% did not eat bread and wheat prepared food, and 38% did not drink milk. In 1975,

Table 1.6

Main Causes of Mortality in Mexico in 1975
(Based on 150 Causes ICD)

Cause	Rate*
1. Influenza and Pneumonias (A90-A92)	89.6
2. Enteritis and other Diarrhoeal diseases (A5)	84.9
3. Heart diseases (A80-A84)	75.9
4. Accidents (AE146)	45.1
5. Perinatal Morbidity and Mortality (A131-A135)	36.2
6. Malignant Neoplasms (A45-A60)	36.0
7. Cerebro-Vascular diseases (A85)	21.3
8. Cirrhosis of Liver (A102)	20.3
9. Injury undetermined whether accidentally or purposely inflected (AE149)	18.9
10. Homocides and injuries purposely caused by other persons (legal intervention)(AE148)	17.7
11. Diabetes Mellitus (A64)	17.3
12. Bronchitis, Emphysema and Athsma (A93)	17.1
13. Tuberculosis (all forms) (A6-A10)	14.2
14. Avitominoses and other nutritional deficiency (A65)	11.7
15. Acute respiratory infections (A89)	8.6
16. Anaemias (A67)	8.2
17. Diseases of Arteries, Anterioles and Capillaries (A86)	6.8
18. Peptic Ulcer (A98)	4.6
19. Bacillary dysentery and Amoebiasis (A4)	4.0
20. Meningitis (A72)	3.4
All Other Causes	187.9
Total	724.7

* Per 100,000 inhabitants

Source: Condensation of Vital Statistics of Mexico, General Direction of Statistics, SIC, Mexico, 1975.

Table 1.7

Age-Adjusted Mortality Rates* According to Cause in Different American Countries in 1975

Cause	Rates per 100,000 Population					
	Mexico	Canada	U.S.A.	Cuba	Venezuela	Nicaragua
Infectious and Parasitic Diseases	129.6	4.1	5.6	22.9	69.6	141.9
Enteritis and Other Diarrhoeal Diseases	78.3	1.2	1.1	10.1		96.1
Influenza and Pneumonia	90.9	12.6	13.5	31.3	42.6	17.7
All Forms of Tuberculoses	16.5	0.7	0.8	2.2	8.8	3.5
Ischemic Heart Diseases	21.0	102.8	116.9	80.1	56.6	10.6
Malignant Neoplasms	38.8	77.5	77.4	68.6	60.2	15.2
Accidents	90.9	57.6	59.5	51.6	55.7	71.2
Cirrhosis of Liver	22.7	7.3	9.0	3.9	7.5	5.1

* 1977

Source: W.H.O., World Health Statistics Annual, Vital Statistics, 1978
OPS, Las Condiciones de Salud en Los Americas, 1973-1976 Washington, 1978

Table 1.8

Proportion of Deaths According to Age
Mexico, 1975

Age Group	%
-1a	27.3
1-4a	8.5
5-14a	3.8
15-24	5.0
25-44	11.5
45-64	14.9
65-74	27.7
+75	
Total	100.0

Source: Lopez Acuña: Unequal Health in Mexico.
Ed. Siglo XXI, U.N.A.M., Mexico, 1980

30% of the population, the poorest sector, consumed 10% of the argicultural production. Meanwhile, the wealthy population, 15% consumed 50% of that production. While in developed countries only 3% of the new borns are underweight, in Mexico 8% are underweight in urban areas and, 17% to 40% are underweight in rural areas. In 1976, only 22% of the children under 4 years of age, in rural areas, and 40% in the urban areas, had reached normal height and weight[8], according to the W.H.O.'s standards.

CHAPTER 2

Medical Care in Rural Communities

2.1 Introduction

In Mexico, a sharp contrast exists between the capital cities and the rural areas. The cities have most of the accoutrements of modern civilization; by contrast in the rural areas, people live in a different world, one in which tradition and primitive patterns prevail and in which the standard of living is much lower.

Thus between villages and cities there is a gap. This gap also exists in the medical care system, where the shortness of resources (as described in the former section) is tremendous, resulting in higher morbidity and mortality rates. The Mexican government has promoted several efforts to provide effective medical care to these areas in different decades and at different levels, but it was not until 1936 that the "Rural Medical Services" were constituted having only 104 Rural Centres. Those services later became the "Coordinated Services of Public Health for the States and the Provinces" as part of the S.S.A.[9].

2.2 Providers

At the present, health and medical care in rural communities is provided by several institutions such as I.M.S.S. It has developed a program for peasants which consist of free delivery of primary medical care and drugs in towns or villages where there are medical offices

attached to a community silo. It also has its regular program for insured population, generally workers and their familites. It has 245 clinics and few general hospitals located in major cities. It covers 1.4% of the rural population.(13)

The I.S.S.S.T.E. with about 138 clinics, provide primary medical care to the bureaucracy living in the states (in major cities) and immunizations to all the public. It has also 509 post aids in small towns.

Where there are ongoing specific governmental or private programs (oil companies, electric plants, and so on) they provide medical care to their workers and their families. These represent isolated efforts to a very specific population and provide limited contributions in primary prevention for the rest of the people in the area.

The practice of traditional medicine, though decreasing, is still common in small towns and is sometimes the only resource. Private medicine, when available, in most of the cases is provided by physicians who were unable to either find jobs in the cities or to enroll in a graduate or residency program.

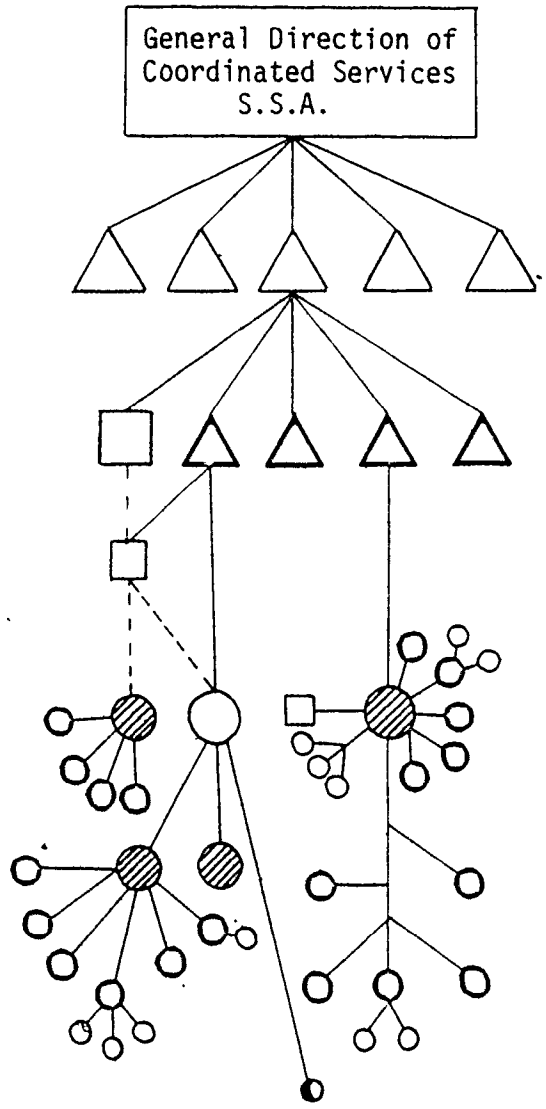
2.3 Organization

The official provider of medical care in rural areas, and provider considered in this study, is the S.S.A. through the Direction of "Coordinated Services of Public Health for the States and Provinces (S.C.S.P.E.T.). It covers 65% of the rural population through 2,002 medical care units.

This provider is organized as follows (Figure 2.1): the

Figure 2.1

Coordinated Services' Organization Scheme



- Statal or Provincial Chiefdom (31 in Total)
- Statal or Provincial General Hospital
- Health District Headquarters (4-10/State)
- District General Hospital
- Health Centre 'A' (0-3/District)
- Health Centre 'B' (1-5/District)
- Health Centre 'C' (0-15/Centre 'A' or 'B')
- Mobile Unit (1-2/District)
- Health House (0-10/Centre 'A','B' or 'C')

central decision making office is located in Mexico City. There are several departments. The most important for this study, are the Administrative, Technical, Preventive Programs, Statistics, and Health Sciences Student's Control. Those departments, jointly, are responsible for delivering health and medical care to the states. Each state is represented by a State Medical Chief assigned to the Statal Chiefdom Office of Coordinated Services, which is constituted of four departments: Technical, Administrative, Evaluation and Planning, and Health Promotion. From the first one depend the statal general hospitals and other medical units. In this regard, each state is divided into health districts or jurisdictions composed by 5-10 health houses, 5-15 health centres type 'C' and 1-5 health centres 'B' and/or 1-3 health centres 'A'. These districts are represented by a medical director or district chief. The headquarters of a district are located in major cities in Centres A or B, according to the size of the population.

Centres A are generally located in capital cities. They provide primary medical care to outpatients only. These clinics include general, family and community medicine, as well as, specialties such as dentistry, pediatrics, gynecology, cardiology, ophthalmology, pneumology, gastroenterology and dermatology. They also have general services such as laboratory and x-rays. They do not dispense drugs.

Centres B might or might not have an attached hospital with 10-40 beds for small surgery, obstetrics, accidents and emergencies. The clinic's services include general, family and community medicine, dentistry, x-rays and laboratory. They are the referal centres. There

Table 2.1

Health and Medical Services Provided in Health Centres of S.S.A. Mexico

Type of Service	Type of Centre			
	A	B	C	Health House
Preventive Medicine:				
Health Promotion	1	1	1	1
Environmental Sanitation	1	1	2	2
Specific Protection:				
Immunizations	1	1	1	1
Screenings	1	1	2	2
Prenatal Care and Deliveries	1	1	1	2
Family Planning	1	1	1	1
Growth and Development Surveillance		1	1	1
Occupational Health	1	1		
Curative Medicine:				
Screenings and Treatment of Acute Diseases	1	1	1	2
Screenings and Control of Chronic Diseases including programs for:	1	1	1	2
Tuberculosis	1	1	1	2
Diabetes	1	1	1	2
Hypertension	1	1	1	2
Rehumatic Fever	1	1	1	2
Leper	1	1	1	2
Cancer	1	1	1	2
Hospitalization	1	1	2	
Surgery		1	2	
X-Rays	1	1		
Laboratory	1	1		
Specialities:				
Dentistry	1	1		
Pediatrics	1	2		
Obstetrics	1	1		
Cardiology	1			
Ophtholmology, etc.	1			
Pharmacy (Dispensing of Drugs)			2	
Rehabilitation:				
Psycotherapy	2			
Physiotherapy	2			
Referrals	1	1	1	1

1 = Yes (always, compulsory activities)
2 = Yes (when feasible)

is no dispensing of drugs for inpatients nor for outpatients.

Centres C deliver primary medical care through actions of primary and secondary prevention such as: health education, promotion of better environmental conditions, immunizations, family planning, maternal/infant care, nutrition, diagnosis and treatment of acute and chronic diseases, detection and control of cases of tuberculosis, rheumatic fever, malaria and skin diseases. Theoretically speaking, this type of centre is the provider of medical care to rural populations, and is located in a town with under 2,500 people. In reality, they are in towns with over 2,500 and under 10,000 people.

These centres C consist in most of the cases of a waiting room, the physicians office and residence, a delivery room, hospital room with 1-3 beds, a kitchen and a nurses station. Centres are equiped with the necessary tools for primary medical care. These centres provide medical care (secondary prevention) on a fee-for-service basis which are not the real cost of the service, but represents an affordable amount for the patient (for instance the physician's visit is only 50¢ Canadian dollars; bed hospital-day - $3.00, delivery - $15.00, etc.). In some cases, when it is proved that the patient can not afford those fees (elderly, orphans, indigenous) they are totally or partially exempted of that fee. Table 2.1 lists the services provided in centres.

The centres are staffed by a full-time salaried auxilliary nurse and a full-time medical student in Social Services. The reason to enroll medical students to staff these centres is relevant here.

In 1935, the School of Medicine of the National University,

offered its final year students the opportunity to spend a five-month-period in a rural town. This allowed them an opportunity to practice their knowledge and their medical skills while helping the most marginal population. In addition, it could be viewed as returning part of the efforts made by the government and people in supporting their career. Since 1968, the Social Services became a one year-complusory service as a result of an agreement between S.S.A. and the National University (U.N.A.M.). In 1975, all the medical schools signed an agreement for an exclusive full-time one year social service. The S.S.A. agreed to pay a monthly scholarship to students working either in Centres A, B, or C.

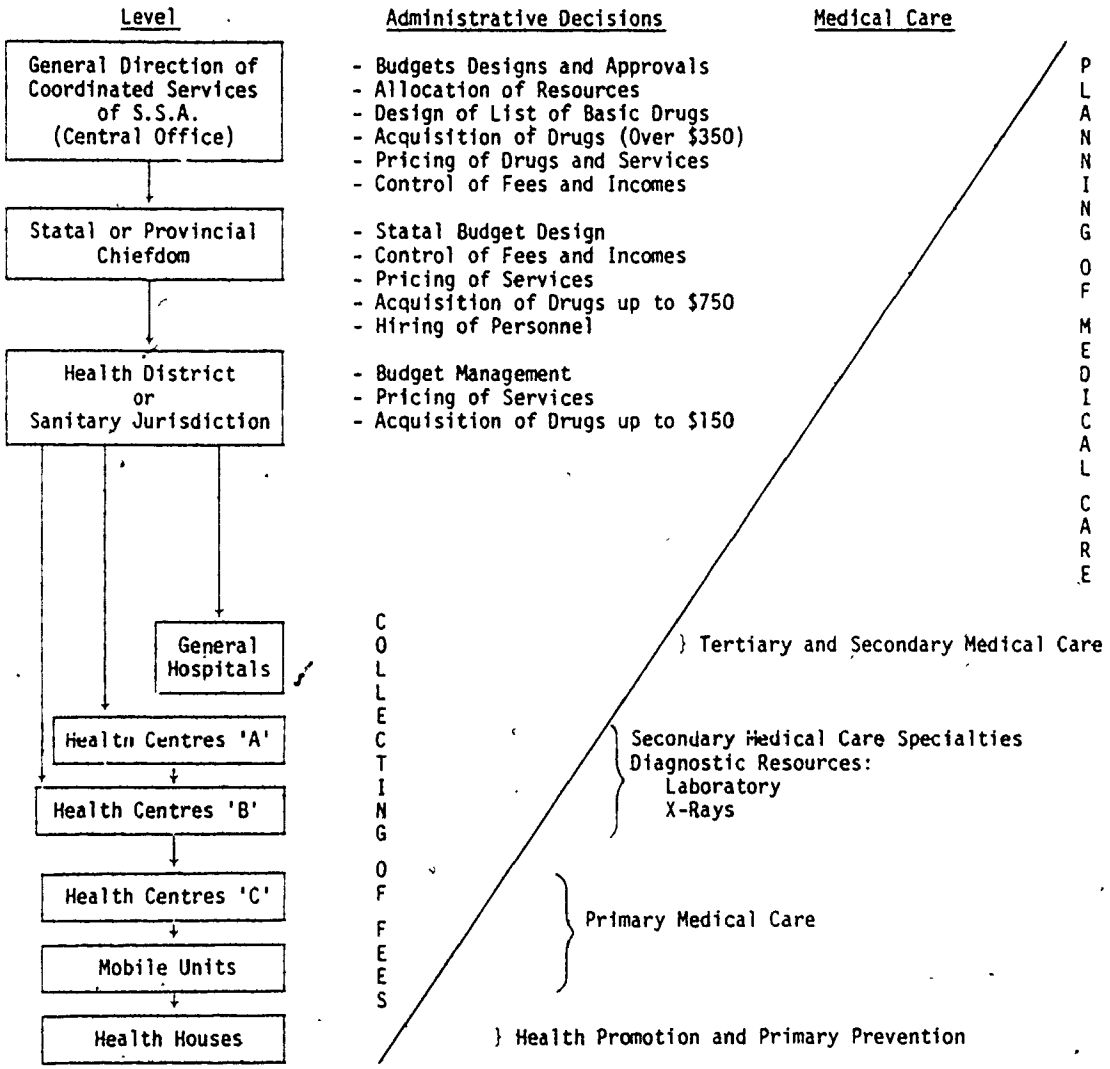
2.4 Administrative System

The administrative department of the State Coordinated Services in each state plays an important role in the provision of medical care. Its main functions are: accounting, budget control, personal management, inventory, acquisitions, transports, etc. The administrative system is highly centralized. At state levels, there are few opportunities for decision making; almost none at district levels and none at local levels (Centres C).

The financing of medical care in rural areas, specifically of the Centres A, B, and C (Coordinated Services) is given by three sources[11], the annual allowance from the federal government, the statal government's assignation, and the income generated from the patient's fees (for medical services, drugs and sanitary control). The first contribution is for salaries of physicians in social services

Figure 2.2

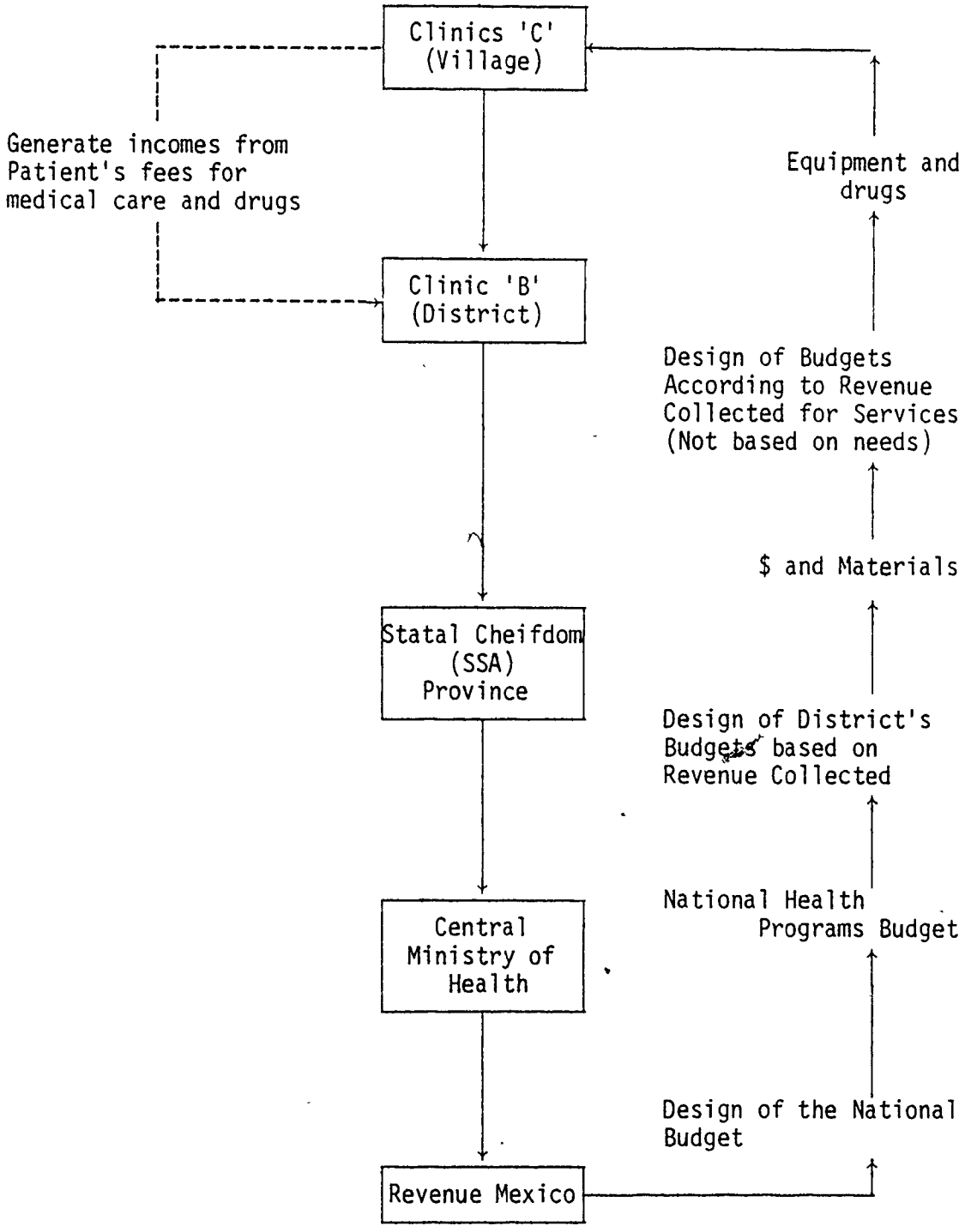
Levels of Administrative Decisions and Medical Care



part of the budget and the acquisition of biological products from S.S.A. The second one is for the maintenance of the centres, salaries of physicians, technicians, nurses and all the clinical personnel. The third one is for the acquisition of drugs, medical equipment and laboratory supplies. According to Abel-Smith's[12] classification it is a health system of an indirect expenditure from the governmental side, in this case - S.S.A. (the most important) and a direct one from the users of the services. This system has the disadvantage of being rigid and centralized. Changes in the patterns of utilization of the centres influence the allocation of resources. This is because the incomes generated from the fees at local levels are sent to the district, from here to the state, and then to the central office where budgets are designed at the end of the year to be used for the following year. The allocation of resources is directly proportional to the amount of income from patient's fees (see Figure 2.2). If the annual income of a centre is the expected amount, its budget will not have an increase. On the contrary, if it shows a great increase, up to 25% is added to the new budget. The administration of the budget is executed at central level by assigning salaries, first supply of drugs for the social service physicians (called medical stock for social services), new equipment, if necessary, biological products and so on. At statal level, budget decisions can be taken for hiring personnel, increasing salaries, acquiring drugs, stationary, medical equipment and furniture. The amount of money allowed to be spent without special permission is $750 Canadian dollars a month ($15,000.00 Mexican Pesos). At the district level,

Figure 2.3

Flow of Patient's Fees



Source: Yanez and Yamamoto: Pharmeutical Services in Huamantla, Tlaxcala. Report No. 1, D.M.G.F.C. Faculty of Medicine, U.N.A.M., Mexico 1977

only $150.00 Canadian dollars ($3,000.00 Mexican Pesos) are allowed to be spent in the acquisition of drugs, stationary, maintenance, equipment and furniture[11]. At the local level, no allowance is given in money. Everything must be sent in products or salaries (as shown in Figure 2.3).

Budget modifications are done at the central level: supply of drugs, pricing of services and drugs and control of utilization of fees at central and statal levels. A budget can be elaborated at statal and central levels. Budget authorization occurs at central level only.

This administrative system represents an important barrier to the implementation of medical care programs, the delivery of medical care, and the acquisition of drugs.

2.5 Pharmaceutical Services

Although the scheme to provide medical care seems to be appropriate to cope with the main health problems in rural communities, in reality, it is not. One of the main reasons is the almost complete absence of therapeutic resources in those centres. There are usually no retail pharmacies or drug stores in the communities and Centres C are the only medical care resources available in such communities.

At the present, there are no formal pharmacy services; instead there is a rudimentary system of distributing and dispensing drugs that comes from the S.S.A. Central Pharmacy in Mexico City.

2.5.1 List of Basic Drugs

Drugs, called the stock of basic drugs for physicians in social services, include medications contained in a list that was designed around 1936 when the Social Services was incorporated in the medical curriculua and implemented. Some drugs were added in 1965 when the Public Health Cooperative Commission was created. Among its functions is the design of basic lists and the control of quality of drugs[13]. This list has been revised only once, in 1979. However, the benefits of that revision have not been published and no adjustments have been made to this list. Therefore, the stock of basic drugs is still composed of those drugs included in the first formulary. The only advantage is that prices have remained unchanged.

The stock of drugs sent to rural areas contains the same amount and sort of medications for all the centres regardless of the geographical pathology, utilization of centres, social or economic patterns of the communities.

This stock of drugs contains 22 drugs in 26 presentations (see Table 2.2). It is inadequate in quality and quantity. A study performed by the Department of General, Family and Community Medicine, National University[14], found that only 62 bottles of procaine penicillin of 400,000 u.i. were available in that stock. This means that only 9-12 episodes of acute infections in infants can be treated in a year period, using 1 bottle/day/5-7 days. Since there is no procaine penicillin of 800,000 i.u., an adult requires two injections each time, giving then a total of six treatments of two bottles

Table 2.2

Annual Stock of Basic Drugs for Centres 'C' Traditional Program

Generic Name	Dosage Forms	Amount
Sulfadiazine	Tablet - 500 mg.	500 Tablets
Sulfamides	Tablet - 500 mg.	125 Tablets
Penicillin G Benzathine	Injection - 1,200,000 U.	1 Amp
Penicillin G Procaine	Injection - 400,000 U.	62 Amp
Penicillin G Crystalline	Injection - 1,000,000 U.	100 Amp
Tetracycline	Injection - 100 mg.	50 Amp.
Tetracycline	Capsule - 250 mg.	225 Capsules
Chloramphenicol	Capsule - 250 mg.	90 Capsules
Chloramphenicol	Suspension - 60 ml.	25 Bottles
Phenylbutazone	Tablet - 200 mg.	250 Tablets
Acetylsalicylic Acid	Tablet - 300 mg.	472 Tablets
Analgesic Combinations	Injection - 5 ml.	225 Injections
B-Complex and Yeast Beer	Tablet - 500 mg.	2,500 Tablets
Dextrose 5% in Water	Solution - 500 ml.	8 Bottles
Sodium Chloride 0.9%	Solution - 500 ml.	8 Bottles
Dextrose 5% in Saline 0.9%	Solution - 500 ml.	8 Bottles
Vials equipments	Package	21 Packs
Methoxomine Hydrochloride	Injection - 20 mg.	5 Injections
Ferrous Sulfate	Tablet - 200 mg.	522 Tablets
Emethine Hydrochloride	Injection - 400 mg.	25 Injections
Diiodohydroxiquinoline	Tablet - 200 mg.	118 Tablets
Neomycin, Kaolin and Pectin	Suspension	15 Bottles
Piperazine Citrate	Syrup - 100 mg/ml	15 Bottles
Expectorants (No. opium preparations)	Syrup	22 Bottles
Insulin, Regular	Injection - 40 U.	1 Injection
Bromodiphenhydramine	Tablet - 25 mg.	1,000 Tablets

* List of basic drugs for physicians in Social Services, S.C.S.P.E.T., S.S.A. - 1975

bottles/day/5 days. The analgesics are mixtures of three or more pharmaceutical components. Anti-diarrheal preparations contain neomycin kaolin and pectin together; diyadohydroxiquinoleine is still included dispite its limited use. With the available drugs 4-8 cases of infectious gastroentritis and 15 cases of diarrhea might be managed. In most of the cases the drugs listed are not the drug of choice, for parasitic and infective diseases, even though these kind of diseases are highly prevalent in the country.

2.5.2 Supply of Drugs

Drugs are supplied at the beginning of the academic year (on February 1st or August 1st) as an annual supply. They are sent to all Centres C where there will be a new physician in Social Services. In Centres B, drugs are sent to the physicians who will be visiting health houses only. Centres A do not receive drugs unless there are physicians in Social Services enrolled in community work or mobile units.

The Administrative Department is responsible for requesting the number of new "stocks" needed from the central office. These stocks are sent to the statal chiefdom from where they are distributed to the districts and then to Centres C. This process takes about 2-3 weeks during which the medical students receive training to manage the Centre, the record system and become familiarized with the ongoing preventive programs.

When a drug or the whole stock has been used up, there is a procedure to replenish it. This process takes about 2-3 months, since it has to go from the Centre C to Centre B, state chiefdom and central

office, where the request is filled and sent back through the same route. This is because the administrative system (described above) does not allow the purchasing of drugs at local levels, and at district levels only $10-15 Canadian dollars can be spent for each Centre C.

A new supply of drugs also depends on the funds available and the amount of money assigned to a Centre for drugs.

2.5.3 Dispensing of Drugs

Drugs are prescribed in all Centres but only in Centres C can they be dispensed. Generally, drugs are prescribed by the physician to outpatients and inpatients (if the case). In most of the cases, the nurse dispenses the drugs which are sold to patients who were prescribed in the Centres only. Prices of drugs are much lower then those in retail pharmacies, with discounts up to 75%. Public health programs (tuberculosis, rheumatic fever, leper, malaria and family planning), provide free drugs to patients entrolled in them. In some cases, women in prenatal care programs may also receive free drugs.

2.5.4 Administrative Issues

According to governmental rules and organizational patterns of S.S.A., at local levels the functions of Centres C, are to prescribe and sell drugs to collect the fees for these sales, to send them to Centre B and to request the extra drugs needed. Centres B are allowed to purchase drugs for Centres C and sometimes for their hospital when there are enough resources (funds in the budget). The manager may agree to spend money on drugs and the total amount in one month must

not exceed one twelfth of the total amount of drugs. Drugs are to be supplied from the central office unless they are not available. Then, permission is required from the statal or central office.

Although the budget is affected by the previous year's income, the initial stock of drugs at the beginning of the year is always the same. It has a total cost of $712.50 Canadian dollars ($14,550 Mexican Pesos). It was found[14] that this amount has remained unchanged since 1971. Considering that this stock is for a community from 2,500 to 10,000 inhabitants, it is rediculous to believe it is large enough for the medical problems in such communities. According to Heredia[15] only 10¢ in Canadian dollars a year ($2.00 Mexican Pesos) are spent on drugs for each person that theoretically S.S.A. should assist, while the I.M. S.S. annually spends $6.05 Canadian dollars ($125.00 Mexican Pesos) per capita. This system then represents an important barrier in the acquisition of drugs and the delivery of medical care.

2.5.5 Effects

With this situation, several effects have been detected[14] in the i) financing of centres and ii) delivery of medical care.

2.5.5.1 Financing Centres

The drug budget for centres has remained almost unchanged from its initial allocation. This has been due to the small amount of drugs sold. Few drugs are sold because they are inappropriate for the regional pathology; physicians resist prescribing them and/or the Centres are poorly utilized by the people. Price of drugs does not seem to be an issue or a barrier for the patient.

Since drugs included in the "stock" are not always the appropri-

ate drugs for the medical problems prevalent in the area, the physician often opts not to prescribe them. This provokes a lack of income from drugs which, in turn, discourages the population from seeking care in the centre. The final result being a lack of income from services.

On the other hand, those pharmaceutical products accumulate in the centres since every year the S.S.A. sends the "stock" to all centres regardless whethèr the last stock was consumed or not. It is common to find enormous numbers of dextrosa and sodium solutions, antibiotic pills such as cloramphenicol and tetracyclines; benzathine penicillin bottles, sulfonamides like sulfisoxazole and sulfadiazine tablets. Most of them have expired usage dates.

2.5.5.2 Delivery of Medical Care

In medical care, as it was described above, one of the main objectives of centres, is to provide secondary prevention - early diagnosis and prompt treatment of acute and chronic diseases or health problems. In most of the cases, given the socio-economic conditions of the communities, this is a major reason for seeking medical care or supporting a program. In secondary prevention, therapeutic treatment is the focus, what happens when a patient seeks care in Centres C? In order to answer this question, two features should be considered: the provider, in this case, the physician, and the consumer or patient.

The physician might opt:

a) to prescribe the drug available although not always the drug of choice. This might happen because there is a widespread belief that every physician-patient-interview should end with a prescription[16].

This practice may then provoke medical Iatrogenesis[17] and poor quality of prescription. Sometimes they are afraid to lose the patient and to discourage the population from seeking medical care in the health centres.

b) Not to prescribe drugs and advise the patient. This might be the best option when the natural history of a pathological process tends to solve by itself. But, in a complicated or severe case, it is necessary to administer some drugs. This study does not pretend to enhance the consumption of drugs but rather to promote a rational prescription and use of them.

c) To sell drugs he/she has acquired on his/her own despite being prohibited by S.S.A. This alternative is the most common since it represents a profitable business for the physician and encourages people to attend the centres. A study has shown[18] that in many cases these prescriptions are useless (vitamins, tonics, dextrosa solutions) but represent a good source of income to the seller.

d) To prescribe drugs and leave the patient to solve the problem of where to find them. Referals are useless in those cases because clinics A and B have no pharmacies. When referals are the options, patients are sent to private hospitals or drugstores.

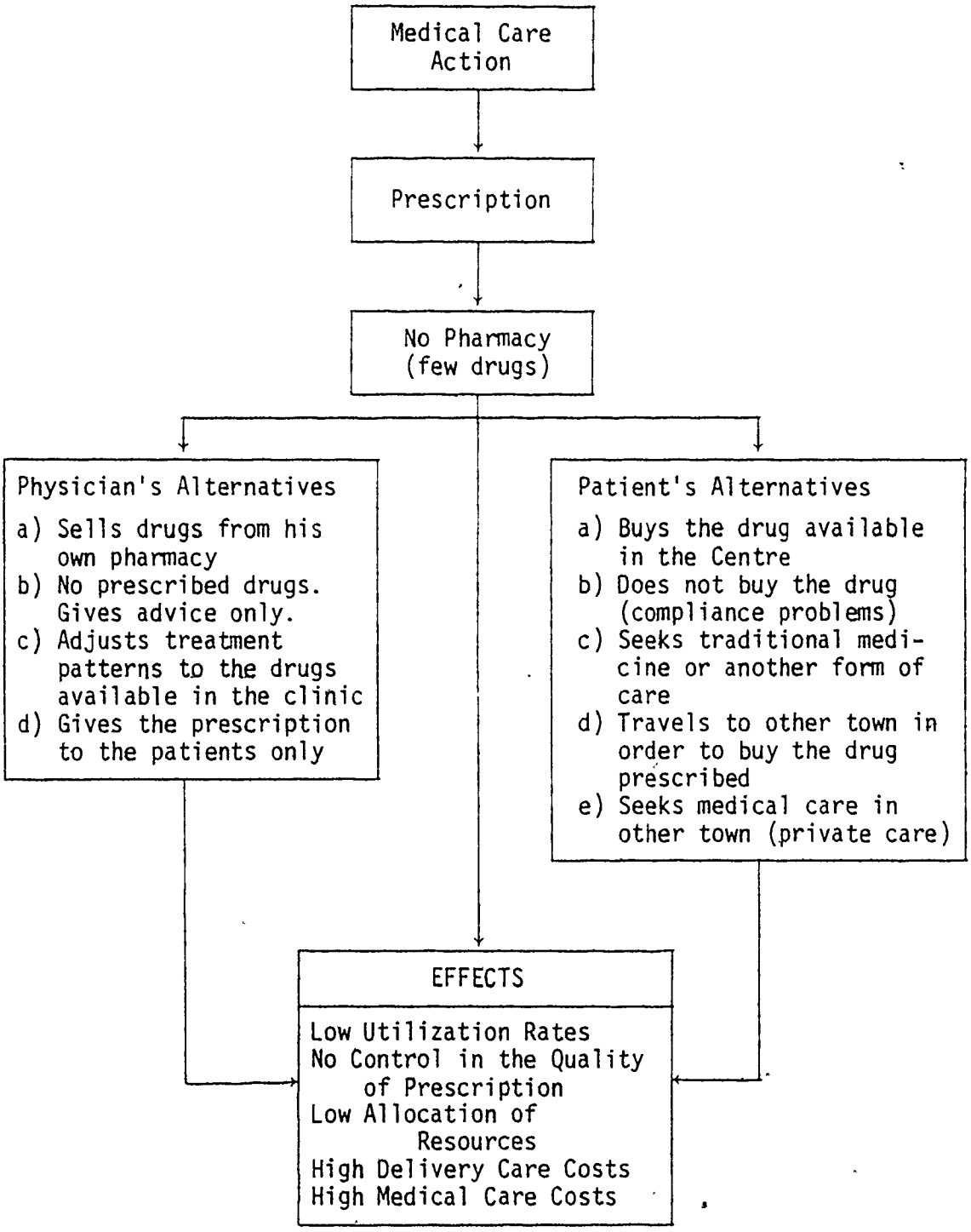
What does the patient do? He/she might also have several alternatives (Figure 2.4).

a) To buy the drug prescribed and available in the health centre unaware of its appropriateness.

b) To buy the drug from the physician's stock paying a higher

Figure 2.4

Effects in the Delivery of Medical Care in Clinics "C" Due to the Lack of Pharmaceutical Services



price despite probably not being able to afford it.

c) To seek home remedies, traditional medicine or other ways to solve the problem[19]. In some cases they use left over drugs from previous prescriptions (it is common that families store drugs without the necessary precautions or without labels).

d) To travel to the nearest city where there are drugstores. This is expensive and time consuming for the patient.

e) Aware that they will not receive complete care, patients might opt to avoid the centre and seek private medical care in the nearest city either in a medical office, health centre or drugstore (consulting the pharmacist). This provokes underutilization of the Centres C and over utilization of Centres A and B.

As a result of this situation, the Department of General, Family and Community Medicine (here after D. of G.F.C.), detected the following effects[20] in Centres C.

a) Low utilization rates of the centres from the population served.

b) Limited number of services provided. Since drugs are not available, family planning, tuberculosis, rheumatic fever, skin disease campaigns and so on, can not be carried out. Deliveries are not normally handled by the health centres.

c) Small number of cases under treatment or control. Where programs are feasible, only a limited number of cases can be enrolled due to the scarce availability of a specific drug.

d) Poor quality of prescription.

e) Low incomes from the patients which results in low allo-

cation of funds from the government.

f) Non-conformity of the staff working in those centres.

g) Inadequate provision of medical care. No solution to prevalent health problems in those communities.

h) Expensive (costly) delivery of medical care for the S.S.A.

For the patients:

a) Compliance problems (in filling the prescription).

b) Lack of encouragement to use the health centres.

c) Weak support of health programs or poor community involvement.

d) Medical care beyond the budget of the average user

e) Delay in solving these problems (time consuming when medical care and drug is not available).

CHAPTER 3

Literature Review

As might be expected, the western literature provides few studies which are directly relevant to the augementation of pharmacy services in rural Mexico. However, the literature has been reviewed primarily to determine the types of outcomes thought relevant to studies involving pharmacy services (even though they may be conducted in a hospital setting) and the methods of measurement.

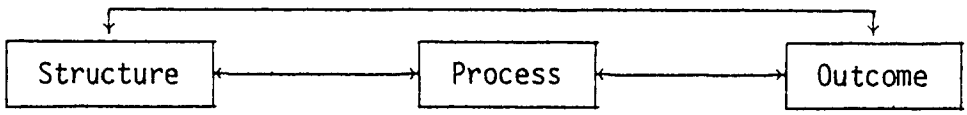
An abundance of literature has been published on various pharmaceutical services projects, over the last several years. Some reports have attempted to define pharmaceutical services, their standards, administrative management as well as their physical planning and environment[21,22,23,24].

A great deal of attention has been given in recent pharmaceutical articles to the need and potential for pharmacists to serve as professional consultants to both physicians[25] and patients in drug selection[26], patient advice[27], and therapy[28].

Certain articles are concerned with the cost of pharmaceutical services[29], where centralized and decentralized unit dose systems[30] are compared. Also comparisons have been done with traditional systems of dispensing drugs[31]. All those articles have demonstrated that innovative pharmaceutical services have increased the level of patient safety and patient control with significant decreased costs[32]. How-

ever, very few articles have been published regarding the evaluation of pharmaceutical services as a component of a comprehensive medical care system. In this regard, Donabedian[33] provides a valuable framework for general evaluations of medical care programs. This framework may be used to determine the appropriatness and quality of the pharmaceutical services.

The provision of health care services and the services themselves can be represented conceptually by the model proposed by Donabedian. This model is diagramatically represented as follows:



These three components are conceptually interelated; as one changes, so do the others. The structural component consists of the physical and operational instrumentalities necessary for providing the service. The process component involves the actual provision of services using the structural component. The outcome component represents the overall objectives or results of the episode of care provided to the patient.

From this description of the model, it can be said that the structure, process and outcome of the pharmaceutical patient care is, actually, part of the process of medical care. He also considers "the entire spectrum of activities or events as a chain in which each link is an outcome of a previous link and a mean to the one that follows".

Instead of measuring global states of health and well being, one can look at each link in the chain and measure the short-term outcomes or procedural endpoints with the knowledge that this outcome becomes, in turn, the process for subsequent outcomes and soon.

Following this report, some articles have appeared in the literature investigating these roles in pharmaceutical services, mainly from the economic view point. For example, McGhan, et al[34] published a paper of the basic principles for evaluating pharmaceutical services in terms of cost-benefit and cost-effectiveness analysis. The authors consider four elements in this analysis: the type of service provided, benefits/effectiveness, indicators and costs. This paper also suggests the following steps in applying a cost-benefit methodology: a) statement of objective; b) establish baseline comparison; c) establish common demoninator; d) cost determination, and e) benefit determination.

Although these authors do not develop their own analysis for evaluating the impact of a specific pharmaceutical services program, they present a valuable methodology and some examples of pharmaceutical studies. They also have base evaluation on Donabedian's principles and on Sorby's paper[35].

Sorby, et al[35] have written an interesting paper which examines the evaluation of innovative pharmacy services, specifically clinical pharmacy. They consider the major question to be answered is whether the introduction of the pharmacy program is achieving significant benefits to patients in terms of the structure, process or

the outcomes of the delivery of health care, which justify the existence of the program. They suggest the component steps of the evaluation process as shown below, for measuring benefits of clinical pharmacy services:

1) Identify the types of staff, by discipline or expertise, to be included in the evaluation team.

2) Analyze the structure of the innovative pharmacy service program with respect to its completeness and maturity.

3) Conduct a task analysis of the innovative pharmacy services program and determine the distribution of time between innovative service such as clinical services, drug distribution services and teaching services.

4) Predict how the innovative pharmacy service program may influence the process and the outcome of health care.

5) Develop the evaluation protocol.

6) Collect the data according to the experimental protocols, and analyze the results for this significance.

7) Reach decisions concerning the magnitude of the impact of clinical pharmacy services in terms of benefit to health care.

Measuring costs of the innovative pharmacy services is also examined by Sorby, et al, and a cost analysis of the clinical pharmacy program can be conducted simultaneously with the evaluation of the impact of the services on patient care.

Sorby has classified the effects on process and outcomes of innovative pharmacy services as listed below:

A) Effects on Process of Health Care:

1. Reduced frequency of prescribing of contraindicated drugs by physicians.
2. Increased rate of prospective detection of contraindicated drug combination.
3. Increased frequency of selection of "drug of choice" by physicians; and
4. Decreased rate of self-administration error of drugs by patients.

B) Effects on Outcome of Care:

1. Decreased morbidity in patient population.
2. Increased percentage of patients in therapeutic control in patient population.
3. Reduced cost of treatment component of health care delivery.
4. Reduced rate of hospitalization attributable to or potentially affected by drug therapy considerations.
5. Better use of health manpower and increased access to appropriate types of health care by patients.
6. Decreased expenditures for health care among patient population; and
7. Decreased incidence and intensity of iatrogenic disease.

Mikeal[36] based on Donabedian's model, presents a protocol for conducting studies designed to evaluate the quality of pharmaceutical services. In his paper, he suggests a "job replica on work sample analysis" as a prospective study to evaluate the components of pharma-

ceutical patient care - structure process and outcome - as they relate to quality assurance of pharmaceutical services. The sampling procedure must be random or stratified-random. These kind of studies should also include previous selection of drugs and the development of the criteria standards to be utilized.

The author concludes: "such a study would be valuable in establishing a baseline which could be used in evaluating any pharmaceutical patient care quality improvement program. It would also be useful in determining the relationship between the quality of pharmaceutical patient care and medical care process on outcomes".

Another study partially based on Donabedian's model is reported by Keys, et al[37]. In this study, abstracted information from patients' chart was used to assess both, process and outcome, to determine the pharmacists' effectiveness in supplying clinical pharmacy services as well as to determine the relationship between these services and patient outcomes. The study was conducted on two medical teaching wards by randomly selecting 48 communications from 41 patients monitored by three pharmacy residents and two staff pharmacists. Process was defined as a communication's potential for benefiting the patient. Measurement of the process included the content of a communication and its relevance to the patient (process was considered as a predictor variable). Outcome was defined as a procedural end point of the communication in question and measured the benefit or improvement to the patient based on change in a symptom or sign (outcome was considered a criterion variable). Results indicated a moderate correlation, signi-

ficant at 0.01 level, between intermediate outcomes and the clinical pharmacy care process. Outcome measurement indicated however, that only 14.5% of the communcations were judged as actually benefiting the patient while 25% were judged as probably benefiting the patient.

There have been other papers such as Young's paper[25] where the methodology of a prospective study is used to determine a discriminant function for selecting patients who should be monitored by pharmacists; to validate the discriminant function and to estimate the number of medical pharmacists required to selectively monitor the patient population in study.

The methodology of "before versus after studies" is used in a project reported by Rabin, et al[38]. This project was designed to compare the study group's use of health services before and after enrollement of a medicaid population in an Health Maintenance Organization. Comparisons of the study and control groups are reported in the following areas: rates of drug prescriptions; physician visit rates; prescription by specific drugs and therapeutic category; per capita costs of prescription drugs and quality of drug prescribing. This study used volunteered population as the study group.

Consumers' perception[39,40] has also been studied as a way to measure patient's satisfaction, where pharmacists are assessed rather than pharmaceutical services.

Considering drugs as the essential part of pharmaceutical services, researchers have evaluated the use of drugs from two groups: the health worker (non-physicians) and the physician. In the first

group, articles have been published considering the role of the pharmacist in selecting the appropriate drug[28,37,41], the nurse's or health workers' criteria[42,43]. However, in most of these articles, use of drugs has been evaluated as part of a medical care program since the objectives have been different from those to evaluate pharmaceutical services as unique components.

In the second group, quality of prescription, as a measure of quality of care programs, considering physician's use of drugs, has been studied at different levels and with different health problems[41, 44,45,46]. The methodology suggested in most of these papers is the use of Randomized Controlled Trials to prospective studies using direct observation or abstracted information from patients charts. Assessments have been done by using indicator conditions or standard criteria previously selected.

On the other hand, patients as consumers of drugs have been studied by Rabin, et al[47] and Stolley[48] among other authors. They have identified some patterns of consumption of drugs.

Despite all this literature published, few papers (cited earlier) deal with the evaluation of pharmaceutical services as part of the medical care system. Furthermore, in the literature review of the last 12 years, none of the articles available evaluates or measures an actual project of introducing pharmaceutical services nor identifying their contribution in the delivery of medical care.

However, the literature has:

a) provided some insight into the types of outcomes thought

to be relevant to the evaluation of pharmaceutical services by other authors,

b) provided some information about the alternative methods of measurement of for example quality of prescription.

Some of these will be incorporated into the design of this study.

CHAPTER 4

Research Proposal

4.1 Background Information

4.1.1 Morelos Project

In order to contribute to government's efforts to solve the basic needs of health care in rural areas, The National University of Mexico (U.N.A.M.) through the Department of General, Family and Community Medicine (D.M.G.F.C.), established a research program in 2 rural towns in the State of Morelos in 1973[49]. This program's major goals were to define main health needs and to design a medical care system that would fit in with the available resources in those towns.

The first part of this program was the prospective study of morbidity and the socio-economic and cultural profile of those towns[50].

In 1974, the second phase consisted of the implementation of the available medical care facilities, a Centre C of S.S.A. in each community. Simlutaneously the communities were re-organized to promote their participation in health tasks. This phase also included the design of a self-financing system based on the re-investment of patient's fees generated from the consumption of services provided in these Centres C. This action led to the design of a list of basic drugs[51] based on the morbidity detected in the prospective study and the morbidity recorded in the centres. The results reported[52] in 1975 were very satisfactory. Geographical and population converage in-

creased as well as daily attendance of the centres. Other services such as family planning and skin diseases control were added. Table 4.1 shows the results of this program. Compared to the old system, the new system resulted in an increase in daily attendance, a 400% increase in centre incomes from patient fees and 308.2% from selling of drugs. However, in this program pharmaceutical services were not implemented as such. Actions in this regard were limited to the design of the list of basic drugs and a record system of controlling them plus a continuous supply of drugs financed by the U.N.A.M. and patient's fees. All the logistic support was provided by the D.M.G.F.C. The main component in this program was the community participation and financing model. They found that modifications in the traditional system must be done at district level rather than in isolated communities.

4.1.2 Huamantla Project

Knowing the results in Morelos (previous project described above) the S.S.A. offered the D.M.G.F.C. the opportunity to undertake a study involving a whole health district in the state of Tlaxcala. The district chosen was Huamantla in Tlaxcala, named after the main city where the headquarters are located. It consisted of a Centre B, 10 Centres C (at the beginning and currently 11), and 5 health houses. This district had a population of about 80,000 people in 1970[53], distributed in 11 municipalities.

It was chosen as a pilot program for a number of reasons: it is close to Mexico City and easily accessible. Although close to Mexico

Table 4.1

Services Provided in the Health Centre "C" S.S.A. in Totolapan, Morelos
1972-1974

Source	1972	1973	1974	Improvement from 1973 (%)
Total number of :				
Visits	2328	2532	4408	74.9
Daily Attendance Average[1]	8.9	9.7	16.9	74.2
Programs*:				
Tuberculosis	18	21	35	66.6
Rehumatic Fever	2	4	12	20.0
Skin Diseases	0	0	126	-
Prenatal Care	23	32	152	375.0
Infant Care	48	42	48	108.5
Family Planning	0	0	24	-
Deliveries	2	4	69	162.5
Hospitalization**	4	6	82	126.6
Incomes:				
Services	5161	4196	22574	438.0
Drugs	823	1025	32612	308.2
Total	5984	5221	55186	957.0

[1] Considering weekdays only (261 days)

* Total number of patients seen for the first time

** Total number of patients entering to the hospital

Source: Rodriquez, D. et al. Primary Care Program in Two Communities of Morelos, Mexico, U.N.A.M., 1975
Yanez, L. Annual Report of Social Service in Totolapan, Morelos, Fac. of Med. (Thesis), U.N.A.M. Mexico, 1975.

City, Huamantla District still has rural municipalities which are isolated and economically depressed villages that are representative of conditions in the rural areas of the country as a whole. Also, like the rest of the health districts in Mexico, it had the same administrative procedures described before with the same budget restrictions. Its centres were also equipped equivalently to other centres and received the same kind and amount of drugs. The district had limited funds and the U.N.A.M. was in a position to complement these funds.

By establishing a collaborative study with S.S.A. in 1975, the U.N.A.M. started working on the profile of that district to determine needs relating to health services in 10 rural centres and to collect data describing health resources available in the district.

This program had as a main goal[20] to provide primary medical care to the population in that district by emphasizing preventive activities. Its educational goal was to promote, among social service medical students, the acquisition of knowledge and medical skills to identify and solve in a scientific and humanistic way, individual and community health problems in rural areas. Thirdly, it attempted to involve medical schools in the delivery of medical care in rural areas.

This program has included three stages: the first was carried out from 1975 to 1976 and consisted of the planning, design and implementation of the program; a diagnostic health survey of the district, the restoration of the medical units and organization of the local medical care system. The second stage from 1977 to 1979 was focused on the introduction of a partial self-financing decentralized admini-

strative model. It also introduced a rudimentary pharmacy service at district level with a regular supply of drugs to Centres C (or the local level) and elaborated the analysis of services provided during this study and before. The third stage will be constituted by the introduction of organized pharmaceutical services based on a decentralized administrative model. Simultaneously and related to these stages, an educational program for medical students in that district has been carried out. Students were selected on the basis of grades to participate as physicians in these centres.

During this five-year-period (1975-1980), all episodes of sickness presented to the Centres C have been summarized and coded for analysis. The diagnostic code used for recording morbidity is based on a special classification compiled by the D.M.G.F.C.[54]. It is an adjustment of the I.C.D.A.-8 and the I.C.H.P.P.C. from WONCA in 1976. It allows specific reference to some of the diagnoses that are common in Huamantla District. This list allows 98 diagnoses grouped in 17 separated categories (according to I.C.A.), that are employed in the analysis of the morbidity (see Appendix A).

In regard to pharmaceutical services, in 1977 a stockroom was established in the Centre B of Huamantla in order to provide medicines in monthly stocks to Centres C. It was financed at the beginning by a grant from U.N.A.M., a contribution from P.I.D.E.R. (Program of Investments for the Rural Development) and an extra supply of drugs from S.S.A.[14]. In 1977, 50% of the incomes generated from patients fees and funds allocated in the budget for this purpose were re-invested in the purchase of drugs.

A new list of basic drugs was designed, based on the previous list used in Morelos and increased to meet the needs and pathological patterns in Huamantla. Useless drugs were retired from the centres. A system to buy, store and distribute drugs were established. Physicians were selected, trained and supervised constantly.

As a result of all these actions, the utilization patterns in terms of number of consultees provided/number of patients seen showed substantial changes: in 1974 only 3,389 consultations were given, meanwhile in 1975[1] there were 5,601 and 11,948 in 1976[2]. They represented increases in 65% and 113.3% respectively. Other changes were in the place where the service is provided. While in 1974 only 18.0% of the total services provided in the health district were in Centres C as compared with A and B Centres, it was 55% in 1975 and 74.3% in 1976 and 1977. Thus the problems are treated at the local level, where they are appearing. Similar outcomes happened with deliveries, in 1974 the Centre B assisted 99.3% of these, in 1976 only 83% occurred in Centre B and 25% in 1978 in contrast to Centres C which delivered 17% and 74.9% of babies(55) in the same years.

The proportional distribution of total patients' visits according to medical care facility has been constant in the other three districts of Tlaxcala during the study period. Centres B delivered 78% of the Services and Centres C only 22% of them. This distribution was similar in the Huamanlta District in 1974 and 1975. In the subse-

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[1] Year in which there were no modifications in the administrative nor clinical systems. Only physicians were supervised.

[2] The actual start of the program involving some administrative modifications and a short supply of drugs.

quent years, those figures were modified in such a way that, in 1976 Centre B of Huamanlta provided 65% of the total medical services and 55% in 1977, meanwhile Centres C provided 35 and 45% respectively. It shows that in the rest of the state, medical care is provided mainly in secondary care units (Centres B) instead of in primary care units, Centres C, according to what it is expected.

The availability of funds allowed the purchase of a large amount of drugs. Authors assumed that this manoeuvre resulted in time and money savings for the patient who could get the drugs at the health centre without travelling far. For instance, in 1978, 94.7% of the patients who received prescription, received the drugs in the health Centres C[14]. Previous data from the before period are unavailable, however, some analysis can be made: the traditional formulary gives about 23% of the treatments to the average population seen in the health centres (regardless appropriateness), but, the same formulary would provide treatment to 2% of the increased population in the Huamantla District!

Income from patient's fees were also modified importantly in Centres C, where: total incomes were $19,688 (Mexican Pesos) in 1974 and 51,956 and 165,255 in 1975 and 1976 respectively. Considering that prices had kept practically constant, it means that Centres C have increased their volume of visits and, potentially, coverage[56].

The incomes from drugs sold in the Centres C were 25% in 1975 and varied from 49 to 65% of their total income in 1976 to 1978. The absolute figures were 13.4/1000 in 1975, 81.6/1000 in 1976, and

139.5/1000 in 1977, which represent increases of 509% in 1976[57] and 941% in 1977, over the 1975 figures.

The recuperations against investments rates in drugs were 0.24 in 1975; 0.58 in 1976; 0.56 in 1977 and 0.85 in 1978[14]. Also, comparing Huamantla with the rest of the statal districts in Tlaxcala, its Centres C had an annual average income during the study period of $19,000 for services provided and $15,000 for drugs, against 6,000 and 3,000 respectively in the rest of the state[56]. It means that the utilization increased in Huamantla while in the other districts, remained unchanged.

In general terms, the results suggest that the program has caused a decrease in the total cost of a consultation and has saved the community population from having to go long distances to the city drugstore, where they would be charged higher prices. It has also resulted in an increase in the services provided as well as in the incomes of centres and hence a better self-financing system by better allocation of resources. Appendix B summarizes data from Huamantla.

The authors of this program[20,57,58] suggest that the improvement observed in the sanitary district of Huamantla, is attributable to the introduction of administrative decentralization, the introduction of a list of basic drugs; the allocation of more resources, and a continuous supervision and assessment of selected and trained physicians in social service.

Further studies are needed since this program, as well as the Morelos Project, were designed to meet other health needs. In those

projects, pharmaeutical services were part of a whole system. A model that allows the detection of 'true' effects of introducing pharmaceutical services, must be designed in order to evaluate their separate component in the delivery of primary medical care in rural communities and to convince decision makers to change policies to allow investment in these pharmaceutical services.

4.2 Design Proposed

4.2.1 Justification

One of the main tasks of modern medicine in the delivery of primary medical care, either in urban or rural areas of developed or developing countries is the restoration of health through therapeutic means. These therapeutic means might be surgical interventions or the prescription of drugs.

In primary care, the most common therapeutic process is the use of drugs. They are easier to manage, cheaper, less risky and more acceptable to the people.

In Mexico City, a household survey[15] showed that the per capita expenditure in drugs was $127.00 per year. Another study[18] reported that 70.3% of poor families interviewed, presented one or more events of illness among the members of the family in a month period. Ninety-two percent used pharmacological products as a main therapeutic resource. Authors report that both figures increase when referred to rural areas. However most of the drugs consumed were considered to relieve symptoms rather than have a therapeutic action. It

can be concluded that with the current available resources in S.S.A., community needs cannot be met.

Drugs are the cornerstone in the delivery of medical care. This is why when comprehensive medical care is offered to a community it must include an adequate system to provide the appropriate and necessary drugs and to maintain a good flow of them. In other words, it should include a feasible and functional pharmacy service.

If the objective, according to present governmental policies, is to provide cheap and appropriate drugs in a sufficient amount[59], to most of the population, this objective must be achieved through optimal utilization of available resources; the restructuring of the administrative system and the introduction of a national list of basic drugs that could cover the health needs in rural populations. The introduction of the formulary of basic drugs alone is meaningless in this situation. It should be accompanied by the implimentation of an adequate and economically feasible system to acquire, store, distribute and sell the pharmaceutical products that could promote a rational prescription of drugs by providing reliable scientific information to physicians.

It is important to make an accurate and reliable diagnosis of the medical care needs in rural Mexico in order to promote modifications in the patterns of public expenditure and, gradually, re-orient the demand for drugs.

This study intends to contribute to the efforts of S.S.A. - U.N.A.M. programs to provide comprehensive medical care in rural communities. The focus of this study is the introduction of pharmaceuti-

cal services in health districts of Tlaxcala, in order to analyse their effects in the delivery of primary medical care.

The reasons for approaching this problem at this stage are:

a) There is an ongoing program in the Health Distrcit of Huamanlta, Tlaxcala. This program has detected the lack of pharmaceutical servcies as a major problem in providing comprehensive medical care.

b) Authorities have given researchers the opportunity to extend this program to the whole Province or State of Tlaxcala.

c) There are financial resources available from U.N.A.M. and S.S.A., to implement a program including pharmaceutical services.

d) Given the experience in Huamanlta District, there is an agreement between U.N.A.M. and S.S.S.A. to modify the administrative system to allow the utilization of Centre's incomes at district level.

e) There is an increasing interest from the government and from U.N.A.M. to provide an adequate supply of drugs in those communities where the cost of medical care is high, due to the lack of resources and the inaccessibility.

f) The government and U.N.A.M. are increasingly interested in studying and analysing data generated from these communities for decision making.

4.2.2 Objectives

a) To establish pharmaceutical servies in rural communities in order to:

i) improve the quality of care,

ii) promote a rational consumption of drugs,

iii) increase utilization rates of Centres C.

b) To analyse the impact of this intervention in terms of:

i) quality of prescription,

ii) compliance,

iii) utilization,

iv) costs,

v) satisfaction.

c) To find an economical and feasible way to provide pharmaceutical products to Centres C in rural areas.

d) To collect data, to evaluate whether it is worthwhile, to spend more money and efforts in the promotion of pharmaceutical services in rural Centres C.

This proposal does not attempt:

a) to assess the quality of a given list of basic drugs,

b) to study efficacy of treatments,

c) to assess medical knowledge and skills of medical students involved in this project. Rather, it will compare two sets of health Centres C of S.S.A. with and without pharmaceutical services as a whole package that includes the administrative system of allocating resources, the list of basic drugs and a system to supply them.

This proposal attempts to answer the following research questions:

4.3 Research Questions

1. Does a pharmaceutical component in those centres lead to a more effective and efficient delivery of medical care than the tradi-

tional system does in terms of:

a) quality of prescription?

b) compliance?

c) patient and doctor satisfaction?

d) costs, for the consumer and the provider?

2. Does the inclusion of pharmacy services in Community Health Centres in Mexican rural areas improve the utilization rates of those centres and increase the variety of services available?

In order to answer these questions, a randomized controlled trial (R.C.T.) is proposed.

4.4 Brief Overview of Design

In the remaining section of this chapter we will describe a randomized controlled trial to answer these questions. In summary, the study will be conducted in the remaining three uncontaminated health districts in the State of Tlaxcala. One health district will be randomly selected to receive the pharmaceutical service intervention; the two remaining will form the control group. After one year the two groups will be compared in terms of quality of prescription (measured from chart review), compliance (prescription filling rate), satisfaction of patients and health care professionals (by questionnaire); utilization and costs. Since the last two outcomes rely on routinely collected data, we can compare before and after changes between experimental and control groups. No before data will be available for the other measures and so a simple comparison of post intervention data will be done.

In addition to allocating districts at random to experimental

and control groups, medical students entering for rural service will be randomly allocated to health centres within the three districts. Individual students factors (e.g. academic performance, urban/rural background), and community factors (e.g. proportion of wage earners) will be considered as potential covariates in a secondary analysis.

This study will take one and one half years to conduct including a three month pretest period, when study measurement instruments will be refined, and a year of intervention.

The components of this design will be described in detail now.

4.5 Study Site

The study site proposed for this project is the State of Tlaxcala, Mexico. The reasons for selecting this state are outlined below.

4.5.1 Justification

a) Since 1975, the D.M.G.F.C. in coordination with the S.S.A., has been developing a study in the Huamantla District (District II of Tlaxcala), and has collected data from Tlaxcala. This study is viewed as another stage of that project, in an area very familiar to the researchers.

b) The administrative system and budget management of the health services in that state have been modified[60] and are susceptible to the changes needed to allow a more rational utilization of its budget and therefore, the implementation of pharmaceutical services and a continuous supply of drugs.

c) Tlaxcala is one of the poorest states in Mexico and its needs are of utmost importance for the Mexican government.

d) Tlaxcala is located in Central Mexico very close (240 km) to Mexico City which allows an easy monitoring and supervising.

e) Its health care system and needs are very similar to most of the rest of the states. Therefore, it might be considered representative of the rural Mexican health care system and conclusions generated from this study may be generalizable.

f) There is a government - S.S.A. - U.N.A.M. agreement to undertake this study in this location.

4.5.2 Geographical and Socio-Economic Considerations

Tlaxcala is the smallest state of Mexico with only 3,914.48 square kilometers and is one of the poorest states (after Ooxaca and Quintana Roo) because of the condition of its soil and the lack of water. It is bounded in the North, East and South by Puebla State and Mexico State in the West. Hidalgo State borders it in the North-West. Tlaxcala's main geographical features are "The Malintzin", an inactive volcano of 4,461 meters altitude; the Zahuapan River and part of the "Sierra de Puebla" a mountain chain in the North-West (Figure 4.1). Its climate is mild year-round with some cold periods during the Winter and little precipitation in Summer. It produces corn, beans and wheat. It has a new growing industrial area. Bull raising, for bull fights, is one of its most important sources of income. Most of the population are peasants although they are becoming industrial workers. It results in a high growth population but also in a high

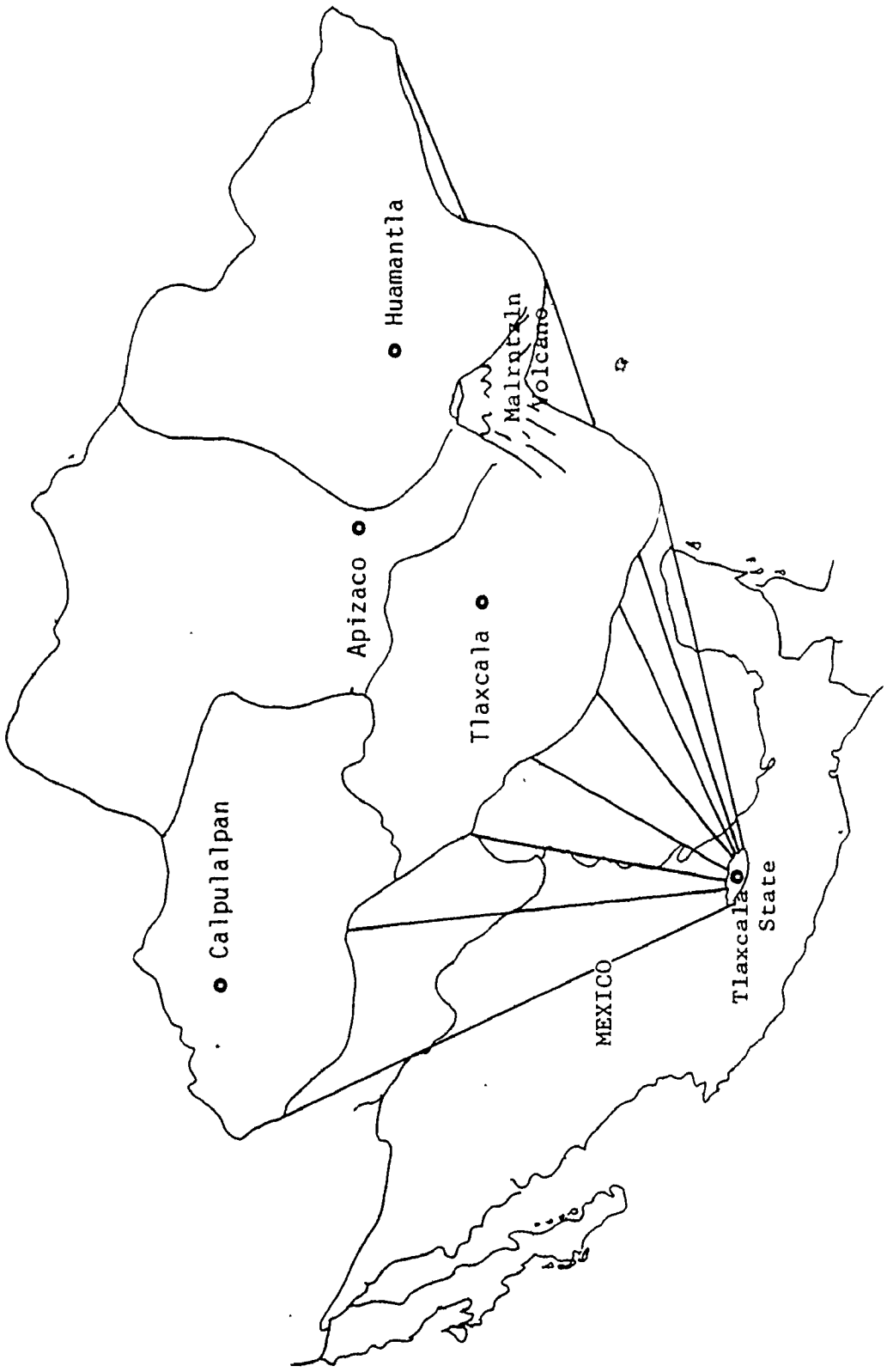


Figure 4.1

Map of Tlaxcala State

migration.

At the present there are 50.76% males and 49.2% females. From the total population, 47.0% are under 15 years old and 25.3% of the population are economically active from this 43.5% are peasants. Seventy-six-point-seven percent of the total population over five years are literate[61]. See Table 4.2 in which main demographic features are depicted.

4.5.3 Health Status

In regard to health status, its morbidity and mortality follow similar patterns of those for the general morbidity/mortality rates in Mexico, with a predominant number of infectious diseases of the digestive and respiratory tract (Table 4.3). Infant mortality rate is higher and in some places reaches up to 150/1000[61].

4.5.4 Health Care Facilities

The health care system has the same structure as the rest of the states, it includes private practices, I.M.S.S. and I.S.S.S.T.E. clinics plus the S.S.A. system of "Coordinated Services of Public Health in the State of Tlaxcala". Considering that S.S.A. plays the most important role in the rural health care, just this institution will be considered in this study.

The state of Tlaxcala is divided in four health districts or sanitary jurisdictions named: District I - Tlaxcala; District II - Huamantla; District III - Apizaco; and District IV - Calpulalpan. Each district is named after the main city where the headquarters (Centre B) is located. The exception is Tlaxcala which has a Centre A. These

Table 4.2

Main Demographic Features of the Health Districts of Tlaxcala State, 1972

District	Population	Natality Rate/1000	General Mortality Rate/1000	Infant Mortality *	Sup. in Km^2	Density	Alphabet %	Econom. Active Pop. %
Tlaxcala (I)	215,374	49.7	10.8	85.4	814.7	264.4	74.6	39.2
Huamantla (II)	82,334	66.4	16.8	102.4	1162.6	71.5	76.4	46.7
Apizaco (III)	99,075	41.8	10.3	108.0	1108.4	89.4	57.0	41.18
Calpulalpan (IV)	42,916	57.1	14.2	105.6	276.2	155.4	51.7	47.0
State	439,699	54.0	14.0	105.9	3361.9	130.8	76.7	43.2

* Rate per 1000 births alive

Source: Planning Departments, Annual Report; S.C.S.P.E.T., S.S.A. - 1972

Table 4.3

Ten Main Causes of General Mortality, According to Health District in Tlaxcala State, Mexico, 1972
(Rates ×100,000 Population)

Cause (According to ICD, List A of 150 Causes for Tabulation of Morbidity and Mortality; WHO - 1965)	Health District					
	Apizaco		Calpulalpan		Tlaxcala	
	Order	Rate	Order	Rate	Order	Rate
Other Pneumonias (A-92)	1	35.3	7	62.7	1	297.8
Symptoms and Other Ill-Defined Conditions (A-137)	2	28.2	8	62.7	4	48.3
Measles (A-25)	3	14.1				
Whooping Cough (A-16)	4	7.0				
Other Forms of Heart Diseases (A-84)	5	7.0	6	68.9	3	98.2
Influenza (A-90)	6	7.0				
Bronchitis, Emphysema and Athsma (A-93)	7	7.0				
Entenitis and Other Diarroeal Diseases (A-5)	8	3.5	1	175.6	2	105.2
Malignant Neoplasma of Prostate (A-57)	9	3.5				
Intestinal Obstruction and Hernia (A-101)	10	3.5				
Acute Respiratory Infections (A-89)			2	119.1	5	30.6
Injury Undetermined Whether Accidentally or Purposely Infected (AE-149)			3	100.3		
Corrhosis of Liver (A-102)			5	75.2		
Other Causes of Perinatal Morbidity and Mortality (A-135)			4	81.5	7	30.6
Cerebro-Vascular Disease (A-85)			9	55.4	10	21.9
Congenital Anomalies of Heart (A-127)			10	37.6		
Other Diseases of Digestive System (A-104)					6	30.6
Senility Without Mention of Psicosis					8	30.6
Avitaminoses and Other Nutritional Deficiency (A-65)					9	26.3

Source: Annual Reports, S.S.A., S.C.S.P.E.T., 1972

districts have 15, 11, 9, 8 Centres C respectively (Table 4.4 and Figure 4.2).

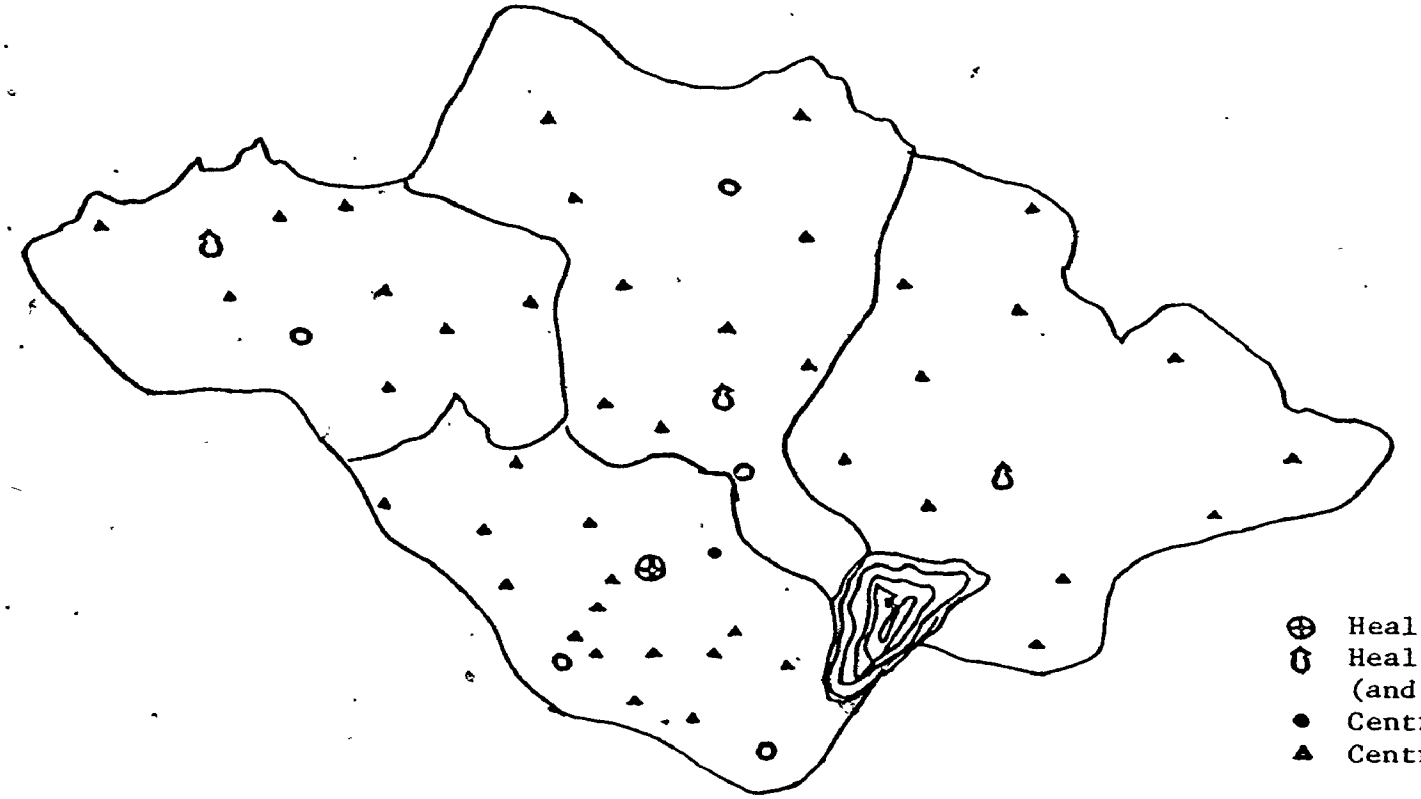
As in the rest of the country, Centre A is an urban centre that provides primary and specialized medical care to out-patients There are 12 Centres B, four of them have an attached hospital. Three of those four centres function as headquarters (Huamantla, Apizaco and Calpulalpan). The rest function as Centres C. There are 43 Centres C. Centres B are open from Monday to Friday from 9 to 3 p.m., hospitals work 24 hours a day year round. Centres C provide primary medical care and nursing aids during day hours from Monday to Friday. Besides, they have a 24 hours emergency care year round. The services provided in these centres are the same listed in Section 2.3. However, in this state (as in most of the states) the delivery of those services has some restrictions due to a) the lack of compliance from the medical students because of poor incentive in medical practice, b) scarce resources mainly diagnostic and therapeutic, c) ignorance of the people about the services and health care facilities at local level, d) poor transport facilities, e) lack of supervision.

4.5.5 Pharmaceutical Services

With the exception of Huamantla, the three remaining districts have the rudimentary resources described earlier. These districts receive the same kind of stock for physicians in social service at the beginning of the year. In Huamantla, Centres B have been supplied with a new list of basic drugs (described in the Manoeuvre section) since 1977. This district has also received a contribution of drugs from the

Figure 4.2

Distribution of Health Centres in Tlaxcala State, Mexico



Source: General Direction of Coordinated Services, S.S.A., 1979

Table 4.4

Health Resources in Tlaxcala State, S.S.A. - 1978

Health District	Hosp. Beds	Medical Care Units						Physicians and Nurses						
		Health Centres			Health Houses	Mobil Units	Total	GPFD & Special	Medical Students	Dentists		General Nurses	Students	Auxillary	Total
		A	B	C						Grad	Students				
Tlaxcala	21	1	3	15	3	1	23	10	17	2	2	18	3	15	67
Huamantla	60	-	1	11	5	-	16	4	17	1	1	1	6	19	49
Aprizaco	74	-	3	9	4	-	16	6	13	1	1	4	1	13	39
Calpulalpan		-	2	8	-	-	10	3	11	-	-	6	1	11	32
Total	257	1	9	43	12	1	65	23	58	4	4	29	11	58	187

Source: Statal Monography, S.S.A., D.G.S.C.E.T., 1978

U.N.A.M. and from the National Program of Investments in Rural Areas (P.I.D.E.R.).

4.5.6 Administrative System

The current administrative system in Tlaxcala, Apizaco and Calpulalpan is the same system described in Chapter 2 (2.4). Huamantla has a different system since 1977[60]. At the first stage of the research described in Section 4.2.1, the changes in the administration of that district were the utilization of 50% of the patient's fees to restore the centres and to buy drugs[20]. At the present, the total income from the selling of drugs is reinvested in acquiring them and in the maintenance of the centres.

4.6 Design

4.6.1 Selection of Design

Since the objective of this study is to measure the effect of the introduction of pharmaceutical service in a Province, a controlled trial is proposed. The opportunity to perform random allocation of pharmaceutical services exists. Hence a Randomized Controlled Trial is the best alternative, and in methdological terms, the best design.

Communities in which the health centres are located, may differ perceptibly in the socio-economic factors, in the services provided, in the physician's working and so on. Innumerable uncontrolled causes may influence the results. In such a case, randomization is:

a) the best way of reducing the likelihood that uncontrolled causes will confound the results, it also,

b) provides the basis for the use of statistical tests.

4.6.2 Unit of Randomization

In this study, four units of randomization can be identified: a) patients, b) physicians, c) centres, and d) districts.

4.6.2.1 Patients

For some studies the best unit of randomization might be patients; however, in this study its not applicable, since the allocation of patients to physicians, centres or districts is not feasible nor appropriate.

The patient would be the appropriate unit of randomization if the intervention were allocated to individual patients. Here, the intervention is applied to the centre as a whole (either receiving or not receiving improved pharmacy services). Randomization by individual patients is thus not considered.

4.6.2.2 Physicians (Medical Students)

One could argue that the main influence on many of the chosen outcome measures is the medical student resident in the centre. Thus although allocation to receive the intervention will be based on geographical considerations (see next section), we feel that it is prudent to first randomly allocate medical students to centres to help control factors associated with the resident health professional. This is certainly feasible given the oranizing role of U.N.A.M. in the rural medical service program.

Physicians from the Medical School, U.N.A.M., will be selected on a grade basis. From the total number of applicants to this project,

a rough approximation of 70 medical students, the required number will be selected according to eligibility criteria. Physicians selected will be randomly allocated to centres within districts.

4.6.2.3 Health Centre or Health District

The Province of Tlaxcala, which is the study site, has four health districts (see Study Site). Each district is composed of 8 to 15 Health Centres C, giving a total of 43. A group of these health centres will receive the pharmaceutical package. According to the administrative structure of the health care system in the Province of Tlaxcala, two units of study can be identified: the health centre and the district. This gives two alternatives for randomization at a) health centre level or b) at district level.

A) Health Centre Level: The best approach would be randomization at the centre level by randomly allocating half of the centres (≃ 20) to the treatment (experimental) group and the other half of the centres as a control group.

Treatment group centres would receive up graded pharmaceutical services while the control group will continue working in the traditional system (i.e., receiving only the annual supply of drugs, plus the record system required).

The advantages of this design are that :

i) maximal power is achieved by equal numbers of units in both groups: treatment and control.

ii) That a large number of small population centres randomly allocated provides more protection against confounding than randomly allocating, a few large population groups. However, this approach, the best in

methodological terms cannot be implemented for the following reasons:

a) Logistic: unacceptability to health authorities because each health district must be homogeneous in its administrative procedure, management and monitoring of its centres. This means that a health district cannot have treatment and control centres at the same time.

b) Possible Contamination: 1. Due to the proximity of centres, people can travel easily from town to town in order to get their prescription filled or seek medical care where drugs are available (in this case to the "treatment" centres). It may mask the "true" effects.

c) Physicians working in the "control" group might refer their patients to the nearest "treatment" centre.

Bearing in mind these practical difficulties, the alternative is to randomize districts and to study these as units and their centres as sub-units.

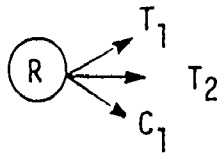
B) Contamination in the Huamantla District: Given that we will randomize at the level of district, several options are available. However, as it has been pointed out before, the Huamantla District has already been under study. Considering this point, important in validating the analysis, a question arises here as to what we can do with this contaminated district? There are two alternatives: 1) to include Huamantla in the randomization, or 2) to exclude it. These alternatives are described below:

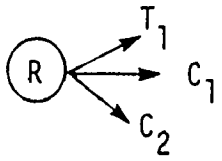
1. To include Huamantla as a treatment district and randomly allocate one more district to the treatment group. The remaining two

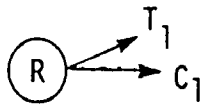
districts will be the control groups. This gives an equal number of units of study in both the treatment and control groups. The main disadvantage is that there will be a selection bias since one health district was already contaminated and its responses in regard to drugs consumption and utilization rates of its health centres are known to be above the rest of the districts. It might be argued that by using its initially higher rates as the before data, subsequent changes would be comparable. However, this district has been under study since 1975 and has received a continuous supply of drugs for over two years. The new intervention represents only a small additional upgrading of pharmacy services compared to current Huamantla procedures. Thus additional improvements in outcomes would be at best small.

2. To exclude Huamantla and continue studying it as a separated extra component of pharmacy package for the provision of drugs. A simultaneous before-after study should be performed in this district, using the results of the previous study as basic data plus the new data required in this proposal in order to make meaningful comparisons with itself and the other districts.

Based on the above considerations, it was decided not to include Huamantla in the main study but to continue to monitor the effect of the provision of pharmaceutical services in this district. Having made this decision we are now faced with the problem of how to allocate the remaining three districts between treatment and control. The three options are:

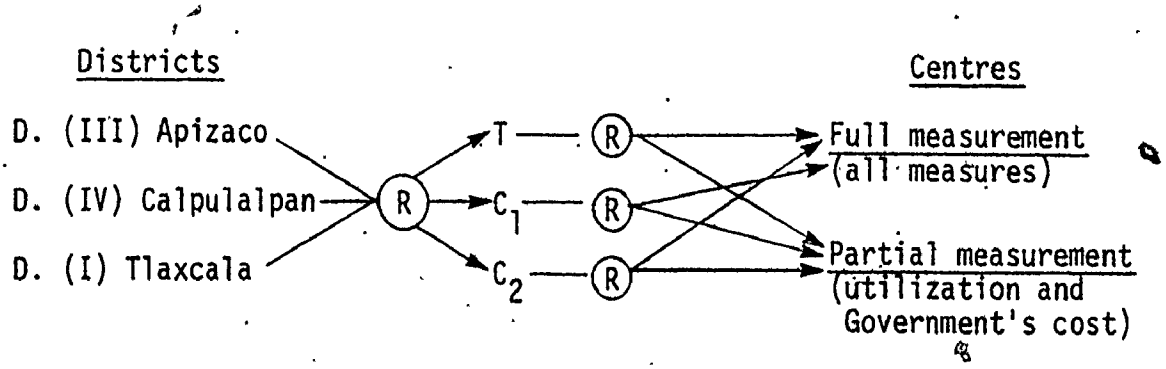
1. 

2. 

3. 

In general, designs 1 and 2 have an inbuilt advantage over 3, in that they have the inherent ability to provide some information on between district variability. Granted the amount of information is small but they do offer the chance to detect extra sources of variation not explainable by centre to centre variation and thus address the issue that "district" itself might be a confounder. Design 1 was ultimately ruled out on the grounds that this would require three "treated" districts and governmental resources could not accommodate this number. For these reasons, design 2 has been selected.

Because of scarce study resource, it will be impossible to study all centres for some of the more intricate outcome measures (quality of prescription, compliance, etc.). Thus, where necessary, a secondary random selection of centres within districts will be adopted. The details of this secondary selection will be discussed later in this proposal. However, in the context of the overall design, the following diagram summarises the research strategy,



4.6.3 Inclusion and Exclusion Criteria

4.6.3.1 Districts

The most important exclusion criteria that arises in this proposal is the contamination factor, on this basis, Huamantla District has already been excluded. The remaining districts will be included since they seem to be very alike in geographical, economical and cultural patterns as it is shown in Table 4.5, when refered to rural population where health Centres C are located.

4.6.3.2 Health Centres

Health Centres eligible are only those centres located within the domain of the three health districts selected. Centres should be or function as a Centre C. They should be managed by medical students in social service and be functioning at least 5 years. New centres might behave differently because they might represent a new "attraction" to the public. Newly opened centres tend to be more sophisticated and have extra resources allocated to them. Promotion and advertising might influence utilization and consumption of drugs. Centres should not be engaged in other research projects that might influence the effects.

4.6.3.3 Physicians

All students in the sixth year of the medical school of U.N.A.M. having an average grade of eight or more, are elegible to participate in this study. It will be preferable if they are interested in community work.

4.6.3.4 Patients

All patients receiving medical care from the health centres or

Table 4.5

Demographic Indicators of Rural Population in Tlaxcala, Apizaco and Calpulalpan Health Districts, 1972

District	Population	General Mortality (1)	Infant Mortality (2)	Medical Units (3)	Physicians (3)	Natality
Tlaxcala	60,528	11.56	95.00	25	11	51.89
Apizaco	70,793	13.79	109.50	13	18	56.50
Calpulalpan	27,271	13.49	103.32	29	40	56.83

(1) Rate per 1000 inhabitants
(2) Rate per 100,000 live births
(3) Rate per 100,000 inhabitants

Source: Dept. de Planificacion y Evaluacion, S.C.S.P.E.T., S.S.A., 1973

residents living within the area under study are eligible for this project.

A general rule for patients that need to be interviewed will be that if after the random selection of patients, they or someone in their families refuse to provide information, or are unable to do so; they will be excluded for the interview.

4.7 The Manoeuvre

The manoeuvre in this study will be the introduction of pharmaceutical services in Centres C to the experimental district in Tlaxcala State.

4.7.1 Definition

In terms of this study, pharmaceutical services will be defined as, the whole system needed to acquire, store, distribute, control, and dispense the pharmaceutical products (drugs and medical supplies) specified in the list of basic drugs to be used within the facility.

This definition also includes as other functions of the pharmaceutical services, the disemination of comprehensive information about drugs and their use to the instituions staff and patients; the monitoring and assurance of quality of drug use. However, given the characteristic of this study, they will not be considered at this stage since the dissemination of drugs information might bias physician's criteria of actual prescription as well as unfairly influence quality of drug use.

Drugs used in this study will be different in the control and

experimental centres; there will be then two types of pharmaceutical services:

a) Traditional pharmaceutical services, described in Chapter 2, Section 2.5, which consists of the current administrative system and the present list of basic drugs (Table 2.2) used in health centres in S.S.A.

Given that traditional pharmaceutical services do not provide record forms, the new record system for reporting pharmaceutical activities and for controlling drugs, designed in this study, will be added to traditional services. This record system will be common for both groups, in order to have the same instrument to collect information about pharmaceutical services activities and drugs consumption.

b) The experimental pharmaceutical services consist of the new administrative system where incomes from patient's fees are re-invested in the centres (see Section 4.1.2) plus the revised list of basic drugs currently used in Huamantla District (see Appendix C) as well as the new pharmacy record system.

4.7.2 General Procedures

4.7.2.1 S.S.A. - U.N.A.M. Agreement

Since 1975, the U.N.A.M. has undertaken a study in Tlaxcala State, therefore the implementation of the present study will extend this working agreement to allow the modification of the administrative system in the experimental district; the purchasing of drugs, vehicles, furniture and medical supplies for the installation of "pharmacies" in Centres C as well as, the introduction of the record system necessary

to gather data.

S.S.A. will contribute its health care units, financial funds for drugs, vehicle, furniture, supplies and S.S.A. personnel salaries. U.N.A.M. will provide the design, monitoring of the study, and the analysis of data generated from this study.

4.7.2.2 Organization

Pharmaceutical services will depend from the Administrative and Technical Departments of S.C.S.P.E.T., S.S.A., and a researcher representative of the U.N.A.M. (D.M.G.F.C.).

At the district level, the traditional system will be represented by the manager and the district chief. In the experimental system, the pharmacist assistant along with the chief and district manager will be the coordinators. At the local level (Centres C) in both systems, the medical students will be the prescriber. The dispenser of drugs will be either the physician or the nurse, when possible.

General coordination and supervision of all centres, both experimental and control, will be U.N.A.M.'s responsibility.

In the experimental district, a central stockroom in Centre B will be established. The pharmacist assistant will be hired to be in charge of it and whose functions will be: the acquisition of drugs (purchases and bargaining when necessary), the control, storing and supplying of drugs to Centres C as well as the control of records related to his/her functions. A driver will distribute the drugs required to each centre. Monthly distribution of drugs will be based on individual centre's needs.

4.7.2.3 Purchasing of Drugs

In the control districts, no initial purchase of drugs will be necessary, since the traditional system includes the provision of an annual stock of drugs. However, according to demand and budget (restrictions), more drugs listed in the old formulary, from the Central Stockroom (in Mexico City) of S.S.A. will be available.

For the experimental district, the current providers in Huamantla might be the providers in this district. The initial acquisition of drugs will be made on a monthly basis considering figures from Huamantla. If the initial budget for a centre or for the whole district were not enough for the initial supply of drugs, extra funds will be provided by the S.S.A. and considered in the analysis as the "starting investment". The following purchases will be based on Centres C demands, budget assignations and revenue from patients' fees. In other words, it is a partially self-financed pharmaceutical service in the sense that income from selling drugs will be re-invested in the purchasing of new drugs to replenish centres. Then, if during the observation period a centre or the whole district does or does not generate enough funds (from patient's fees) only the budget allocations and those scarce resources will be used to buy more drugs. It will be considered as a risk of no effect of pharmaceutical services in increasing utilization rates among the population.

4.7.2.4 Storage and Control of Drugs

Primarily drugs will be gathered and stored by a convenient classification in the district stockroom located in Centre B. In

Centres C, they will be stored in the nursing section when available, otherwise in the physician office. Drugs will be organized according to physician's or pharmacist's convenience. It is suggested by alphabetical order or therapeutic action. For the central pharmacy stockroom, it is suggested the same order recommended by Smith and Mackewicz [62] shown in Figure 4.3, be followed, although it will depend on the space available and the amount of medicines and equipment.

To control drugs, inventory cards and index cards for classifying drugs will be available and are described in Section 4.7.2.6.

4.7.2.5 Dispensing/Selling of Drugs

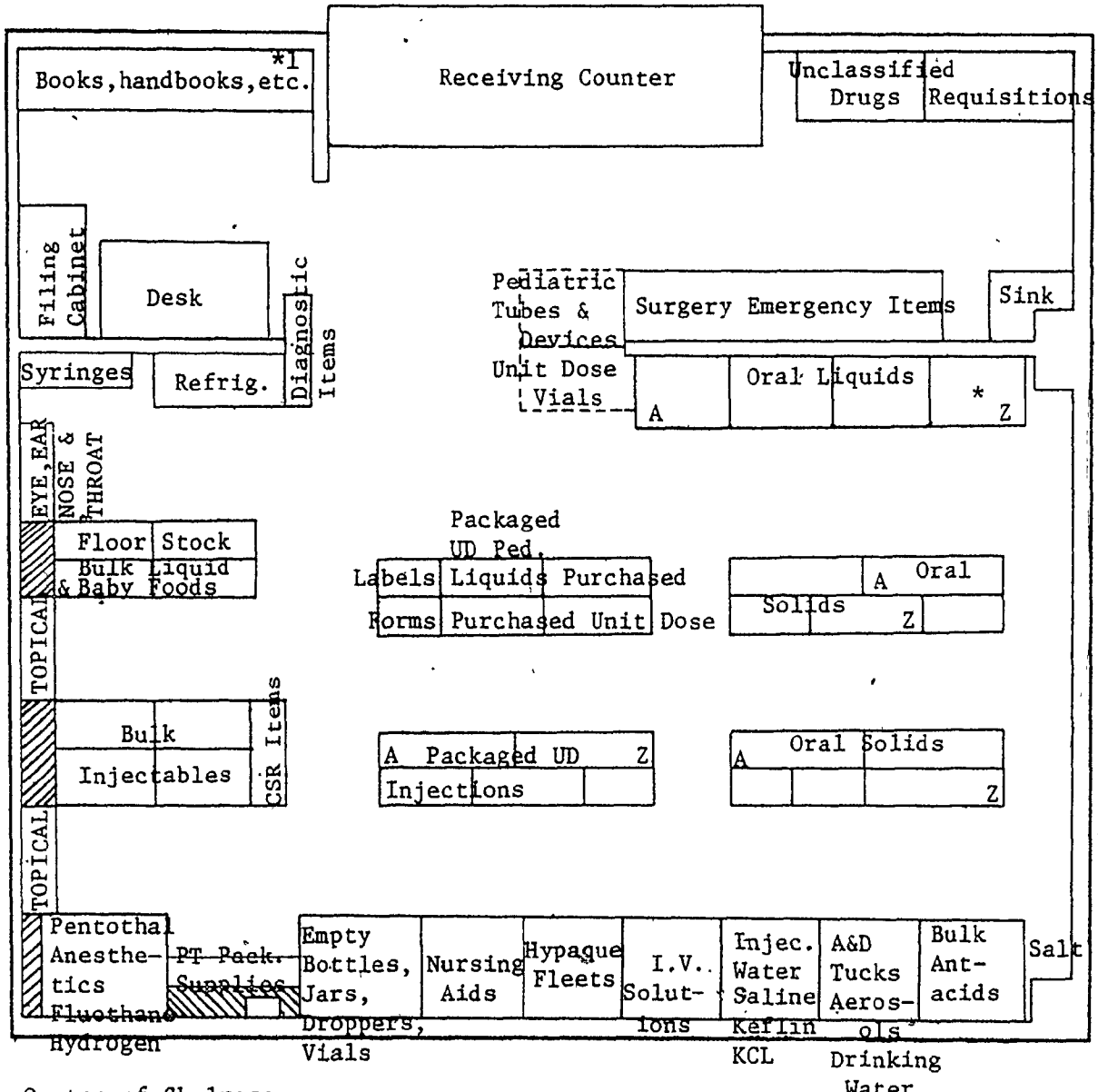
Drugs will be available only at Centres C and only for those patients seen in those units as outpatients or inpatients. Physicians in Centres C will prescribe the drugs, and either the nurse or the physician will dispense them. Drugs prescribed will be recorded on patient's file and clinic day sheet. Drugs dispensed will be recorded in the day sheet and in the patient's bill.

Patients have to pay cash for their drugs except when they are eligible to get them free as in the case of tuberculosis, family planning or rheumatic fever programs. If the case, patients will get drugs with an extra discount, according to S.S.A. rules.

Prices of drugs in the control centres will be the prices listed on the national list, which is based on government prices that represent up to 70% savings for the patient. In experimental centres, prices will depend on the bargaining with manufacturers, but it is expected to obtain up to 25% off the actual price in the surrounding private retail pharmacies or drugstores.

Figure 4.3

Pharmacy Stockroom



On top of Shelves:

* Cardboard boxes (various sizes)

*1 Classifying cards

Source: Perspectives in Clinical Pharmacy - Smith, W.I. and Mackewicz, W. Op. Cit.

4.8 Measurement

4.8.1 Introduction

Kerr and Trantow[63] suggest that the quality of health services might be measured by the extent to which the system approaches the capability to provide all required services to all people at all times within certain constraints dictated by adherence to rules of optimality to prevent misallocation and maldistribution of resources. Then, in order to make valid comparisons it will be necessary to choose some outcomes that measure the impact of pharmaceutical services to all people at all times. The best ones would be changes in morbidity and mortality rates as measures of the impact of increased health care[64,65,66]. It is believed that mortality is not an indicator which is susceptible to change in the short term and therefore, will not be considered here.

Morbidity could be measured from information contained in the medical record or from household survey with a health index questionnaire. Although the validity of morbidity as a direct measure of health status is attractive, neither of these approaches were thought to be suitable for application in rural Mexico. Firstly, the quality of health records would not be sufficient to comprehensively quantify the extend and intensity of episodes of ill health. Secondly, available questionnaire based health indexes are largely oriented to the standards of a highly developed country. It was thus not though economically feasible to convert an existing index to the rural context nor even possible to invest the required resources in executing such a

sophisticated measure even if a suitable instrument were available.

The provision of a new list of basic drugs (formulary) in the pharmaceutical package suggests that suitable measures might be those associated with the efficacy of drugs[67] measured through: improvements in therapy such as shortened duration of disease (more speedy recovery). In diseases which may be controlled but not cured, a good outcome would lengthen the course by prolonging life. However, this type of outcome measure, is not feasible at the moment because in the first case, recovery will not only depend on the availability of drugs but on the patient's compliance and patient management as well as the efficacy of the drug. On the other hand, it is not feasible to follow-up patients for long periods of time in rural areas where the population is widely dispersed. Secondly, when dealing with chronic diseases, long-term studies are required to detect changes in life expectancy.

4.8.2 The Development of Outcome Measures

Thus having reluctantly abandoned true outcome measures as the basis for judging the intervention's impact, we might look to measurement of the process of care for our assessment. The danger here is clearly strength, or even certainty, of the link between process and outcome. In other words, can we be sure that changes in process will lead to subsequent changes in health status?

Like most health studies of this kind, a number of process measures have been selected. They were chosen primarily to be sensitive to the "active ingredient" of the intervention and thus revolve around the prescription of pharmaceutical therapies. They were, however,

also selected on the basis of their association with health outcome. The strength and certainty of this link obviously varies from measure to measure. In the next section, we introduce each measure in order of priority. This priority being determined by our perception of the strength of the process/outcome link.

4.8.2.1 Quality of Prescription

Given that the main goal of introducing pharmaceutical services is to enhance the quality of medical care, it is necessary to include a measure that reflects the benefits of this intervention in patient care. In order to focus attention on the anticipated effects of the intervention, we will concentrate on the quality of prescription as an important part of quality care.

This attribute (quality of prescription) might be thought to depend more upon physicians' knowledge and prescription criteria than upon the availability of drugs. However, the common belief that each consultation should end with a prescription[68], has caused the physicians in rural Mexico[69] to dispense a drug available even when it is not the drug of choice nor a biological equivalent. Thus the availability of more varied drugs might allow the physicians to improve care by selecting the more appropriate drug.

Quality of prescription is defined as[70] using the right drug for the right patient at the right time in the right amounts. This is a composite definition which we have decided to split into two components to ease measurement,

a) for a particular condition, was the drug choice and dosage appropriate?

b) for a particular drug, was the patient's condition compatible with the drug and dosage?

The first measurement approach starts from a necessarily small set of (indicator) conditions and asks how well they were treated; the second starts from a group of drugs and asks how well they were used. We feel both methods of measurement are required and that they complement one another.

The advantages of an indicator condition approach are that:

a) by limiting the focus on a small set of conditions, we can develop objective criteria for appropriate drug use, including alternative therapies.

b) We can include episdoes where a drug should have been prescribed and was not.

c) We can improve the strength of association with outcome by suitable choice of conditions (see later discussion).

The main disadvantage, of course, is the potential lack of breadth in assessing quality through a very small number of conditions.

The advantages of a drug based measurement are that it:

a) can cover a wider field and potentially all instances of drug use (or a random sample thereof),

b) is more directly related to the intervention,

c) can be reasonably sure of the link with outcome by basing the criteria on a drug's known efficacy and side effects.

The disadvantages are:

a) that explicit objective criteria could not be developed for

all situations and some subjective assessment will be required for unusual drugs,

b) that situations where no drug was prescribed when it should have, will be missed from a drug based sampling approach.

4.8.2.1.1 Medical Problems as Indicator Conditions

The indicator condition approach to measuring quality of care has been used in previous studies[71] and it has also been well established in the medical literature. An indicator condition is defined by Chambers, et al[72] as a "clinical situation (for example a disease, complaint, injury or health state) that is reasonably frequent in the practice being studied and which there is sound evidence that good care is beneficial. Indicator conditions are characterized by criteria that reflect clinical manoeuvres (including the use of drugs) known to result in more good than harm when correctly applied or more harm than good when inappropriately applied, or both. The care provided for these conditions is compared with these criteria to determine whether a specific episode of care satisfactorily meets those standards." From this statement, we conclude that the indicator conditions for this study should be selected to reflect the medical practice of the communities and represent the main complaints among the population seen in the health centres, requiring prescription of drugs. To detect suitable health problems for this purpose, a review of the morbidity and mortality registered in those centres during the last 3 years, will be performed.

According to Huamantla data[20], the 10 most frequent health

Table 4.6

Ten Main Causes of Morbidity in Centres C of Huamantla District, Tlaxcala, Mexico
1977

Diagnoses	Number	%
1. Acute respiratory infections of upper tract	1,983	13.4
2. Infectious gastroenteritis and other diarrheal diseases	1,376	9.3
3. Acute bronchitis	503	3.4
4. Infective and parasitic diseases of skin	476	3.2
5. Infectious diseases of urinary tract	317	2.1
6. Intestional parasitic diseases	279	1.9
7. Nutritional deficiency (Grades II and III)	225	1.5
8. Accidents, poisonings and violence	210	1.4
9. Amoebiasis	205	1.4
10. Disorders of menstration and other diseases of female genital organs	208	1.4
Sub-Total	5,778	39.0
All Other Causes	9,054	61.0
TOTAL	14,832	100.0

problems in 1977, represented 39% of the total cases seen in the health centres; and the six most frequent problems represented 33.3% of the total cases (Table 4.6). In addition to covering a high proportion of cases, the top six conditions offer situations in which effective drugs treatment is an important component of care. Obviously, coverage and thus comprehensiveness would be improved with more conditions being included. However, since a substantial amount of development work is necessary to determine the associated criteria, we feel that six conditions is the most which is practically manageable.

To avoid bias during the observation, two health problems will be analysed first at the initial stage of the study, two more in the mid-term and the remaining two at the end of the year. In this way, physicians will not know what problem is going to be studied.

The development of indicator conditions will follow the criteria given by Chambers, et al[72].

Indicator conditions charts will be developed by two physicians working in the D.M.G.F.C., who have had the experience of the social service year in Centres C or rural communities. It will be preferable if they have participated in the Huamantla project, and are currently involved in community activities similar to those being studied.

Issues in validity (the degree to which an instrument measures the concept it is intended to measure) of the criteria layed out on the indicator conditions charts are addressed here. This method is valid, in terms of content validity, because the selected indicator conditions will cover approximately 30 to 33% of the cases diagnosed in the

health centres. These cases will include both sexs and different age groups.

Criteria concurrent validity, will be established for each indicator condition by comparing the study criteria for drug use with the criteria of two clinicians from the D.M.G.F.C. or from hospitals of the S.S.A., considered as specialized in the disease or health problem assessed by the indicator condition. If available, results will be related to current international literature.

Since the indicator conditions approach requires good quality record-keeping as an essential component, the need to keep organized and complete notes on patient's files, will be emphasized during the annual training of physicians by S.S.A. During the periodic visits to communities, physicians will be encouraged to improve the record-keeping even though in some cases it is not necessary to have a comprehensive information of the disease and patient. In such case, having the diagnosis and prescription allows one to judge the quality of prescription, i.e., an episode of common cold treated with antibiotic (a very frequent practice) is obviously considered an inadequate prescription regardless patient's age or sex.

To collect information about indicator condition episodes from health centres, two abstractors will be needed. These abstractors will be the two assistant researchers visiting the centres.

They will be trained for the following activites: a) to detect and randomly select patients having the indicator condition, from the clinic day sheet (Appendix D-1), and b) to copy (or abstract if necessary) relevant data from the patient's file. Since an abstractor will

only copy information, it will not be necessary to conduct inter- and intra-observer variation agreement studies with them, unless, during the pre-test period it is demonstrated to be necessary.

Data will be collected during periodic visits to centres (see data gathering section). The collection will involve looking at the clinic day sheet to find cases diagnosed with the indicator condition. From the day sheet, the patient's file number is noted to obtain data from the patient's file. Data will be obtained if feasible by xeroxing the information from the file, otherwise abstractors will record information on form shown in Appendix D-3.1. Data recorded on it will be copied exactly as it is in the patient's file from the different sections of the clinical history (Appendix D-2). Data will include information about clinical findings (signs and symptoms), diagnosis, treatments specifying brand and generic names of drugs as well as strength, form and dose prescribed. It also will contain additional information if necessary according to indicator conditions characteristics.

These data will be assessed in Mexico City by the independent or external researcher, in a blind way, based on the criteria of the indicator conditions layed out on charts that show the main symptoms to base diagnosis and treatment criteria according to rural Mexico resources, as well as at different stages of a disease considering patient's characteristics, as recommended by the Natural History of Disease approach[73]. Treatment criteria and scoring of quality of prescription for each indicator condition will follow similar process

as the one for Sibley, et al[71,74]. Appendix D-3.2, depicts an example of a chart for one indicator condition selected as being suitable, based on Huamantla experience, and the criteria for rating data (D-3.3).

In order to blind the assessor, form D-3.1 has been designed in such a way that the information section identifying abstractor, group, centre and patient, can be detached. The only identifier will be "Case No. ..." which is in numerical order of cases according to the way they appear regardless of indicator condition, centre or group.

Observer agreement will be measured by giving the independent assessor a sample of cases for a second reading.

The indicator condition and data gathering forms will be pre-tested in order to detect potential source of bias, confounders, applicability as well as to measure reliability by using different abstractors and/or different assessors.

To measure quality of prescription, only cases of patients falling in the age and sex group specified by the indicator condition chart to be studied, are eligible. Patients should not present more than one indicator condition or other health problem at the same time. Multiple diagnoses present may affect patterns of prescription and management.

Given the scarce resources available, a sample of centres in each group will be studied. Number of cases per indicator condition and per centre will be discussed in the sample size section.

The proportion of cases appropriately prescribed versus not well prescribed in a year period, will be compared within each group

and between experimental and control groups.

4.8.2.1.2 Quality of Prescription - Direct Assessment

The indicator condition approach discussed above is based on the detailed assessment of a small number of conditions. The second measure of quality of prescription, which we will call the direct assessment, is less sophisticated but can be carried out across the full spectrum of drugs which may be used.

The basic approach will be to use the clinic day sheet to randomly sample from all visits resulting in a drug prescription during a period of time. Using simple explicit criteria for the common drugs and subjective ratings by study personnel for the more unusual drugs, we will assess the quality of prescription. The assessment will be one of three classifications, for this patient in this condition the drug, if taken, would: a) do more good than harm, b) produce no effect, or benefits which match the potential side effects, c) does more harm than good.

Two primary sources of data are available for this decision - the day sheet and the patient's file. One possible approach would be to develop criteria (as the one shown in Appendix D-4) that can be applied solely on the basis of information contained in the day sheet (Appendix D-1, described in detail in the next section). This is basically presenting complaint, diagnosis, age and sex (but duration and previous treatment may be useful). The advantage of such criteria would be that they could be applied to all centres (rather than a sample) without need for travel or data abstraction. The alternative

would be to develop more sophisticated criteria for the common drugs which are dependent upon notes in the medical chart. At this stage no decision can be made and the chosen approach must await further development and pretesting. However, both are similar to the indicator disease method in the steps one must take to develop, validate and test the reliability of chosen criteria.

4.8.2.2 Utilization

Since under utilization of the health centres has been hypothesized as an effect of the lack of pharmaceutical services, and having the premise that a health program should be justified by the extent it is available to most of the population, it is clear that the introduction of pharmacy services is expected to increase utilization rates of health centres. It is also clear that the introduction of pharmaceutical services is expected to improve the quality of medical care, measured as appropriate prescription. On this basis it is important to know if this intervention influences patient utilization rates for conditions now treated by effective medications, in other words, we would like to answer the question, are more people coming to have their diabetes, tuberculosis or diharrea treated now that effective treatment is available? It is also likely that measures of utilization might reflect changes in the proportion of centre visits for primary prevention as compared with treatment. Therefore, utilization is considered a variable likely to be affected, in the short-term, by the introduction of pharmaceutical services. Since for most communities the only reasonable health care alternative to the centres

is to visit the local traditional healers, we can assume that increasing utilization also increases access to effective treatment. However, the strength to the link to health outcome is clearly more questionable for the process measure of utilization than the two previous measures.

For purposes of this study, utilization means the number of patients that seek and receive medical care from the health Centre C, either for the first or subsequent visits, for the same or different health problems; in the health centre or at home.

Utilization will be measured in absolute and relative figures. In absolute figures as the total number of services delivered per Centre C, per district and per group. It will be classified by type of services and some demographic variables. In relative figures, it will be measured as the utilization rate per 1000 inhabitants of the population theoretically covered by the health centre.

The main instrument to gather utilization data, as in the former study will be the Clinic Day Sheet (Appendix D-1). This form was redesigned by the author from the one used in Huamantla and currently being introduced in the rest of the state. This was designed to provide information about descriptive and demographic variables, type of encounter, disease entity, treatment, type of service or program, filling of prescription and cost. A more detailed description of the clinic day sheet follows below:

a) Descriptive/Demographic variables such as patient's file number, age, sex and residency, will provide information about the

characteristics of the population seen in the health centres as well as the geographical coverage of each centre. It is important because this study hypothesizes that by having drugs available the utilization rates will increase in number and hopefully as it was seen in Morelos and Huamantla projects, it will increase geographical coverage. The structure of the population traditionally seen in these centres is also expected to change. For example, we may see relatively more adult males as the clinic utilization increases.

b) Type of encounter: this item allows us to distinguish where the encounter takes place. It also will provide information on whether the centre is seeing more new cases and/or more visits per patient which might suggest better compliance for chronic patients or gradually more effective follow-up.

c) Disease entity: will allow us to describe the health problems physicians deal with, which might be important to base further studies in the evaluation of the new formulary, and help in planning medical education programs.

d) Treatment: this column identifies the treatment given to the patient as advice, prescription of drugs or surgery. It will provide information about physicians' prescription patterns and use of drugs.

e) Type of service or program: classifies the encounter according to the sort of preventive care given to the patient. It includes codes for primary preventive programs and secondary preventive programs either acute or chronic diseases or health problems. It will allow

us to determine if the pharmaceutical component changes the pattern of medical care delivery. In other words, it will show if the intervention only influences patient utilization rates for conditions now treated by effective medication or if it increases primary prevention as well.

f) Filling of prescription: it will indicate if the prescription was filled in the centre. If not, we will be able to determine if availability of drugs in the centre was the reason.

g) Costs column: refers to the amount of money paid by the patient for services received and drugs bought in the health centres. This variable along with filling prescription and treatment are not as relevant as those which relate to utilization rates, but they will be considered for the remaining outcome measures described later in this section.

Both groups will be furnished with these clinic day sheets which will be filled in by the physician at the time of the consultation.

For the before period utilization data will be taken from the annual S.S.A.'s reports and the President's Annual Report.

All centres (and all population seen by the centres) in both groups will be considered in the analysis. Comparisons will be done at the end of the year considering overall figures of services provided, classified by the variables described above. Comparisons will be based on a centre average in the before and after period.

4.8.2.3 Compliance

Traditionally compliance refers to the fact that patients take the drug prescribed. Strategies to improve compliance have been measured by pill counting[75] including the design of special devices[76], and by lab tests.

It seems clear that receiving the drug does not ensure compliance. It is also clear that failure to obtain the drug results in noncompliance. Then the first strategy to measure and to improve compliance should be the act of filling the prescription. It might be argued that filling prescription is not a measure of compliance; according to Haynes, et al[75], it is classified as an indirect measure, and given the conditions of rural Mexico, the author of this thesis prefers to keep it below the name of "compliance" as filling the prescription.

Since the aim in this study is to provide an adequate amount of appropriate drugs to health centres that results in compliance in terms of receiving the drug at the health centre level, the act of filling the prescription is an appropriate measure of part of compliance behaviour. A convenient measure to base comparisons between control and experimental centres will be compliance.

Thus, for this study's purpose, compliance refers to the filling of the prescription, either in the health centre where it is prescribed or out of it (nearest city, local drugstore, hospital, etc.). The prescription filling rate is considered as the outcome event.

To measure compliance, health problems (episodes or diseases),

that were prescribed will be randomly selected (see Cost section 4.8. 2.4), from the clinic day sheet by the assistant researcher during his/her visit to the centres. For acute health problems, compliance will be ascertained one week after the visit, and for chronic problems two weeks, to allow the prescription to be filled.

The nurse will collect data in a household survey during her daily home visit to those cases randomly selected. A questionnaire (Appendix D-5) instrument has been developed to collect the necessary information. Questions will be in regard to whether the drug or drugs were acquired, if yes questions are added in regard to place, cost, and length of time since the prescription was issued and filled. If not, the reasons why the prescription was not filled. Questions will be added to record drug removal and whether the patient's health was improved.

Information about compliance will be collected during a year period. This interval of measurement should allow the detection of seasonal variations (it seems that during the harvest season peasants have higher ability to buy drugs), if present.

Comparisons will be based on the proportion of cases of the experimental and control groups that filled the prescription in the centres or out of them. No before versus after comparisons will be done because of the lack of information for the before-period.

4.8.2.4 Costs

One of the most common problems faced by the consumers is the cost of receiving care from the centre because it implies expenditures

beyond their economic capacity when they have to travel or seek supplementary medical care not received from the health centres. The Government has also been faced with economic restrictions because the under utilization of these centres has resulted in fewer patient's fees than expected, to help finance the centres.

Although it is not intended to perform a comprehensive economic analysis, it is obvious that "cost" is a variable very likely to reflect changes due to the contribution of pharmaceutical services. It might also be the crucial concern of decision makers as to whether they support the improvement of pharmaceutical services or to question them.

To measure cost, two points of view will be considered: i) consumer's and ii) provider's.

i) Consumer's (patient's) point of view. Consumer's cost are the total amount of money spent by the patient or patient's family to treat a disease or an episode of a health problem. It includes the medical visit fees, drug costs, travel expenses, if necessary, hospitalization and cost of referals if needed.

Patient's cost will be collected by the nurse during her home visits. She will interview the patients randomly selected (by the assistant researcher), if they are able to provide information. Otherwise, she will interview the patient's parents, tutor or closest relative, whoever is looking after the patient.

A questionnaire (Appendix D-6) designed for this purpose will include questions in regard to price of drugs, cost of transportation

and cost of services. All cases classified by place where prescription was filled, will be added and divided among the number of patients in each classification to get the total average cost for health problem, per group.

Data collection of information regarding drug compliance and drug costs will occur in all the sampled centres for one year as described before, to detect changes in cost due to inflation, new fees for services, and so on.

To measure cost and compliance, cases will be randomly selected as follows: first, from the clinic day sheet, all cases that receive prescription will be listed. Secondly, by using the random number tables, the required number of cases is selected. Odd number cases will be assigned to measure compliance and even number cases to measure costs. This procedure will provide two different lists. Therefore, on the whole, different patients will be counted. Thus, a given patient with multiple visits may appear on one or both lists more than once.

Since the before data available refers only to Huamantla District where conditions were different, no before-after comparison will be performed. Instead, comparisons between and within groups will occur.

Eligibility for cost and compliance patients will be those who were diagnosed and received prescription in the health centres, if they live within the sampled centres' domain, preferable in the town where the centre is lcoated since it is difficult to travel from town to town.

ii) Provider's (S.S.A./Government) point of view. This is the theoretical cost that the S.S.A., would spend for each patient seen in the health centres. This will be measured by taking total incomes from the total expenditures in pharmaceutical services. This product, then will be divided by the number of medical visits in each centre.

This calculation will give us the unit cost per service per users of the health centres. By substituting the denominator for the total population theoretically covered by the centre, we will have the cost per person (per capita cost) in the area.

Provider's cost will be taken from the budget sheet and the financial report considering all expenses due to establishing the pharmacy(ies), salaries, new equipment; drugs, vehicle, drivers, pharmacist, stationery, in the case of the experimental centres. For the control groups only salaries, stationery and drugs will be included in the cost. All centres will be considered in the comparison of experimental and control groups, since the data is routinely available through government records.

4.8.2.5 Satisfaction

Undoubtedly, a measure of satisfaction is worth including in this study. This intervention attempts not only to provide extra resources, but also to improve general conditions for the delivery of medical care and the acceptance of it.

Satisfaction will be included as an outcome measure to find out if patients feel more satisfied with the resources of the health centres with comprehensive pharmacy service, as well as if the physi-

cian working in that health centre report greater satisfaction with their role and greater effectiveness in treating the health problems of the people.

Satisfaction will consider two points of view: i) patient's and ii) physician's.

i) Patient's satisfaction. Although utilization of the health centre is a measure of community satisfaction, a random selection of families, both users and non-users of the health centres will be drawn and interviewed with the questionnaire (Appendix D-7) designed for this study. This questionnaire includes questions about care received from the centres, if users, or place where they seek medical care, if non-users; health outcomes and whether they are or were satisfied with the service and facilities there. This questionnaire will be pre-tested in order to measure reliability and feasibility to apply it.

Families to be interviewed will be randomly selected as follows: The randomization process will be based on lists from the "X National Census" (X-Censo Nacional) carried out in January 1980. Data from this census are still being processed but it is likely the list of families of each town where the centres are located can be obtained. These lists are organized by community, blocks, households and families.

If the government restricts the use of these lists, the "electors list", which is available in each municipality, will be used. This list includes all citizens (population over 18 years old, if

single, or over 16 years old, if married) classified by community, blocks and household. It will be necessary to translate this list into a "family list". This was done previously in Morelos project.

Once having the family list from either source, families will be numbered and randomly selected by using a random number method.

All families living within the area of sampled centres' domain will be eligible for the random selection. Families refusing interview will be excluded from the study.

Data will be collected by the assistant researcher at the end of the year. A training will be provided to the assistant researcher for recording satisfaction.

The nurse will not collect information on patient satisfaction since she might bias the data if she feels evaluated. Also her presence in the community might make people unwilling to disappoint her when dealing with satisfaction questions. Mailed questionnaires are not feasible because of the educational level of the population and the rudimentary postal system.

Questionnaires will be scored by the independent researcher who will be tested to measure intra-observer agreement.

Scoring of questionnaires will be blind. In order to make the independent researcher blind, no information will be provided about the group from which the questionnaires come. Questionnaires will be identified by a code known by the main researcher only.

Comparisons between control and experimental groups will be done at the end of the year. No before versus after comparisons will be done.

ii) Doctor satisfaction. This will be measured at the end of the year by a questionnaire (Appendix D-8). It will be distributed among the physicians of all centres in both groups; to be filled during the last week of the year. This questionnaire will be collected during the last meeting. It contains questions about how well the physicians felt during that year in treating patients with the available resources in each centre. These questionnaires will be analyzed by the same external researcher. None of these questionnaires identify the group, so that the assessment is blind.

To measure satisfaction in this way, all physicians of the experimental and control group will be included. The proportion of physicians satisfied as compared to non-satisfied, will be compared between both groups.

4.8.2.6 Additional Explanatory Data

a) Availability of Drugs: this is an outcome measure added to provide extra useful information about the effects of pharmceutical services. It will be measured as the proportion of medical visits that received a prescription which was filled at the health centre where it was prescribed.

In a year period, all the episodes for the different services and diagnostic categories will be taken in account. This information will be obtained from the clinic day sheet. All centres will be included.

b) Amounts Dispensed: this refers to the total amount of each drug available in the formularies that was sold or consumed in a year

period. It will provide information about the patterns of prescription, the appropriateness of each formulary and acceptance of them by the physician. This measure will display drugs as the most frequent drug prescribed, less prescribed and never prescribed or used. All centres will be included.

c) Criteria for Prescribing (Physician's Choices and Alternatives): an extra measure of the use of drugs across medical problems will be achieved considering physician opinion through the application of a questionnaire (Appendix D-9) that provides explanatory information why the physician prescribes a given drug of inferior quality and efficacy, as well as to get acquainted about physicians' alternatives to manage the case in study.

From the clinic day sheet a number of cases that receive prescriptions regardless of diagnoses, will be sampled by the random number tables method. These cases will be selected from the last month of the study data collection period and only physicians working in the sampled centres will be interviewed.

4.8.2.7 Summary of Outcome Measures

A summary of the outcome measures selected is contained in Table 4.6. The table indicates the sampling frame to be used, the number of centres involved, and whether before data will be collected.

4.8.3 Pre-Test in General

The data collected will consist of information written by physicians on specific forms. This study, then, depends on the reliability and validity of the provider of this information.

Table 4.7

Outcome Measures

Outcome Measure	Target Population	Sampling Unit	Sampling Frame	Sampling Technique	Data Gathering Instrument	Centres Studied	Comparisons
Utilization	All medical visits	Medical visit	-	All services provided	Clinic day-sheet	All centres	Before-After Control vs Exp.
Quality of Prescription (Indicator conditions)	Medical visits receiving prescription	Episode of an indicator condition	Clinic day-sheet	Random	Indicator Condition Forms	Sampled (4/district)	Control vs Exp.
(Direct Assessment)	Medical visits receiving prescription	Visit resulting in prescription	Clinic day-sheet	Random	Use of drugs forms	All centres	Control vs Exp.
Compliance	Medical visits receiving prescription	Episode	Clinic day-	Random	Questionnaire	Sampled	Control vs Exp.
Patient's Cost	Users of health centres receiving prescription	Episode	Clinic day-sheet	Random	Questionnaire	Sampled	Control vs Exp.
	Districts,	Health Centre	-	All centres	Budgets, Reports	All centres	Before vs After Control vs Exp.
Satisfaction: Patient's	Community	Families	Census	Random	Questionnaire	Sampled	Control vs Exp.
Physicians	Health Centres	Physicians	--	All physicians	Questionnaires	All centres	Control vs. Exp.

In this study, the reliability and validity of patients (when interviewed), physicians and data gathering instruments is assumed. However, it is important to know if the needed information will be successfully recorded on these forms. It is also necessary to detect the errors that may occur in recording information and the degree of completeness, which might vary from centre to centre and from item to item. We propose an extensive pre-test period to address this issue.

This pre-test period is also justified by the fact that these forms have not been used previously and also because the physicians filling those forms (clinic day sheet, patient's chart, and so on) will receive initial training but will work largely unsupervised in the field.

By running this pre-test period we will be able to: a) estimate the degree of completion for each of the items of interest, b) estimate inter-observer variation for questionnaire instruments, c) to have indications of the feasibility of applying the questionnaires, and d) to identify required changes in forms.

Obviously, the method used during the pre-test will be the same for the actual study with the exception that the respondents will be different from the main study.

From Huamantla experience, we expect a rough estimate of 300 visits per month, per centre. If we have a three-month-period (October to December of 1981), and we plan to study 3-4 centres, we will have a population of approximately 2700 visits to sample about 300-500 visits to study during this pre-test.

4.9 Data Collection

4.9.1 Secondary Sampling of Centres

For those outcome measures based on routine data collection procedures, e.g. utilization, government costs, all centres in the three districts will be available for analysis. For those outcomes specifically introduced for study purposes, e.g. quality of prescription, filling rate, etc., study personnel will have to travel to the centres to abstract information on patients.

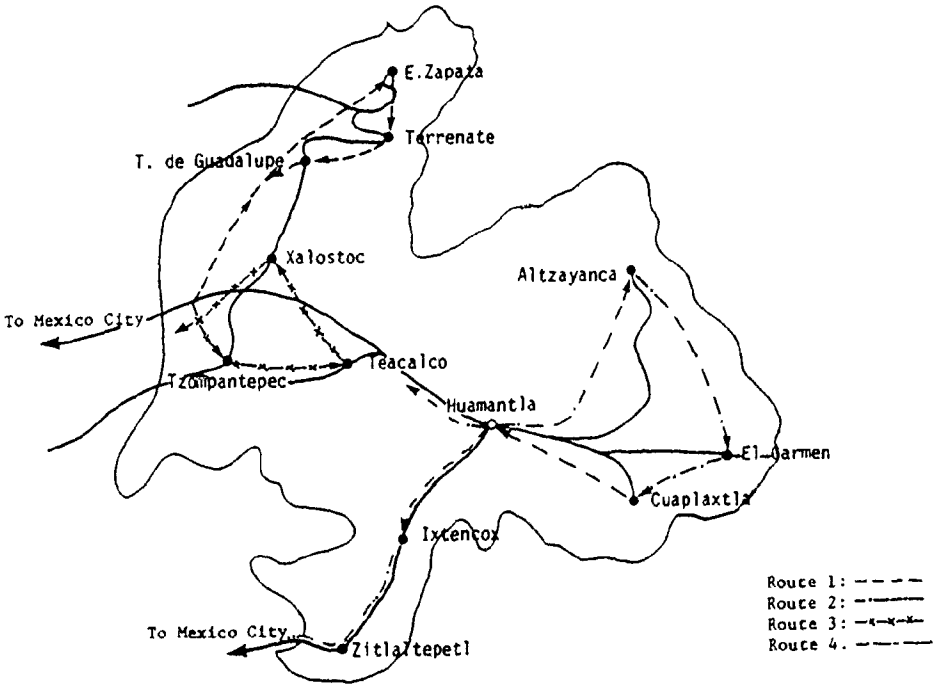
In order to reduce the amount of travelling involved and thus reduce the costs of the study, we have decided to limit this second group of measurements to a selected subset of centres. From experience in Huamantla and knowing the volume of data required we feel that four centres in each district could reasonably be included. These will be selected using random numbers at the start of the study.

Study staff will visit all centres for supervision activities on a regular basis (perhaps 2-3 centres per day trip from Mexico City). Special data collection trips twice a month to each selected centre would allow the study representative to complete all data collection tasks within a full day visit. This schedule would also allow for visits to district headquarters when necessary.

Figure 4.4 is included to show supervisory routes used for the Huamantla Study. It is expected that this study will involve similar kinds of routes in the three new health districts. Activities for the assistant researcher will be the collecting and copying of data as shown in Figure 4.5.

Figure 4.4

Supervision Routes in Huamantla, Tlaxcala



		Hours			Hours
Route 1:	Mexico-E.Zapata	2.30	Route 2:	Mexico-Altzayanca	3.00
	Visit Zapata	2.00		Visit Altz.	2.00
	Zapata-Terrenate	0.30		Alta.-El Carmen	0.30
	Visit Terrenate	2.00		Visit El Carmen	2.00
	Terrenate-Toluca	0.05		El C.-Cuaplaxtla	0.15
	Toluca	2.00		Visit Cuaplaxtla	2.00
	Meals Time	2.00		Meals Time	2.00
	To Mexico	2.00		To Mexico	2.00
	Total:	13.05		Total:	13.45
Route 3:	Mexico-Tzomp.	2.00	Route 4:	Mexico-Huamantla	2.00
	Visit Tzompantepec	2.00		Visit Huamantla	3.00
	Tzomp.-Teacalco	0.30		Humantla-Ixtencox	0.05
	Visit Teacalco	2.00		Visit Ixtencox	2.00
	Teacalco-Xalostoc	0.20		Ixtencox-Zitl.	0.10
	Visit Xalostoc	2.00		Visit Zitlaltepetl	2.00
	Meals Time	2.00		Meals Time	2.00
	To Mexico	2.00		To Mexico	2.00
	Total:	12.50		Total:	13.15

4.9.2 Data Collection Schedule

The data for this study will be collected through the year. This timing process will allow for seasonal and perhaps other variations such as change in the prescribing patterns of physicians, different pathologies as well as different patterns of utilization of the services and drugs that might affect the outcomes in question. Data concerned with indicator conditions will be collected through each of the four quarters from February 1st, 1982 to January 31st, 1983. Data from different indicator conditions will be collected each quarter (see Measurement section). Table 4.8 depicts the schedule table for this study.

4.9.3 Data Collection Instruments

The major data collection instruments for this study will be the already described clinic day sheet; patient's file*, pharmacy cards; questionnaires; budget sheets, the monthly and annual financial and activities reports submitted by physicians and districts to S.S.A.

4.9.4 Record System

The current patient's record system and report activities forms will be kept as shown in Appendix D. This proposal will implement and supply the extra registration forms required for a) recording centre activities; b) controlling drugs, and c) providing extra specific information.

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* Diagnoses and charts to assess indicator conditions will be based on the D.M.G.F.C.'s classification of Diseases.

Table 4.8

Schedule Study

Time Required	5 Months Sept. '81 - Jan. '82	12 Months Feb. '82 - Jan. '83	6 Months Feb. '83 - July '83
Study Period	Preparation phase	Experimental phase	Analysis phase
Activities	Preparation Pre-test (Oct.-Dec.'81) Randomization Implementation of Pharmacy	Training of Physicians Data collection Continuous assessments	Final Analysis Report

4.9.4.1 Recording Centres Activities

The clinic day sheet that has been used in Huamantla (Appendix D-1, F.C-1) has been re-designed and will be used in both groups: control and experimental. This sheet is used at the time of the patient-physician interview. It includes variables such as patient's file number, sex, age, residence, diagnosis, treatment, cost of drugs, and services received (see Utilization section).

The available monthly report of physician's activities and the annual report for centre, district and states will be consulted if necessary.

4.9.4.2 Controlling Drugs

The controlling of drugs will include forms to provide information about type and number of drugs available at a given time; drugs issued; location of drugs, classification, costs, etc. For this purpose the author has designed a series of records based on the Huamantla experience and McMaster Medical Centre. They include:

i) List of drugs available - each centre will be furnished with a list of drugs and quantity available in that centre. For control centres the list will be the one presented in Table 2.2, for experimental centres it will the list in Appendix C.

ii) Inventory cards (Appendix D-10) - are individual cards for each drug and each type of formulation (e.g. suspension, tablets, etc.).

An inventory of all drugs will be done at the beginning and at the end of each academic year. The total amount of each drug will be recorded on those cards. New drugs entering to that stock or

issued, will be recorded there, daily by the pharmacist in the case of the central stockroom in the experimental district or by the physicians in Centres C.

Inventory cards will be used in control and experimental centres. These cards include: drug's brand name and generic name; quantity available, expiration date, to whom it was issued, date, price and minimum stock level.

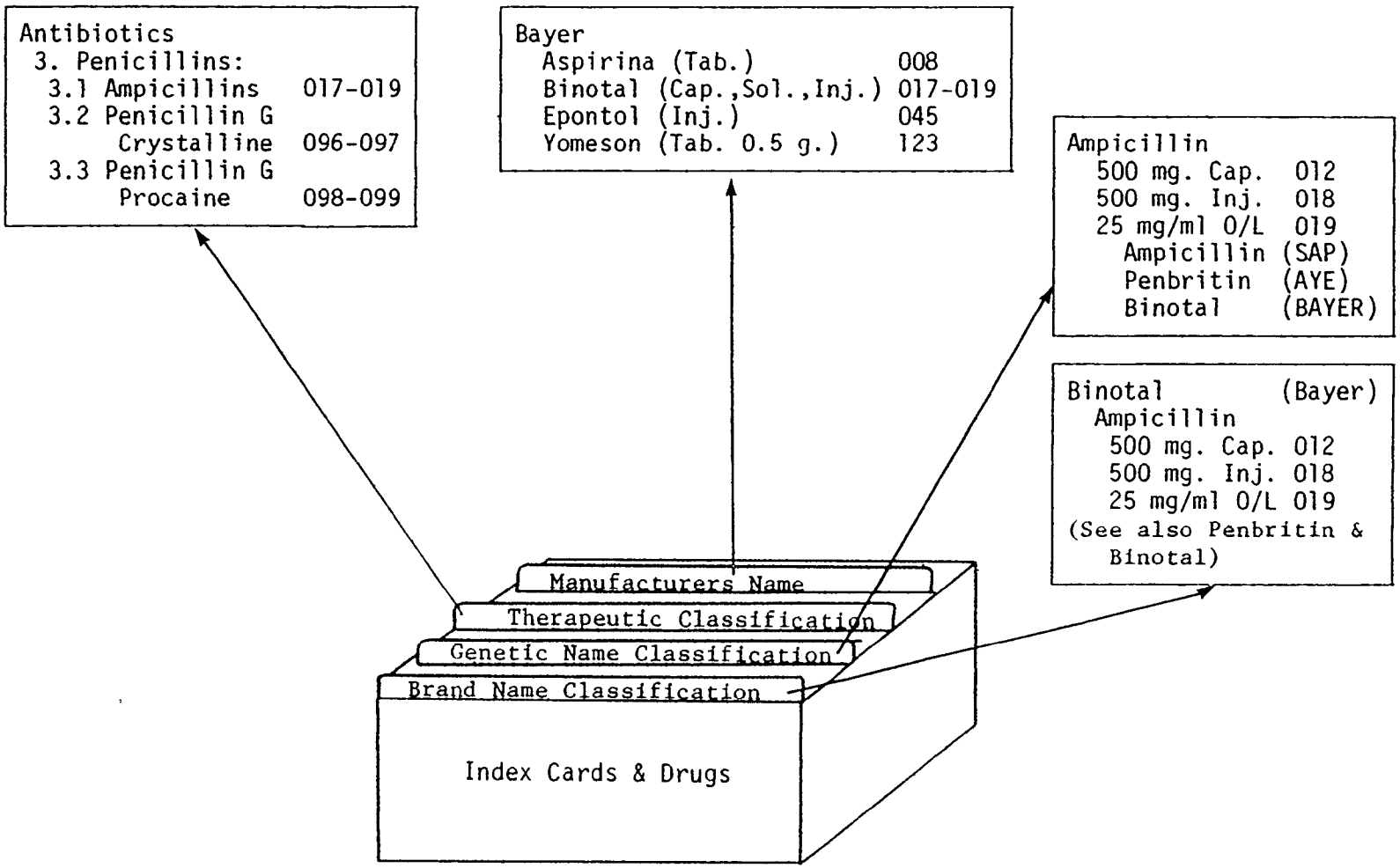
iii) Index Cards (Figure 4.5) - this is a series of cards that might help to locate a certain drug. All centres will be provided with an index card box of this specific list of basic drugs. This box will contain brand name classification cards (Ph-C-1), generic name cards (Ph-C-2), therapeutic action cards (Ph-C-3) and manufacturers names (Ph-C-4).

iv) Requisition of drugs - when a drug is in its minimum stock level or it is sold out, it must be replenished using form Ph-R-2 (Appendix D-11). To order drugs, the applicant (physician or nurse) will fill out Section 1, the provider (pharmacist or S.S.A.) will fill out Section 2 at the time the requisition is filled. When it is received by the solicitor, he/she will complete Section 3. This form will be used by experimental and control centres, at local and central levels.

v) Selling of drugs - drugs sold or dispensed will be recorded in the clinic day sheet, in column 16 the name of the drug prescribed, in column 17 whether the drug was acquired in the centre or not; if yes - column 20 will show the amount paid by the patient or if

Figure 4.5

Index Cards for Classifying Drugs



it was referred.

Patient bill forms (Form B-1, Appendix D-12) will remain unchanged and provide information, if necessary, about drug prescribed and costs.

Total income from the sale of drugs will be taken from the clinic day sheet and it will be summarized in the financial monthly report (Form F-1 shown in Appendix D-13). This form is currently used in Centres C managed by the D.M.G.F.C. and it will be kept in this study.

4.10 Sample Size Considerations

As described in the Design section, districts will be the unit of randomization to allocate the intervention and centres will be randomly selected for follow-up observation. Since the decision to study three health districts has been justified, this will not be a subject of further discussion. The number of health centres and the number of cases selected will be based on outcome measures requirements.

4.10.1 Utilization

Since all centres in the three districts selected for study will be assessed for utilization, the total sample size available is known to be 32. Randomization by district will result in one of the three possible configurations depending upon which district is randomized to receive the intervention. The possible sample sizes are thus:

Randomization	Control	Experimental
1	24	8
2	23	9
3	17	15

From the point of view of statistical power randomization, 1 would be the worst and 3 the best.

Although randomization will be by district, the analysis will be conducted as if it were done by centre. This is a cluster sampling situation and for simplicity, no "clustering" effect is assumed for purposes of sample size estimations. However, a sample 10% larger (100% for quality of prescription) than the sample size estimate will be drawn.

From the data available from the previous study in the Huamantla District, we have estimated the variation in utilization (visits per year per 1000 population) that might be expected between centres and from year to year within centres. Since the "before" is currently underway, utilization is still in progress and might not be available prior to the time of intervention, we have calculated statistical power (the probability of observing a statistically significant result given an underlying real difference of a particular size) assuming:

1) Analysis will consist of a single comparison of "after" utilization rates between control and treated centres.
2) Changes in utilization from before to after will be calculated and mean changes compared between control and treated communities.

In theory, one would expect approach 2 to be preferred if there was

substantial centre to centre variation in utilization. As it turned out this approach proved less sensitive but still might be recommended on other methodologic grounds as providing the most valid evidence of an effect if present.

4.10.1.1 Analysis 1

Independent 2 sample Student's t-test between mean "after" utilization. From Huamantla data, the between centre standard deviation of utilization was 120, the resulting power is given below:

Randomization	Real Mean Difference in Utilization				
	60	90	120	150	180
Worst	0.32	0.56	0.77	0.91	0.97
Best	0.39	0.66	0.87	0.96	0.99

4.10.1.2 Analysis 2

Independent 2 sample Student's t-test on the changes in utilization. Again, from the Huamantla experience, the standard deviation of changes in utilization was observed to be 260. The resulting power is thus:

Randomization	Real Difference in Utilization					
	120	180	240	300	360	420
Worst	0.29	0.50	0.71	0.87	0.95	0.98
Best	0.35	0.60	0.81	0.94	0.98	0.996

In fact, the observed mean change in Huamantla was about 270 visits per year per 1000 population. If this effect can be replicated in the new trial, we can clearly expect better than 80% power using the analysis approach 2 and assuming the worst randomization split. We thus judge that the available sample size is adequate to detect reasonable effects.

For the remaining outcome measures, sample size should be based on number of patients or cases rather than on number of centres. Number of centres will be influenced by increasing or decreasing cases observed or followed-up in each centre. Here sample size calculations are much more difficult since there is no information on centre to centre variation. To a certain extent we can reduce variability by selecting more episodes per centre but the limiting factor will still be the between centre variance. Therefore, data gathering during the pre-test period will be required on which to base calculations. However, if we assume for the moment that there will be no centre to centre variation, the sample size for the following outcome measures can be determined in the usual way.

4.10.2 Justification of Decision to Choose Independent Samples

If we assume that similar number of cases in each sample will be required to measure each of the variables (quality of prescription, compliance, cost and satisfaction); the same cases selected to measure one variable might be used to measure the remaining variables. This procedure has the advantages of assuring a predetermined population, saving time, money and efforts since the same patient is interviewed to collect data to measure two or more variables. It also might allow

questionnaires to be combined. However, it has the disadvantages of introducing a bias because the continuous questioning and data collecting from the same patient, might increase the awareness of patients and physicians of what is being measured. The independent or external researcher, who is blind to the intervention and will score data, might identify the groups. Furthermore, the population studied might become very atypical, when referred to indicator conditions because general health problems not classified as such, will be missed. When measureing satisfaction, if only users of the centres are considered, the population at large with a likely higher rate of dissatisfaction, will be missed as well. Thus, independent random samples will be drawn for each outcome measure. Furthermore, the sample for satisfaction measure will be drawn from the general population.

4.10.3 Quality of Prescription: Indicator Condition (Adequacy rate for prescription)

π_C = Control centre adequacy rate = 20%

π_T = Treated (experimental) centre adequacy rate = 40% (minimum)

Sample Size for 90% Power = 88 per group[77]

Adding 100% to protect against centre to centre variation results in a total of approximately 200 episodes per group.

This measure would be expected to be more sensitive than utilization and thus requires fewer centres for adequate power.

4.10.4 Compliance: Measured as Rate of Filling Prescription

π_C = 75%

π_T = 95% (according to Huamantla in 1978)

Sample Size for 90% Power = 48 per group[77]

In order to allow for some centre to centre variation, in addition to binomial sampling variation, we propose to double this estimate to 100.

We believe from a practical stand point that about four health centres in each district could be sampled for these outcomes. This strategy gives a total of 12 centres distributed: eight centres in the sampled control group and four centres in the treatment group. Thus, to measure quality of prescription, we require 50 episodes per centre in the treatment group and 25 per centre in the control group. The number of episodes per indicator condition, will depend on the frequency and distribution of the health problem represented by the indicator condition in study, but equal proportion of each indicator will be studied in each group.

To measure compliance, according to this number of centres, we will require 25 home visits per each of the experimental centres sampled and 12-13 per centre in the sample of the control group.

4.10.5 Sample Size for Other Outcome Measures

As pointed out before, sample size determination for measuring cost, satisfaction, availability of drugs and use of drugs, will be based on the pilot study to estimate variability. On this basis the determination of how many episodes per centre to rate, will be made.

4.11 Analysis

4.11.1 Methods of Data Preparation

Given that there are funds and facilities for processing data at the U.N.A.M. Computer Centre, precoded sheets will be used to collect data. The precoded clinic day sheet has been used in Huamantla. However, since small changes have been made, it will be re-tested during the pre-test or pilot study.

Open-ended questions used in some questionnaires will be used in the pilot study in order to capture all the possible answers. After the pre-test study, close-ended or partially close-ended response alternatives will be developed whenever possible.

The Computer Centre will carry out the data coding, keypunching and editing as well as the preparation of data file and tapes. In general, all data preparation necessary for the analysis of this study as well as the preparation of the appropriate software and assistance in putting the data into an accessible form, will be done by this Computer Centre and the available resources of the D.M.G.F.C. (Figure 4.6).

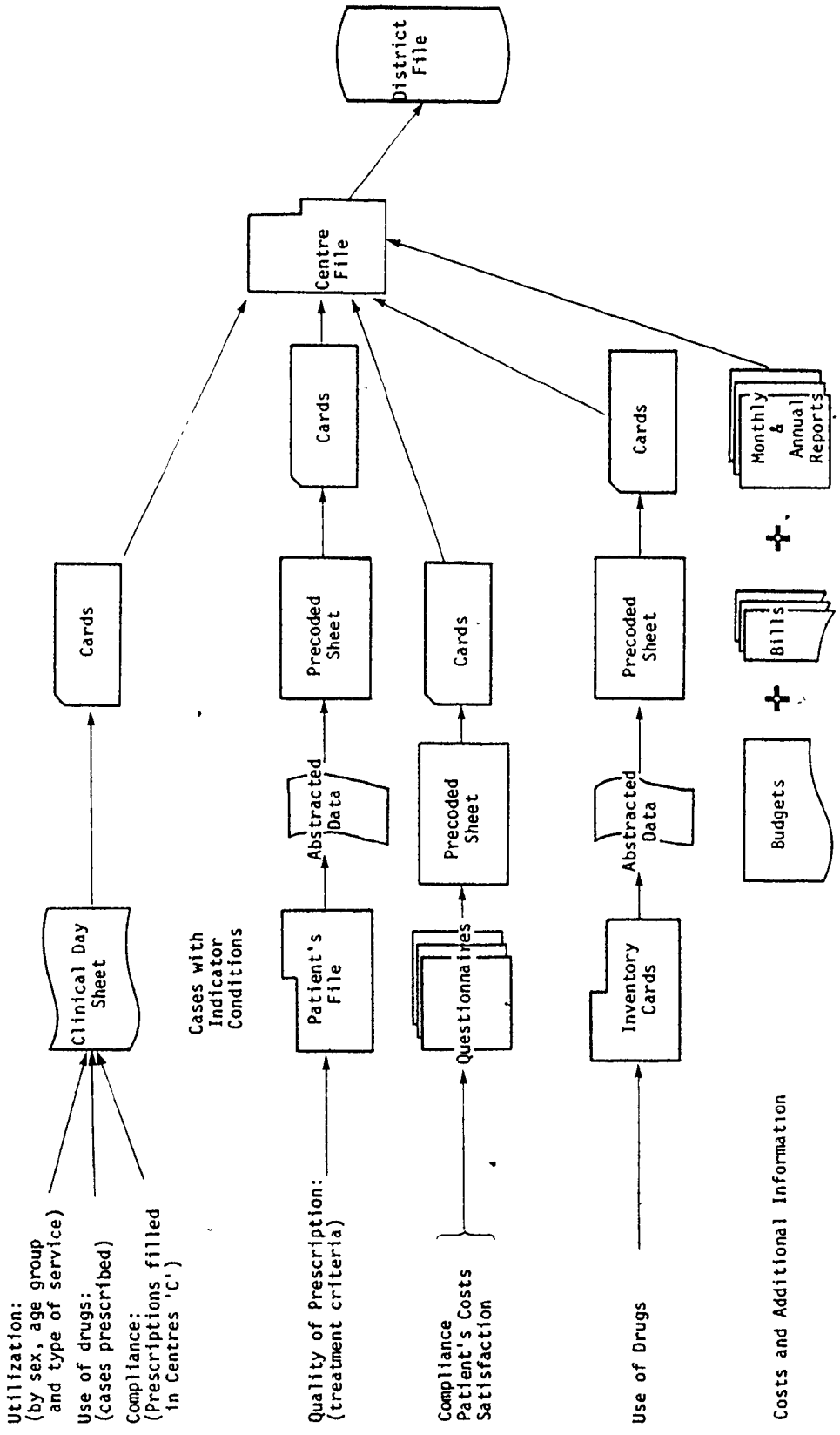
4.11.2 Analysis Strategy

4.11.2.1 Simple Analysis

Since the design of this study is basically a randomized controlled trial, the starting point for analysis is clearly a comparison of control and experimental groups on each outcome measure after the intervention. Randomization provides the foundation for this simple

Figure 4.6

Preparation of Data



approach to analysis. However, it is prudent to investigate other confounding variables which may explain part of the observed post trial differences. In the analysis section which follows, we will indicate for each outcome measure the simple approach.

4.11.3 Allowance for Confounders

In general, if before data is available, one would assume that confounders express their influence through the before level of the measurement and that adjustment for the before trial level would effectively handle all confounders. This would be achieved by either a Student's t-test applied to before/after changes or more generally, through analysis of covariance.

For those outcome variables where no before data is available, we cannot adopt this simple method of handling confounders. Individual factors of importance here would be physician characteristics and perhaps community characteristics which might affect the outcome. Examples would be physician medical school grades, whether they came from an urban or rural community, and their previous experience in working with poor people. Community factors would include general prosperity, percent wage earners, and availability of alternative medical care.

Each potential confounder will be quantified (usually on a simple two level basis) and considered in terms of its relationship to the outcome of interest. Adjustment of between groups differences would be carried out for those factors found to be important. These may vary depending on the outcome being considered.

4.11.4 Description of the Analysis

4.11.4.1 Quality of Prescription: Indicator Conditions

This outcome measure will result in a binary outcome: appropriate, not appropriate. The simple analysis will involve comparing the proportion of epidsodes judged adequate between treated and control centres. The statistical methods depend to a certain extent on the amount of extra centre to centre variation observed. Within centre variation will be binomial and thus we have a potential problem with unequal variances. By taking an arc sin $\sqrt{p}$ transformation, we can avoid this problem and then simply compare groups with an unpaired Student's t-test on the transformed data.

4.11.4.2 Quality of Prescription: Direct Assessment

This measure results in a three level classification. For the purposes of analysis, two binary outcomes will be constructed. The first would reflect the proportions that are judged to produce more good than harm, and the second, the proportion producing more harm than good. Each of these could then be analysed using the approach described for indicator conditions.

In looking at two proportions, we are able to distinguish between the two possible results depicted in Table 4.9. Result 1 shows a clear improvement in situations producing more good than harm, but result 2 shows that while this proportion has increased, so has the proportion resulting in more harm than good!

No before data are available for this measure so that confounders will be investigated as for the indicator condition outcome.

Table 4.9

Direct Assessment Analysis

	Control	Experimental	
		Result 1	Result 2
More Good Than Harm	30%	60%	40%
No Effect Good=Harm	40%	20%	20%
More Harm Than Good	30%	30%	40%
Total	100%	100%	100%

4.11.4.3 Utilization

This outcome measure will consider the total number of medical visits or services provided in a year period per health centre. Given that each health centre has different population (coverage) it would not be appropriate to compare absolute figures (although it will allow us to know the total amount of work handled by each centre); utilization rates (total number of visits/1000 inhabitants) will be compared instead.

The availability of before data allows us comarisons of before versus after interventions within the centres themselves and then a simple way to do this is to submit the "After-Before" difference to a paired t-test. Comparisons between control and experimental group will required of an unpaired t-test.

Confounders in this outcome measure might be physicians' community involvement, accessibility of the centre to the population offered, travel facilities, other medical facilities in the area, proportion of population enrolled in a medical care program and general income. This will be handled by adjusting through an analysis of covariance (Y = utilization, as the dependent variable and each of the confounders as the independent variables on a two level basis: yes, no).

Data available and to be collected will include variables for explaining changes in utilization by looking at the type of visit, whether it was for the first time or subsequent; preventive or curative service; patient characteristics, diagnosis, and so on. This explana-

tory information will be displayed in statistical tables or graphs as descriptive statistics.

4.11.4.4 Compliance

This outcome measure is referred to as the "prescription filling rate" which is defined as the total number of episodes in which a prescription was given and filled divided by the total number of episodes that received a prescription. It is again a binary outcome: filled, not filled; that calls once more for the arc sin $\sqrt{p}$ transformation of the proportion of episodes where the prescription was filled. In order to make comparisons among treatment and control centres, an unpaired Student's t-test will be applied to this transformed data.

Given that the data source (questionnaire) provides information about the place where the prescription was filled, total figures can be subdivided by whether the drug was available in the formulary of the centre or not. Similar analysis as the one cited above can be carried out on these data.

Explanatory information giving reasons for not filling prescriptions can be summarized as well by obtaining the information from the questionnaires and from the clinic day sheet. Figures of each category selected will be displayed on tables comparing treatment and control centres. If necessary, a t-test will be performed in the same fashion as it is proposed for the analysis of indicator conditions.

4.11.4.5 Costs

4.11.4.5.1 Patient's View Point: Patient costs are not recorded exactly but as being in one of a number of cost ranges. This is es-

sentially grouped data and we can either summarize it as a mean cost (using the estimation procedure for grouped data), or a median. Either way the summary cost per centre is then compared between treated and control centres using a Student's t-test.

No before data is available, therefore, adjustments will be done for the after data on the basis of confounders detected.

4.11.4.5.2 Government's View Point: will be measured through rates as follows:

a) Cost per Visit $\frac{\text{Net Investment in a Health Centre}}{\text{total number of medical visits in that centre}}$

b) Cost per Inhabitant $\frac{\text{Net Investment in a Health Centre}}{\text{total population of that centre's coverage}}$

c) Revenue/Investment

$$\text{index} = \frac{\text{total revenue in that centre}}{\text{total investment in that centre}}$$

d) Revenue per Capita

$$= \frac{\text{total revenue in a centre}}{\text{total number of consumers (and/or non-users)}}$$

All these rates will be submitted to a paired t-test for the before-after comparison, and an unpaired t-test on changes for the control-experimental comparison.

Since before data is available, adjustment for confounders will be performed through an analysis of covariance. Variables might be allocations of resources (low vs. high), utilization, communities general income, proportion of wage earners, and so on.

4.11.4.6 Satisfaction

To analyse data from the questionnaires, two alternatives might be considered:

1) Both, physician's and patient's satisfaction will be analysed by individual questions, giving more weight to those questions addressing satisfaction. The proportion of cases (physicians or patients) in each group will be compared in a t-test as before.

2) Other alternatives will be to score the overall questionnaires based on an *a priori* system developed by the D.M.G.F.C. and assessed by the external researcher in order to avoid bais. The proportion of cases satisfied will be used to apply a t-test to show differences between control and experimental centres, if some.

No before data is available, therefore adjustment for confounders will be investigated.

4.11.5 Criteria for Success

This study will be considered a success if it fulfills the following criteria.

a) Quality of prescription is at least 40% better in the Centres C receiving the new pharmacy services than in control Centres C.

b) At least 50% increase in utilization rate is observed after the introduction of the new pharmacy services compared to previous levels of utilization within experimental Centres C and compared with control Centres C.

c) Compliance is 80% better in the treatment centres than in

the control centres.

d) If the average cost of services per episode of health is decreased (a 20% minimum) in treatment Centres C and the investment in new pharmaceutical services is justified by improved medical care (better quality of prescriptions), higher compliance (prescription filling rate) and larger community coverage (increased utilization).

In general terms, we expect improvement in those outcome measures directly linked with the health outcome as depicted in Table 4.10.

It is expected that this analysis will help delineate the effects of introducing pharmaceutical services in Mexican rural centres.

4.12 Ethical Issues

In this study, it is not likely that any major ethical problems will arise since communities are not denied health care nor prescription drugs. People living in the same geographical areas are free to utilize the services offered either in the experimental or control health centres.

In regard to confidentiality of medical records, it is not an ethical issue in rural communities of Tlaxcala. We expect the population will look upon the experimental manoeuvre as favoured treatment. For this reason, no informed consent will be required to access the record system.

A significant outcome in terms of improved utilization, quality of prescription, compliance, use of drugs, satisfaction and lower costs will encourage people to support pharmaceutical services from different

Table 4.10

Criteria for Success

O. Measure	Outcome							
Quality of Prescription								
Indicator Conditions	↑	↑	↑	↑	=↑	↓	↓	↓
Direct Assessment	↑	↑	↑	↑	=↑	↓	↓	↓
Compliance	↑	↑	↑	↑	=↑	↑	↑↓	↓
Utilization	↑	↓	↑↓	↓	=↓	↑	=↑	↓
Cost								
Patient's	↓	↓	↓	↑	↑=↓	↓	=↓	↑
Government's	↓	↓	↑	↑	↑=↓	↓	=↓	↑
Satisfaction								
Patient's	↑	↑	↑	↑=	↑=	↓	=↑	↓
Physician's	↑	↑	↑	↑=	↑=	↓	=↑	↓
	(1)	(2)				(3)		

(1) Outcomes expected
(2) Successful outcomes
(3) Failure

perspective.

The rate and the extent to which other health centres get organized and implemented pharmaceutical services will depend on the outcome in the experimental district. Therefore, any minor inconveniences caused by this study, if some, is justified since it will play an important role in decisions taken by those who decide on health care policies.

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APPENDIX A

Classification of Diseases to be Used in the Primary Medical Care Program. Department of General, Family and Community Medicine, Mexico

Appendix A

Classification of Diseases to be Used in the Primary Medical Care Program Department of General Family and Community Medicine Mexico

Correlated with

1) International Classification of Diseases 9th Revision W H O 1965*
2) International Classification of Health Problems in Primary Care ICHPPC-2) W O N C A 1976*

* Considering list of four-digit categories and [illegible]
** For ICHPPC progressive numbers from 301-337 were used

Position No		Correlation ICHPPC	ICD 8
I	INFECTIVE AND PARASITIC DISEASES		
a	Intestinal Infectious Diseases		
01	Typhoid Fever	part of [illegible]	[illegible]
02	Infective Gastroenteritis and Other Bacterial and Protozoal Diarrhoeal Diseases except Amoebiasis	part of [illegible] part [illegible] 03	[illegible]
3	Amoebiasis	part of 01	006
b)	Tuberculosis		
04	All Forms of Tuberculosis, including Meningitis and Meningo Encephalitis Tuberculosis	004 05	010-019
c)	Zoonotic Bacterial Diseases		
05	Brucellosis	part of 331	023
d)	Other Bacterial Diseases		
06	Leprosy	part of 331	030
07	Whooping Cough	006	033
08	Streptococcal Diseases	[illegible]	034-035
09	Tetanus	331	[illegible]
e)	Poliomyelitis and Other Enterovirus Diseases of Central Nervous System		
10	Poliomyelitis	008	040-044
f)	Exanthemic Diseases		
11	Chickenpox	009	[illegible]
12	Measles	[illegible]	055
13	Other Viral Exanthem	010-011, 013-014 part of 331	050-051 053 054 056-057 excl [illegible] 999
g)	Other Viral Diseases		
14	Infectious Hepatitis	015	070
15	Rabies	part of 331	071
16	Mumps	16	072
h)	Other Arthropod-borne Diseases		
17	Malaria	021	084
	i) Venereal Diseases		
18	All Forms of Syphilis	022	090-097 [illegible]
19	All Gonococcal Infections	023	098
	j) Mycoses		
20	All Dermatomycosis	024	110-111
21	Moniliasis	025-026	[illegible]
22	Deep Mycoses and Systemic Mycosis	part of 331	113-[illegible]
	k) Helminthiasis		
23	All Intestinal Helminthiasis	028	123 excl [illegible] 126-129
	l) Other Infective and Parasitic Diseases		
24	Trichomoniasis Urogenitalis	027	131
25	Acariasis	part of 030	133 0
26	Other Infective and Parasitic Diseases	017-020 029 part of 030 part of 031	000 020-022 036,038-039 045-046,050-052 053-054 060-068 073-079,080-083 085-089 099-103 104 excl [illegible] 120-122,123 1 124-125 130 132 133 except [illegible] 134-136
II	NEOPLASMS		
27	Malignant Neoplasm of Cervix Uteri	part of 036	180

Position No		Correlation ICHPPC	ICD-8
28	Other Malignant Neoplasms	32 035 part of 36 [illegible] 039	140-163 [illegible] 181-199
[illegible]	Benign Neoplasms	[illegible]	210-228
30	Benign Neoplasms of Unspecified Nature	[illegible]	230-239
III	ENDOCRINE NUTRITIONAL AND METABOLIC DISEASES		
31	Diseases of Thyroid Gland	[illegible] 049 part of 057	240-246
32	Diabetes Mellitus	053	250
33	Avitaminosis	part of 5[illegible]	260-266
	Deficiency Anaemias [illegible]		
34	All Nutritional Deficiency	[illegible] 53	67 269
	Obesity	[illegible]	
[illegible]	Other Endocrine Nutritional and [illegible]	[illegible] part [illegible]	[illegible]
IV	DISEASES OF BLOOD AND BLOOD FORMING ORGANS		
	Anemias	[illegible]	280 285
	[illegible]		
	[illegible] anaemias [illegible]		
38	Other Diseases of Blood and Blood-Forming Organs	[illegible] 65	286-289
	Diseases of Blood and [illegible] Forming Organs [illegible]		
V	MENTAL DISORDERS		
39	Psychoses Except Alcoholic	[illegible]	[illegible] 292-299
40	Neuroses	[illegible]	
41	Alcoholism (All Forms and Manifestations) accidental intoxication and poisoning [illegible]	[illegible]	[illegible]
42	Mental Retardation When Non-Attributable to Other Diagnosis	085	[illegible] 315
43	Other Mental and Psychological Disorders	[illegible] 082 084 086	[illegible] 301 302 304-305 306 exc [illegible] 307-309
VI	DISEASES OF THE NERVOUS SYSTEM AND SENSE ORGANS		
44	Meningitis or Meningoencephalitis (when there is no mention of cause) -Tuberculosis meningitis-S-04 -parasitic cerebral infection S-chap I)	part of 091	320-324
45	Epilepsy	089	345
46	Tension and/or Vascular Headache	76 090	306 8 346
47	Diseases of Peripheral Nervous System	part of 091	350-352 354-358
	DISEASES OF THE EYE		
48	Conjunctivitis, Ophthalmia and Other Inflammatory Diseases of the Eye	092-093 part of 099	360-369
49	Other Diseases and Conditions of Eye	094-098 part of 099	370-379
	DISEASES OF THE EAR		
50	Otitis Externa or Media With or Without Mastoiditis	100-102	380-382
51	Other Diseases of the Nervous System and Sense Organs	087 088 part of 091 103-107	330-333 [illegible] 347-349 384-389
VII	DISEASES OF THE CIRCULATORY SYSTEM		
52	Rheumatic Fever and Conditions Associated (Syndenham's Chorea and Chronic Rheumatic Heart Disease)	108	390-398 excl [illegible] as fourth digit
53	Arterial Hypertension	119-122	400-404
54	Ischaemic Heart Disease	109-111	410-414
55	Cerebrovascular Diseases	123-124	430-438
56	Diseases of Arteries and Veins	125-132	440-448 450-458
57	Other Forms of Heart Diseases and Circulatory System	112-118	420-429
VIII	DISEASES OF THE RESPIRATORY SYSTEM		
a)	Acute Respiratory Infections		
58	Acute Upper Respiratory Infections	133 part of 134	460-463 465,501

Position No.		Correlation	
		CHPP	ICD-8
59	Bronchitis, Bronchiolitis and Laryngotracheitis	117-118	466 466 490
60	Influenza	[illegible]	[illegible]
61	Pneumonia and Broncho Pneumonia	[illegible]	480-486
VIII	**Other Respiratory Diseases**		
62	Chronic Bronchitis and Emphysema	[illegible] part of [illegible]	[illegible]
63	Asthma	[illegible]	[illegible]
64	Chronic Upper Respiratory Tract Diseases	part of [illegible] 136 [illegible]	500 502-507
65	Other Diseases of Respiratory System	141 144-14	508 513-519
IX	**DISEASES OF THE DIGESTIVE SYSTEM**		
66	Diseases of Teeth, Oral Cavity, Salivary Glands and Jaws	148-149	520-529
67	Peptic Ulcer	[illegible]	531 534
68	Gastritis and Duodenitis	part of [illegible]	535
69	Appendicitis	[illegible]	540-543
70	Hernias	155 157	550-553
71	Functional Disorders of Intestines	159 161	561 564
72	Cholelithiasis and Cholecystitis	part of 166	574-575
73	Cirrhosis of Liver	part of 165	571
74	Other Diseases of the Digestive System	part of 153 158 160 162-164 part of 165 part of 166, 167	530 536-537 560, 562-563 565-570 572-573 576-577
X	**DISEASES OF THE GENITO-URINARY SYSTEM**		
75	Infective Diseases of Urinary System	part of 168 (if mention of infection) 169-170 172 part of 174	part of 580-583 (if mention of infection) 590 part of 593 5 595 597 part of 599
76	Diseases of Male Genital Organs (-Venereal Diseases S-Chapter 1)	175-180	600-607
77	Disorders of Menstruation	189-193	626
78	Infective Diseases of Female Genital Organs Excl -Venereal diseases (Chap 1) -Breast diseases (5-79)	183-185	612-614 616 0 620-621 3 622 629 3 [illegible]
79	Other Diseases of Genito-Urinary System -Mastitis during pregnancy childbirth and puerperium, 5-83	part of 168 171 173 part of 174 181-182 186-187 part of 194	580-584 without mention of infection 591-592, 593 excl part of [illegible] 594 596 598 part of 599 610-611 615 616 excl [illegible] 624 excl [illegible] 0-3 623-625 627-628 629 excl 3-[illegible]
XI	**COMPLICATIONS OF PREGNANCY, CHILDBIRTH AND PUERPERIUM**		
80	Infective Complications of Pregnancy and Peurperium	198 part of 202 205 part of 206	630 635 670 671 678
81	Toxaemias of Pregnancy and Peurperium	199, part of 202	636-639
82	Abortion and Threatened Abortion	part of 197 200-201	632 3 640-645 631 632 excl [illegible]
83	Haemorrhage and Other Complications of Pregnancy and Peurperium -for diagnosing deliveries without mention of complication, there is another special classification not included in this list	196, part of 197 part of 202 part of 206	633 634 672-677
XII	**DISEASES OF THE SKIN AND SUBCUTANEOUS TISSUE**		
84	Infections of Skin and Subcutaneous Tissue	207-211	680-686
85	Other Diseases of Skin and Subcutaneous Tissue	212-227	690-698, 700-709
XIII	**DISEASES OF THE MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE**		
86	Arthritis and Rheumatism, Except Rheumatic Fever	228-229 part of 230 part of 231	710-712, 713 excl 1, 714-718 717 excl 0-2

Position No.		Correlation	
		HPP	ICD-8
		part of [illegible]	[illegible]
87	Painful Syndromes Related to the Vertebral Column	[illegible] 240	[illegible] 25 [illegible] part of 725 8 [illegible]
88	Other Diseases of the Musculoskeletal System and Connective Tissue	part of [illegible] part of [illegible] part of [illegible] [illegible] 241-246	[illegible]-724 725 excl [illegible] part of 725 8 [illegible] 726-727 729-734 736-738
XIV	**CONGENITAL ANOMALIES**		
89	Congenital Anomalies	[illegible]	[illegible]
XV	**PERINATAL MORBIDITY AND MORTALITY**		
90	Certain Causes of Perinatal Morbidity and Mortality	[illegible]	[illegible]
XVI	**SYMPTOMS AND ILL-DEFINED CONDITIONS**		
91	Symptoms and Ill-Defined Conditions	[illegible]	[illegible]
XVII	**ACCIDENTS, POISONINGS AND VIOLENCE** (list XVII [illegible] correlation)		
92	Fractures, Dislocations, Sprains and Strains	[illegible] part of [illegible]	800-848
93	Lacerations and Injuries Incl injuries caused by [illegible] animals	323 [illegible] 329 part of 33 part of 3[illegible]	87[illegible]-883 890-897 [illegible]-907 910-918
94	Burns	328 part of 332	940-949
95	Toxic Effects (All)	part of 334 part of 335	960-988 989 excl [illegible]

*Source: [illegible]

Appendix B

Huamantla Data

Table B-1

Medical Visits According to Medical Units in Huamantla District
1974-1977

Medical Unit	1974 No.	1975[1] No.	1976[2] No.	1977[3] No.[5]
Centre B[4]	15,392	6,891	9,105	3,801
Centre C	3,389	5,601	11,948	10,712
Health Houses	-	37	356	319
Total	18,781	12,529	21,409	14,832

(1) Observation Period
(2) Irregular Supply of Drugs
(3) Continuous Supply of Drugs
(4) Supply of Drugs for Inpatients Only
(5) Includes a Period of 8 Months Only

*Source: Report No. 1, Primary Med. Care Program. U.N.A.M., 1977

Table B-2

Utilization Rates of Health Centres C, S.S.A.
Huamantla District
1974-1976
(Rates/1000 Inhabitants)

Health Centre C	1974*	1975	1976*
Altzayanca	61.3	273.3	556.5
Cuaplaxtla	123.7	314.4	382.2
El Carmen	87.1	110.0	242.0
E. Zapata	429.5	176.4	810.9
Ixtenco	166.7	291.2	275.9
Teacalco	38.2	176.4	235.5
Terrenate	186.7	325.5	656.1
T. de Guadalupe	216.0	350.6	908.1
Tzompantepec	20.8	112.3	809.6
Xalostoc	180.0	132.2	441.3
Total	116.7	201.1	416.1

* Population Calculated

Source: Population Projections. D.G.E., 1975
Annual Report of Activities, S.C.S.P., S.S.A., 1974-75-76

Table B-3

Annual Incomes from Medical Services Provided and Drugs Issued in Huamantla District from 1975-1978
(In Thousands Pesos)

Centre	1975		1976		1977		1978	
	Services	(Drugs) Medicines	Services	Medicines	Services	Medicines	Services	Medicines
Centres C	40	13	84	82	162	140	186	342
Centre B	360	23	373	34	452	56	570	106
Total	400	36	457	116	614	196	756	448
% Per Year	92.0	8	80	20	76	24	63	37

Source: Financial Monthly Reports, S.S.A.-U.N.A.M.; 1975-1978
Cited in Yañez and Yamamoto, Op. Cit.

Table B-4

Index of Revenue Against Investment in Drugs Huamantla District
1975-1978

Year	Investment	Revenue	Index	Centre B	Centre C
1975	36,042	149,641	0.24	0.31	0.18
1976	115,645	199,641	0.58	0.34	0.95
1977	195,710	348,188	0.56	0.57	1.24
1978	447,797	622,668	0.85	1.17	2.26

Source: D.G.S.C.S.P.E., S.S.A., Annual Budget, 1975-1978
Lopez-Acuna; Op. Cit.

Table B-5

Proportion of Incomes From Selling Drugs in Centre B and C
of Huamantla District
1975-1978

Centre	Year			
	1975 %	1976 %	1977 %	1978 %
B	63	29	29	24
C	37	71	71	76
Total	100	100	100	100

Source: Yanez and Yamamoto: Pharmaceutical Services, U.N.A.M., 1979

Table B-6

Number and Proportion of Prescriptions Filled in Health Centres C of Huamantla District 1978

Type of Medical Service	Cases Prescribed	Prescriptions Filled		Prescriptions Referred	
		No.	%	No.	%
General Medicine	1,656	1,586	96	70	4
Preventive Programs	11,625	11,011	95	614	5
Total	13,281	12,597	95	684	5

Source: Idem Table B-5

Table B-7

Annual Average Income per Medical Unit and Type of Service Provided in Huamantla District, Compared with Remaining Districts, 1978
(In Thousands Pesos)

Year	Huamantla District		Average in Remaining 3 Health Districts	
	Centre B	Centre C	Centre B	Centre C
Medical Services	574	19	146	6
Drugs	68	15	13	3
Total	642	34	159	9

Source: Ponce de Leon, Op. Cit.

Table B-8

Annual Income Average in Huamantla District Compared to Annual Average Income in the Remaining Health Districts, 1975-1978
(In Thousand Pesos)

Year	Huamantla District		Average Remaining Districts	
	Centre B	Centre C	Centre B	Centre C
1975	463	5.4	100	3.7
1976	501	16.6	110	4.4
1977	650	27.4	155	7.6
1978	941	48.0	172	8.5

Source: Ponce de Leon, Op. Cit.

Appendix C

List of Basic Drugs for the Program
S.S.A.-U.N.A.M., Tlaxcala

Appendix C

List of Basic Drugs for the Program
S S A - U N A M Tlaxcala

Code	Brand Name	Generic Name	
001	Adrenital	Epinephrine	Amp 2 ml
002	Agarol	Mineral Oil	Susp 177 ml
003	Aldomet	Methyladopa	Tabs 250 mg
004	Alupent	Isoproterereol	Syrup 10mg/5ml
005	Aminofilina	Aminophylline	Amp 0 25 mg
006	Artosin	Tolbutamide	Tabs 5 gr
007	A - S Cor		
008	Aspirina	Aspirin	Tabs 500 mg
009	Atropigen	Atropine	Amp 2 mg/ml
010	Avapena	L-Amino-Pyridine	Amp 20 mg
011	Bectivo	Ammonium Chloride	Syrup (Infant)
012	Bectivo	Ammonium Chloride	Syrup (Adult)
013	Benadryl	Diphenhydramine HCl	Cap 25 mg
014	Benadryl	Diphenhydramine HCl	Syrup 12 5 mg/5ml
015	Benadryl	Diphenhydramine HCl	Amp 50 mg
016	Benzanil	Benzathine Penicillin G	Amp 1,200,000 U
017	Benzanil	Benzathine Penicillin G	Amp 600,000 U
018	Bicarsol	Sodium Bicarbonate	Amp 50 ml
019	Binotal	Ampicillin	Cap 500 mg
020	Binotal	Ampicillin	Amp 500 mg
021	Binotal	Ampicillin	Susp 250 mg
022	Bioxiquin	Diiodohydroxiquin	Tabs 210 mg
023	Bioxiquin	Diiodohydroxiquin	Tabs 650 mg
024	Bonadoxina	Meclizine and Pyridoxine	Tabs 25 mg
025	Bonadoxina	Meclizine and Pyridoxine	Drops
026	Bonadoxina	Meclizine and Pyridoxine	Amp 1 ml
027	Buscapina	Hyoscine Butyl	Amp 0 02 gr
028	Buscapina	Hyoscine Butyl	Tabs 0 01 gr
029	Calcium Sandoz	Calcium glucoheptonate	Amp 10%
030	Casec	Calcium caseinate	Bt 95 gr
031	Cedilanid	Lanatoside C	Amp 400 mg
032	Cloramfenicol	Chloramphenicol	Cap 250 mg
033	Cloramfenicol	Chloramphenicol	Susp 250 mg
034	Cloramfenicol	Chloramphenicol	Amp 1 gr
035	Cloramfeniofteno	Chloramphenicol	Eye drops 5 mg
036	Cloruro de Potasio	Potasium Chloride	Am Sol
037	Complejo B Carnot	Vit B_1, B_6 and B_{12}	Tabs
038	Complejo B Carnot	Vit B_1 B_6 and B_{12}	Amp 10 ml
039	Corpotasin	Potasium Chloride	Tabs
040	Dextrabot	Dextrosa	Sol 500 mg 5%
041	Diabinese	Chloropropamide	Tab 250 mg
042	Digoxina Nativelle	Digoxin	Tabs
043	Efortil	Ethylamine Etano Chloride	Amp 10 mg
044	Emetina	Dihydro emetine	Amp 30 mg
045	Epamin	Diphenylhydantoin	Cap 30 mg
046	Epamin	Diphenylhydantoin	Cap 100 mg
047	Epamin	Diphenylhydantoin	Susp
048	Epontol	Propanidid	Amp 0 5 gr
049	Eprofil	Thiabendzaole	Tabs
050	Epson	Magnesium Sulfate	Amp 2 ml
051	Ergovin	Ergonovine	Amp 2 ml
052	Escabinsan	Bencille Benzoatne	Sol
053	Espasmo Cibalgina	Antipyrine	Tabs
054	Espaven Enzimatico	Dimethyl Polisiloxane	Tabs
055	Flebocortid	Hydrocortisone	Amp 500 mg
056	Flebocortid	Hydrocortisone	Tabs 100 mg
057	Fenobarbital	Phenobarbithal	Tabs 100 mg
058	Furoxone	Furazolidine	Susp
059	Garamicina	Gentamicin	Inj Ped
060	Garamicina	Gentamicin	Amp 200 mg
061	Gantricin	Sulphisoxazole	Tabs 500 mg
062	Glicerina Sup	Glycerine	Sup
063	Metronidozole	Gyatricol	Tabs 250 mg
064	Metronidozole	Gyatricol V	Ovulos
065	Metronidozole	Gyatricol Susp	Susp
066	Hydrazone	Hain	Tab 50 mg
067	Homatropine	Homatropina	Oral drops
068	Indocid	Indomenthacin	Cap 25 mg
069	Insulina Simple	Cristalline Insuline	Amp
070	Insulina NPH	N P H Insuline	Amp
071	Kantrex	Kanamycine	Amp 75 mg
072	Kantrex	Kanamycine	Ampt 500 mg
073	Kaopectate	Kaolin and Pectin	Susp
074	Ketalar	Ketamine HCl	Amp 20 ml
075	K 25	Vit K	Amp 25 mg
076	Lasix	Furosemide	Amp
077	Lasix	Furosemide	Tabs
078	Lassar	Lassar s Paste	Paste
079	Mandelamine	Methamine Mandelate	Tabs
080	Manitol	Mannitol	Sol
081	Melox	Aluminum Hydroxide	Tabs
082	Melox	Aluminum Hydroxide	Susp
083	Methergin	Metylergonovine Maleate	Amp
084	Meticorten	Prednisone	Tabs 5 mg
085	Metocarbin	Methocarbamol	Caps 500 mg
086	Myambutol	Ethambutol	Tab 400 mg
087	Neo Melubrina	Dimethylpirazolone	Amp 5 ml
088	Neo Melubrina	Dimethylpirazolone	Tab 500 mg
089	Uvabaina Arnaud	Ouabain	Amp 0 25 mg
090	Pantomicina	Erithromycin	Cap 250 mg
091	Pantomicina	Erithromycin	Susp 125 mg
092	Pas	Para-Aminosalicylic Acid	Tabs
093	Penic Sodica Criste	Cristalline Sodium Penicillin	Amp 5 000 000 U
094	Penic Sodica Criste	Cristalline Sodium Penicillin	Amp 1,000 000 U
095	Penprocilina 400	Procaine Penicillin	Amp 400 000 U
096	Penprocilina 800	Procaine Penicillin	Amp 800,000 U
097	Permanganato de K	Potasium Permanganate	
098	Persantin	Dipyridamole	Tab 25 mg
099	Piperazina	Piperazine	Susp 100 ml
100	Piridium	Pyridium	Tabs
101	Poly-VI Sol	Vitamines C and D	Sol
102	Premarin	Conjugated Estrogens	Tabs 2 5 mg
103	Primodus	Progesterone and Estrogens	Amp
104	Primperan	Metoclopramide	Comp 10 mg
105	Procto Glyvenol	Oxyeridon	Paste
106	Raucitol	Reserpine	Amp 1 ml
107	Robitusin	Guaifenesin	Syr 125 ml
108	Sobee	Soya Flour	Pwd
109	Solucion Fisiologica	Sodium Chloride	Sol 250 ml
110	Solucion Fisiologica	Sodium Chloride	Sol 500 ml
111	Solucion Fisiologica	Sodium Chloride	Sol 1000 ml
112	Solucion Glucosada	Dextrose 5% in Water	Sol 250 ml
113	Solucion Glucosada	Dextrose 5% in Water	Sol 500 ml
114	Solucion Glucosada	Dextrose 5% in Water	Sol 1000 ml
115	Solucion Hartman	Dextrose 5% in Water	Sol 500 ml
116	Suero Antiviperino	Snake Bite Antiserum	Sol
117	Sulfantiazol [illegible]	Snake Bite Sol [illegible]	
118	Sulfato Ferroso	Snake Bite Iron	
119	Syntocinon	Oxytocin	Amp [illegible]
120	Tempra	Acetaminophen	Sol
121	Tempra	Acetaminophen	Sol (Infant)
122	Tessalon	Benzonatate	Sol (Infant)
123	Tetraciclina	Tetracycline	Amp 100 mg
124	Tetraciclina	Tetracycline	[illegible] 250 mg
125	Vasodilan	Isoxsuprine HCl	Amp 20 mg
126	Valium	Diazepam	Tabs 2 mg
127	Valium	Diazepam	Tabs 5 mg
128	Valium	Diazepam	Amp 10 mg
129	Vanquin	Pyrvinium Pamoate	Susp
130	Vioformo	Iodochlorhydroxyquin	Paste
131	Wintomilon	Nalidixic Acid	Tabs
132	Xilocaina Pesada	Lidocaine	Amp 2 ml
133	Xilocaina Topica	Lidocaine	Paste
134	Xilocaina 2%	Lidocaine	Amp 50 ml
135	Yomesan	Niclosamide	Tabs 500 mg
136	Neogynon	Ethinyl Estradiol and Norgestrel	Tabs
137	Norinyl	Norethindrone	Tabs
138	Riglovis	Ethinyl Estradiol and Quingestanal	Tabs

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Appendix D

Record System and Data Gathering Instruments

Appendix D-1

PRECODED CLINIC DAY SHEET

(1) Centre______________ [][][] (2) Physician________________________ [][] (3) Day

Column No. (5)	(6)	(7)		(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	
Patient Name	Patient Number	Age		Sex	Occupation	Residency	Type of Consultation	Diagnoses/Health Problem	Code	Duration	Previous Treatment	
		Years	Months									
								1.				1.
								2.				2.
								3.				3.
								1.				1.
								2.				2.
								3.				3.
								1.				1.
								2.				2.
								3.				3.
								1.				1.
								2.				2.
								3.				3.
								1.				1.
								2.				2.
								3.				3.
								1.				1.
								2.				2.
								3.				3.
								1.				1.
								2.				2.
								3.				3.
								1.				1.
								2.				2.
								3.				3.

1 of

Appendix D-1

PRECODED CLINIC DAY SHEET

________________ [][]   (3) Day of Week__________[]   (4) Date: [][][][][][]

(12) Diagnoses/Health Problem	(13) Code	(14) Duration	(15) Previous Treatment	(16) Treatment	(17) Filling Drugs	(18) Program	(19) Service Fees	(20) Drugs Fees	(21) Total Fees
				1.					
				2.					
				3.					
				1.					
				2.					
				3.					
				1.					
				2.					
				3.					
				1.					
				2.					
				3.					
				1.					
				2.					
				3.					
				1.					
				2.					
				3.					
				1.					
				2.					
				3.					
				1.					
				2.					
				3.					
				TOTAL:					

2 of 2

Instructions to Fill in the Clinic Day Sheet (C-1)

No.

1 Centre: First cell is for the district number where:
1. Tlaxcala
2. Huamantla
3. Apizaco
4. Calpulalpan

The subsequent two cells are for the Centre number from 01 to 15, in alphabetic order.

2 Physician Number: According to the alphabetic list of U.N.A.M.

3 Day of Week: From 1-7 starting on Sunday.

4 Date: Cells 1 and 2 for the Month; 3 and 4 for the Day; and 5 and 6 for the Year.

5 Patient's Name: Beginning with Family name.

6 Patient's Number: According to S.S.A. Rules.

7 Age: When over 24 months old, use columns for Years (01,35, etc.). If under 24 months, use columns for Months (02 months, 18, etc.)

8 Sex: 1 if Male; 2 if Female.

9 Occupation: From 01 to 14 according to specific classification.

10 Residency: Place where the patient or patient's family (if under 1 year old) has lived during the last 6 months:
1. From the Village/Town
2. From the Centre's coverage area (According to S.S.A.)
3. From outside the coverage area.

11 Type of Consultation: Include categories from 01 to 10 according to the place where the consultation takes place and whether it was a first or subsequent visit.

12 Diagnoses of Health Problem: The first row refers to the diagnoses, or problem from which the patient seeks medical care. The remaining 2 rows allow other diagnoses detected by the physician.

13 Code: Diagnoses code according to the classification of diseases of the D.M.G.F.C.

14 Duration: In this cell, the duration of diagnosis detected for first time, is recorded according to 5 categories.

15 Previous Treatment: Allows to record 9 categories.

16 Treatment: Refers to the medical treatment provided in the

No.

health centre (advice, drugs, surgery, etc.). Names of medical interventions or drugs and advice given will be recorded.

17 Filling Drug: Allows to record:
1. If prescription filled in the Centre
2. If prescription is not filled in the Centre due to patient's circumstances
3. If prescription is not filled in the Centre because drug is not available, though included in the list
4. If prescription is not available in the Centre because drug is not included in the list.

18 Program: Allows for 21 categories based on the primary and secondary prevention programs of the S.S.A. and the type of service provided.

19 Fees for Services: The amount of money paid by the patient for the service received or the specific code when it is free.

20 Fees for Drugs: The amount of money paid by the patient for drugs received or the specific code when they are given free.

21 Total Fees: The sum of columns 19 and 20 or the corresponding code when necessary.

Appendix D-2

Front Page

No. of Expedient: _____

Name: _____

Birth Date: _____ Sex: _____

List of Problems	Date of Initiation	Problem Status

Solutions Propossed

Clinical History

IDENTIFICATION SECTION

Name:_____ File No.:_____

Birth Date:_____ Sex:_____

Marital Status:_____ Informer:_____

Date:_____

PRESENT ILLNESS

Previous Illnesses/Backgound Information:

Adolescence:

Adulthood:

Risk Factors:

Smoking: From:_____ Amount:_____ To:_____

Alcohol: From:_____ Amount:_____ To:_____

Drug Adiction:_____

Religion:_____ Wage/Salary:_____

Continued with General Amnonesis

ROUTINE QUESTIONS

General Symptoms:

Skin and Appendages:

Organs of Sense:

Respiratory System:

Cardiovascular System:

Gastrointestinal System:

Urinary System:

Nervous System:

Endocrine System:

Blood:

Locomotor System:

PHYSICAL EXAMINATION

Date	Height	T/A	Pulse	Temp.	Resp.

General Inspection:

Skin and Appendages:

Head:

Neck:

Chest:

Abdomen:

External Genitals

Rectal Examination:

Vaginal Examination:

Date	Height	T/A	Pulse	Temp.	Resp.

Arms and Legs:

Column:

Neurological Examination:

Diagnosis:

Laboratory Test:

Treatment:

EVOLUTION NOTES

No. of Expedient:_____

Name:_____

Date and Hour	a) Clinic Manifestations b) Diagnosis c) Treatment d) Observations

Occassional Visit	Expedient:_____ Name:_____ Age:_____ Sex:_____

Date	Weight	Height	T/A	Pulse	Temp.	Resp. Freq.

Clinical Manifestations:

Diagnosis:

Treatment:

Lab and X-Rays:

Next Appointment:_____ Physician:_____

Date	Weight	Height	T/A	Pulse	Temp.	Resp. Freq.

Clinical Manifestations:

Diagnosis:

Treatment:

Lab and X-Rays:

Next Appointment:_____ Physician:_____

Appendix D-3.1

Quality of Prescription Indicator Conditions

Centre: [][][] Date: [][][][][][][]
Abstractor: []
Patient's Name:_____ No. _____
Patient's Age:_____ Sex _____
Diagnosis:_____ Case No. _____
Clinic Day Sheet Reviewed:_____
---detach here---

1. Identification:

   Patient's Age:_____ Sex:_____ Case No. _____

   Diagnoses:_____
(or Indicator Condition)

2. Description of health problem (signs and symptoms and/or evolution, as described in the medical record):

3. Treatment

a) Specific treatment, drugs

Drugs (brand and generic names and form and strength)	Dose & Administration	Duration
1.		
2.		
3.		
b) Other general measures		
1.		
2.		
3.		
c) Other treatments		
1.		
2.		
3.		

SCORE:

Appendix D-3.1

Instructions to Fill in the Quaility of Prescription Sheet

1. Centre: Identifies the Health Centre according to the code used in the "Clinic Day Sheet"

2. Date: The two left cells are for the day; the middle two cells are for the month, and the last two cells are for the year

3. Abstractor: Code of the research assistant who abstracts information from the Clinic Day Sheet and patient's file

4. Clinic Day Sheets Review From-To:
   Refers to the date of Clinic Day Sheets reviewed during a visit, in order to find indicator conditions

5. Case No.: Filled in by the main researcher

6. Identification Section:
   Should include Patient's sex and age, as well as case number and diagnosis.

   Patient's Sex: Male
   Patient's Age: 13 years
   Case Number: 3
   Diagnosis: Write down the diagnosis as it is in the Clinical History or Day Sheet, followed by the corresponding indicator condition name in brackets, e.g.
   Acute diarrhea
   (Gastroenteritis)

7. Description of Health Problem Column:
   Describes the health problem identified as an indicator condition. Information will be extracted from the patient's file. From the "Present Illness" section of the Clinical History, when it refers to a patient seen for the first time in the Health Centre. If it refers to a subsequent patient, information might be obtained from the evolution notes in the Clinical History, when dealng with chronic problems. From "Occasional Visit" section in the case of new acute problems.
   If no information is available in these sections, go to "List of Problems". If still no information, re-

cord the one from the Clinic Day Sheet: Diagnosis and Treatment columns. Place a note why a full description of the health problem is not included.
Information should be recorded as it is in the patient's file. DO NOT ASSUME SIGNS, SYMPTOMS OR EVOLUTION NOT RECORDED. DO NOT CHANGE THE WORDING.

8. Treatment Section:

Refers to the names (brand and generic) of each drug prescribed for that indicator condition. Strength, form, dose and duration should be included as shown below:

e.g. Gyatricol (Brand Name)
Metronidazole (Generic Name)
Tabs. 250 mg. (Form and Strength)
1 Tab /After each meal (3/day orally; Dose and administration)
During 10 days (Duration)

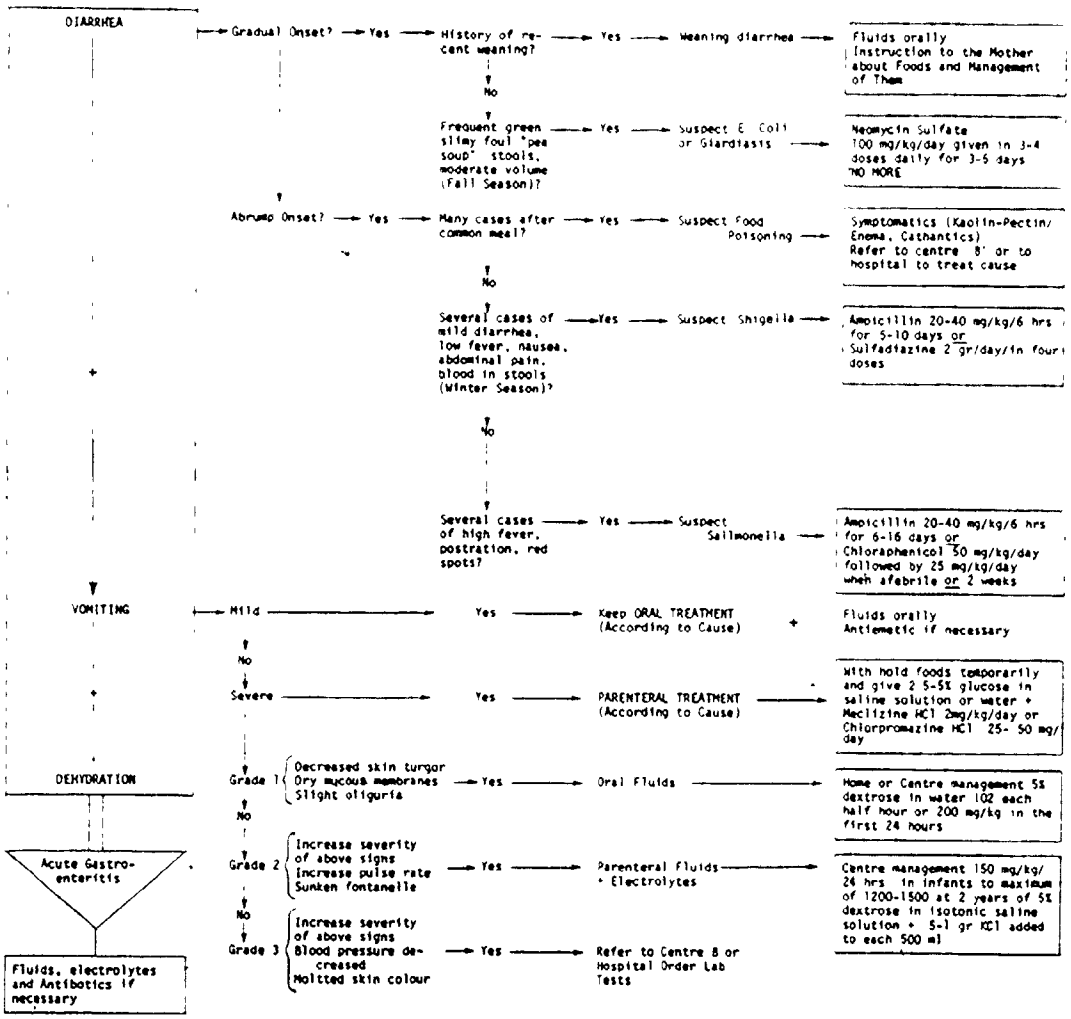
9. Scoring Section:

To be filled by the external researcher in Mexico City. This score will be based on the corresponding "Indicator Condition Chart" and the scores given there

Appendix D-3.2

Indicator Conditions Chart
Acute Gastroenteritis in Children Under Two Years Old

Section I



References: 78 - Op Cit., 79 - Op Cit , 80 - Op. Cit , 81 - Op Cit

Appendix D-3.3

Criteria for Scoring
Acute Gastroenteritis in Children Under Two Years Old

Definition of an Episode: *Infant under two years of age presenting diarrhea with/without vomiting and/or dehydration*

Section II - Criteria for Prescription

1. Once the disease is diagnosed as a primary or secondary health problem.

2. When the diagnosis is suspected because of clinical findings or lab reports and differential diagnoses have been considered and discharged.

3. When a child has presented mild diarrhea for more than 12 hours. If the cause has not been determined, or suspected, treat it symptomatically.

4. When a child has presented severe diarrhea for more than 6 hours. If cause has not been determined, or suspected, treat it symptomatically and restore fluids and electrolytes.

5. When a child has presented diarrhea and other symptoms or signs are present (vomiting, fever, dehydration) for more than 3-6 hours. If cause has not been determined or suspected, treat symptomatically.

6. When the cause of diarrhea in a child is suspected or identified, treat according to cause and restore liquids and electrolytes.

In mild diarrhea and no vomiting or occasional vomiting, treatment should be administered orally, unless hydration requires I.V. administration.

1. Kaolin-Pectin: Used in older children as a symptomatic when mild diarrhea is the only sign. Dose 15-30 ml. orally (1-2 tbsp.) a day or when necessary for no more than 3 days. Not used when child is dehydrated.

2. Neomycin Sulfate: Used only when E. coli, Amoeba or Giardia is suspected.
   Dose: 100 mg/kg/day given in 3-4 daily doses for 3-5 days.
   It might be administered I.M., I.V. or orally.

If organism is Neomycin-resistant change for Colistin 5-10 mg/kg/day orally in 2-3 doses for 3 days
Other alternatives after failing with the former drugs are:

a) Gentamycin: 25 mg/kg/day orally divided in 2 doses for 3-5 days.

b) Kanamycin: 15 mg/kg/day I.M. in 2 divided doses.

c) Polymyxin B: 3.5-4 mg/kg/day I.M. in 3 divided doses.

USE THESE DRUGS ONLY WHEN ORGANISM-RESISTANT

3. Ampicillin: Used only when infective agent is suspected or demonstrated by lab-tests and the organism is ampicillinsensitive.
Dose: 25-50 mg/kg/day divided in 3 doses (20-40 mg/kg/every 6 hours). This is a "first choice drug". Not to be used in 5% dextrose. Ampicillin in the first week of life should be administered in 100 mg/kg/day I.V. or I.M. in 2 or 3 divided doses, for 5 to 10 days.
If resistance to ampicillin, and shigellosis is suspected, give sulfadiazina starting with 2 gr/day oral or I.M. in four doses accompanied by equal counts of sodium bicarbonate, and then 1-2 gr C/4 hours. Use it cautiously for 3-5 days.
Other alternatives might be tetracycline 25 mg/kg/day orally or I.M. in 4 divided doses during 3-5 days. Leave these 2 drugs as the last alternative.

4. If salmonella is suspected or demonstrated and there is no risk of complications, treat it sysmptomatically. If some risk and organism is ampicillin-resistant, use chloramphenicol (never used as a first choice because it might produce the Grey Syndrome). It might be used orally as palmitate in suspension or I.M. or I.V. at a dose of 100 mg/kg/day divided in 4 doses during 3-5 days followed by 50 mg/kg/day for 2 weeks.

5. Restoration of fluids and electrolytes:

a) Mild dehyration (Grade I): 5% dextrose in water orally, 1 oz. each half hour or 200 ml/kg in the first 24 hours.

b) Moderate dehydration (Grade II): 150 ml/kg/24 hrs. in infants to a maximum of 1000-1200 ml at 1 year of 5% dextrose in isotonic saline solution plus 5 g-1 gr. KCl added to each 500 ml as soon as urine has been passed.

c) Severe dehydration (Grade III): Refer to hospital. If it is feasible to manage at Centre, replace volume as follows:
Calculate deficit + Normal maintenance

Requirements + Allowance for Continuing losses and add electrolyte replacement after having lab test, as follows:

Deficit: 1/2 isotonic saline with 5% dextrose
Maintenance: 1/5 isotonic saline with 5% dextrose plus KCl as in (b).

6. Antiemetic Agents: In case of mild vomiting antiemetic drugs might not be necessary, otherwise use them cautiously and only when necessary.

   a) Chloropromazine HCl: single dose of 0.5 mg/kg I.M. or orally, or 1 mg/kg rectally. The dose may be repeated every 4 to 6 hours if necessary. NOT OVER 40 mg/day.

   b) Meclizine HCl: 2 mg/kg in a single dose or every 6-12 hours orally.

Section IV - Contraindicated Drugs

1. Sulfas, Tetracyclines, Chloromphenicol, Polynyxin B, Kanamycin, Gentamycin and Sulfomidaes: Used as a "first drug or choice".

2. Other antibotics not listed in Section III.

3. Combinations of Kaolin-Pectin and bismuth mixtures or Kaolin-Pectin and antibiotics, because of their respiratory depressant action.

4. Use of Kaolin-Pectin in dehydrated children.

5. Mixtures of analgesics or antibiotics.

6. Use of alkaloids and/or diphenoxylate hydrochloride (Lomotil).

7. KCl before urine has passed.

Section V - Scoring

1. Appropriate Prescription, when:

   a) A case is diagnosed as a non-infective gastroenteritis (mild diarrhea, no vomiting or mild and no dehydration or mild) is treated symptomatically with adequate amount of fluids and replacement of electrolytes orally.

   b) The cause has not been established and diarrhea and dehydration are treated symptomatically, either orally or parenterally according to severity.

c) When severe vomiting appear, cause is undetermined and child is treated symptomatically (including antiemetics) in parenteral administrations.

d) Cause is established and specific treatment is given using drug of choice first in the appropriate dose, and length of time. No more than one antibiotic is given at the same time. Adequate management of vomiting and dehydration according to severity.

e) When second choices are used after failing with first "drug of choice" or organism has been demonstrated by lab test to be resistant. Drugs should be used in the right dose, and time and administration along with the restoration of fluids and electrolytes.

2. Inadequate Prescription:

a) When antibiotics are used in mild cases.

b) When antibiotics are used in cases where cause is to be determined or susceptible organism is not suspected.

c) When antibiotics or antidiarrheal drugs are used without restoring fluids and electrolytes.

d) When prescriptions are right but doses and/or duration are excessive or inadequate.

e) When using more than one antibiotic.

f) When using alternative drugs as a first choice.

g) When using oral administration of drugs in severe vomiting or dehydration.

h) When hydration and electrolytes replacement is excessive or inadequate.

i) When using contraindicated drugs (2-7 in Section IV).

3. Less than appropriate:

a) Diarrhea is treated asymptomatically when cause has not been determined, but restoration of fluids does not fulfill requirements.

b) When fluids and electrolytes replacement are adequate, but diarrhea is not treated when necessary.

References: 74 - Op. cit., 80 - Op. cit., 81 - Op. cit., 82 - Op. cit.

Appendix D-4

Quality of Prescription Use of Drugs Chart (Direct Assessment)

Drug: Chloramphenicol
(Bacterial. Streptomyces venuzuelae. Also synthetic.)

Generic Name	Brand Names	Presentation Form
ex. Chloramphenicol sodium succinate Chloramphenical palmitate	ex. Chloromycetin Topic Ophthalmic Otic Systemic Chloroptic	ex. Cream, 10 mg., 1% Ophthalmic -Hydrocortisone, 2.5mg/5ml -.5%, 7.5 ml Otic drops, .5%, 15 ml Cap. 100 and 250 mg Amp. 1 gr Palmitate Susp, 125 mg, 60 ml Ophthalmic, .5%, 10 ml

Duration of Treatment: No less than 3 days nor more than 10 days. If resistance further study of patient and health problem

Uses: a) Age Group: Adults, children and full term infants over 2 weeks.
General dose: 50-100 mg/kg/day in divided doses of 6-8 hours.

b) Health Problems: Effective against many organisms, but especially the gram-negative organisms (calm-thyphoide group). Useful in certain urinary infections and in many other conditions but should be reserved for serious infections caused by susceptible organisms when less potentially hazardous therapeutic agents are ineffective or contradicted.

Side Effects: Nausea, vomiting, diarrhea, enterocolitis, unplesant taste, dryness of mouth. Serious, even fatal blood dyscrasias with bone marrow depression may occur. Reduce or stop drug and treat as necessary. Neurotoxicity may occur and is evidenced by headache, mental depression, confusion, optic neuritis, digital paresthesia, peripheral nuritis can cause Gray syndrome or fetal death, since drug does cross placental barrier.

Contraindications: Use cautiously in pregnant women, preferable not used. Patient with blood dyscrasias, Never as first antibiotic choice, except in those cases of typhoid fever or paratyphoids.

Incompatibilities: Polymixin B, Tetracycline, vancomycin, hydrocortisone, and B complex vitamins.

Criteria for Rating Use of Chloramphenicol:

Appropriate: when used in patients over 2 weeks old presenting a typhoid group disease and using the dose and time indicated before.

When used as a second choice because first antibiotic was ineffective or organisms is shown by lab test to be susceptible to chloranphenicol.

Inappropriate: used when contraindications above described are present. When it is used as a first antibiotic in all the remaining infective and non-infective cases. When used as a second antibiotic and susceptibility of organisms has not been demonstrated.

References: 82 - Op. cit., 83 - Op. cit., 84 - Op cit., 85 - Op. cit.

Appendix D-5

Patient's Questionnaire to Record Compliance

Centre: [][][][] Date: Dy [][] Mn [][] Yr [][]

Patient's Name:_____ Patient's No.:_____

Address:_____

Respondent:_____ Interviewer:_____

Health Problem:_____ Code: [][][]

Prescriptions: A _____ [][][]

B _____ [][][]

C _____ [][][]

	A	B	C
1. Did you buy the drugs prescribed?	[]	[]	[]
1. Yes	[]	[]	[]
2. No (go to Question 10)	[]	[]	[]
2. Where did you buy it (A, B, C)?	[]	[]	[]
1. In the health centre?	[]	[]	[]
2. In a local store?	[]	[]	[]
3. In a local drugstore or physician office?	[]	[]	[]
4. From a neighbour?	[]	[]	[]
5. In other health centre:_____	[]	[]	[]
6. In a drugstore out of town?	[]	[]	[]
7. In a physician office out of town?	[]	[]	[]
8. In a hospital?	[]	[]	[]
9. Other (specify):_____			
3. How much did you pay for it (A, B, C)?	[]	[]	[]
0) Unknown	[]	[]	[]
1) Less than $10.00 (Mexican Pesos)	[]	[]	[]
2) $10.00 - $25.00	[]	[]	[]
3) $26.00 - $50.00	[]	[]	[]
4) $51.00 - $75.00	[]	[]	[]
5) $76.00 - $100.00	[]	[]	[]
6) $101.00 - $150.00	[]	[]	[]
7) More than $150.00	[]	[]	[]
8) Free (because of the program)	[]	[]	[]
9) Exempted (because of economic conditions)	[]	[]	[]

	A	B	C
4. When did you buy them?	[]	[]	[]
0) Unknown	[]	[]	[]
1) At the moment of the consultation	[]	[]	[]
2) Less than 1 day after the prescription	[]	[]	[]
3) Between 1-3 days	[]	[]	[]
4) Between 3-5 days	[]	[]	[]
5) More than 5 days but less than 10 days	[]	[]	[]
6) More than 10 days	[]	[]	[]
5. Did you travel to get it (A, B, C)?	[]	[]	[]
0) Unknown	[]	[]	[]
1) Yes	[]	[]	[]
2) I sent for them (it)	[]	[]	[]
3) No (Go to Question 11)	[]	[]	[]
6. Where did you go or sent for it (A, B, C)?	[]	[]	[]

Name of the town or city:_____

7. How did you get there?	[]	[]	[]
1) By walking	[]	[]	[]
2) By bus	[]	[]	[]
3) By car	[]	[]	[]
4) By taxi	[]	[]	[]
5) By horse/burro	[]	[]	[]
6) By bicycle	[]	[]	[]
7) Other:_____			
8. How much did you pay to get there (bus fare, gas, etc.)	[]	[]	[]
0) Unknown	[]	[]	[]
1) Less than $5.00	[]	[]	[]
2) From $5.00 - $10.00	[]	[]	[]
3) From $11.00 - $25.00	[]	[]	[]
4) From $26.00 - $50.00	[]	[]	[]
5) From $51.00 - $100.00	[]	[]	[]
6) More than $100.00	[]	[]	[]
9. How long did it take from here to there?	[]	[]	[]
1) Less than 30 minutes	[]	[]	[]
2) Between 30 minutes - 1 hour	[]	[]	[]
3) Between 1 - 2 hours	[]	[]	[]
4) More than 2 hours (specify):_____			

(Skip to Question 10)

	A	B	C
10. May I see the drug(s)?	[]	[]	[]
1) Patient shows it	[]	[]	[]
2) Patient refuses to show it	[]	[]	[]
3) Patient gives a justification for not showing it	[]	[]	[]
11. Why did you not buy the drugs?	[]	[]	[]
1) I had no money	[]	[]	[]
2) Drugs were not available in the Centre	[]	[]	[]
3) Already had the drugs from an old prescription	[]	[]	[]
4) Seek other sources of cure in the community	[]	[]	[]
5) Seek other sources of cure out of the community	[]	[]	[]
6) Inability to travel to get them	[]	[]	[]
7) Patient died	[]	[]	[]
8) Mild problem	[]	[]	[]
9) Patient recovered	[]	[]	[]
12. Did he/she take the drugs prescribed?	[]	[]	[]
0) Unknown	[]	[]	[]
1) Yes	[]	[]	[]
2) No	[]	[]	[]
13. Calculate amount of drug consumed	[]	[]	[]
1) Complete	[]	[]	[]
2) Almost complete	[]	[]	[]
3) Half	[]	[]	[]
4) Almost empty	[]	[]	[]
5) Empty	[]	[]	[]
14. How is the patient now?	[]	[]	[]
0) Unknown	[]	[]	[]
1) Cured	[]	[]	[]
2) Worse	[]	[]	[]
3) Without change	[]	[]	[]
4) Died	[]	[]	[]
15. What kind of medical care did you receive in the Centre?	[]	[]	[]
1) General consultation (home visit or office visit)	[]	[]	[]
2) Follow-up in primary preventive program	[]	[]	[]
3) Follow-up in secondary preventive program	[]	[]	[]
4) Delivery	[]	[]	[]
5) Minor surgery	[]	[]	[]
6) Immunization	[]	[]	[]
7) Nursing aids	[]	[]	[]
8) Emergency	[]	[]	[]

Appendix D-6

Patient's Questionnaire to Record Costs

Centre: [][][] Date: Dy [][] Mn [][] Yr [][]

Patient's Name:_____ Patient's No.:_____

Address:_____

Respondent:_____ Interviewer:_____

Health Problem:_____ Code: [][][]

Prescription: A _____ [][][]

B _____ [][][]

C _____ [][][]

	A	B	C
1. What kind of medical care did you receive in the Centre?	[]	[]	[]
1) General consultation (home or office visit)	[]	[]	[]
2) Follow-up in a first preventive program	[]	[]	[]
3) Follow-up in a second preventive program	[]	[]	[]
4) Delivery	[]	[]	[]
5) Minor surgery	[]	[]	[]
6) Immunization	[]	[]	[]
7) Nursing aids (injection, immunization, check-up)	[]	[]	[]
8) Emergency	[]	[]	[]
2. How much did you pay for the services received (consultation, delivery, first-aid, etc.)	[]	[]	[]
0) Unknown	[]	[]	[]
1) Less than $10.00 (Mexican Pesos)	[]	[]	[]
2) Between $11.00 - $50.00	[]	[]	[]
3) Between $51.00 - $100.00	[]	[]	[]
4) Between $101.00 - $150.00	[]	[]	[]
5) Between $151.00 - $200.00	[]	[]	[]
6) Between $201.00 - $250.00	[]	[]	[]
7) More than $250.00	[]	[]	[]
3. Did you get your drugs in the health centre?	[]	[]	[]
1. Yes, all (go to Question 4)	[]	[]	[]
2. No (skip to Question 4)	[]	[]	[]

	A	B	C
4. How much did you pay for them?	[]	[]	[]
0) Unknown	[]	[]	[]
1) Less than $10.00	[]	[]	[]
2) Between $11.00 - $50.00	[]	[]	[]
3) Between $51.00 - $100.00	[]	[]	[]
4) Between $101.00 - $150.00	[]	[]	[]
5) Between $151.00 - $200.00	[]	[]	[]
6) Between $201.00 - $250.00	[]	[]	[]
7) More than $250.00	[]	[]	[]
5. Did you go to another care unit besides the Centre (to solve the present problem)?	[]	[]	[]
1. Yes (go to Question 6)	[]	[]	[]
2. No (Stop)	[]	[]	[]
6. Why did you go to another place?	[]	[]	[]
1) The patient got worse	[]	[]	[]
2) I didn't trust the Centre	[]	[]	[]
3) I was advised to seek further care	[]	[]	[]
4) I was referred	[]	[]	[]
5) For laboratory tests, X-rays	[]	[]	[]
6) To buy the drugs	[]	[]	[]
7. Where did you go?	[]	[]	[]
1) To Centre B	[]	[]	[]
2) To other Centre C	[]	[]	[]
3) To private services	[]	[]	[]
4) To a hospital	[]	[]	[]
5) To traditional medicine	[]	[]	[]
6) Other: _____			
8. How much did you pay?	[]	[]	[]
1) For the service	$ _____		
2) For the treatment - drugs	$ _____		
- surgery	$ _____		
3) For the hospitalization	$ _____		
4) For the diagnostic tests	$ _____		
5) For the diagnostic X-rays	$ _____		
6) Ambulance	$ _____		
7) Others: _____	$ _____		
8) Total Cost:	$ _____		

	A	B	C
9. How much did you pay to go there (bus fare, gas, etc.)?	[]	[]	[]
0) Unknown	[]	[]	[]
1) Nothing	[]	[]	[]
2) Less than $5.00	[]	[]	[]
3) Between $6.00 - $10.00	[]	[]	[]
4) Between $11.00 - $25.00	[]	[]	[]
5) Between $26.00 - $50.00	[]	[]	[]
6) Between $51.00 - $100.00	[]	[]	[]
7) Between $101.00 - $250.00	[]	[]	[]
8) More than $250.00	[]	[]	[]

Total Cost

	Paid to Centre C	Other Unit or Private Service	Total
For Services			
For Drugs			
For Travel Expenses			
Other Costs (associated to the solution of the health problem			
Total			

Appendix D-7

Patient's Satisfaction Questionnaire

Centre: [][][] Date: Dy [][] Mn [][] Yr [][]

Family/Patient's Name: _____ Code: [][][]

Address: _____

Informant: _____

Interviewer: _____

1. Do you know there is a health Centre C in this town? []

   1. Yes (go to Question 2)
   2. No (go to Question 13)

2. Have you or someone in your family been in the Health Centre: []

   1. Yes (go to Question 3)
   2. No (go to Question 12)

3. When was the last time (he/she) had gone there? []

   0) Unknown
   1) Less than a week
   2) More than a week
   3) Less than a month
   4) More than a month
   5) Sometime in this year
   6) More than a year ago
   7) Informant does not remember

4. Why did you go to the centre then? []

   0) Unknown
   1) Immunization Program
   2) Health Education Program
   3) General Medicine
   4) Follow-up in Primary Preventive Program
   5) Follow-up in Secondary Preventive Program
   6) Surgery
   7) Delivery
   8) Nursing Services
   9) Other: _____

5. The care received there consisted of []

0) Informant does not remember
1) Medical visit only
2) Medical visit and medicines
3) Medicines only
4) Delivery
5) Minor surgery
6) Nursing aids
7) Immunizations
8) Other:_____

6. What did you pay for services and/or drugs received? []

0) Unknown
1) Too much, unaffordable
2) Expensive but affordable
3) Just right
4) Just enough
5) Too little
6) It was free

7. Were you (he/she) satisfied with the care received there? []

1. Yes, the problem was satisfactorily managed
2. Yes, the service was good despite the outcome (worsening,death,etc.)
3. The service was fair
4. No, the care was difficient
5. No, I(or he/she) required other care in the other medical unit

8. Will you go there again? []

1. Yes (go to Question 10)
2. No (go to Question 9)

9. Why not? []

1. We can not afford the centre
2. We do not like the centre
3. We did not receive comprehensive care
4. We did not receive medicines
5. We did not trust the staff
6. We prefer other source of medical care (go to Question 13)

10. Do you often require the services of other centres, hospitals or private units besides the centre? []

1. Yes, always
2. Sometimes
3. Never (go to Question 15)

11. What kind of services? (Skip to Question 12) []

1. General consultation
2. Surgery
3. Lab and X-ray
4. Specalized care
5. Preventive Programs
6. Pharmacy Services
7. Hospitalization
8. Traditional medicine
9. Other, specify:_____

12. Why haven't you been in the centre? []

1. I/we have not been sick []
2. We can not afford the centre []
3. We do not like the centre []
4. We do not receive comprehensive care []
5. We do not receive drugs []
6. We do not trust the staff []

13. Where do you go when you have a health problem? []

1. To centre B
2. To other centre C:_____
3. To private service
4. To a hospital
5. To traditional medicine

14. What you pay there is: []

0) Unknown
1) Too much, unaffordable
2) Expensive, but affordable
3) Just right
4) Too little
5) It is free

15. Are you satisfied with the medical care there? []

1. Yes
2. No

Appendix D-8

Physician Satisfaction Questionnaire

Type of Centre: [] (1. Treatment, 2. Control)

1. How do you rate your work in the centre? []

   1. Very satisfactory
   2. Pretty satisfactory
   3. Fair
   4. Unsatisfactory

2. What were the main limitations to provide medical care? []

   a) Diagnostic resources such as: _____
   b) Treatment resources such as: _____
   c) Funds: _____
   d) Community Paticipation: _____
   e) Others: _____

3. Were the drugs available appropriate? []

   1. Yes, always
   2. Usually
   3. Scarcely
   4. Not at all

4. Was the list of basic drugs enough? []

   1. Yes (If yes, go to Question 5)
   2. No (If no, go to Question 8)

5. Were you able to prescribe more than 80% of the patients? []

   1. Yes
   2. No

6. Were prices of drugs accessible to population? []

   1. Yes, always
   2. Usually
   3. Seldom
   4. Never

7. Were drugs appropriate to the local pathology? []

1. Yes, always
2. Usually
3. Seldom
4. Never

(Skip to Questions 8 and 9)

8. Why is the present list not appropriate? []

1. There are not enough drugs
2. There are not appropriate drugs
3. The drugs available are not appropriate nor enough
4. Drugs are too expensive
5. Drugs are expensive but appropriate
6. Drugs are expensive and inappropriate
7. Drugs are cheap but inappropriate
8. Drugs are cheap but not enough
9. Drugs are cheap but not enough nor appropriate
10. Others: _____

9. Would you think that by increasing the amount of drugs will be enough? []

1. Yes
2. No

10. Would you add more drugs to the present list? []

1. Yes
2. No

11. Which ones?

_____ _____ _____

_____ _____ _____

_____ _____ _____

12. Would you cut some of the drugs included in the present list of basic drugs? []

1. Yes
2. No

13. Which ones?

_____ _____ _____

_____ _____ _____

_____ _____ _____

14. Why? []

1. Inappropriate drugs
2. Too expensive
3. Useless in this centres, because of low prevalence of cases
4. Useful but serious side effects
5. Other: _____

15. Would you keep present prices? []

1. Yes, in all the drugs
2. Yes, in some of the drugs
3. I would increase the price of all
4. I would increase the price of some
5. I would decrease the price of all
6. I would decrease the price of some

16. Do you feel happy with the present system of delivery care? []

1. Yes
2. No

17. Taking all things in to account, how would you consider the delivery of medical care in this centre? []

1. Very good
2. Pretty good
3. Fair
4. Bad
5. Unsatisfactory

18. If you were a decision maker, what modifications would you make in the centre?

1. In the Budget? Why? _____
2. In the physical unit? Why? _____
3. In the salaries? Why? _____
4. In the patient's fees? Why? _____
5. In the record system? Why? _____
6. In the activities of the Centre? Why? _____
7. In the pharmacy? Why? _____
8. In the staff? Why? _____

Appendix D-9

Quality of Prescription Questionnaire To Assess Physicians in Centres C

SECTION I:

1. Physician's Code: [][][][] 2. Centre: [][][]
3. Interviewer's Code: [][] 4. Date: [][][][][][][]

SECTION II:

1. Patient's Age: [][][][] 2. Sex: []
3. Diagnosis (Case): _____ Code: [][][]
4. Other Diagnosis: _____ Code: [][][]
   _____ Code: [][][]
5. Prescriptions:

	Drug Name	Code	Dose	Treatment Duration
A.	_____	[][][]	_____	_____
B.	_____	[][][]	_____	_____
C.	_____	[][][]	_____	_____

SECTION III:

1. Is this the appropriate drug for the case?

	A	B	C
1. Yes	[]	[]	[]
2. No	[]	[]	[]

2. Why did you choose drug A, B, C?

	A	B	C
1. It is the drug of choice.	[]	[]	[]
2. It is an equivalent drug.	[]	[]	[]
3. It is the drug available.	[]	[]	[]
4. It is a less expensive drug.	[]	[]	[]
5. It is the drug I trust (I know)	[]	[]	[]
6. Patient influenced the decision (because			
a) he/she already had the drug at home	[]	[]	[]
b) he/she trusted this drug	[]	[]	[]
c) he/she can get it easily around here)	[]	[]	[]

7. Other reasons, specify: _____

SECTION III (continued)	A	B	C
3. Do you have another "drug choice" for this case?	[]	[]	[]
1. Yes (go to Question 4)	[]	[]	[]
2. No (go to Section IV)	[]	[]	[]
4. Which one? A _____			
B _____			
C _____			
Rated by interviewer as:	[]	[]	[]
1. Equivalent appropriate drug	[]	[]	[]
2. Equivalent inappropriate drug	[]	[]	[]
3. Unknown drug	[]	[]	[]
4. Different but appropriate drug	[]	[]	[]
5. Different and inappropriate drug	[]	[]	[]
5. Why you did not prescribe A, B, C?	[]	[]	[]
Because it is listed in the formulary but:			
1. Was not available at the time of the visit	[]	[]	[]
2. It is too expensive	[]	[]	[]
3. Side effects	[]	[]	[]
4. The disease has become resistant to it	[]	[]	[]
5. Patient does not trust it	[]	[]	[]
Drug is not listed in the formulary, therefore			
6. It is not available in the centre	[]	[]	[]
7. I do not know if patient can get it in the local drugstores	[]	[]	[]
8. I ignore its cost, form supplied and/or strength	[]	[]	[]
9. Other reasons, specify: _____			
6. Would you include it (A, B, C) in the present list?	[]	[]	[]
1. Yes	[]	[]	[]
2. No	[]	[]	[]

SECTION IV:

Overall evaluation from the researcher's viewpoint

7. Physician prescribed	[]	[]	[]
1. Appropriate drug enough in time and quantity	[]	[]	[]
2. Appropriate drug insufficient in time and quantity	[]	[]	[]
3. Equivalent drug, enough in time and quantity	[]	[]	[]
4. Equivalent drug insufficient in time and quantity	[]	[]	[]

SECTION IV (continued)	A	B	C
7. Physician prescribed (continued)	[]	[]	[]
5. Similar drug that should be used as a second	[]	[]	[]
6. Placebo	[]	[]	[]
7. Prescribed drug	[]	[]	[]
8. Other (contradicted) management_____			
_____			
8. Physician choices	[]	[]	[]
1. Appropriate drug enough in time and quantity	[]	[]	[]
2. Appropriate drug insufficient in time and quantity	[]	[]	[]
3. Equivalent drug, enough in time and quantity	[]	[]	[]
4. Equivalent drug insufficient in time and quantity	[]	[]	[]
5. Similar drug that should be used as a second	[]	[]	[]
6. Placebo	[]	[]	[]
7. Prescribed drug	[]	[]	[]
8. Other (contradicted) management_____			
_____			
9. Researcher rates the prescription as:	[]	[]	[]
1. Appropriate (alternatives 1, 2 and 6 when indicated of Questions 7 and 8)	[]	[]	[]
2. Inappropriate (Questions 7 and 8 answered with alternatives 3, 4, 7, 8)	[]	[]	[]

Appendix D-10

Inventory Card (PhI-1)

Name:_____ Code: ☐☐☐

Brand Name:_____

Generic Name:_____

Strength and Form:_____

Manufacturer:_____

Minimum:_____

Maximum:_____

CODE: ☐☐☐

Date	Expiry Date	Received	Issued	Balance	Total Cost	Unit Price	Issued to	Quan. Requested	Notes

Appendix D-11

Requisition of Drugs Sheet (Ph-R-1)

Ph-R-1

Primary Medical Care Program S.S.A.-U.N.A.M.
Pharmacy Services
Requisition of Drugs Form

Centre:_____ Requisition No.:_____

Physician:_____ Account Code:_____

Section 1 To be filled by Solicitor (columns 1-3)			Section 2 To be filled by Supplier (columns 4-9, but 5)					
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Drug Code	Description (Name, strength & form)	Qty. Requested	Qty. Supplied	Cor.	Unit Price	Total Cost	Selling Price	Expiry Date
TOTAL								

Solicitor Signature:_____

Pharmacist Signature:_____

Date Requested:_____

Notes: (Reasons for not supplying amount requested or changes in brand names or costs)

_____
Pharmacist's Signature

Section 3: (To be filled by Solicitor when receiving drugs)

1. Check (✓) column 5 if amount received is correct or the number received.
2. If amounts are correct, sign at the bottom, recording date.
3. If amounts are incorrect and no reasons are given in Section 2, fill in form Ph-R-2 and send it back to the pharmacist along with this copy.

Signature:_____ Date:_____ To Health Centre

To Pharmacy

Appendix D-12

Bill

Medical Program in Rural Areas
S.S.A.-U.N.A.M.

Bill for Services and Drugs

Health Centre "C"

Date:_____

Patient's Name:_____

Patient's Number:_____

Code		Description	Qty.	Unit Price	Total $
Drugs					
Service					
		Total Amount Paid		$	

Cashier Signature:_____

To Financial Report Bill No.:_____

To Patient's File

To Patient

Appendix D-13

Financial Report

Medical Care Program S.S.A.-U.N.A.M.
Financial Report

Centre:_____ Month:_____

Service Provided	Number of Cases		$ Income $
	That Paid	Free	
Medical Visits:			
Programs - First			
- Subsequent			
General - First			
- Subsequent			
Hospitalization:			
Patients hospitalization			
Bed-days			
Deliveries			
Surgeries			
Nursing Services			
Drugs			
Health Certificates			
Total			

Bills from No._____ to No._____ Total of _____

Date:_____ Physician's Signature:_____