BASIC DESIGN STUDY REPORT ON THE PROJECT FOR CONSTRUCTION OF PRODUCTION FACILITIES OF LIVE ATTENUATED MEASLES AND POLIOMYELITIS VACCINES IN THE REPUBLIC OF INDONESIA

MAY, 1989

JAPAN INTERNATIONAL COOPERATION AGENCY

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PREFACE

In response to a request of the Government of the Republic of Indonesia, the Government of Japan has decided to conduct a Basic Design Study on the Project for Construction of Production Facilities of Live Attenuated Measles and Poliomyelitis Vaccines and entrusted the study to the Japan International Cooperation Agency (JICA).

JICA sent to Indonesia a survey team headed by Dr. Konosuke Fukai, Chairman, Board of Directors, the Research Foundation for Microbial Diseases of Osaka University from December 1 to December 20, 1988.

The team exchanged views with the officials concerned of the Government of Indonesia and conducted field surveys in Bandung area. After the team returned to Japan, further studies were made. Then, a mission was sent to Indonesia in order to discuss a draft report and the present report has been prepared.

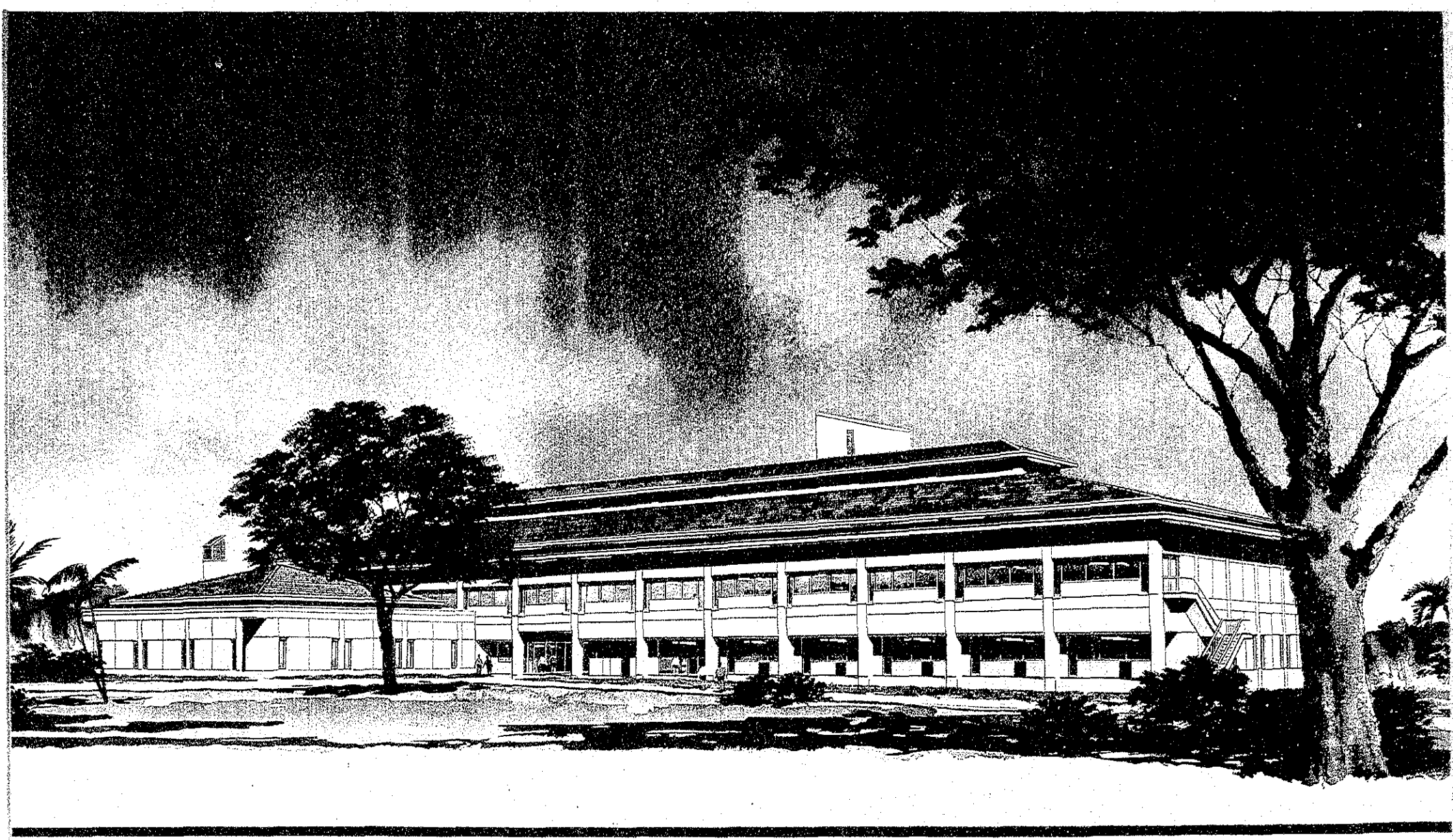
I hope that this report will serve for the development of the Project and contribute to the promotion of friendly relations between our two countries.

I wish to express my sincere appreciation to the officials concerned of the Government of the Republic of Indonesia for their close cooperation extended to the team.

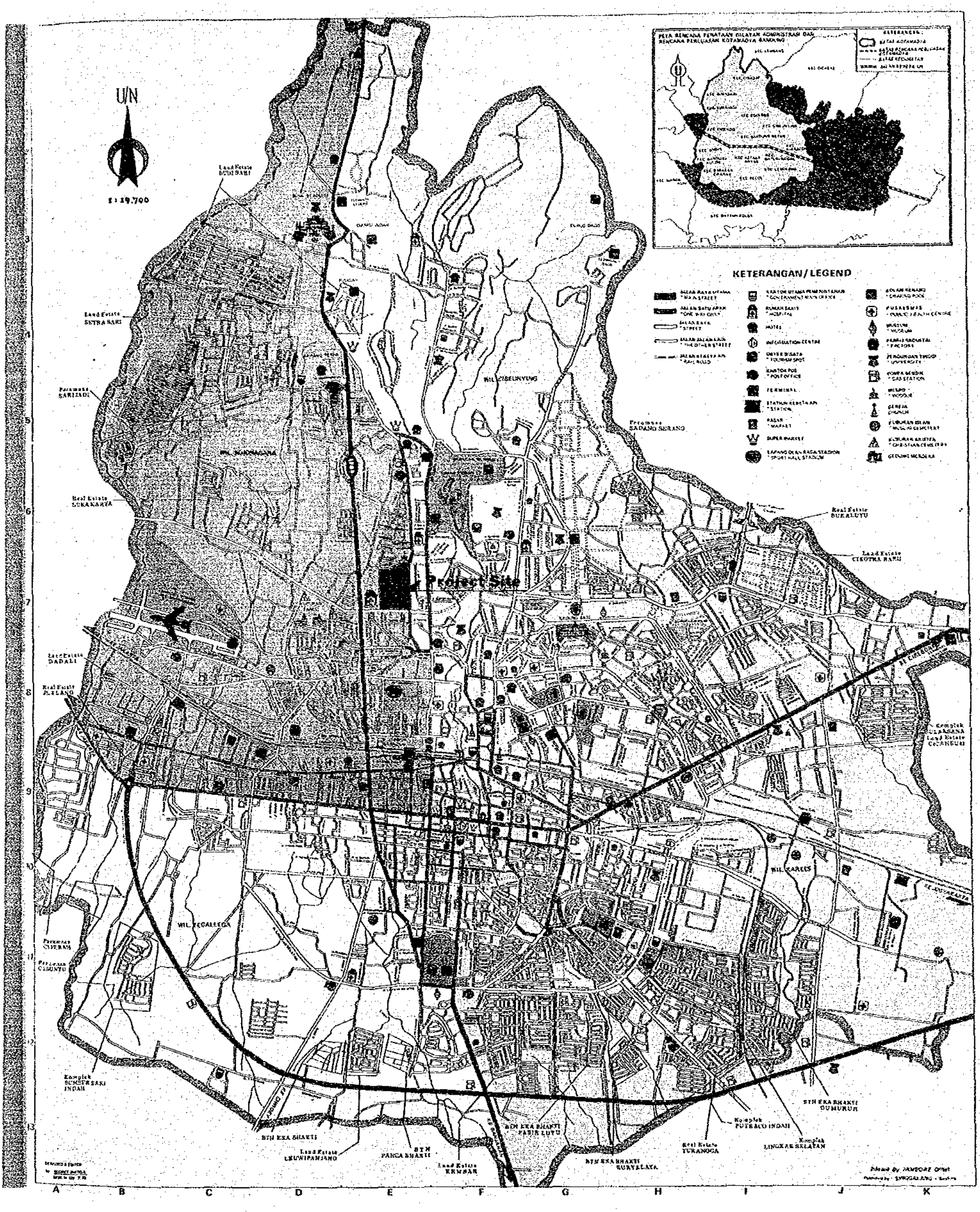
May 1989

Kensuke Yanagiya

Kensuke Yanagiya
President
Japan International Cooperation Agency



BANDUNG


U/N
KETERANGAN / LEGEND
Project Site
WIL. CIBEUNYING
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Real Estate SUKAKARYA
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Land Estate TURANGGA
Land Estate KEMBAR
Land Estate LEUWIPANJANG
Komplek LINGKAR SELATAN
BTN EKA BHAKTI
BTN PANCA BHAKTI
A B C D E F G H I J K

IMUNISASI
perlu untuk semua bayi

Ikutilah Bapak Presiden.
Mintakan imunisasi lengkap untuk bayi di POSYANDU atau PUSKESMAS terdekat.

Presiden didampingi Ibu Tien Soeharto memberikan imunisasi Polio dalam rangka Hari Anak-anak Nasional 1986 (Foto SETNEG/Sukil)

Abbreviations of Organizations and References

ABT	Additional Budget
AMSL	Average Mean Sea Level
ARI	Acute Respiratory infections
APBN	National Development Budget
BIKEN	The Research Foundation for Microbial Research of Osaka University
CDC	Communicable Diseases Control
E/N	Exchange of Notes
EPI	Expanded Program on Immunization
FDA	Food and Drugs Administration (U.S. Government)
FDC	Food and Drugs Control
GL	Ground Level
GMP	Good Manufacturing Practices (U.S. Government)
HC	Health Center (PUSKESMAS)
HEPA	High Efficiency Particulate Arrestors
INPRES	President's Special Budget
JIS	Japan Industrial Standard
JICA	Japan International Cooperation Agency
JPRI	Japan Poliomyelitis Research Institute
LPG	Liquefied Petroleum Gas
NASA	National Aeronautics and Space Administration
NDP	National Drug Policy
NIHRD	National Institute of Health Research and Development
NQCLDF	National Quality Control Laboratory for Drugs and Food
OECF	Overseas Economic Cooperation Fund
OPV	Oral Polio Vaccine
PABX	Private Automatic Branch Exchanger
PIP	Preventive Innoculation Plan
PLN	National Power Company
QC	Quality Control
RP	Rupiah
RPW	Regency Pharmaceutical Warehouse
SII	Indonesian Industrial Standard
SPF	Specific Pathogen Free
UNICEF	United Nations Children's Fund
VAT	Value Added Tax
WHO	World Health Organization

SUMMARY

The Republic of Indonesia (hereafter, simply called Indonesia) has a very large population (170 million), a high rate of population increase (2.1%), and an uneven population pyramid. Although the government is placing great emphasis on the promotion of public health, the infant mortality rate, often regarded to be an indicator of the state of healthcare in a country, is still very high (71 per one thousand births) in Indonesia. Of the causes of death, the largest group (28%) is due to infectious diseases such as tetanus, measles, diphtheria, pertussis and tuberculosis. These causes of death and sicknesses also apply to infants but in this instance it is possible to prevent the majority of these infectious diseases through immunization. Because of this, the Government of Indonesia is emphasizing the importance of immunization programs.

Medical services are mainly provided by hospitals, clinics and health centers (HC) and these HC also carry out immunization programs. Currently, POSYANDU (integrated health service post) are managed and run at the village level and medical staff are dispatched from the HC to carry out immunization programs.

Within the Ministry of Health are the Directorate General of Communicable Disease Control (CDC), the Directorate General of Food and Drugs Control (FDC) and the National Institute of Health Research and Development (NIHRD). The CDC carries out the implementation of vaccine immunization programs, and the FDC is responsible for the control of the import and manufacture of vaccines. Bio Farma is a state-owned enterprise which is solely responsible for the production of vaccines under the control of the Ministry of Health. NIHRD is the organization that is responsible for virological research.

Improving the quality and promoting of domestic production are important objectives for the pharmaceutical administration of Indonesia. Moreover, the GMP (Good Manufacturing Practices: i.e. Standards relating to the quality control and production of pharmaceuticals) that are promoted around the world, have been introduced positively in Indonesia.

The majority of the essential drugs and vaccines are produced by the state-owned enterprise which aims to provide good quality and inexpensive products to meet the requirement.

Since the middle of the 1970s, the health and medical development budget of the Ministry of Health has tended to increase proportionately. Countermeasures against infectious diseases constitute a major item accounting for the Ministry of Health's budget and this item also shows a tendency to increase annually.

The Government has been implementing five-year development plans (REPELITA) since 1970 and it is now commencing the fifth five-year development plan, REPELITA V for 1989 to 1993. Amongst the main objectives outlined in the health plan, the prevention and elimination of infectious diseases is high in priority, along with the improvement of community health services and the improvement of referral health services.

Over the period from 1970 to 1990, the World Health Organization (WHO) is implementing the Expanded Program on Immunization (EPI). In Indonesia, immunization is being implemented with respect to the six major infectious diseases of pertussis, diphtheria, tetanus, tuberculosis, polio and measles. The REPELITA IV program has met with great success as far as increases in the immunization coverage were concerned and the objective was reached for 65% of the population with respect to the abovementioned diseases. The next objective of the government is to raise the immunization coverage from 65% to 95%. However, the immunization coverage for measles and polio, which use live attenuated virus vaccines, is low (45% to 60%) in comparison with the other vaccines. The reasons for this are as follows:-
(1) It is necessary to carry out immunization of the infant within one year after its birth. (2) It is necessary to provide the means (called the "cold chain") for the storage and transportation of live vaccines. (3) There is a dependency upon imports for those live attenuated virus vaccines which cannot be produced domestically, and delivery and customs inconsistencies have tended to hinder the implementation of immunization programs. For these reasons, domestic production is necessary to ensure a consistent supply of vaccines and delivery without delays.

In order to participate fully in EPI and to ensure a consistent supply of vaccines, the Government of Indonesia submitted a request to the Government of Japan for technical cooperation relating to the integrated and mass production at low cost of measles and polio vaccines in Indonesia.

In response to this request, Japan International Cooperation Agency (JICA) dispatched a feasibility study survey team for the technical cooperation to Indonesia in April, 1986.

Subsequently in August, 1987, the Government of Indonesia requested for Grant Aid for the construction of measles and polio vaccines manufacturing and quality control facilities and animal houses.

In response to this request, JICA dispatched a preliminary survey team for the technical cooperation and Grant Aid in February, 1988. The team confirmed the need for the technical cooperation for transfering the fundamental technology of measles and polio live vaccine production, as well as the need for Grant Aid for constructing the facilities.

In December 1988, JICA dispatched a basic design survey team to Indonesia. The team members discussed with the government officials of Indonesia and with Bio Farma (the executer of this project) on the background, purposes and setup of this project and the scope of cooperation etc. The team also investigated the existing related facilities, the construction site, the infrastructure, construction and collected other relevant data. After returning to Japan, the team analyzed and studied the survey findings, designed the facilities, selected the equipment and materials and made a staffing plan. The team then prepared a draft report of the basic design survey and presented the report in Indonesia in April 1989.

The purpose of this project is to construct the facilities which are necessary for transfering the fundamental technology for measles and polio vaccines production. The Government of Indonesia requested "to domestically produce 7,500,000 doses of measles vaccine and 20,000,000 doses of polio vaccine (3 vaccinations/year) yearly for about 5,000,000

babies and to raise the immunization coverage by means of their consistent supply and timely vaccination." This request is therefore considered to be appropriate in view of the current situation of immunization programs in Indonesia.

Although the primary aim of this project is to construct facilities for the fundamental technology transfer, this facility will also be able to produce the abovementioned quantities of vaccines through its operating method.

The following facilities are planned in this project:-

Building structure: Reinforced concrete

Number of storys: 2 storys (plus a secondary third story)

Total floor area: 7,129 m^2

Configuration:

1. Production Section (Location: 2nd story) 2,859 m^2

   Principal Rooms: Cell culture room, virus culture room, pooling room, filling room, blending room, media preparation room, cold room for media, washing room, pure water preparation room, packaging room, etc.

   Principal Equipment: Laminar flow cabinet, autoclave, freeze-dryer, incubator, deep freezer, filtration device, vial washing machine, washing machine, D.W.I. Production equipment, labeling equipment, etc.

2. Quality Control Section (Location: 1st story) 1,553 m^2

   Principal Rooms: Observation room, virus titration room, cell culture test room, neutralization room, marker test room, sterility test room, pathological testing room, immunological testing room, washing room, etc.

Principal Equipment: Laminar flow cabinet, bio-clean bench, laboratory bench, fume hood, bio-microscope, incubator, autoclave, freezer, etc.

3. Animal Houses (Location: 1st story) 1,759 m^2

Principal Rooms: SPF chicken breeding room, seed chicken breeding room, incubator room, cynomolgus monkey room, green monkey room, nephrectomy room, washing room, house for test animal, feed preparation room, etc.

Principal Equipment: SPF chicken cage, incubator monkey cage and rack, autoclave, dissecting equipment set, washing machine, etc.

4. Machine Room and Auxiliary Facilities
(Location: 1st - 3rd story) 958 m^2

This facility will produce live attenuated vaccines by the cell culture method. It must therefore have an extremely clean environment and highly advanced technology. Furthermore, it must comply with GMP standards in order to obtain the Sabin stocks of polio vaccine from WHO. All these stringent conditions must be satisfied.

In addition, the cost of domestic production should be within a reasonable range compared with the current import price (Government's purchase price) of the final products. The following basic policies were made in consideration of these conditions:-

a) Measles vaccine and polio vaccine should be produced in one building in order to reduce the total floor area without affecting the operation and functioning of the facility.

b) The working spaces with respect to level of cleanliness should be organized rationally and economically.

c) The generators and boilers should be synchronized with those which are currently in use in the existing facilities so as to reduce the capacity of new machinery.

d) Indonesian building materials and machinery should be used as much as possible. However, Japanese materials and machinery should be used for spaces with a high level of cleanliness (class 10,000 and above). Experts on clean room construction should direct the building work.

e) The air-conditioning system should not only comply with GMP standards, but should also be reliable and easy to operate and maintain. Its running cost must be low.

f) Some of the production machinery should be shared.

The facility is to be constructed in the grounds of Bio Farma, which is located in Bandung. It will be situated in the north east corner of the site, next to the existing infusion solution production facility. There are presently 5 wells on the site and they supply all the water required at Bio Farma. This facility will also utilise the wells. Discharged water is treated within Bio Farma. Commercial power is used only for lighting, while power generated by the private service generators is used for production purposes. The power required for this facility is to be obtained from the existing generators, which will be upgraded. The existing telephone switchboard is very old and does not have sufficient extension capacity. Therefore, it should be replaced.

In Indonesia, this project will be assigned to the following persons:- The General Manager, who will assume overall responsibilities, is the Secretary General of the Ministry of Health and the Operation Manager, who will be responsible for management and administration, is the Director General of Food and Drug Control of the same ministry. The President Director of Bio Farma is responsible for the implementation of this project and for the operation, maintenance and management of the facility after its completion.

Bio Farma is a state-owned enterprise under the jurisdiction of the Ministry of Health. It was established in Jakarta in 1890 for the production of smallpox virus vaccines. It was moved to Bandung in 1920 and since then has been engaged in the production of serums and vaccines and in clinical examinations. It's existing facilities has a total floor area of 26,500 m^2 on a site of 93,000 m^2. Bio Farma currently has a total staff of 435.

All of the vaccines that are produced in Indonesia are manufactured by Bio Farma. Those which relate to EPI are for pertussis, tuberculosis, tetanus and diphtheria. In the case of measles and polio, all of the requirements are met by importing the vaccines.

As the result of the fundamental technology transfer, this project has adopted the objective of establishing a complete system for the production of measles and polio vaccines from raw materials. However, in order to proceed with the production of the vaccines, it is necessary to acquire a very high level of biological technology and to also acquire the techniques to operate the facility equipment. For this reason it has been decided that the project should proceed in the following stages:-

1) Training of Indonesian staff in Japan for the transfer of the vaccine production technologies should be in progress while the facility is being constructed.

2) After the trainees return to Indonesia upon the completion of the facility, they will receive on-the-job training under the guidance of the experts from Japan and at the same time, technology transfer will be provided by the experts to other newly posted personnel. At this stage, it is necessary to also acquire the basic technologies concerning the breeding of SPF chickens, the collection of fertilized eggs, the breeding of monkeys, the collection of kidney cells and their cultivation, etc..

3) Performing the complete trial production of both vaccines from raw materials.

4) Performing full-scale production of both vaccines from raw materials.

5) Establishing complete production cycles for the production of both vaccines from raw materials.

6) Comparative outdoor clinical tests will be carried out in two stages, before and after the mass production of the vaccines.

The construction period for this facility is about 23.5 months. The construction work is to be divided into 2 phases. The measles vaccine production section and the quality control section will be constructed in Phase One while the polio vaccine production section and the animal houses will be constructed in Phase Two.

Of the total expenses required for this project, the proportion to be borne by the Indonesian Government is estimated to be 343 million Rupiah (about 26 million Yen). This will cover ground preparation, infrastructure preparation, construction permits application expenses and other expenses.

When this facility is completed and the full-scale production of vaccines is started, a total of 87 employees will be required for the facility operation. Technical cooperation is to be carried out in parallel to train the currently-employed skilled workers for the important positions in the operation of the facilities.

The production costs, after the establishment of the integrated mass production system, are heavily influenced by the acquisition market prices of raw materials. However, the estimated production costs are considered reasonable in comparison with the 1988 prices of imported products, including labeling cost etc., as shown below.

	1988 CIF and miscellaneous prices	Calculated production price
Measles	230 Rp/dose	261 Rp/dose
Polio	125 Rp/dose	99 Rp/dose

The success of the technology transfer and the establishment of a complete system for the production of measles and polio vaccines, will ensure a consistent and timely supply of vaccines. This will make an extremely important contribution towards the health and medical policy objectives of Indonesia. Furthermore, there is currently a worldwide trend for the increase of vaccine production.

The design and provision of a building for measles and polio vaccine production and the provision of related equipment for this facility is considered to be an appropriate project under the Grant Aid program of the Japanese Government.

Finally, in order to further increase the effectiveness of this project, we would like to make the following recommendations to the related organizations representing both Governments:-

1) The facilities are to be constructed and operated along the lines of an economic entity, even though it is technically a state-owned enterprise. Therefore, its business operation must be sound. This requires 1) production management technology for plant operation, 2) facility maintenance and management technology, 3) GMP technology and 4) training etc. Therefore, it is necessary to make studies and consideration not only for the guidance and transfer of production technology, but also for staff training, planning and budgetary aspects.

2) The final goal of this project is the establishment of the integrated mass production system for the two vaccines. But the project should be paralleled by the improvement of the cold chain system, improved training and staff planning for the Ministry of Health.

3) When the full-scale production of the two vaccines is started, the operation of the facility should be financially viable since the income generated by the vaccine production can cover the production costs. However, until then, the project should have sufficient funds allocated to cover its total operation costs

(including personnel expenses, cost of consumable supplies, maintenance and management expenses, cost of energy consumption, materials cost and other related costs).

C O N T E N T S

CHAPTER 1 INTRODUCTION

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The Republic of Indonesia has many demographic problems, such as the large population, the high rate of population increase, the uneven distribution of population and the unbalanced structure of the population. There are many problems concerning public health, such as the high infant mortality rate.

Infectious diseases account for a significant proportion of the causes of death in Indonesia as well as in other developing countries. Many of these infectious diseases can be prevented by immunization. The Indonesian Government has provided immunization against six diseases (diphtheria, pertussis, tetanus, tuberculosis, measles, polio) since 1976 in compliance with WHO's Expanded program on Immunization (EPI). Vaccines of measles and polio are not yet domestically produced partly because of the technological problems involved in producing live attenuated vaccines of low toxicity. The immunization coverage of these two vaccines is very low in comparison with the other vaccines because of the difficulty in the handling of live attenuated vaccines (freezing for storage, time limit of immunization etc.). Both vaccines are currently purchased from foreign enterprises selected by international bidding through UNICEF (The funds are provided by UNICEF and other foreign aid programs). However, immunization plans are sometimes hindered by problems of delivery period and customs clearance. Indonesia is faced with a need for domestic production because WHO's EPI has increased the global demands for both vaccines and their current supply is limited.

Because of this, the Indonesian Government has made a request to the Japanese Government for "the technical cooperation for integrated mass production of a large amount of measles and polio vaccines at low cost in Indonesia. They are necessary for executing a systematic immunization program for the population of 170 million."

In response, the Japanese Government decided to dispatch a preliminary survey team for the above project. The Japan International Cooperation Agency (JICA) dispatched the "Contact mission of Republic of Indonesia Vaccine Project" from April 8 to April 15, 1986. The leader of the team was Executive Director Dr. Isao Yoshioka of the Japan Poliomyelitis Research Institute (JPRI). The mission investigated the

possibility and the range of technical cooperation for the production of the measles and polio vaccines and had a discussion with the Indonesian Government's personnel concerned in order to confirm their intentions and requirements.

Subsequently, the Indonesian Government again requested for technical cooperation regarding the measles and polio vaccines in 1987. This time, in addition to the abovementioned technical cooperation, they also requested for the construction of 4 independent buildings. These include a building for the production and quality control of the measles vaccine (2,000 m^2), an animal house for the measles vaccine (250 m^2), a building for the production and quality control of the polio vaccine (2,000 m^2) and an animal house for the polio vaccine (450 m^2).

In response to this request, JICA dispatched a preliminary survey team of "Fundamental Technology Transfer for Live Attenuated Measles and Polio Vaccines" from February 29 to March 9, 1988, headed by the Chairman, Board of Directors, Dr. Konosuke Fukai of the Research Foundation for Microbial Diseases of Osaka University (BIKEN). As a result, it was confirmed that in addition to technical cooperation, Grant Aid for facilities would also be necessary.

In order to make a more complete study, JICA dispatched a basic design survey team concerned with the "Construction of Measles and Polio Vaccines Production Facilities", headed by Dr. Fukai from December 1 to December 20, 1988.

The basic design survey team confirmed the background, content and implications of the request through meetings with the Indonesian organizations concerned. It also conducted a study and a field survey of the current facilities, production activities, personnel resources, financial conditions and the future prospect of Bio Farma, which is to be the user of the proposed facilities (vaccine manufacturer).

Upon their return to Japan, the basic design survey team prepared a final draft report after analyzing and studying the discussions and confirmations made in Indonesia as well as the materials and information collected there.

The team then submitted and explained the final draft report to the Indonesian Government's personnel concerned from 16 to 22 April, 1989. Both parties had a series of discussions and agreed to the contents of the report in principle. The Minutes of Discussions were exchanged on April 20, 1989.

The member list of the survey team, the schedule of the field investigation, the minutes and other materials are appended at the end of this report.

CHAPTER 2 BACKGROUND OF THE PROJECT

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2-1 Current Status of Health Care in Indonesia

2-1-1 Health and Population Indices, Main Health Problems

Indonesia has the fifth largest population in the world after China, India, the U.S.S.R. and the U.S.A. The size of the country measures about 5,000 km east-west, and about 1,750 km north-south. The country is made up of some 13,700 islands but only about 6,000 of these are inhabited, with most of the population living on the five major islands and 30 lesser islands.

This huge population (approximately 164 million in 1985) and the high rate of population increase (2.1%) have resulted in problems such as the uneven distribution of population and the non-uniform age pyramid.

(1) Population Increase and Configuration

The rate of population increase was 2.3% in the 1970s and 2.1% in the middle of the 1980s. In 1985, the population was 164 million and increasing at the rate of 3.5 million per year. According to a census conducted in 1985, there were approximately 4.9 million births (one every 6 seconds), and 1.5 million deaths (one every 21 seconds). Of the number of deaths, that of children (age under 4) comprise more than 40% of the total. It is estimated that in the year 2000, the population will have grown by more than 52 million since 1985 to reach a total of approximately 216 million people.

The proportion of the population which is under four years old was 13.1% in 1985 but in the year 2000, this will have decreased to less than 11% even though it is expected to have risen in absolute figures.

In the population pyramid, the numbers between the ages of 5 and 9 is greater than the numbers aged under four. The proportion of children is decreasing while the proportion of women of childbearing age (15 to 49) is increasing. In 1980, women of childbearing age constituted 24.5% of the total population but this figure is expected to reach 27% by the year 2000. These statistics indicate the importance of family planning.

Table 2-1 Population 1980 and 1985, Average Annual Growth Rates 1970-85, Population Density and Projected Growth from 1985 to 1990 by Region and Province

Province/Region	Population 1980 (mil.)	Population 1985 (mil.)	1971-80 (%)	1980-85 (%)	Population density 1980 (per km²)	Population density 1985 (per km²)	Projected total growth 1985-1990 (%)
DI Aceh	2.61	2.97	2.93	2.62	47	54	13.2
North Sumatra	8.35	9.42	2.60	2.42	118	133	12.1
West Sumatra	3.41	3.70	2.21	1.65	68	74	8.0
Riau	2.16	2.55	3.11	3.28	23	27	16.9
Jambi	1.45	1.74	4.07	3.83	32	39	20.0
South Sumatra	4.63	5.37	3.32	3.01	45	52	15.4
Bengkulu	0.77	0.94	4.39	4.19	36	45	22.2
Lampung	4.62	5.91	5.77	5.01	139	177	27.0
SUMATRA	28.00	32.60	3.32	3.08	59	69	-
DKI Jakarta	6.48	7.89	3.93	3.93	11,023	13,365	20.6
West Jawa	27.45	30.83	2.66	2.35	593	666	11.7
Central Jawa	25.37	26.94	1.64	1.21	742	788	5.6
DI Yogyakarta	2.75	2.93	1.10	1.27	868	925	6.0
East Jawa	29.17	31.26	1.49	1.38	609	652	6.5
JAVA	91.22	99.85	2.02	1.81	690	755	-
Bali	2.47	2.65	1.69	1.42	444	476	6.7
West Nusa Tenggara	2.72	2.99	2.36	1.91	135	148	9.3
East Nusa Tenggara	2.74	3.06	1.95	2.26	57	64	11.3
East Timor	-	0.63	-	2.58	37	42	13.0
NUSA TENGGARA	7.93	9.34	2.01	1.92	96	106	-
West Kalimantan	2.49	2.82	2.31	2.55	17	19	12.8
Central Kalimantan	0.95	1.12	3.43	3.21	6	7	16.5
South Kalimantan	2.06	2.27	2.16	1.94	55	60	9.5
East Kalimantan	1.21	1.51	5.73	4.41	6	7	23.5
KALIMANTAN	6.71	7.72	2.96	2.81	12	14	-
North Sulawasi	2.12	2.31	2.31	1.80	111	122	8.8
Central Sulawesi	1.28	1.51	3.86	3.22	18	22	16.6
South Sulawesi	6.06	6.61	1.74	1.74	83	91	8.5
Southeast Sulawesi	0.94	1.12	3.09	3.51	34	40	18.2
SULAWESI	10.40	11.55	2.22	2.11	55	61	-
Maluku	1.41	1.61	2.88	2.66	19	22	13.4
Irian Jaya	1.17	1.37	2.67	3.15	3	3	16.2
MALUKU & IRIAN	2.58	2.98	2.79	3.17	5	6	-
INDONESIA	147.49	164.05	2.32	2.15	77	85	10.9

Source: CBS, Ulasan Singkat Hasil Survei Penduduk Antar Sensus 1985, Seri SURAS No. 4, January 1987. Projected population from S.G. Masle Mamas, Proyeksi Penduduk Indonesia 1985-2005, CBS, n.d.

Table 2-2 Indonesian Population Estimates (1983-1988)

(Units: million population)

Year	Population
1983	158.1
1984	161.1
1985	165.2
1986	168.7
1987	172.2
1988	175.6

Table 2-3 Population Structure by Age (1983-1988)

(Units: million population)

Population structure (age)	1983 population	(%)	1988 population	(%)	Ratio of Increase (over 5 years)
0 - 4	23.1	(14.6)	24.3	(13.8)	5.2
5 - 9	20.8	(13.1)	22.4	(12.7)	7.7
10 - 14	18.7	(11.8)	20.5	(11.7)	9.6
15 - 19	16.6	(10.5)	18.4	(10.5)	10.8
20 - 24	14.7	(9.3)	16.3	(9.3)	10.9
25 - 29	12.7	(8.0)	14.4	(8.2)	13.4
30 -	51.5	(32.7)	59.3	(33.8)	15.1
TOTAL	158.1	(100)	175.6	(100)	11.1

(2) Infant Mortality

According to the 1985 Inter-Census Population Survey, the infant mortality rate of Indonesia was 71 per 1000 live births. This figure was 65% five years ago, and has dropped by 50% since 1971. This big reduction in the infant mortality rate is the result of the provision of the social base (through immunization, improved water supply and

drainage, and progress with the eradication of mosquitos) and although the differences between the urban and rural areas are still large, they are gradually being reduced to the extent that some effect can finally be seen.

Such phenomena are not limited to Indonesia alone, but can be said to be common for many parts of Asia. Nevertheless, they have been particularly pronounced in the case of Indonesia although the figures are still poor compared to the other ASEAN countries. While the infant mortality rate for Indonesia since 1965 has been approximately twice those for the Philippines and Malaysia, the rate of reduction in the infant mortality from 1980 to 1985 has been higher than those for both of these countries, and so the mortality is expected to drop below that of the Philippines and Malaysia in the future.

In the first half of the 1980s, there were approximately 5 million births per year, with approximately 370,000 infant deaths before one year of age. The fact that the ratio of infant mortality represents approximately 27% of the total number of deaths greatly affects the figure for the Indonesian average life expectancy. In 1985, the average life expectancy for men was 57.9 years, and that women was 61.5 years. These figures represented increases of more than 13 years for men and 7 years for women since 1960.

Table 2-4 Infant Mortality Rates in Indonesia. 1971-1985 (per 1000 live births)#

Data Source	Reference date	Urban	Rural	Total
1971 Census	1968/69	104	137	132
1980 Census	1977/68	88	112	112
1985 Inter-Censal Survey	1982/83	57	74	71

CBS. Proyeksi Penduduk Indonesia 1985-2005, p. 26.

Table 2-5 Infant Mortality Rates and Reduction Rates in Selected Asian Countries, 1965-1985

	1965	1980	1985	ARR* 1965-80	ARR 1980-85
Indonesia	138	112	71	-1.4	-8.7
Philippines	72	55	48	-1.8	-2.7
Malaysia	55	31	28	-3.8	-2.0
Thailand	88	55	43	-3.1	-4.8
Singapore	26	12	9	-5.0	-5.6
Bangladesh	153	136	123	-0.8	-2.0
Burma	122	101	66	-1.3	-8.2
China	90	71	35	-1.6	-13.2
India	151	123	89	-1.4	-6.3
Nepal	184	150	133	-1.4	-2.4
Pakistan	149	126	115	-1.1	-1.8
Sri Lanka	63	44	36	-2.4	-3.9

* ARR = Average Annual Reduction rate, in per cent.

Source: World Bank. World Development Report, 1982, 1983, 1987. The 1980 and 1985 rates for Indonesia are taken from Table 3.1 above.

(3) Causes of Infant Death

Despite the fact that infants under the age of one account for approximately 2.5% of the entire population, their mortality rate is approximately 27% of the total mortality for all age groups, as shown in Fig 2-2. The causes of infant death are shown in Tables 2-6, 2-7 and these four major causes account for about 67% of infant deaths. Approximately 28% are due to immunizable diseases such as tetanus, measles, diphtheria and pertussis. Another 20% is due to the handling at time of delivery, and a further 4% is due to congenital abnormalities. Many of the deaths at the time of delivery and congenital abnormalities are the result of malnutrition of the mother during pregnancy and the lack of proper facilities for childbirth. Tetanus accounts for 19% of all infant deaths and these deaths are concentrated in the first month after birth, which is also the period after childbirth accounting for 39% of all infant deaths. Practically all of these infant deaths due to tetanus are the result of the handling received during and after delivery.

The mortality rate in the first month of birth is 28%. Diarrhoea accounts for approximately 24% of all infant deaths between the ages of one and 11 months and respiratory infection for approximately 22%. After this, come the immunizable diseases such as tetanus, measles, diphtheria and pertussis which account for 20% of all deaths of this age group. Of these, tetanus accounts for 6.7% and measles acounts for 12%. When considering that measles brings on secondary diseases such as pneumonia and acute respiratory infection, it can be said that 60% to 70% of the deaths of children in this age group can be prevented by vaccination.

Table 2-6 Selected Causes of Neonatal and Post-Neonatal Mortality, 1980 and 1986

Causes of Mortality	Neonatal Deaths				Post-neonatal Deaths			
	1980 (direct cause)		1986 (underlying cause)		1980 (direct cause)		1986 (underlying cause)	
	%	Rate*	%	Rate	%	Rate	%	Rate
Diarrhoea	8.8	349.1	2.3	62.9	32.3	1,939.7	24.3	1,056.5
Acute respiratory infections	10.8	426.7	2.3	62.9	30.3	1,823.3	21.7	943.3
Tetanus	43.1	1,706.9	39.5	1,094.2	4.5	271.6	6.6	289.3
Perinatal causes	22.5	892.3	42.3	1,169.7	--	--	2.9	125.8
Measles, diphtheria, pertussis	--	--	1.4	37.7	1.9	116.4	13.3	578.5
Congenital abnormalilies	2.0	77.6	6.4	176.1	1.3	77.6	2.9	125.8
Nervous system disorders	2.0	77.6	--	--	11.0	659.5	9.2	402.5
Anaemia, malnutrition, avitaminosis	--	--	--	--	0.6	38.8	1.7	75.5
All others/undetermined causes	12.8	504.4	5.9	163.6	29.0	1,745.6	26.6	1,157.0
All causes	100.0	3,957.0	100.0	2,767.1	100.0	6,013.0	100.0	4,351.7

* Per 100,000 live births.

Source: Ratna L. Budiarso, "Pola Kematian Bayi Pada Sruvai Kesehatan rumah Tangga 1985/1986," p.9.

Table 2-7 Distribution of Infant Death (under age 1) by Underlying Cause, 1980

Causes of Mortality	% of infant	Rate per 10,000 live births	Est. No. of infant deaths 1985*
Tetanus	19.3	1,383.5	71,400
Perinatal causes	18.4	1,320.6	68,100
Diarrhoea	15.6	1,119.4	57,700
ARI (including bronchitis and asthma)	14.4	1,031.3	53,300
Measles	7.5	540.8	27,800
Nervous system disorders	5.6	402.5	20,700
Congenital disorders	4.2	301.8	15,500
Diphtheria, pertussis	1.0	75.5	3,700
Anaemia, malnutrition	1.0	75.5	3,700
Other and undetermined causes	13.0	930.7	48,100
All causes	100.0	7,181.6	370,000

* See footnote to Table 3.3 above.

Source: Prosiding Seminar Survai Kesehatan Rumah Tangga 1986, p. 161, and Retna L. Budiarso, "Pola Penyakit Penyebab Kematian Bayi; Survai Kesehatan Rumah Tangga 1985/86," paper presented at the Seminar on Child Survival and Development, Jakarta, 29-30 June 1987.

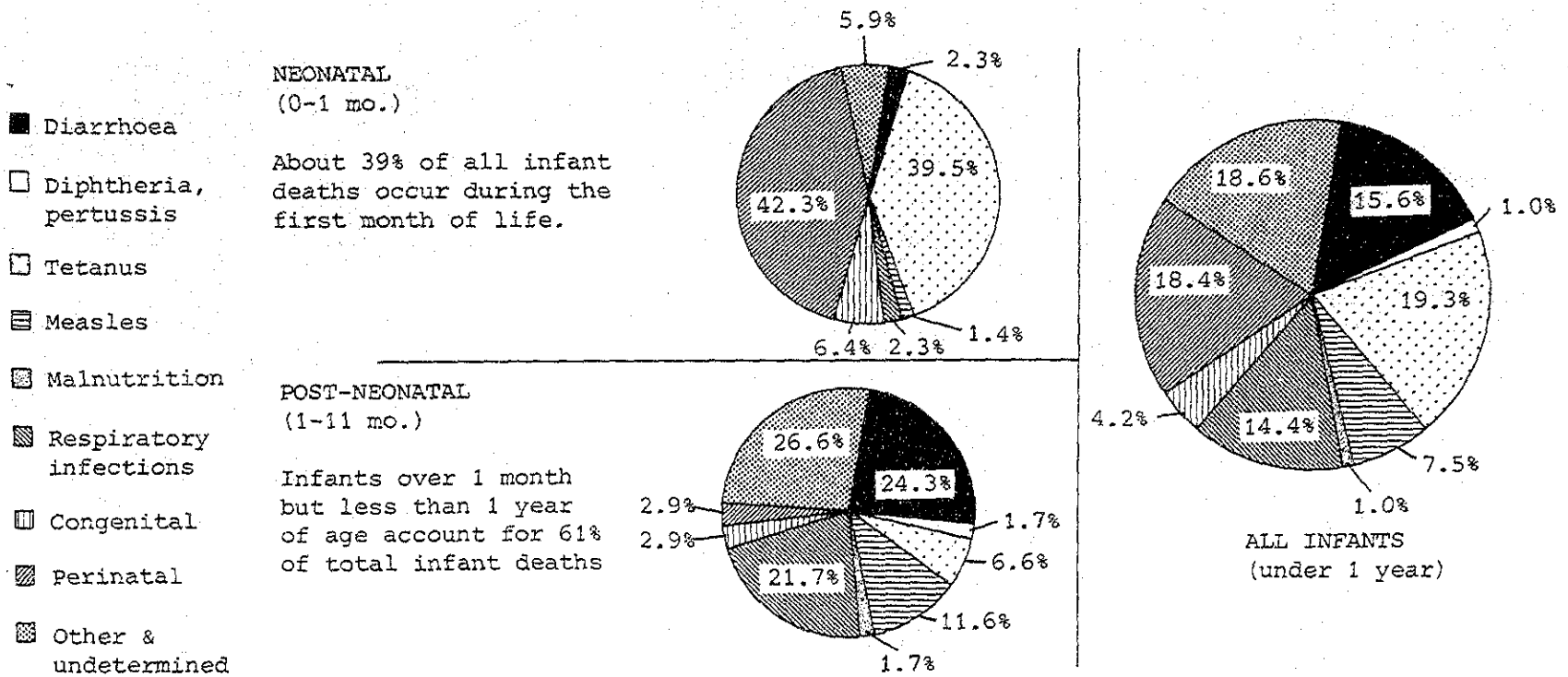


Fig. 2-1 Main causes of Infant Mortality, 1986

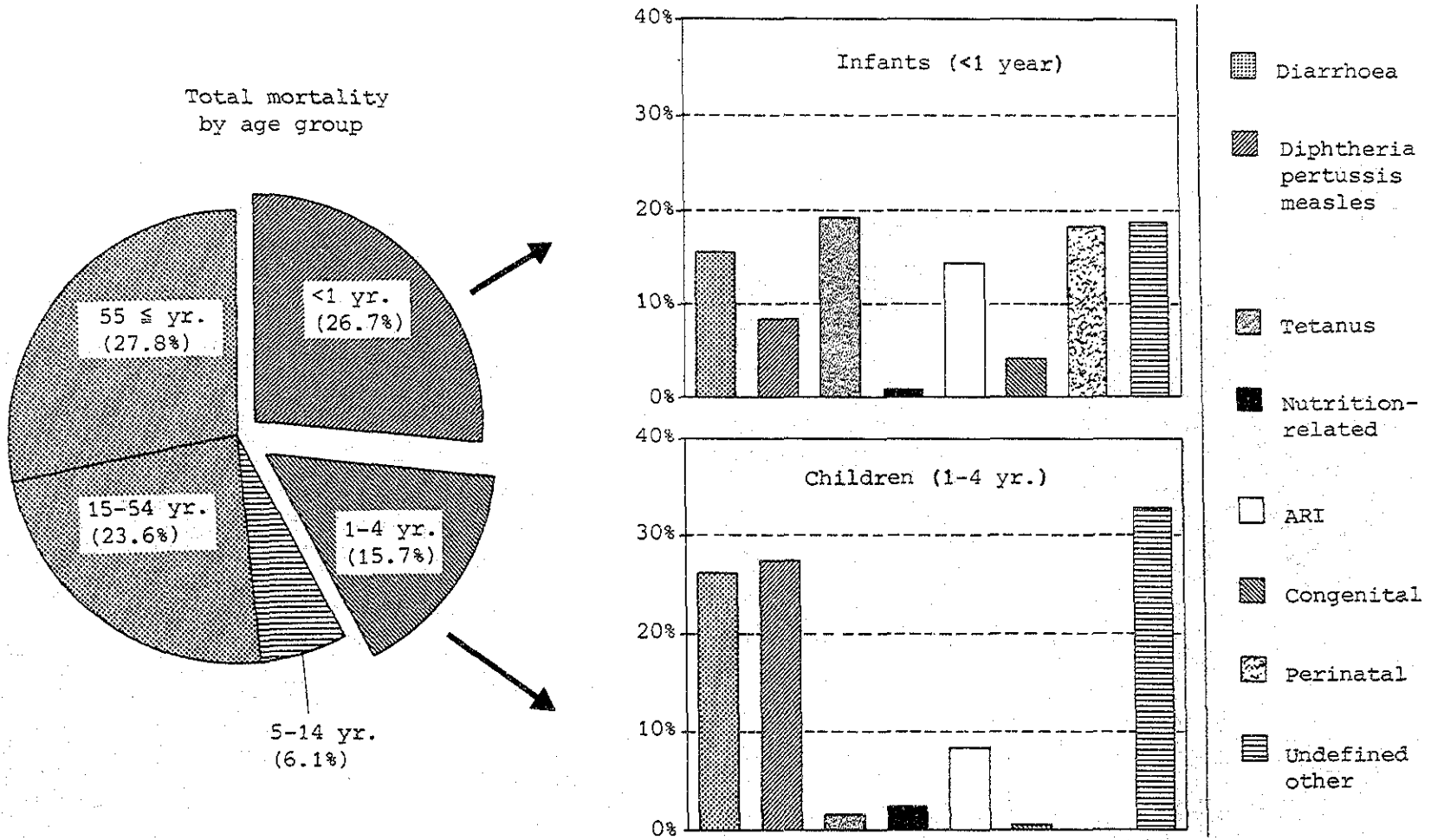

Total mortality
by age group
55 ≦ yr.
(27.8%)
<1 yr.
(26.7%)
15-54 yr.
(23.6%)
1-4 yr.
(15.7%)
5-14 yr.
(6.1%)
Infants (<1 year)
Children (1-4 yr.)
40%
30%
20%
10%
0%
Diarrhoea
Diphtheria
pertussis
measles
Tetanus
Nutrition-
related
ARI
Congenital
Perinatal
Undefined
other

Fig. 2-2

(4) Child Mortality

Last year, the child mortality (one to four years old) was 16% of that for the total population. In 1985, there were 181,000 deaths. The breakdown of the causes showed the same pattern as that for infant deaths. In addition to diarrhoea, measles, diphtheria, pertussis and tetanus, there were also diseases such as pneumonia and acute respiratory diseases brought on by measles. This means that approximately 64% of these deaths can be prevented by vaccines. In addition to these causes, malaria is also prominent for this age group.

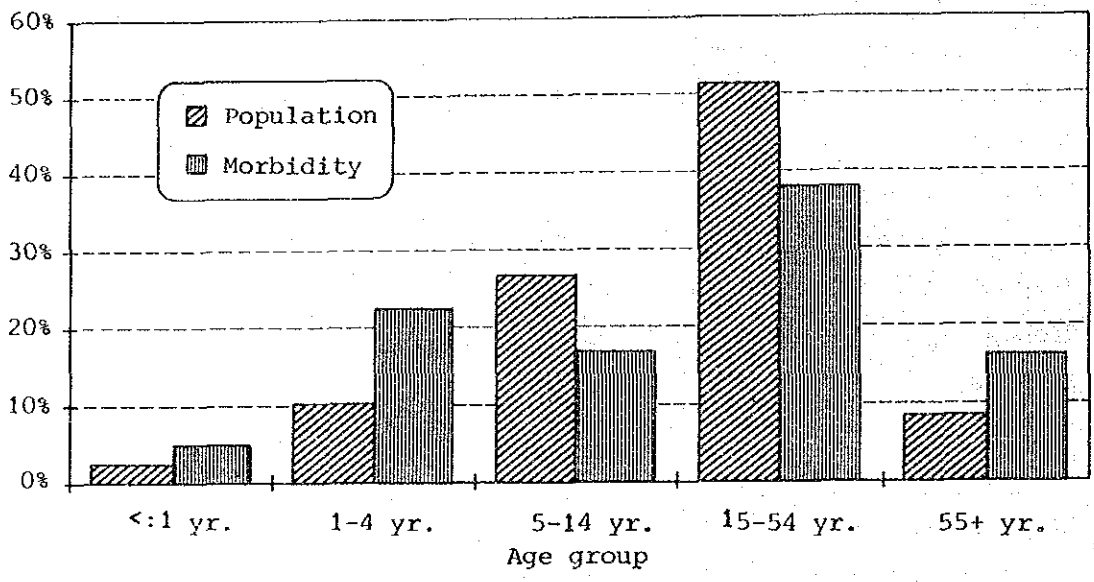
Table 2-8 Major Underlying Causes of Death Among Children Aged 1-4, 1986

Causes of Death	Rate per 100,000 children	Per cent child deaths	Cumulative per cent	Est. no. of deaths 1985
Diarrhoea	278.4	26.4	26.4	47,800
Measles, diphtheria, pertussis	291.5	27.6	54.0	50,000
ARI (acute respiratory infections)	88.4	8.4	62.4	15,200
Malaria	55.7	5.3	67.7	9,600
Accidents, injuries	52.4	5.0	72.7	9,000
Nervous system disorders	49.1	4.7	77.4	8,500
Anaemia, malnutrition, avitaminosis	26.2	2.5	79.9	4,500
Bronchitis, asthma	26.2	2.5	82.4	4,500
Tetanus	16.4	1.6	84.0	2,900
All others	170.5	16.0	100.0	29,000
All causes/undetermined	1,054.8	100.0	--	181,000

(5) Morbidity

When these figures are compared to those for the total population (approximately 13%), there is a high ratio of infant and child morbidity (more than 26% of the total for morbidity).

For infants, acute respiratory infection, diarrhoea and skin diseases account for approximately 70%, and if the figures for children (1 - 4 years of age) are added, then the number of malaria and nervous system disorder increases. A high proportion of these are immunizable diseases, and the implementation of immunization can be expected to lower the morbidity.



Source: Concluded from Prosiding pp.72 & 150.

Fig. 2-3 Percentage Distribution of Population and Morbidity by Age Group, 1986

Table 2-9 Age-Specific Morbidity Rates, 1980 and 1986

Age Group	Rate* 1980	Rate* 1986
1	15.8	16.3
1- 4	19.4	18.1
5-14	7.2	5.7
15-54	9.9	6.1
55+	25.2	15.1
All ages	11.5	8.3

* Per 100 persons in the age group.
(Household Health Survey)

Table 2-10 Major Causes of Infant and Toddler Morbidity, 1986

Cause	Under 1			1-4		
	Rate*	%	Cum %	Rate*	%	Cum %
ARI	70.2	42.4	42.4	73.8	40.6	40.6
Diarrhoea	25.0	15.1	57.5	20.6	11.4	52.0
Skin infections	20.1	12.2	69.7	26.3	14.5	66.5
Bronchitis, asthma, other respiratory infections	13.3	8.0	77.7	12.9	7.1	73.6
Nervous system disorders	7.5	4.5	82.2	11.5	6.3	79.9
Tuberculosis, diphtheria. pertussis, measles	6.8	4.2	88.0	5.4	3.0	87.3
Malaria	2.6	1.6	83.8	7.9	4.4	84.3
Other infections	15.5	9.4	97.4	18.4	10.2	97.5
All causes	165.7	100.0	--	181.5	100.0	--

* Per thousand persons in the age group.

(6) Nutrition

The majority of children under the age of five suffer from malnutrition and the proportion of children whose standard weight is less than 70% is 12.8%.

Table 2-11 Nutritional Status of Under-fives (weight for age), * 1986

	Adequately nourished 80%	Undernourished		
		Mild 70-79%	Moderate 60-69%	Severe 60%
INDONESIA	47.1	40.0	11.1	1.7
Rural	44.3	41.5	12.2	2.0
Urban	56.7	35.1	7.4	0.9
Male	50.4	38.0	10.0	1.6
Female	43.8	42.0	12.3	1.8

* Harvard Standard

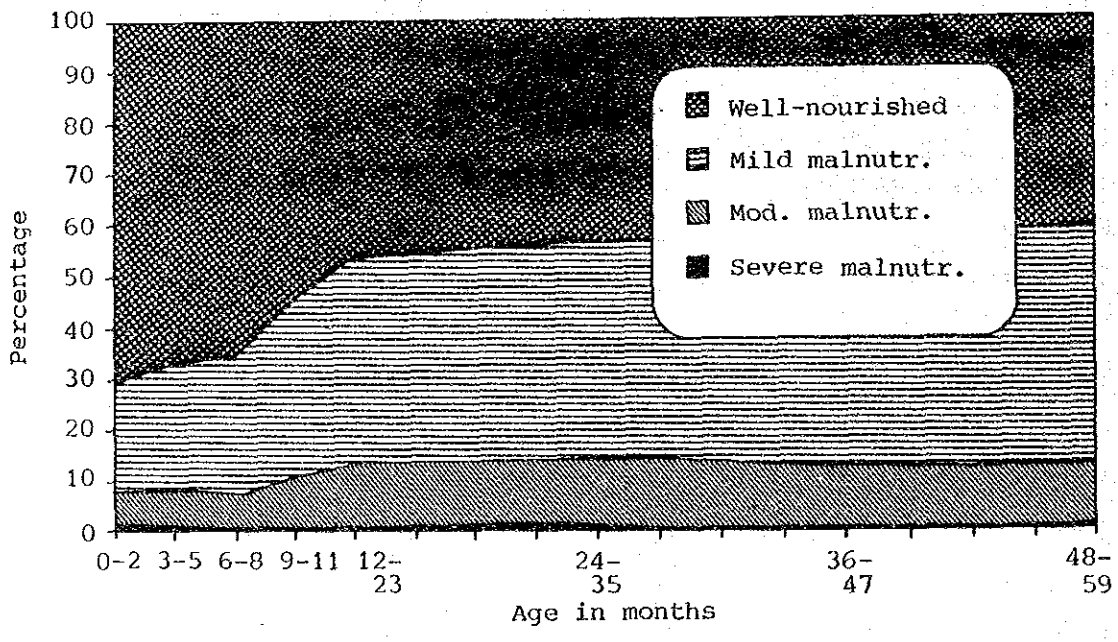


Fig. 2-4 Nutritional Status by Level and Age Group, 1987
Urban + Rural

2-1-2 Current Status of Health Care Services

The major medical treatment services are provided by hospitals, clinics, health centers (HC) ("PUSKESMAS") and sub-centers (two to five per health center). The hospitals and clinics are under the jurisdiction of the Directorate General of Medical Care, Ministry of Health, and the health centers are the responsibility of the Directorate General of Community Care, Ministry of Health.

(1) Hospitals

The provision of hospital and other medical treatment facilities suffer badly from the disadvantageous geographical conditions produced by the many islands dispersed over a wide area, as well as the socio-economic environment as reflected in the insufficiency of the budget for health, and insufficiency of medical staff and equipment.

The hospitals can be broadly classified into public and private hospitals. The public hospitals can be further subdivided into 1) national hospitals (those run by the Ministry of Health and autonomous hospitals under the jurisdiction of the Ministry for the Interior), 2) military hospitals and 3) public hospitals that are not run by the Ministry of Health. The private hospitals consist of 1) corporate hospitals run by social insurance corporations, and 2) hospitals established by religious groups.

Of the national hospitals, 15 are under the jurisdiction of the Ministry of Health, while the others are state, provincial or municipal hospitals under the jurisdiction of the Ministry of the Internal Affairs. Public hospitals established by bodies other than the Ministry of Health include hospitals established by the Ministry of Transportation, the Ministry of Posts and Telecommunications and the Ministry of Agriculture.

By decree of the Minister for Health, the National hospitals are divided into several classes according to the content of their services, the number and level of staff, and the system of referral, etc. These factors are combined to produce the four classes of A, B, C and D.

The definition of an A-class hospital is that the number of beds should be 1,000 or more, that all expert medical departments are represented, and that each of these specialist medical departments have expert medical staff in attendance. Moreover, the A- and B-class hospitals are also used as educational hospitals by the Faculty of Medicine at the National University. Hospitals of C-class or higher are those which have departments of (1) Surgery, (2) Internal Medicine, (3) Obstetrics and gynecology, and (4) Pediatrics.

The hospitals that are currently designated as A-class hospitals are the two hospitals of Dr. Cipto Mangunkusumo Hospital (in Jakarta) and the Dr. Soetomo Hospital (in Surabaya). Moreover, there are 15 B-class hospitals, 78 C-class hospitals and 222 D-class hospitals. In addition to these, there are also E-class hospitals that only have one department. Under these hospitals are the health centers (HC) and the sub-centers that take on the role of primary health care.

(2) Health Centers ("PUSKESMAS") and Integrated Health Service Posts ("POSYANDU")

The health centers (HC) are known as "PUSKESMAS" and provide health services to the low-income segment of the population residing mainly in agricultural villages and cities. For this reason, the government is making efforts to increase their number.

The sub-centers are medical treatment facilities smaller than the health centers and in 1980, there were 4,753 health centers and 8,342 sub-centers. However in 1988, the numbers had risen to 5,500 and 12,000 respectively so that in each sub-region ("kecamatan") there was at least one health center and several sub-centers. This meant that there was a network with one health center for each 31,000 population, and 1 sub-center for each 14,500 population.

Nevertheless, the areas that the health centers can cover are small because of the relatively undeveloped transportation system particularly for the agricultural areas. In order to provide adequate coverage for remote areas, mobile HC on trucks and boats have been in use since 1976/1977.

The work of the health centers include:- 1) medical treatment, 2) child and maternal health care, and family planning, 3) prevention of communicable diseases, 4) improvement of environmental hygiene, 5) health education, 6) public health nursing, 7) making records and reports, 8) Improvement of nutrition, 9) health education in school, 10) improvement of dental hygiene, 11) promoting mental health and 12) examination.

At the end user level, there are the Integrated Service Posts ("POSYANDU") that are operated and managed by the residents of the villages. Each village has one such post responsible for (1) preventive inoculation, (2) mother and child health, 93) improving nutrition, (4) family planning, (5) taking measures with respect to diarrhoea, and so on.

However, to-date it is still not possible for all of the POSYANDU to completely perform all of those tasks mentioned above. For the time being, the aim is to perform a minimum of two of the tasks designated. From the progress that has been made to-date, the improvement of nutrition and the spread of family planning practises are the two most common tasks that have been achieved.

In 1988, there were more than 200,000 POSYANDU in more than 60,000 villages which means that there is one per 170 infants (of under age 4) but as shown in Fig. 2-5 and Table 2-12, there are very large regional variations (with the distance to the nearest POSYANDU being from 2 to 15 kilometers) and the immediate objective is to have one POSYANDU for each 100 infants.

The organization and daily activities of the POSYANDU are the responsibility of the community and their success or failure is dependent upon the physical support and staff skills that the regional HC can provide. The doctors at the HC and the POSYANDU under their charge perform the training of the administrators, the scheduling of the inoculators, midwives and other persons, the ordering and distribution of medical equipment and vitamins, etc. as well as other duties. In 1984, there were 17 POSYANDU for each health center but after this, they became more widespread thereby resulting in an average of 25 in 1987. However, this rapid spread of

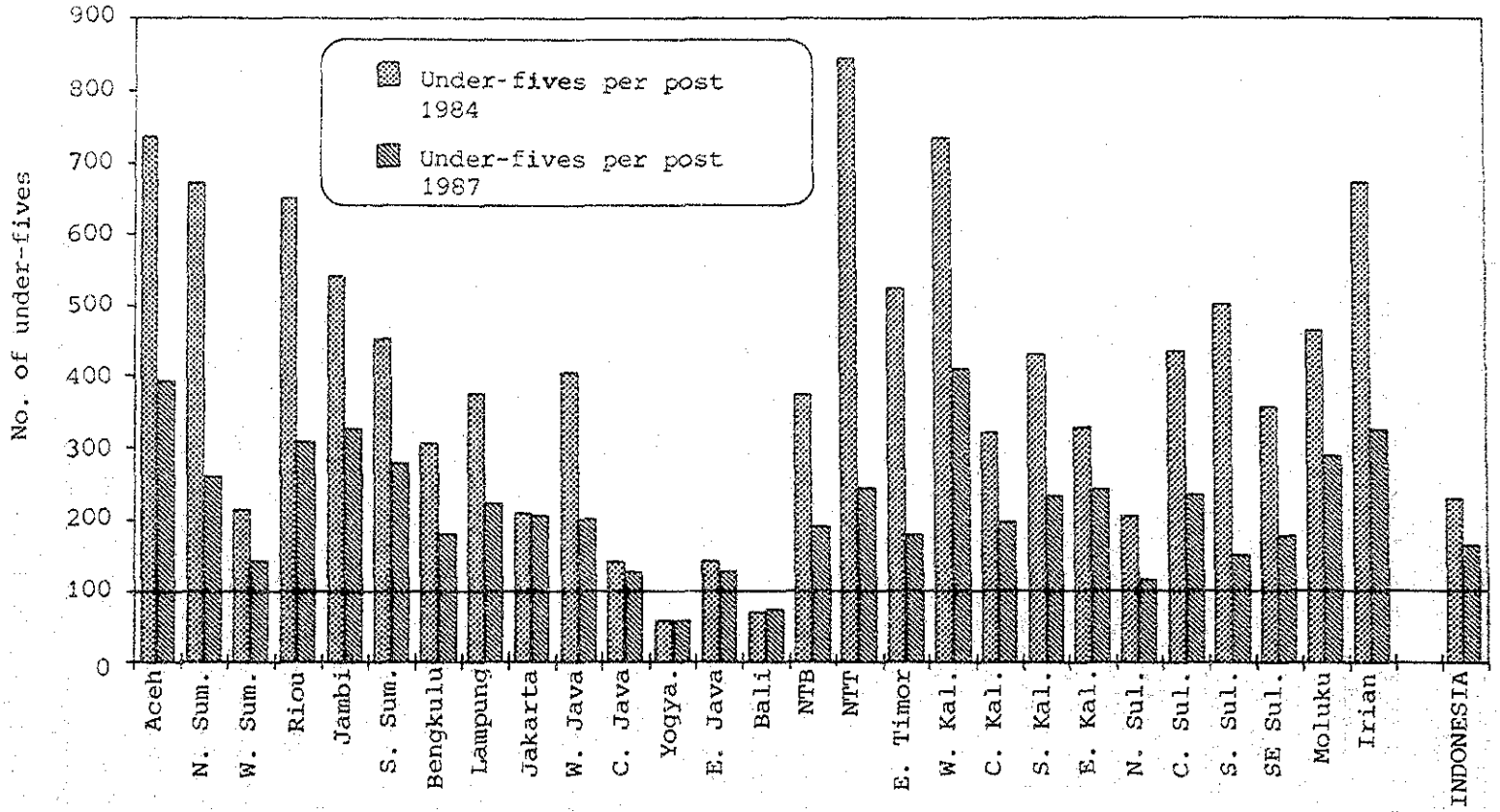


Fig. 2-5 Number of Under-Fives per Integrated Service Post, 1984 and 1987 by Province

Table 2-12 Average Area Served per Integrated Health Post and Child Population Density, 1987

	Service area (km^2) per post	Under-fives per km^2	Present no. of POSYANDU
DI Aceh	47	8	1,186
North Sumatra	12	21	5,748
West Sumatra	12	11	4,000
Riau	71	4	1,330
Jambni	51	6	874
South Sumatra	34	8	3,082
Bengkulu	25	7	834
Lampung	7	30	4,513
DKI Jakarta	1	1,794	5,100
West Java	2	97	22,200
Central Java	1	98	26,550
DI Yogyakarta	1	89	4,826
East Java	2	75	28,443
Bali	1	51	3,851
West Nusa Tenggara	8	25	2,607
East Nusa Tenggara	26	10	1,870
East Timor	25	7	592
West Kalimantan	139	3	1,058
Central Kalimantan	167	1	914
South Kalimantan	30	8	1,246
East Kalimantan	187	1	1,082
North Sulawesi	8	15	2,430
Central Sulawesi	71	3	986
South Sulawesi	13	12	5,678
Southeast Sulawesi	25	7	1,110
Maluku	79	4	948
Irian Jaya	580	1	728
INDONESIA	14	12	133,786

the POSYANDU only served to highlight the insufficiencies of the current staffing and the inadequacy of transportation facilities for the HC. Furthermore it also increases the personnel, administrative and operational responsibilities of the current medical staff.

(3) Medical Staff

The number of staff (including the medical staff, administrative staff and others) associated with the Ministry of Health was 91,250 in 1980 and of this number, 36% were engaged with the central administration, 63% were engaged with regional government and the remaining 1% involved with other sections.

Nevertheless, there is still a serious shortage of medical staff and the government is proceeding further with its efforts to train more medical staff. There are 14 national universities and 13 private universities for training doctors and each year, they produce 1,500 doctors. These newly graduated doctors are required to practise for three to five years at the HC as general practitioners after they have finished their 6-year medical course. The training of specialist doctors is through post graduate courses and so although the HC are staffed to 80% sufficiency with doctors, there continues to be a shortage of specialist doctors.

There are 225 nursing schools and these are divided into SPK that provide 3-year training courses for those with up to junior high school education, and academies that provide 3-year training courses for those who have finished high school. Each year, a total of 6,000 nurses graduate from these courses.

Table 2-13 Plan for Increasing Medical Personnel

(Units: persons)

Category of Medical Personnel	REPELITA III	REPELITA IV
1. Specialist doctors	2,733	3,424
2. General practitioners	7,529	13,614
3. Dentists	1,292	1,773
4. Other medical technicians	1,219	5,283
5. Social-medical center workers	44,651	76,238
6. Treatment personnel	12,011	38,461
7. Treatment assistants	29,433	50,461
8. Office workers	63,221	94,643
Total	162,129	283,897

In 1987, there were 4,496 pharmacists and of this number, 2,197 worked in pharmacies, 512 worked in pharmaceutical plants, 97 were in pharmaceutical wholesaling and 206 were engaged at hospitals. The work of pharmacists is supported by assistants at the pharmacies and some hospitals but many hospitals employ assistants only, and not qualified pharmacists.

2-1-3 System and Organization for Communicable Diseases Control

(1) Central Government Level

The central government organization is represented by the Ministry of Health, as shown in fig. 2-6. The sections concerning communicable diseases are the Directorate General of Communicable Disease Control (CDC), the Directorate General of Food and Drugs (FAD) and the National Institute of Health Research and Department (NIHRD).

The organization for the immunization program is as follows: the CDC is responsible for a) formation of a vaccine immunization program, b) ordering production of vaccines and c) domestic transportation of vaccines. The FAD is responsible for the import and production of vaccines at the public pharmaceutical manufacturing company Bio Farma, which is under the jurisdiction of FAD, while the NIHRD is concerned with research on viruses.

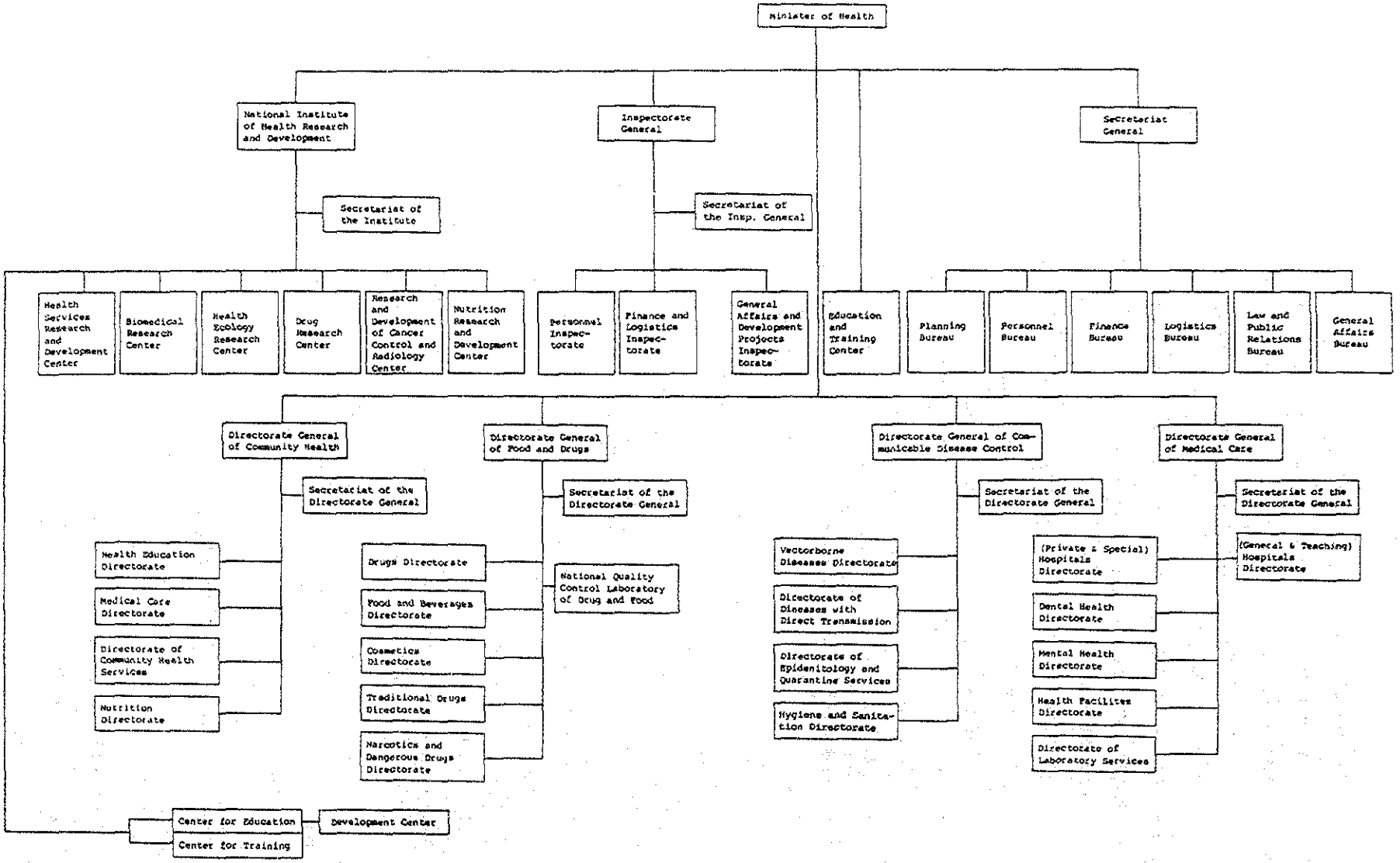
(2) Regional Level

At the regional level, the administrative organizations for countermeasures with respect to communicable diseases, are generally under the regional health administration bodies. Health administration in the regional areas is carried out, as shown in Fig. 2-7, by a dual system comprising the general regional administration organizations under the Ministry of the Internal Affairs and the regional administration organizations under the Ministry of Health. In addition to countermeasures against cmmmunicable diseases, the establishment and monitoring of family planning programs is directly administered from the Ministry of Health and the implementation of these plans is undertaken by the general administrative organizations under the Ministry of the Internal Affairs.

At the level of the 27 provinces, there are the Health Offices of the Ministry of the Internal Affairs and the representative offices (known as "kanwil") of the Ministry of Health. However, the personnel in charge of these offices are dispatched from the Ministry

of Health and they serve these two positions concurrently. The offices in charge of health (known as "kanded bupati") come next, at the level of the Ministry of Health in the 304 regencies. Below that are the health centers (known as "PUSKESMAS") at the level of the 5,353 districts. These HC have a central role in undertaking countermeasures against communicable diseases at the end-user level of the system. They are short-staffed but nevertheless have general practitioners, nurses, midwives, assistants and other technical staff. Immunization plans are formulated at these HC. The procedure for implementation of immunization consists of gathering the residents at the POSYANDU after which inoculation is then performed by the staff of the HC who have gone there just for that purpose. This means that the residents to be inoculated have to be notified and their numbers indicated to the HC beforehand, so that there is no wastage of the vaccines.

Fig. 2-6 The Organization of the Ministry of Health, Republic of Indonesia



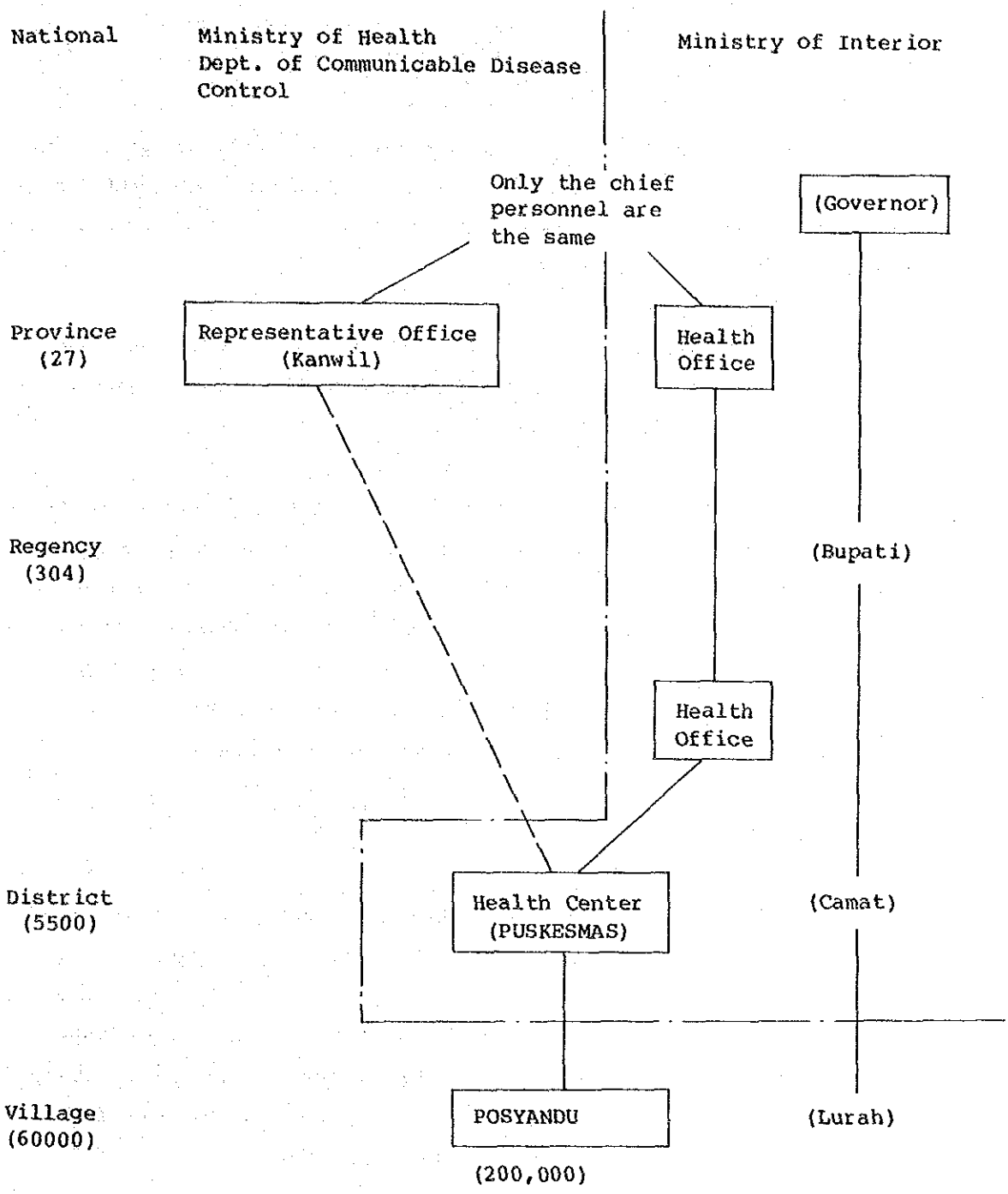


Fig. 2-7 Health Administration at the Regional Level

2-1-4 Current Status of the Pharmaceutical Industry

(1) Pharmaceutical Manufacturers and Production

In 1987, there were 40 foreign-owned pharmaceutical producers in Indonesia (of which 6 were Japanese companies), as well as 247 domestic producers (of varying scales), all of which were concentrated on the island of Java.

The distribution of pharmaceuticals is undertaken by 892 wholesalers through 2,051 pharmacies, 1,025 licensed drugstores and other institutions for the whole country.

The number of registered drugs in 1987 was 12,606 and of these, some 8,818 were trade names, with the remainder being generic names. Some 10,447 items (82.87%) were produced by domestic manufacturers and 2,000 (15.87%) were produced by the foreign manufacturers, with the remaining 159 types (1.20%) being imports. The import of finished products is limited only to those products that for economic or technological reasons cannot be produced in Indonesia.

(2) Drug Consumption

From 1973 to 1985, the consumption of drugs has been steadily growing at the rate of between 10.42% and 56.25% each year, even though there was a temporary drop in 1988. Table 2-14 shows the changes for the consumption between the years of 1973 and 1986. The value of consumption per capita is US$3-4 but in the rural areas it is practically nil, and there are still places where folk medicines ("jamu") or faith healers ("dokun") are relied upon.

Approximately 47% of the total value of drug consumption is through the pharmacies, with 32% through the drugstores, and 21% through hospitals and HC.

Table 2-14

Year	Total value of marketed drugs (million US $)	Percentage of increase/decrease
1973	92	22.67 %
1974	120	30.43 %
1975	160	33.33 %
1976	250	56.25 %
1977	304	21.60 %
1978	350	14.47 %
1979	420	20 %
1980	480	14.28 %
1981	530	10.42 %
1982	591.7	11.64 %
1983	486	- 17.86 %
1984	420	- 13.58 %
1985	470	11.90 %
1986	456 *)	- 2.98 %

*) Estimated, based on the first quarter data of 1986, i.e. US $ 136 million.

Source: IPA
Indonesia Pharm Audit

1) Drs. E. Lembong, G.P. Farmsi Pusat, Pengaruh Kelesuan Ekonomi Dunia Terhadap Kehidupan Kefarmasian di Indonesia.

(3) Drug Administration

The development of pharmaceuticals (viz. the pharmaceutical industry) is one of the five major objectives of the Government of Indonesia's long-term plan for the promotion of public health. This plan recognizes the importance of the role of pharmaceuticals and has led to the establishment of the NDP (National Drug Policy) in 1983. The aims of the NDP are as follows:-

a. To ensure the availability of drugs in accordance with the actual demand of the people
b. To ensure that the drugs required by the people are fairly distributed.
c. To ensure the effectiveness, stability, quality and efficacy of marketed pharmaceuticals, and to recommend methods for their rational and effective use.
d. To prevent the misuse and abuse of pharmaceuticals.
e. To contribute to promoting the domestic production of pharmaceuticals and the growth of the economy.

In addition to these aims, there are also the following policies that are to be implemented in stages:-

. Planning a system of inspection and registration of pharmaceuticals so as to ensure the efficacy, stability and high quality of marketed pharmaceuticals.
. Recommending rational methods of pharmaceutical use in the implementation of the selection of the essential drugs .
. Improving the systems for the production, supply and distribution of pharmaceuticals.

In addition to these functions, the provision of an information system and the fostering of human resources should also be mentioned.

(4) Essential Drugs Supply and Management

There are very large regional differences in the conditions for the supply of pharmaceuticals and this is one of the present problems. This is partly due to the complex budget processing and scheduling procedures in the industry.

Besides promoting the further diffusion of POSYANDU with resident participation so as to increase the autonomy in the regional areas, it is also necessary to plan for the improvement to the supply of the essential drug kits as an emergency measure.

(5) Drugs Production and Supply

The production of the essential drugs for the HC and the regional C-class and D-class hospitals is undertaken by the government enterprises, Indo Farma, Kimia Farma and Phapros (The vaccines are all produced by Bio Farma). Approximately 80% of the essential drugs are produced by the government enterprises and these expenses are provided by the President's Special Budget ("INPRES"). However, current production is said to be no more than 70-80% of what is necessary and practically all of the essential drugs for primary health care are supplied by the government enterprises. The production of these essential drugs in the future will enable the timely supply of high quality and inexpensive pharmaceuticals.

Indo Farma is presently having a new factory, which will conform to GMP standards, constructed on the outskirts of Jakarta, with the completion scheduled for the end of 1989 (This factory was designed by an Italian consultancy firm). The factory will have a scale which would be capable of producing the full amount of essential drugs for up to the year 2000.

These essential drugs will have to be supplied to the regional hospitals and HC and to ensure this, from 1981/1982, the Regency Pharmaceutical Warehouses (RPW) have been established as facilities to provide the planned supply, management and quality control (maintenance) for pharmaceuticals. In regional areas, these RPW play an important role in the supply of pharmaceuticals through various types of financial sources, and in the scheduling adjustments.

These RPW will be responsible for the periodic supply of the essential drugs according to necessity at each of these regional facilities, and of the total of 283 RPW which are scheduled to be established, some 180 are already operational.

(6) Drug Inspection and Quality Control

The inspection of drugs in Indonesia has been undertaken by the National Quality Control Laboratory for Drug and Food (NQCLDF) (completed in 1984 through Grant Aid of the Government of Japan) and its 27 branches nationwide.

The NQCLDF was established (1) to provide quality control standards for drugs, foodstuffs, cosmetics and toxic substances, and (2) to carry out the approval, testing, examination and management of information for new drugs.

However, there are no facilities or equipment for the examination of the polio and measles vaccines that are to be produced through the implementation of this project and because of this, it will be necessary to include the facilities and equipment for self-examination of the products, as part of this present project.

(7) GMP in Indonesia

Following the establishment of the GMP (Good Manufacturing practices: i.e. Standards relating to the quality control and production of pharmaceuticals) by the American FDA in 1963, the WHO General Assembly produced a report on the use and implementation of the GMP in 1969. This was revised at the 28th Assembly in 1975 and since the final recommendations for the implementation of the GMP and its degree of verification (verification system on the basis of the GMP, for use in international trade), the GMP has come to be used in various countries. (In Japan, it has been implemented since April, 1976.)

In recent years, technical cooperation amongst ASEAN countries has been the basis for the issue of the "ASEAN GMP Guidelines," which was carried out initially focusing on Indonesia. The first edition of these guidelines was published in 1984 and the second edition in 1988. (The members representing Indonesia are Dr. Slamet Soesilo of the FDC, and Drs. Darodjatun, President Director of Bio Farma).

The implementation of the GMP would be carried out over a period of five years beginning in 1989. As already mentioned, there are nearly 300 manufacturers both large and small and in view of these circumstances, the implementation of the GMP requires the setting up of detailed implementation regulations. The forced compliance of these regulations is by no means an easy task. However, a few of the foreign-owned manufacturers are constructing new facilities so as to pass the GMP standards when they are implemented in the future. Moreover, the new factory of Indo Farma that is currently being constructed, as well as the implementation of this present project will spur on the implementation of GMP in Indonesia.

(8) Promotion of Domestic Production

The promotion of domestic production of drugs is the one of the major objectives of the pharmaceutical administration. In line with the policy, the ratio of domestic demand for the essential drugs and vaccines is increasing each year. The promotion of the domestic production of pharmaceutical raw materials is therefore required.

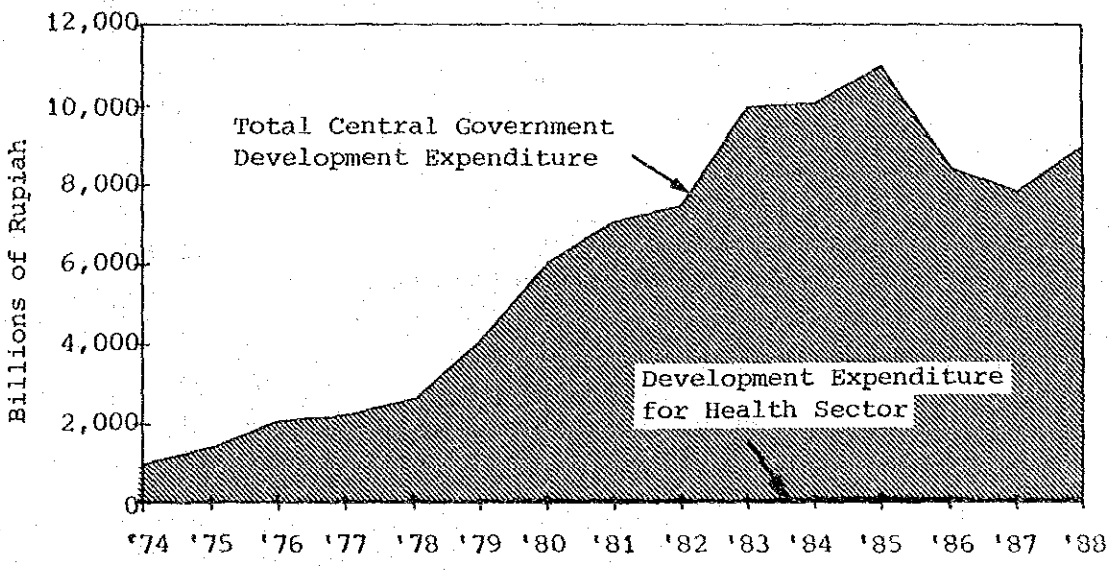
The domestic production of pharmaceuticals is also being promoted through various types of restrictions on foreigned-owned ventures. Some of these restrictions with respect to the system for the approval and registration of new pharmaceuticals, are as follows:-

- The production of new pharmaceuticals by the foreign-owned pharmaceutical companies is to be limited to the production of revolutionary new pharmaceuticals and that which uses extremely high-level technologies.
- The licensing of production of pharmaceuticals will only be approved when the developer of the license (the foreign-owned manufacturers) are willing to pass these licenses to domestic manufacturers, or when the licensed manufacturer is a government enterprise.

2-1-5 Changes in Health and Medical Expenditure

(1) National Expenditure

In recent years, the National Development Expenditure has occupied about 55% of the Gross National Expenditure. From the 1970s to the initial part of the 1980s, the Indonesian economy has shown solid development and growth but was delivered a severe blow with the drop in oil prices in 1986. As a result, the National Development Expenditure had temporary but large-scale cuts across practically all fields but is nevertheless now showing signs of recovery. Fig. 2-8 shows the changes that have occurred for the National Development Expenditure from 1974 to 1988.



Source: Annexes to the President's Address to MPR. 1973 & 1975, & to DPR. 1954 & 1987, 1987 & 1988 figure are budgeted amounts, not actual expenditure, from Nota Kawangan dan RAPBN 1987/ 1988 & 1988/89.

Fig. 2-8 Health Sector Development Expenditure vs. Total Development Expenditure 1974-1988 (Including Project Aid)

However, the National Expenditure for health and medicine has continued to increase, even through the ratio of such increases has been small, and has been maintained at approximately level. Table

2-15 shows the favorable growth that has been achieved for the development expenditure relating to health and medicine as part of the Total Central Government Development Expenditure ("Repelita II, III") prior to the drop in oil prices.

Table 2-15 Government Development Expenditure by Sector*
(billions of Rupiah **)

Sector	1974-1979 REPELITA II Amt.	%	1979-1984 REPELITA III Amt.	%
Agriculture and irrigation	1,745.2	19	3,048.9	14
Industry, mining and energy	1,653.4	18	4,117.9	19
Transportation and communications	1,631.8	18	3,384.3	16
Regional and local development***	1,024.5	11	2,142.9	10
Public enterprises***	790.0	9	370.3	2
Education	758.2	8	2,276.8	10
Health and family planning	262.0	3	829.1	4
Others	1,261.4	14	5,679.2	26
Total	9,125.5	100	21,849.4	100

Source: Indonesian National Development Information Office, Indonesia: Economic Update 1982/83; and Central Bureau of Statistics.

* Includes only development expenditure of the Central Government, which in recent years has accounted for around 55 per cent of total central government expenditures.

** Before 1978 the exchange was US$1=Rp415; by 1982 the exchange rate was Rp661 per US$1; in March 1983 the Rupiah was devalued from US$1=Rp703 to Rp930; on September 12, 1986 the Rupiah was devalued from US$=Rp1,134 to Rp1,644.

*** The portion of provincial and local government development expenditure financed by the central government.

**** The portion of development expenditure by Government-owned enterprises which is financed by the central government.

(2) Health and Medical Expenditure

In Indonesia, there is a relatively small proportion of expenditure with respect to health and medicine. The combined health and medical expenses per capita for the public and private sector for 1986/1987 was approximately 14,561RP (or approximately US$8.90), of which government spending accounted for approximately US$3.20).

From the middle of the 1970s, the health and medical development expenditure of the Ministry of Health stood at approximately 1.5% of the Gross National Expenditure. (In the case of other South-east Asian countries such as Burma, Sri Lanka, Thailand, the Philippines and Singapore, etc., the proportion is approximately 3.5 to 7.0%.) However, recently, the proportion of the GNP occupied by the National Gross Health and Medical Expenditure has dropped to 2.7% in 1982/1983, 2.3% in 1984/1985, and 2.2% in 1986/1987. Of this, public expenditure accounted for no more than 30%.

The sources for the public medical budget are shown in Fig. 2-9 but the President's Special Fund ("INPRES") and national budgets such as that for the Ministry of Health account for most of this. There is the trend for increases in the amount of assistance from overseas and in the profit from government enterprises that are the major pharmaceutical manufacturers.

Until the drop in the oil prices in 1986, there had been favorable growth for the national health and medical expenditure, but as shown in Table 2-16, substantial cuts had to be made. In particular, there were large cuts in the development budget relating to preventive medicine and primary health care, which are activities covered by the HC and POSYANDU. These organizations can be said to form the backbone of the health and medical administration of Indonesia.

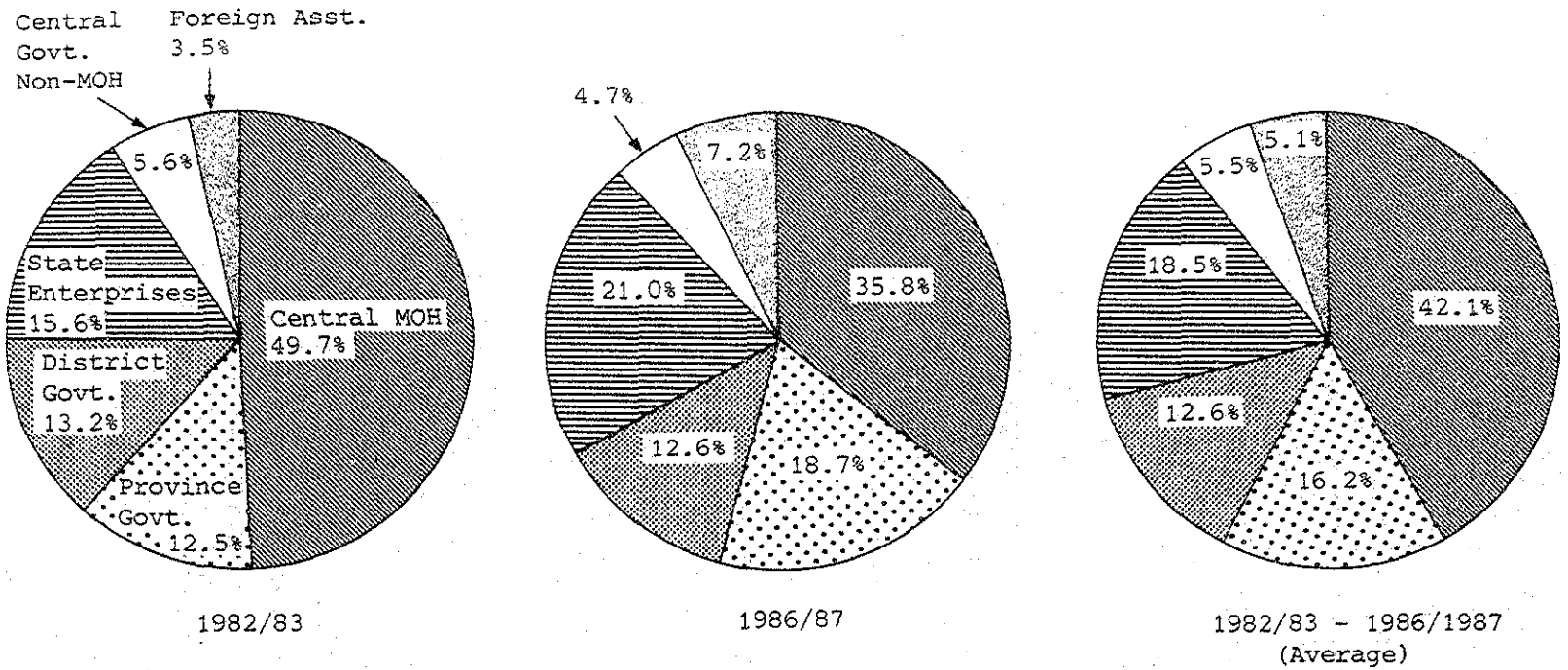


Fig. 2-9 Public Health Expenditure, by Source

Table 2-16 Trends in Central Government Health Expenditure (billions of Rupiah, in fixed 1983 prices)

	1982/ 83	1983/ 84	1984/ 85	1985/ 86	1986/ 87	1987/ 88	% change 1982/83- 1987/88
Development	111.5	108.4	101.7	94.8	65.2	22.9	- 79.5 %
Routine	78.5	82.4	93.5	116.8	138.8	140.2	+ 78.6 %
INPRES (special Presidential fund)	98.4	98.4	98.4	114.6	114.6	76.2	- 22.6 %
SBBO (subsidy for hosp. operation and maintenance)	6.5	8.1	8.2	9.5	9.8	8.0	+ 23 %
TOTAL	295.0	297.5	301.9	335.6	328.4	247.3	- 16.2 %

* 1987/88 figures are budget allocations; for other years they represent actual expenditure.

Source: Planning Bureau, Department of Health, 1987.

(3) Budget for the Prevention of Immunizable Diseases

With the exception of the general office expenses of the Ministry of Health, the distribution of the budget over the various activities is as shown in Table 2-17. The proportion of the budget for measures against immunizable diseases is large and its ratio has been increasing yearly. Moreover, EPI had an additional budget of 800 million RP allocated to it in 1986.

Table 2-17 Detailed Allocation Budget per Health Programme (Million Rupiah)

No	Program	1983/1984		1984/1985		1985/1986	
		Budget	%	Budget	%	Budget	%
1.	Young generation	334.9	0.3	350.0	0.3	350.0	0.3
2.	Training and Education	9,107.3	7.9	12,993.5	11.2	15,041.8	13.4
3.	Health Education	1,130.6	1.0	1,653.1	1.4	1,964.6	1.8
4.	Health Services	69,001.4	60.0	60,584.8	52.4	51,442.2	46.1
5.	Communicable Diseases Control	21,958.4	19.1	24,196.1	20.9	25,867.7	23.2
6.	Nutrition	3,403.1	3.0	3,935.3	3.4	5,199.9	4.7
7.	Food and Drug Control	2,521.7	2.2	4,429.1	3.8	3,244.5	2.9
8.	Role of Women	388.9	0.3	300.0	0.3	300.0	0.3
9.	Water Supply	1,854.8	1.6	1,374.1	1.2	1,692.0	1.5
10.	Environmental Health	595.0	0.5	574.0	0.5	600.0	0.5
11.	Health Research and Development	768.8	0.7	1,257.7	1.1	1,374.6	1.2
12.	Efficiency	822.8	0.7	916.5	0.8	874.9	0.8
13.	Infrastructure	3,140.9	2.7	3,076.2	2.7	3,647.0	3.3
	TOTAL	115,028.6	100	115,640.4	100	111,599.5	100

2-1-6 Outline of the National Health Plan

Every five years since 1970, Indonesia has been implementing 5-year development plans known as "Rencana Pembangunan Lima Tahun" abbreviated as "REPELITA."

The fourth 5-year development plan Repelita IV was implemented from 1984/1985 to 1988/1989 and the Repelita V to follow it will be announced this year.

(1) Outline of the Health Plan in Repelita IV

The main objectives of Repelita III were used to formulate Repelita IV, with emphasis placed on the following points:-

1. To organise programs and such enlightenment activities which will motivate the general populace to lead healthier lives. In particular, childcare will be emphasized.
2. To establish the sanitary facilities fundamental to environmental hygiene, and to improve the living environment.
3. To improve the status of nutrition, in particular with respect to the nutrition of infants.
4. To reduce sicknesses due to communicable diseases, to control elephantiasis, and to supply pharmaceuticals to the general population at affordable prices.
5. To use family planning to control the number of births.
6. To increase the number of medical staff through education and training.

In order to achieve the main objectives of Repelita IV, the following five items (known as "pance karya husada") were implemented:-

1. Provision of medical treatment facilities
2. Increases in the medical treatment personnel
3. Regulating, procuring and monitoring pharmaceuticals hazardous to health
4. Improving the level of nutrition and environmental sanitation
5. Management and the improvement of regulations

Specific examples of the means to achieve this are indicated below.

1) Typical examples of the effort that is being made are (1) reducing the death ratio, and (2) disease countermeasures. These and other countermeasures are described in more detail in Table 2-18 and Fig. 2-10.

Table 2-18 Death Rate for Each Repelita

	End of Repelita II (1978)	End of Repelita II (1983)	End of Repelita IV (1988)
1. Converted mortality	13.5	11.7	10.1
2. Infant mortality	103.0	90.3	70.0
3. Child mortality	20.9	17.8	14.0
4. Average life expectancy	52	56	59

Notes: 1. Converted mortality: Number of deaths per thousand people
2. Infant mortality: 0-12 months; Per 1000 live births
3. Child mortality: 1-4 years; per 1000 children under age 5
4. Average life expectance (years): Average life expectancy of the population

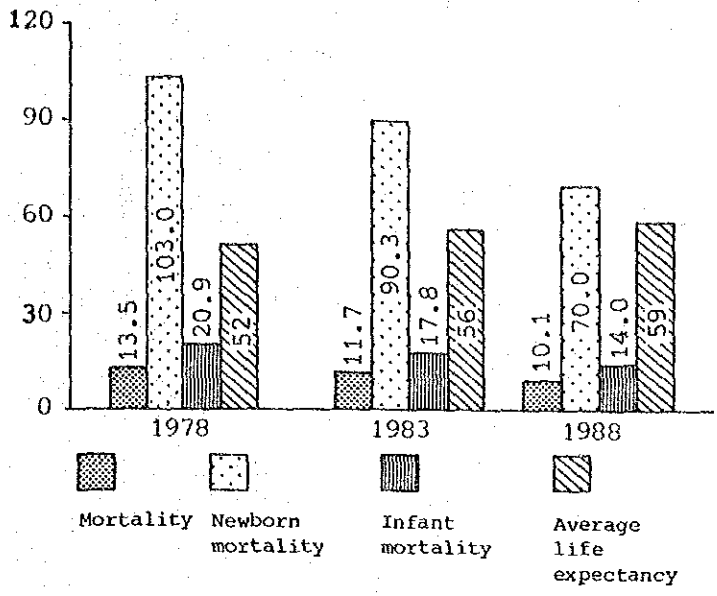


Fig. 2-10 Death Rate and Average Life Expectancies at end of Repelita II, III and IV

Table 2-19 Comparison of Disease Countermeasures

Units: millions

Countermeasures	Repelita III	Repelita IV
1. Malaria countermeasures		
a. House disinfection (number of houses)	16.5	23.0
b. Patient treatment (number of persons)	40.0	50.0
2. Countermeasures for new tuberculosis patients Long-term, short-term treatment (number of persons)	120.0	120.0
3. Cholera countermeasures Patient treatment (number of persons)	1.1	27.7
4. BCG countermeasures	16.5	23.8
5. Countermeasures for malnutrition patients (number of persons)	36,000	64,448

2) The objective values for the increases in the number of personnel are indicated in Fig. 2-11.

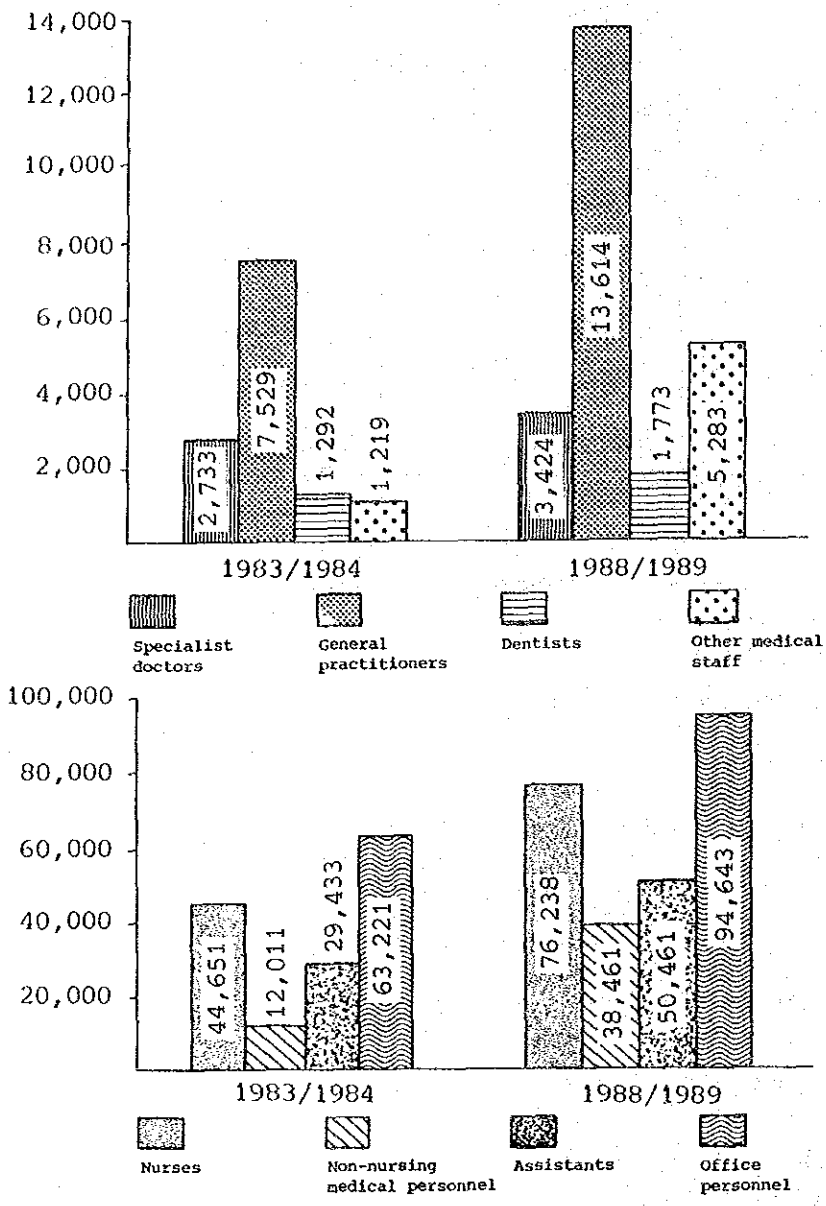


Fig. 2-11 Medical Personnel for Repelita III and Repelita IV

3) In Repelita IV, the development expenditure for health plan is as described below. The crisis in government finances brought on by the drop in oil prices in 1986, has led to modifications for some items, but not to the implementation of the plan although relatively more emphasis was placed on primary health care.

Table 2-20 Development Budget Relating to Medical Treatment (1984/1985 to 1988/1989)

(Units: million RP)

	1984/85	1984/85 - 1988/89
Medical treatment, social welfare, role of midwives, educaion, family planning	407,998.0	3,516,515.7
Medical treatment sector	253,300.0	2,051,652.5
Medical enlightenment plan	1,800.0	13,320.5
Medical implementation plan	191,234.6	1,439,137.2
Communicable diseases and local disease eradication plan	37,917.6	455,004.8
Food and drug monitoring plan	16,447.3	100,529.0

(2) Outline of Health Plan in Repelita V

Currently, the final announcement for Repelita V is being prepared for March, 1989, but an English draft was presented prior to this in November, 1988.

The main objectives of Repelita V are as follows, in terms of priority:-

1) To improve the community health services
2) To improve the referral health services
3) Prevention and control of diseases
4) Health education
5) Education, training and development of health
6) Control, procurement and monitoring of drugs, food and substances causing health hazards
7) Nutrition improvement
8) Potable water supply
9) Environmental health for human settlement
10) Health research and development
11) Improvement and monitoring the efficiency of health infrastructure
12) Improvement of physical health facilities
13) Younger generation and the health development
14) Strengthening the role of women in health development

In the abovementioned objectives, the "prevention and control of diseases" has been prioratised as the third item. This shows the importance the Government of Indonesia is placing on preventive medicine and primary health care. The improvement of community health services is for everyone regardless of age or region (i.e. including the people living in remote islands, small inland tribes and urban slums), so that they can live in optimum sanitary conditions. Various objectives have been set to achieve this:-

a) Overall objectives to be achieved

1. Objective involving reductions
   i) Reduction in infant mortality 62 → 50 (per 1,000 births)
   ii) Reduction in maternal mortality 4.5 → 3.4 (per 1,000 births)
   iii) Morbidity
   iv) Malnutrition and undernourishment
2. Every health center to be capable of organizing community participation.
3. 60% of Health center will cover the low income working population.
4. Increase the numbers of HC, sub-centers, HC with beds, and mobile HC such that the ratio against the population could be maintained.
5. Increase the manpower, facilities, operational cost and maintenance cost.

b) Objectives involving the improvement of the regional medical treatment system

1. Increase in Facilities	HC	5,424	→	6,127
	Sub-centers	2.2/HC	→	3/HC
	HC with beds	1,067	→	1,200
	Mobile HC	3,521	→	5,000

2. Physical rehabilitation for the existing HC building

3. Increasing the number of POSYANDU so that there is one per 100 children under the age of 5 years old.
4. Placement of 18,000 midwives including the necessary equipment at the village level.
5. Replenishment of all the equipment over 5 years old, 10% of which must be phased out every year by stages.
6. Improving all HC as well as providing them with information system
7. Increase in the number of staff at the HC.
   Example: dentists, assistant pharmacists, assistant nutritionists, survey technicians and others at each HC.
8. Having all HC perform all of the 13 basic health services

The basic health services are also to be improved, particularly the following items: (a) mother and child health, (b) family planning, (c) improvement of nutrition, (d) prevention and elimination of communicable diseases, (e) environmental improvement, and (f) health education.

The health and medical activities are to be considered as part of the community activities so that the autonomous and positive participation of the residents is encouraged to increase the level of health of the populace.