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Sixth Meeting of the Advisory Panel
on Preventive Medicine
Manila, The Philippines
4-6 April 1989

REPORT*

* This document has not been edited.

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PREFACE

The Philippines pharmaceutical industry can be characterized as essentially a formulating and a packaging industry. Except for ampicillin, amoxycillin and cloxacillin, all the raw material requirements for pharmaceutical production are imported.

In order to have quality pharmaceutical products more affordable and accessible, a national drug policy (NPD) was enunciated. One of the pillars of the NPD is to achieve relative self-reliance in the manufacture of strategic pharmaceutical products. The objective is to develop the capability to manufacture the pharmaceutical chemicals (i.e. intermediates and basic) so that the Philippines is not totally reliant on foreign sources and avoid the detrimental effects and vagaries of such dependence.

In this regard, the Philippines Government tapped the financial assistance of UNDP and the technical expertise of UNIDO to undertake a study that would identify areas where possible upstream integration of existing pharmaceutical production capabilities can be done (DP/PHI/87/019).

To ensure that the premises of the technical recommendations of the international experts are valid, an independent ad hoc group of experts was convened in Vienna on 27-28 October 1988. As a result of the meeting, there is now more confidence in the technical recommendations of the study and further socio-economic analyses can be undertaken.

In the field of vaccine production, the Government of the Philippines is ready to negotiate a large-scale investment and technical assistance project with interested investors or bilateral donors. Urgent high level advice was required by the Government to ensure that the negotiated agreement would most

adequately fulfill their needs. Due to the complexity of the problem, as well as the sometimes contradictory recommendations of prior studies in this field (such as the Intercare Study, a previous UNIDO study covering ASEAN countries, and the study of DP/PHI/87/019) the following actions were suggested by the above independent group of experts:

- To upgrade the Quality Control Laboratory for biologicals at the Biological Production Services, Alabang irrespective of the decision which might be taken with regard to the upgrading of the vaccine production facilities.

- To obtain the view of the UNIDO "Advisory Panel on Preventive Medicine" on the "Intercare Study on the Alabang Vaccine Complex" in order to provide the urgently required advice for the Philippines Government.

As a follow up of this recommendation and of the discussions of Mr. D. Siazon, Director General of UNIDO with Dr. A. Bengzon, Secretary of Health during his visit to Manila in November 1988, the Philippine Government requested UNIDO to field its "Advisory Panel on Preventive Medicine" for trouble shooting by giving the most needed technical advices to upgrade the vaccine production facilities and by reconsidering the technical recommendations of the "Intercare Study on the Alabang Vaccine Complex".

I. ORGANIZATION OF THE MEETING

Opening of the Meeting

The meeting was opened by Dr. Alfredo R.A. Bengzon, Secretary, Department of Health. In his inaugural address he reminded that the Expanded Programme on Immunization (EPI) was endorsed by President Corazon Aquino in 1986 as one of her first acts. He expressed that the domestic vaccine production has not only technical, health and financial aspects but also political aspects. Finally he requested the members of the Panel and the resource persons to give advice and guidance in their personal capacity and not only "through their corporate lenses".

Dr. Charles Merieux, Chairman of the Panel greeted the representatives of the Philippine Government and participants of the meeting and summarised the achievements of the previous Advisory Panel meetings and UNIDO Symposia on Blood and its Derivatives. The list of these meetings are given in Annex VII.

The Director of Industrial Operations Technology Division of UNIDO and Secretary of the Advisory Panel highlighted the importance of the Advisory Panel on Preventive Medicine in advising and guiding of UNIDO programme on industrial production of biologicals (IPB). As examples of major achievements she specifically mentioned the rehabilitation type of projects and the pilot plants for demonstration of production of human and veterinary biologicals within the same premises. She emphasized that production of human and veterinary vaccines within the same premises, but stricly following the GMP requirements, could financially be more viable due to better utilization of technical capacities and personnel capabilities.

Mr. Rhais M. Gamboa, Undersecretary, Department of Health and National Project Director of DP/PHI/87/019 briefed the members of the Panel and the resource persons on the terms of reference of the meeting (Annex III) and the guide questions and issues for discussion (Annex I).

The Agenda of the Meeting

The Agenda of the Meeting is given in Annex IV.

Documentation

The "Alabang Vaccine Complex, A Medium-Term Development Plan" prepared by the Integrated Health Care Services, Inc. (INTERCARE) in August 1987 and referred throughout this report as the Intercare Study on the Alabang Vaccine Complex was distributed among the members of the Panel and resource persons in well advance as the basic document for this meeting. A summary paper of the Intercare recommendations VS existing situation at the Biologicals Production Service (BPS) and another paper on the perspectives of the Alabang Vaccine Laboratory Development Programme are attached as Annex V and VI, respectively.

Visits

The participants of the meeting visited the Biologicals Production Services at Alabang on 4 April 1989. The programme of this visit is given in the Agenda (Annex IV).

II. GENERAL RECOMMENDATIONS

The Panel visited the Biologicals Production Service (BPS) and reviewed the Intercare Study on the Alabang Vaccine Complex as a basis for recommending the Philippine Government's future development activities in accordance to the needs for implementing the EPI and consistent to the National Drug Policy.

The Panel discussed all of the relevant aspects of vaccine production and formulated its recommendation in line with the Guide Questions/Issues which were agreed by its members (see Annex 1).

1. The BPS shall continue to produce the following biological products: BCG, tetanus toxoid, DPT, anti-venom, cholera, typhoid, diagnostic antigens and anti-sera, animal and human rabies vaccine and PPD. However, it is recommended that these products should be tested by an independent recognized reference laboratory in order to confirm that these products meet international standards.

2. It was the opinion of the Panel that cholera/ typhoid combination should be discontinued. Production of Semple rabies vaccine should be phased out as soon as practical and it should be replaced with the verocell rabies vaccine.

3. New vaccines such as DT (Diphtheria-Tetanus) and possibly Td (adult) could be considered to be produced in BPS.

So far as the production of other EPI vaccines (OPV and measles), and Hepatitis B or any other are concerned, the creation of the proper basic infrastructure in BPS is a prerequisite.

4. As a first stage, the building of facilities to carry out blending, filling, packaging and storage properly serviced with utilities and a new quality control department and support facilities operating at the highest standards of G.M.P., should be established. This would enable the government to adopt a very flexible policy regarding filling of imported bulk concentrates and locally produced vaccines.

5. As a second stage, the BPS could contemplate the production of the vaccines such as OPV, measles, hepatitis B from basic and or intermediate raw materials.

6. A feasibility study should be undertaken to confirm the suitability and the economic and financial viability of the suggested approaches in paragraphs 4 and 5.

7. Until vaccines mentioned in paragraph 3 are produced locally, importation should continue.

8. A Sub-group of the Panel worked out specific technical recommendations concerning immediate measures to be taken and introduced at BPS to improve the safety of the operations and quality of the product. Details given in Annex 2 .

9. The establishment of a National Quality Control Authority with its own laboratory in addition to the Quality Control Department of BPS is recommended. Appropriate regulations should be promulgated and the necessary staff recruited and trained as soon as possible.

10. The training of the BPS staff in all disciplines of production, quality control and management is highly recommended. Such training programs carried out overseas and with consultant advice locally could be secured from United Nations agencies.

Renumerations and incentives of the BPS staff should be reviewed as soon as possible.

11. The staff of the National Quality Control Authority and the Quality Control Department of BPS may be trained within the scope of the International Federation of Pharmaceutical

Manufacturers Association's special training program for such staff.

12. Technology transfer for biologicals production (imported bulk or basic) from reputable manufacturers, as listed in UNIDO's Directory, or from appropriate institutions could be considered. Different modalities of such technology transfer can be agreed upon. While joint venture might be the best option, this requires mutually acceptable conditions.

III. BRIEF SUMMARY OF THE DISCUSSIONS

The Panel agreed that the upgrading of domestic vaccine production of international standard should be decided on the technical, health, financial and political aspects of this venture. Hence the health and political aspects will be tackled by the Government, the Panel decided to focus its attention to the technical and financial aspects. It was also agreed at the beginning of the discussions that the EPI and other vaccines should be handled separately.

One of the members stressed that only the immediate objectives of a vaccine project in the Philippines be discussed, since beyond 1992 any recommendation or plan of action would not be realistic. Another member appreciated that the Government had a serious intention to improve the present situation of Alabang Vaccine Complex and therefore stressed that after a general diagnosis given, the discussion should be focused on the "treatment" that is on the immediate programme, its costs, financial obligation of the Government. The human resources and training, the facilities and quality control are the priority areas to be taken into account when discussing any development programme. Another member expressed that first priority be given to improve the following areas: quality control, training and utilities.

The Secretary of the Panel felt that the Intercare study could be accepted in general, however she pointed out some shortcomings such as there were no details given for the different options and their economic and financial viability. She also emphasized that no distinction was made in the study between the quality control of BPS and a national quality control laboratory.

After a lengthy discussion the meeting agreed that two separate quality control laboratories be established on long term; one national quality control authority with its own laboratory facility which could be set up at BFAD and an improved quality control laboratory at BPS within the shortest possible period of time. It was also unanimously agreed that the training of the new quality control staff should be started immediately.

The Panel agreed that BPS should continue its operation, however it was high ligthed that safety be regarded as a priority issue. One participant

emphasized the complexity of the safety issue, its 3 components: safety of product (or operation), safety of operator and safety of environment. A member of the Panel expressed a new formulation, filling and packaging department in line with the GMP requirements would also require priority. He also emphasized that the present operation could not be regarded as manufacture per se, it was only an attempt to end up in a product. Several members suggested that decision should be made concerning the existing buildings and the site selection for new construction.

The Panel agreed that the follow up product diversification should be addressed only if the new infrastructure, utilities, quality control department and formulation, filling and packaging department were in operation.

A member of the Panel characterising the biologicals production stated that discipline, harmonization and syncronization were required. He also suggested that the modalities for technology transfer were different by companies, the key element for the success was the human resources, therefore continuous training was required. He also expressed that research and development is not an alternative of acquisition of know-how and definitely not an alternative for short and medium terms development.

Several members of the Panel suggested that a joint venture would be the best alternative for further development, however the Government should consider different incentives to attract investors. More details on the Government's investment incentives, National Drug Policy and the legal framework are given in the Philippine Pharmaceutical Industry Development Study, DP/ID/SER.A/1166, 1166/Add.1 and 1166/Add.2

The Panel agreed that a feasibility study be prepared for the investment project including a central formulation, filling, packaging department with utilities and services and a new quality control department for quality control of all raw materials, phase products or intermediates and finished products, all in conformity with GMP. It was also agreed that companies could be invited to prepare jointly the feasibility study if interested in joint venture.

Finally the Panel agreed that its next meeting be held in the first quarter of 1990 in Cameroon.

ANNEX 1

GUIDE QUESTIONS/ISSUES FOR DISCUSSION DURING THE UNIDO CONSULTATION

Crystal Ballroom, Hyatt Regency Manila, April 4 to 6, 1989

(1) Given the current vaccine product lines of the Biologicals Production Service (BPS) and given the Intercare recommendations:

> What vaccines should Biologicals Production Service (BPS) continue producing? What are the quality control and quality assurance requirements to be considered?

What vaccines should BPS reconsider for production (e.g. cholera vaccine)? Why?

What new vaccines should BPS consider for production (e.g. Hepatitis B)? Justifications?

Is there a need for a National Control Authority in addition to the capacity of BPS? Please give suggestions/guidelines on functions and requirements for establishing such a national control unit.

(2) Provision of Vaccines:

a) What should be imported in finished form?
b) What should be imported in bulk form?
c) What should be produced from basic or intermediate raw materials?

(3) For each new vaccine considered to be produced in different levels (i.e. finished form, bulk form and basic production) and for those currently produced but whose production need to be improved, recommend possible sources, technology availability, modality of transfer and key technical personnel required.

(4) For those vaccines currently produced and for those considered for future production (as well as possible expansion) recommend suitability of existing buildings and equipment:

> a. For basic production,
> b. For blending, filling and packaging.

Consider improving existing buildings as an option to constructing new ones.

(5) Considering that a key element in vaccine production is the availability of trained personnel, where can BPS personnel in quality control, production and management go for training, particularly for current products?

Annex 2

SPECIFIC TECHNICAL RECOMMENDATIONS

The sub-group made the following specific technical recommendations for immediate action which apply for both the production and quality control facilities, equipment, processes and safety measures (item 8 of general recommendations).

I. Facilities

All the building facilities of BPS should be revamped in order to minimize the potential contamination of the product and the risk of personnel being exposed to contaminants. All surfaces (walls, floors, ceilings, laboratory benches, etc.) should be covered by materials which can easily be cleaned and disinfected, e.g., all working bench tops should be covered by formica, walls and floors should be covered by epoxy paint or by latex, wires and any other exposed connections should be covered with a duct or conduit and properly identified as per fermentation suit of DP products. Wooden surfaces should be sealed and painted and/or replaced with aluminum structures. Proper light fixtures should be installed in order to improve lighting. Remove non-productive equipment and accessories such as desks, chairs, books, etc. from the working area (production and/or quality control). Proper areas should be selected for the storage of equipment, accessories and reagents that are utilized for production and processing such as vessels, connections, etc.

II. Equipment

Install sterilizers for decontamination in the production units. All sterilizers, cold rooms, freezers, incubator rooms, autoclaves, etc. should have proper recorders and charts which should be signed and stored in the proper record and for validation purposes. The generous use of laminar flow modules should be introduced at critical operations such as innoculation, fermentation, filling, etc. All equipment not involved in the production task should be removed and stored in proper areas. Steam traps should be installed for condensate throughout the feeding lines into the production units. Proper incinerators should be built into the facilities. Exhaust from the fermentors should be passing through the incinerator prior to final removal.

III. Process

Proper product description and standard operating procedures for each step of the production, processing and quality control should be prepared. Proper forms and other documentation should be established and implemented for recording of each step of manufacture and validation of the process. Validation and internal audits should be performed in order to standardize all of the production and processing activities. Continuous monitoring of the production environment should be established.

IV. Safety

All different warning signs identifying particular hazards should be placed throughout the facilities. Clothing policy should be established in the laboratory: common uniform should be worn and people have to change to different uniforms when entering hazardous areas. Movement of personnel should be restricted to their actual working unit. Immunization policy should be established for all personnel working within the laboratories. A policy utilizing protective devices should be implemented when personnel are working with glass containers and with air pressure and/or vacuum . Protective attire such as shoes, gloves, caps, masks, glasses,etc. should be worn in production areas whenever required. Safety regulators for pressure air lines should be installed throughout the facility. Pipetting devices should be mandatory in order to avoid mouth pipetting. A circle of quality should be introduced involving the regular meeting of the staff to discuss norms, policies and procedures , and internal audit and self-criticism.

V. Maintenance

Regular and preventive maintenance procedures should be established.

Terms of Reference for the High Level Advice to the Government of the Philippines by the Advisory Panel on Preventive Medicine to Validate the Intercare Study on the Alabang Vaccine Complex.

Background:

One of the major health programs of the Philippine government is its Expanded Program on Immunization (EPI). This program is expected to remain as a key element of public health services into the future. Hence, the Philippine Government wants to assure the availablity of adequate logistical requirements for EPI, including vaccines and biologicals.

For many years, the Philippine Government, through its Biologicals Production Service (BPS), which is under the Department of Health (DOH), has been producing vaccines such as BCG, tetanus toxoid and antivenin. Other vaccines have generally been provided for through donations by bilateral agencies as well as some NGO's such as the Rotary Club. It is however, expected that within the next five years, some of this assistance may terminate and the Philippines will be faced with the problem of sourcing its vaccine requirements.

It is also recognized that by engaging in vaccine production, the Philippines can have access to new technology.

However, the opportunities in vaccine production also bring with them major concerns, including the investment requirements and the availability of technology.

To properly develop the BPS, the Philippine government, with the assistance of the United States Agency for International Development, commissioned a study to define the developmental strategy for the BPS. This study, known as the Intercare Study, has been presented to the DOH and has basically been the blueprint followed in the BPS upgrading efforts.

During the review of the results of the Philippine Pharmaceutical Industry Development Study held in UNIDO Vienna, the issue of vaccine and biologicals production in the Philippines was discussed. Consequently, there was a consensus that the Advisory Panel on Preventive Medicine will be requested to review the basic recommendation of the Intercare Study. Such review has been scheduled for April 4 to 6, 1989 in Manila.

The following sections are a summary of the objectives, methodology and expected output for the consultation sessions.

Objectives:

1. To review and validate the Intercare Study recommendations as a basis for determining the government's developmental activities for the Biological Production Service.

2. To solicit the opinions of the Advisory Panel on Preventive Medicine based on their worldwide experience in the area of vaccines and biologics production.

Expected Output:

A set of recommendations regarding the issues listed in the attached guide questions, as well as other relevant areas not covered by the guide questions but deemed necessary by the Advisory Panel on Preventive Medicine.

Methodology:

Open plenary discussions shall be conducted by the Advisory Panel on Preventive Medicine, the Intercare group, the DOH and interested observers on the issues outlined in the guide questions and on the recommendations of the Intercare study.

If necessary, small group discussions may be undertaken to tackle specific issues or areas . The panel is expected to come up with a report specifying its recommendations .

Annex IV

AGENDA OF THE MEETING

Crystal Ballroom, Hyatt Regency Manila, April 4 to 6, 1989

4 April 1989, Tuesday

1000	Opening of Meeting National Anthem
1000-1100	1. Introductory Addresses by Dr. Alfredo R. A. Bengzon, Secretary of Health; Dr. Charles Merieux, Chairman of the Panel; Dr. A. Tcheknavorian-Asenbauer, Secretary of the Panel.
	2. Backgrounder on this Project and Terms of Reference for the Consultation Meeting, Undersecretary Rhais M. Gamboa
1115-1245	Break
1300	Visit to Biological Production Services (Alabang
	1. Perpectives of the Vaccine Development Program, Assistant Secretary Quintin Kintanar
	2. Brief Audio Visual Presentation on the Biological Production Services (BPS)
	3. Tour of the Biological Production Services Facilities and Laboratories.

5 April 1989, Wednesday

0900-1200	Discussion on the issues and recommendations of the Intercare Study on the Alabang Vaccine Complex.
1200-1300	Break
1300-1500	Continuation of previous discussion
1500-1530	Break
1530-1800	Other Matters concerning UNIDO programme on Industrial Procuction of Biologicals

6 April 1989, Thursday

0900-1000	Conclusion, Recommendation and Closing

VISIT TO BIOLOGICALS PRODUCTION SERVICES (ALABANG)

April 4, 1989

1:30 PM . . . . Perspective of the Alabang Vaccine Laboratory Development Program - Dr. Quintin K. Catanar, Asst. Sec.

1:40 PM . . . . Current Status of BPS Program & Services - Dr. Bernardo T. Mora

1:45 PM . . . . Slide Presentation on the Biologicals Prod. Service at BCG Building

2:00 PM . . . . Tour of BPS Facilities

2:00 - 2:15 PM — BCG Unit - Mr. Edison Sabio

2:15 - 2:30 PM — Rabies Unit - Mrs. Dolores Mercado

2:30 - 2:45 PM — Tetanus Unit - Mrs. Petra Lojo

2:45 - 3:00 PM — Pertussis Unit - Miss Amparo Sobremonte

3:00 PM . . . . Break (snack)

3:30 PM . . . . Continuation of the Tour

3:30 - 3:45 PM — Diphtheria Unit - Mr. Leland Nano

3:45 - 4:00 PM — Cholera Unit - Mrs. Lolita Umali

4:10 - 4:25 PM — Antigen Unit - Mr. Manuel Dancel

4:25 - 4:40 PM — Quality Control Section - Miss Maria Redimano

4:40 - 4:45 PM — Animal House Section - Mr. Cesar Flores

4:45 - 5:00 PM — Support Services - Engineer Manuel San Juan

SUMMARY PAPER OF INTERCARE RECOMMENDATIONS VS EXISTING SITUATION AT THE BIOLOGICALS PRODUCTION SERVICE

INTRODUCTION

BPS produces BCG, Cholera, Cholera-Typhoid, Typhoid, Semple and Flury Rabies Vaccines, Tetanus Toxoid and Antitoxin, Cobra Antivenin, certain diagnostic Antigen and Antisera. Intercare has recommended continuing production of BCG, Tetanus, Cobra Antivenin, certain diagnostic Antigen and Antisera and suspending production of Cholera, Cholera-Typhoid, Typhoid, Semple and Flury Rabies Vaccine and shifting to Oral Attenuated Typhoid Vaccine for the Inactivated Typhoid Vaccine and buying Vero-cell rabies vaccine in bulk or undertaking its local production to replace Semple Rabies Vaccine. The Flury Rabies vaccine production should be transferred to the Bureau of Animal Industry (BAI).

At present, BPS imports DPT, Oral Polio and Measles in finished product for EPI requirements, however, it has started its trial production of DPT by fermentor this year. Intercare has recommended the importation of Polio and Measles in bulk when FSLPSS facilities in BPS are already established.

SUMMARY PAPER OF INTERCARE RECOMMENDATIONS VERSUS CURRENT BPS SITUATION

I. WHAT TO PRODUCE AT BPS?

PLAN	PRESENT SITUATION	INTERCARE RECOMMENDATION
A. SHORT-TERM (1989-1991) Production of the following vaccines and sera:		
1. BCG	continuing production	continue
2. Tetanus Toxoid	continuing production	continue
3. DPT	production started 1988	resume manual production
4. Antivenin	continuing production	continue but separate building
5. Rabies, Semple	continuing production	discontinue and order vero-cell derived rabies vaccine
6. Cholera Typhoid	continuing production	suspension
7. Cholera	continuing production	suspension
8. Typhoid	continuing production	replace with oral attenuated typhoid vaccine
9. Antigen-Antisera	continuing production	continue
10. Rabies, LEP	stop production	transfer to BAI

PLAN	PRESENT SITUATION	INTERCARE RECOMMENDATION
11. PPD 2TU (Purified Protein Derivative)	continuing production on BCG lab.	continue production but transfer to FSLPSS *
B. MEDIUM-TERM (1992-1995)		
1. BCG		continue
2. Tetanus		continue by fermentor
3. DPT		continue by fermentor
4. Antivenin (Polyvalent/ Lyophilized)		continue
5. Vero cell rabies vaccine		start production
6. Oral Typhoid		start pilot production
7. Polio		start production
8. MMR (Measles, Mumps, & Rubella)		start production
9. Antigen-Antisera		continue
10. PPD 2TU (Purified Protein Derivative)		continue
C. LONG-TERM (1996-2000)		
1. BCG		continue
2. Tetanus		continue

* FSLPSS - Filling, Sealing, Labelling, Packaging, Storage System

PLAN	PRESENT SITUATION	INTERCARE RECOMMENDATION
3. DPT		continue
4. Polio		continue
5. Measles		continue
6. MMR (Meales, Mumps & Rubella)		continue
7. Vero-cell rabies		continue
8. Antivenin		continue
9. Hepatitis B		pilot production
10. Polysaccharide vaccine		pilot production
11. Antigen-antisera		continue
12. PPD 2TU (Purified Protein Derivative)		continue

II. HOW TO PRODUCE? TECHNOLOGY

VACCINES	BPS EXISTING TECHNOLOGY	INTERCARE RECOMMENDATION
1. BCG	static	none
2. Tetanus Toxoid	static	by fermentor
3. DPT	submerge	by fermentor
4. Anti-Rabies, Semple	nervous tissue	vero-cell
5. Antivenin	hyper-immune serum	
6. Cholera Typhoid	static	

VACCINES	BPS EXISTING TECHNOLOGY	INTERCARE RECOMMENDATION
7. Cholera	static	
8. Typhoid	static	
9. Antigen-Antisera		
10. Rabies, LEP	tissue culture	transfer to BAI
11. Measles	none	tissue culture
12. Polio	none	tissue culture
13. MMR (Measles, Mumps & Rubella)	none	tissue culture
14. Hepatitis B	none	
15. Polysaccharide vaccine	none	

III. CURRENT OPERATING REQUIREMENTS	BPS EXISTING TECHNOLOGY	INTERCARE RECOMMENDATION
1. BCG		
A. Equipment	ampoule washing machine, autoclave hot-air sterilizer diluent, ampoule filling & sealing machine, automatic dispenser sealing machine, distilling apparatus, compressor, incubator, air conditioner (window type), warburg miscroscope	voltage regulator, automatic stand-by generator, centralized aircon
B. Facilities	building and coloroom	construction of new bldg. & coldroom
2. TETANUS		
A. Equipment	analytical balance, pH meter, microscope, brewer automatic machine, crimping machine, condensing unit, seitz filter, Normann filter, distilling apparatus, vacuum pump, servall mixer, hot air oven, incubator, laminaire flow cabinet, centrifuge, autoclave, spectrophotometer	1-IF-400 liter fermentor as in DPT, 1 rapid centrifuge continuous, 1 filtration mega-flow unit as in DPT, 1 laminaire, flow hood, 1 incubator, 1 double door autoclave
B. Facilities	building and coldroom	construction of new building and coldroom
3. DIPTHERIA		
A. Equipment	balance, miscrocope binocular, PH meter, autoclave, magnetic mixer, seitz filter,	

CURRENT OPERATING REQUIREMENTS	BPS EXISTING TECHNOLOGY	INTERFACE RECOMMENDATION
	oven sterilizer, incubator, water bath, pipette automatic machine, pipette washer, laminaire flow hood	
B. Facilities	building and coldroom	construction of new building and coldroom
4. PERTUSSIS		
A. Equipment	microscope, PH meter, spectrophotometer, fermentor, crimping machine, pipetting machine, condensing unit, seitz filter, animal balance, analytical balance, meat grinder, gynatory shaker, rotary pump, Meta press filtration unit	
B. Facilities	building and coldroom	construction of new building and coldroom
5. RABIES, SEMPLE		
A. Equipment	balance, millipore cow, roto seal crimping machine, pipetting machine, condensing machine, millipore vacuum pump, hydrosol, bone drill, saw cutter, auto dispenser, cooler, delloid mill, freezer, freeze drying machine, sterilizer, oven, incubator, water bath, laminaire flow hood, clay clay adams centrifuge	1 M1141-00008 colligencell culture, system complete with accessories, 1.5 liter capacity, 2 upgrade 2.5 liters vessel and accessories, 2 upgrade 5 liters vessel & accessories, 1 rapid continuous flow refrigerated centrifuge, 1 megaflow filtration unit & accessories

CURRENT OPERATING REQUIREMENTS	BPS EXISTING TECHNOLOGY	INTERCARE RECOMMENDATION
B. Facilities	building and coldroom	construction of new building and coldroom
6. ANTIVENIN		
A. Equipment	PH meter, analytical balance, rough balance, seitz filter	none
B. Facilities	building and coldroom	construction of new building and coldroom
7. CHOLERA TYPHOID		
A. Equipment	microscope, PH meter, spectro-photometer, seal crimping machine. distilling apparatus, autoclave, vial washing machine, automatic manual bottle cleaner, oven, water bath, incubator, laminaire	none
B. Facilities	building and coldroom	
8. CHOLERA		
A. Equipment	microscope, PH meter, spectro-photometer, seal crimping machine, distilling apparatus, autoclave, vial washing machine, automatic manual bottle cleaner, oven, magnetic mixer, water bath, incubator, laminaire	none
B. Facilities	using facilities of CT	

CURRENT OPERATING EQUIPEMENTS	BPS EXISTING TECHNOLOGY	INTERCARE RECOMMENDATION
9. TYPHOID-MEDIA		
A. Equipment	same as in cholera	As FGLPS9: 2 IE washer, 2 modular, 1 rubber stopper washer, 1 ehhelyne autoclave, 1 double door autoclave, dryer stainless steel, central washing, washer drums, washer demijohns, washer flasks, washer test tubes, auto-clave/dryer double door, big dry heat oven, small dry heat oven
B. Facilities	same as in CT	
10. ANTIGEN-ANTISERA		
A. Equipment	stereoscope, deep freezer, dry heat oven, water bath, balance	
B. Facilities	building and coldroom	

CURRENT OPERATING REQUIREMENTS	BPS EXISTING TECHNOLOGY	INTERCARE RECOMMENDATION
11. RABIES, FURY		
A. Equipment	balance, millipore cow, roto seal crimping machine, pipetting machine, condensing machine, millipore vacuum pump, hydosol, auto dispenser, cooler, freezer, freeze drying machine, sterilizer, oven, incubator, water bath, laminaire flow hood, clay adams centrifuge	
B. Facilities	using facilities of Rabies vacuum semple	
12. MEASLES		
A. Equipment		1 tissue culture propagation, 2 laminar flow hood vertical, 2 roller apparatus floor model 7520 (5 rows x 4), 2 roller apparatus bench model 7510 (2 rows x 5), 2 roller apparatus bench model 7300 (1 row x 5), 4 multistir, 4 position heavy duty, 6 bell stir 10" x 10" heavy duty, 2 centrifuge

CURRENT OPERATING REQUIREMENTS	BPS EXISTING TECHNOLOGY	INTERCARE RECOMMENDATION
		refrigerated & accessories, walk-in incubator 35 C, walk-in cold room 0 C to 5 C, 2 ultraflow freezers, upright (-70 C), 2 nitrogen tank, big, 2 nitrogen tank, small, 200 polyclave reusable KBS TC bottles, 2 incubators, 2 double door autoclaves, 2 washers
13. POLIO	none	same as in measles
14. MMR (measles, mumps & rubella)	none	same as in measles
15. HEPATITIS B	none	1 17-400 germeator, 1 rapid centrifuge continuous, 1 filtration megaflow unit, 1 Laminar flow vertical, 1 incubator, 1 double door autoclave, 1 400-L stain less steel
	steel tank,	tank

CURRENT OPERATING REQUIREMENTS	BPS EXISTING TECHNOLOGY	INTERCARE RECOMMENDATION
16. POLYSACCHARIDE VACCINE	none 1 400-Liter fermentor as in DPT, less tank,	1 400-liter fermentor as in DPT, 1 400-liter stainless tank, 1 rapid centrifuge continuous, 1 megaflow filtration unit, 1 laminar flow hood vertical, 1 incubator, 1 shaker (flash)

IV. CURRENT QUALITY CONTROL	EXISTING BPS	INTERCARE RECOMMENDATION
1. Technology	1. In-vivo tests: a. potency b. toxicity c. pyrogenecity d. safety e. skin reactivity 2. In-vitro tests: a. sterility b. bacterial count c. viability d. heat stability e. tissue culture	Full development of quality control for: a. Virology b. Immunology c. Biostat. d. Epidemiology e. Toxicology f. Genetics (Karyotyping) g. Histopathology h. Veterinary neurovirulence
2. Requirements A. Equipment	dehumidifier, apparatus for moisture content, mettler analytical balance, torsion balance, animal weighing balance, pH meter, spectrophotometer, millipore filter, inspissator, oven (hot air sterilizer), incubator, water bath, laminar flow cabinet	1. Bacteriology and serology and virology & genetics a. laminar flowhood, vertical incubators: i. 787 x 533 x 838 ii. 1041 x 483 x 838 iii. CO_2 walk-in incubator 35°C walk-in cold room 0° C to 5° C ultraflow freezer (-70° C) upright

CURRENT QUALITY CONTROL	EXISTING BPS	INTERCARE RECOMMENDATION
		ultraflow freezer (-40^{o} C) upright
		crushed ice maker
		centrifuges: preparative ultra-centrifuge, accesories, portable refrige-rated accessories,
		microfuge
		microscope: epiflourescent, inverted w/ phase contrast
		b. Binocular research water bath
		c. Serological, dual chamber and cover
		d. Serological 850 x 600 x 400 refrigerator.
		e. Blood bank refrigerator 17 cu. ft.
		2. Chemistry
		Atomic ab-sorption spectropho-tometer
		dyna-lyte 200 Na 1/K1 Analyzer

CURRENT QUALITY CONTROL	EXISTING BPS	INTERCARE RECOMMENDATION
		peptide synthesizer model 9500/AT
		DNA synthesizer model 87500 CIF Mla.
		Kjeldahl 6 units:
		digestion apparatus
		distillation apparatus
		analytical balance, digital
		platform bal. digital, Pressca
		pH meter digital and accessories
B. Facilities	old quality control building	construction of new bldg. coldroom

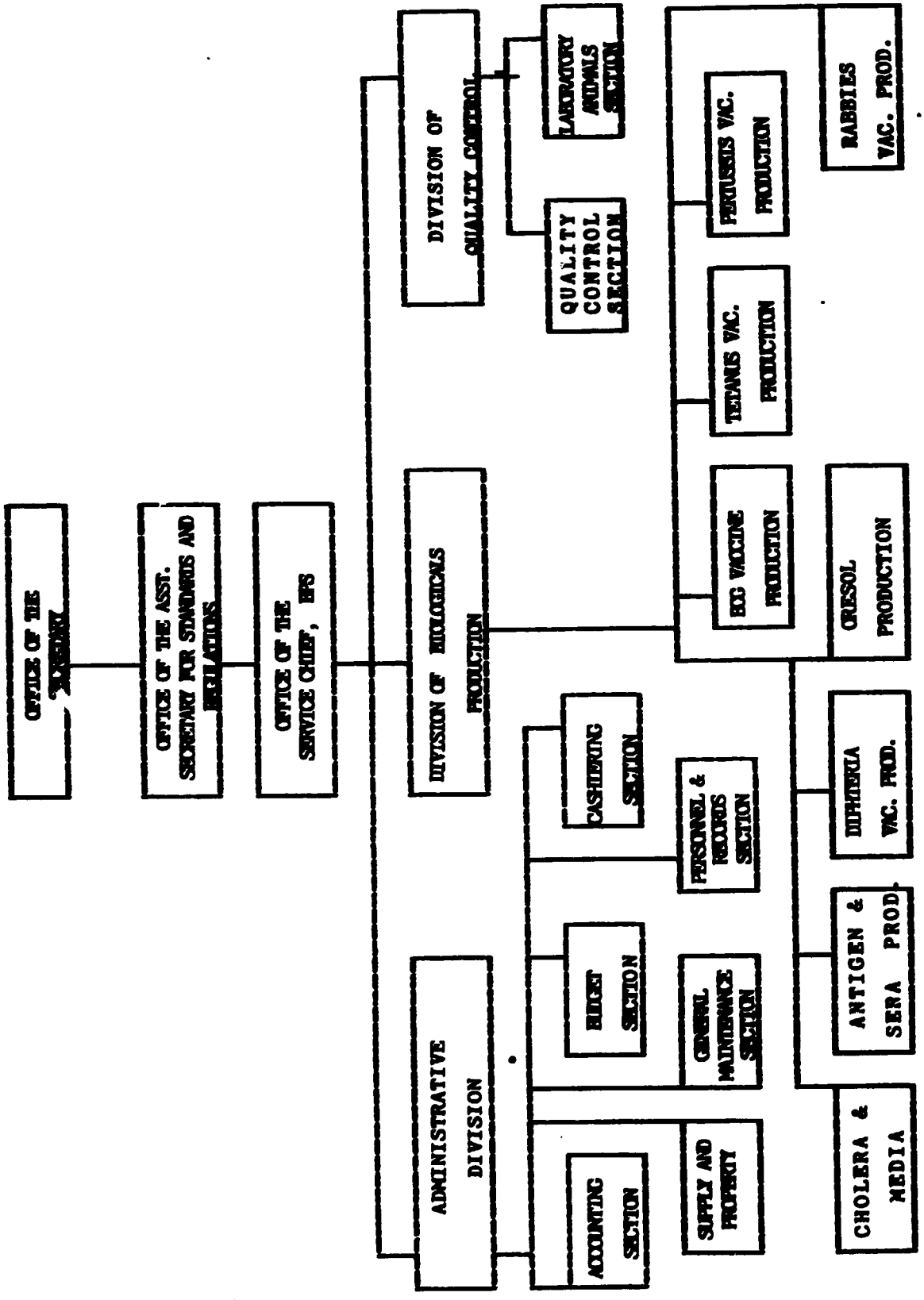
LABORATORY ANIMALS			
1. Technology	A. Breeding B. Feeding C. Bedding		should be scientific, should be clean and hygienic, should be regularly cleaned and disinsectization should be undertaken.
II. Requirements			
	A. Equipment	incubator balance triple beam grinder corn scale floor toledo ventilating fan refrigerator sprayer exhaust fan	
	B. Facilities	Buildings and facilities are very old and ready to collapse	To construct new building to inc-clude provision for adequate shelter, good lighting, ventillation, wire screens against burning and abundant water for drinking & washing purposes, proper disposal of animals and suitable air-conditioning. Animal building should have a double door opening inside so that movements in and out the area will have only a minimum of contamination.

V. TECHNICAL MANPOWER	INTERCARE RECOMMENDATION	EXISTING
1. BCG		Professionals: 6 1 B.S. Pharm. w/ training in BCG production abroad 4 B.S. Med. Technologist, 1 with training in BCG production abroad 1 B.S. Chem. w/ training in Quality Ctrl. of Biologicals abroad Non-professionals (NP): 12
2. Tetanus	Each trainee for the the consultant in DPT the consultant in DPT and Ty vaccines production should have a B.S. degree in Public Health or Microbiology	Professionals: 7 1 B.S. Pharm w/ training in production of Tetanus Toxoid and Antitoxin and titration of Polio and Measles abroad NP: 10
3. Diphteria	Each trainee for the In-Service training by the consultant in DPT and Ty vaccines prod. should have a B.S. deg. in Public Health or Microbiology	Professionals: 2 3 B.S. Med. Technologist, 1 with training in DPT prod. abroad NP: 5
4. Pertussis/EPI	Each trainee for the In-Service training by the consultant in DPT and Ty vaccines prod. should have a B.S. deg. in Public Health or	Professionals: 4 2 B.S. Commerce, 1 with training in Pertussis production abroad

TECHNICAL MANPOWER REQUIREMENTS	INTERCARE RECOMMENDATION.	EXISTING
	Microbiology	2 B.S. Medical Technologist, 1 with training in Pertussis production abroad NP: 10
5. Cholera	Each trainee for the In-Service Training by the consultant in DPT and Ty vaccines production should have a B.S. degree in Public Health or Microbiology	Professionals: 1 B.S. Pharm. with training in Polio vacc. production and biological standardization of Polio and Measles vaccines abroad 1 B.S. Med. Technologist 1 B.S. Commerce NP: 14
6. Rabies	Virologist with M.S. or Veterinarian	Professionals: 5 2 B.S. Pharm., 1 w/ training in Flury Rabies vaccine prod. abroad. NP: 6
7. Antigen-Antisera		Professionals: 4 3 B.S. Med. Technologist, 1 with training in Immunoelectrophoresis and 1 with training in Food Bacteriology abroad 1 B.S. Chemistry
8. MMR	Virologist with M.S.Microbiology or	

		Veterinary Medicine	
9.	Polio	Veterinarian or M.S. Microbiology	
10.	Measles	Veterinarian or M.S. Microbiology	
11.	Hepatitis B	Veterinarian or M.S. Microbiology	
12.	Quality control	Biostatistician Biochemist Microbiologist (M.S. Microbiology) Veterinarian (neuro-virulence and neuro-pathology) Immunology (M.S. Immunologist)	Professionals:8 3 B.S. Pharm., 1 with training in DPT prod., 1 with training in Polio prod. and control and Measles and Polio quality control abroad 3 B.S. Medical Technologists. NP: 10
13.	Laboratory	Veterinarian	Professionals:2 2 Animal Husbandry, 1 w/ training in Care and Mgmt. of Laboratory Animals abroad NP: 21

BPS ORGANIZATIONAL CHART



ALABANG VACCINE LABORATORIES
12-YEAR PROGRAM OF VACCINE PRODUCTION

YEAR 1	a.	Continue ongoing production of BCG VACCINE, INACTIVATED TYPHOID VACCINE, TETANUS TOXOID, TETANUS ANTITOXOID, SEMPLE and FLURY, RABIES VACCINES, COBRA ANTIVENIN, ORESOL and DEHYDRATED BLOOD PLASMA.
YEAR 2	a.	Continue ongoing production as year 1, including production of DPT VACCINE by Manual method.
YEAR 3	a.	Continue ongoing production as in year 2.
	b.	Import DPT, ORAL POLIO, and MEASLES VACCINES (50% of current requirements in bulk form and 50% in ready to use form).
YEAR 4	a.	Continue ongoing production as in year 3.
	b.	Start DPT production with use of fermentors.
	c.	Import bulk vaccines not yet produced by AVL.
YEAR 5	a.	Continue ongoing production as in year 4, including fermentor-produced DPT VACCINES.
	b.	Suspend manual method of DPT production as soon as fermentors are able to produce DPT.
	c.	Decrease importation of DPT in bulk to approximately 50% of previous year's order as my be estimated to fill deficiency in local production.
	d.	Continue bulk order for ORAL POLIO and MEASLES VACCINES.
YEAR 6	a.	Continue ongoing production of VACCINES, other biologicals and related products.
	b.	Phase out bulk importation of DPT.
	c.	Start production of ORAL POLIO and MEASLES VACCINES.
	d.	Decrease bulk order of ORAL POLIO and MEASLES VACCINES in relation to capacity of AVL to produce them.
	e.	Start pilot production of ORAL ATTENTUATED TYPHOID VACCINE.
YEAR 7	a.	Continue ongoing production of VACCINES, other biologicals and related products, including ORAL POLIO and MEASLES VACCINES.
	b.	Limit bulk imports of ORAL POLIO and MEASLES VACCINES in relation to AVL's capacity to meet EPI needs.
	c.	Start production of ver-cell derived RABIES VACCINE.
YEAR 8	a.	Continue ongoing production of vaccines, other biologicals and related products which should now include vero-cell derived inactivated RABIES VACCINES.

YEAR 8
b. Assist in the setting up of the National Control Authority under a designated agency of the Ministry of Health, (e.g.,Bureau of Foods and Drugs) having consultative links with the College of Public Health, U.P. during developmental stage, working arrangements for operational collaboration between the National Control Authority (NCA) and the AVL should be arrived at and spelled out in detail.
c. Start pilot production at MEASLES - MUMPS - RUBELLA (MMF) VACCINE.

YEAR 9
a. Continue ongoing production of vaccines, other biologicals and related products, including MMR VACCINE.
b. Start production of HEPATITIS B VACCINE under the initial supervision of a consultant.

YEAR 10
a. Continue ongoing production of vaccines, other biologicals and related products, including HEPATITIS B VACCINE.

YEAR 11
a. Continue ongoing production of vaccines and other biologicals and related products.
b. Commence pilot production of POLYSACCHARIDE VACCINES.

YEAR 12
a. Continue ongoing production of vaccines, other biologicals and other related products which should now include the POLYSACCHARIDE VACCINES.

Annex VI

PERSPECTIVES OF THE ALABANG VACCINE LABORATORY DEVELOPMENT PROGRAM

I. SCOPE

This paper summarizes the various perspectives to be taken when considering the Alabang Vaccine Laboratory Development Program:

1. The Philippine Development Plan,
2. The Health Plan,
3. The DOH Expanded Program of Immunization, and
4. The Philippine National Drug policy.

II. PHILIPPINE DEVELOPMENT PLAN PERSPECTIVE

The over-riding concern of the Philippine Development Plan is the achievement of a better life for every Filipino. For the medium term plan period from 1987 - 1992, the goals are:

1. Alleviation of poverty from 59% of to 45% of all families (see figure 1),
2. Generation of more productive employment,
3. Promotion of equity and social justice, and
4. Attainment of sustainable economic growth.

It is clear that good health is a pre-condition for or a contributor to the achievement of a better life as well as to the four development goals named above. If we have to develop fully and fast, the vicious cycle of poverty, ill health and death, and low economic productivity needs to be broken (see fig. 2).

III. THE HEALTH PLAN AND THE EPI PERSPECTIVE

The health component of the Philippine Development Plan specifically identifies the following objectives:

1. To improve the health and nutritional status of the population,
2. To contribute to the achievement of health for all by the year 2000 through Primary Health Care, and
3. To promote family planning as a means to improve family well-being.

The relevant health indicators and targets for the medium term are:

	1987	1992
Ave. Life Expectancy	63.7 years	65.2 years
Crude Death Rate	31.3/1000 pop	28.6/1000 pop.
Infant Mortality Rate	54.7/1000 live births	47.8/1000 live births

Immunization of high risk target populations with effective vaccines is perhaps one of the most cost-effective public health measures to improve health and attain the improvement in health indicator targets above. This will have immediate and dramatic effects on morbidity and mortality from certain "immunizable" diseases particularly in children.

In the Philippines an estimated 100,000 infants die every year and many more live with ill health and poor growth. Many of them are preventable by immunization.

In terms of morbidity and mortality, 8 groups of diseases which are completely or partially "immunizable" have been reviewed to indicate the trend in the last 20 years from 1966 to 1986 and the magnitude of the health impact in terms of number of cases in 1986 (see figures 3 to 10).

In response to these public health problems, the Department of Health has embarked on an Expanded Program on Immunization or EPI using BCG, DPT, OPV, Measles and Tetanus Toxoid. The vaccine needs for 1989 by regions are given below. Part of the requirements of the EPI is now supplied by the vaccine production of the Biological Production Service (figure 11).

IV. THE PHILIPPINE NATIONAL DRUG POLICY PERSPECTIVE

A landmark policy - The Philippine National Drug Policy was enunciated by Pres. Corazon Aquino in 1987 to bring safe, effective and good quality essential drugs to the people. It has four component pillars.

Q - Quality Assurance of all pharmaceutical and biological products through strict enforcement of upgraded standards and requirements for drug establishments, drug products, and drug outlets by the Bureau of Food and Drugs.

R - Rational Drug Use through better education and information on drug use for health providers and the general public. Two of the most significant moves in this regard are: (1) the passage and

implementation of the Generics Act of 1988, and (2) the completion of the first Philippine National Drug Formulary of Essential Drugs.

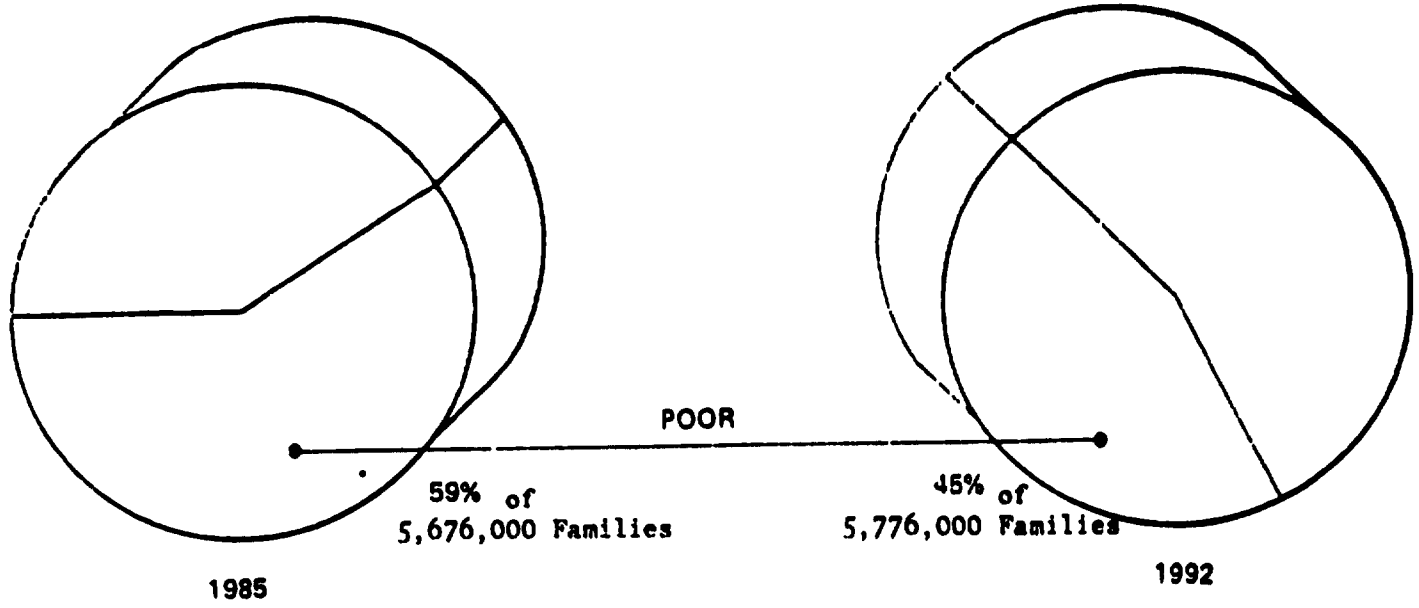
S - Self-Reliance in the production of the active ingredients of strategic pharmaceutical and biological products.

T - Tailored Procurement and improved distribution and use of drugs and medicines by government and institutions to maximize the benefits from limited resources.

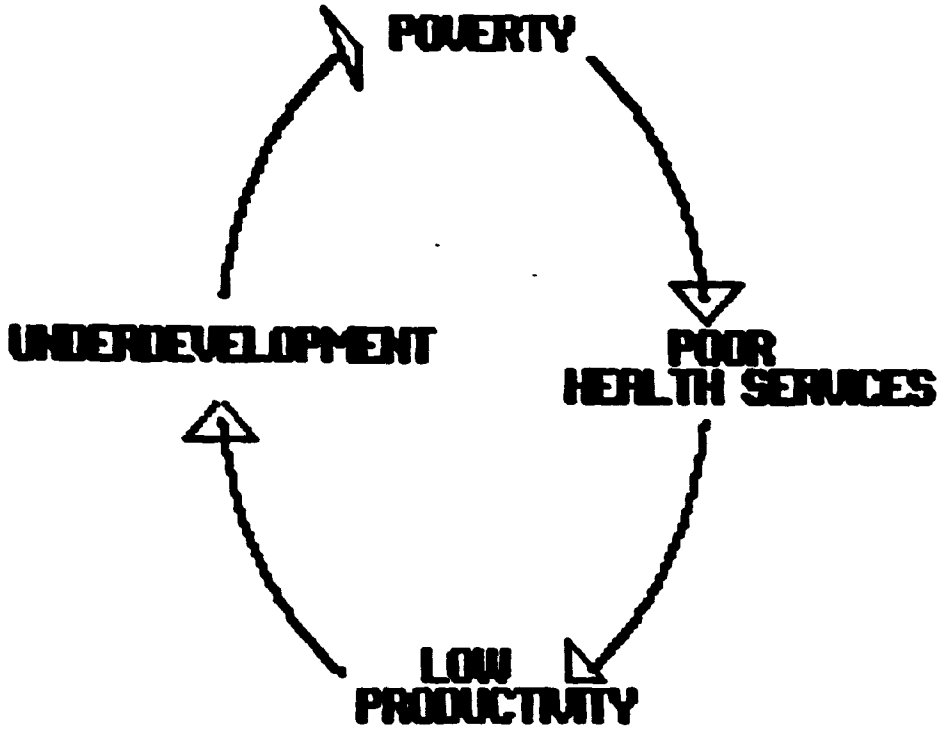
The Alabang Vaccine Laboratory Development Program now being undertaken by the Biologicals Production Service is one of the important elements under the Self-Reliance Pillar.

Considering the great significance of this project vis-a-vis our development and health goals as described earlier, we are proceeding with haste but cautiously. Thus, this review and validation by the UNIDO Panel of the Intercare study and recommendations.

Figure 1
POVERTY REDUCTION TARGETS
Percentage Share to Total Families



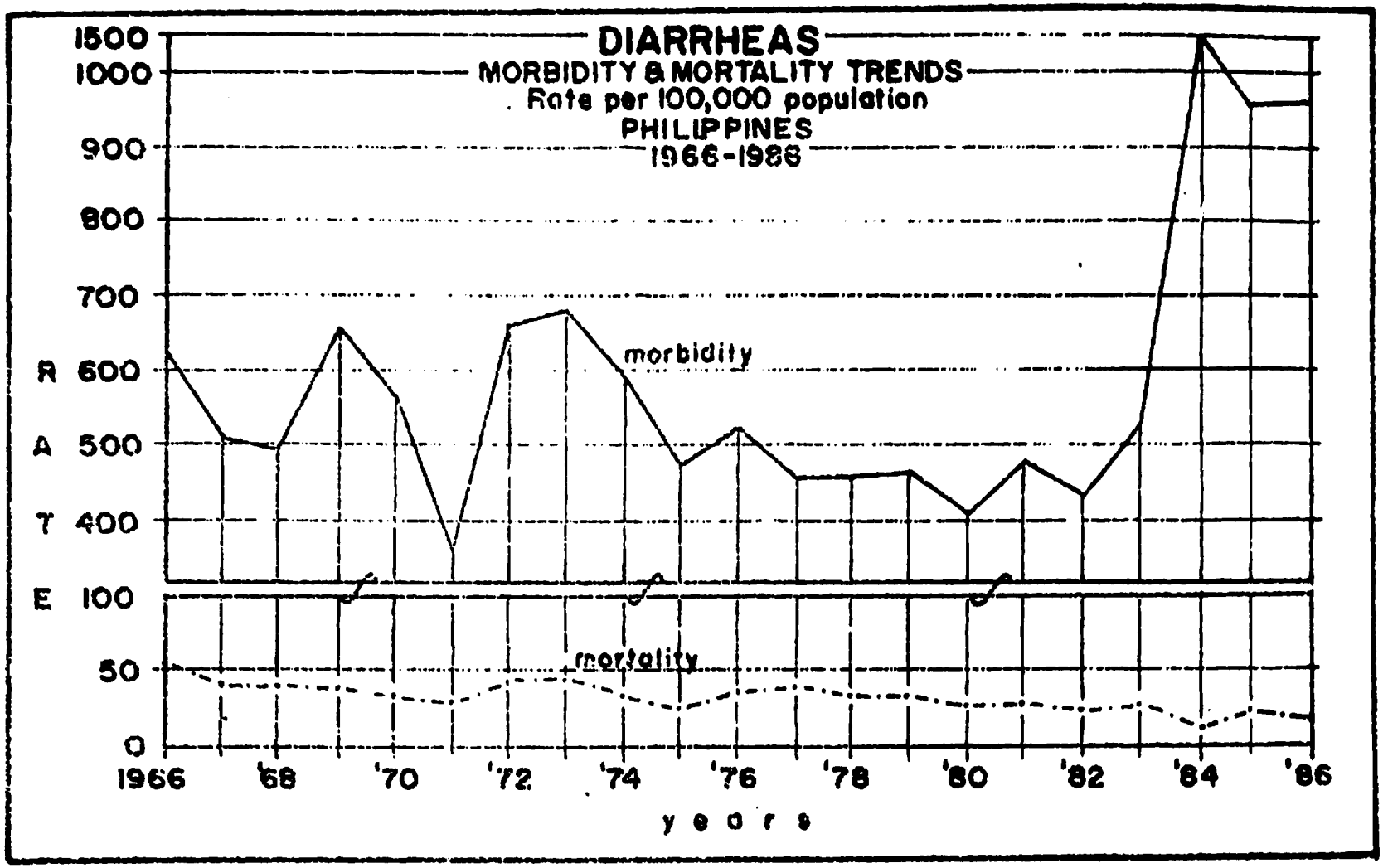
Source: Philippine Development Plan 1987 - 1992



THE VICIOUS CYCLE OF POVERTY
AND UNDERDEVELOPMENT

Figure 2

FIGURE 3

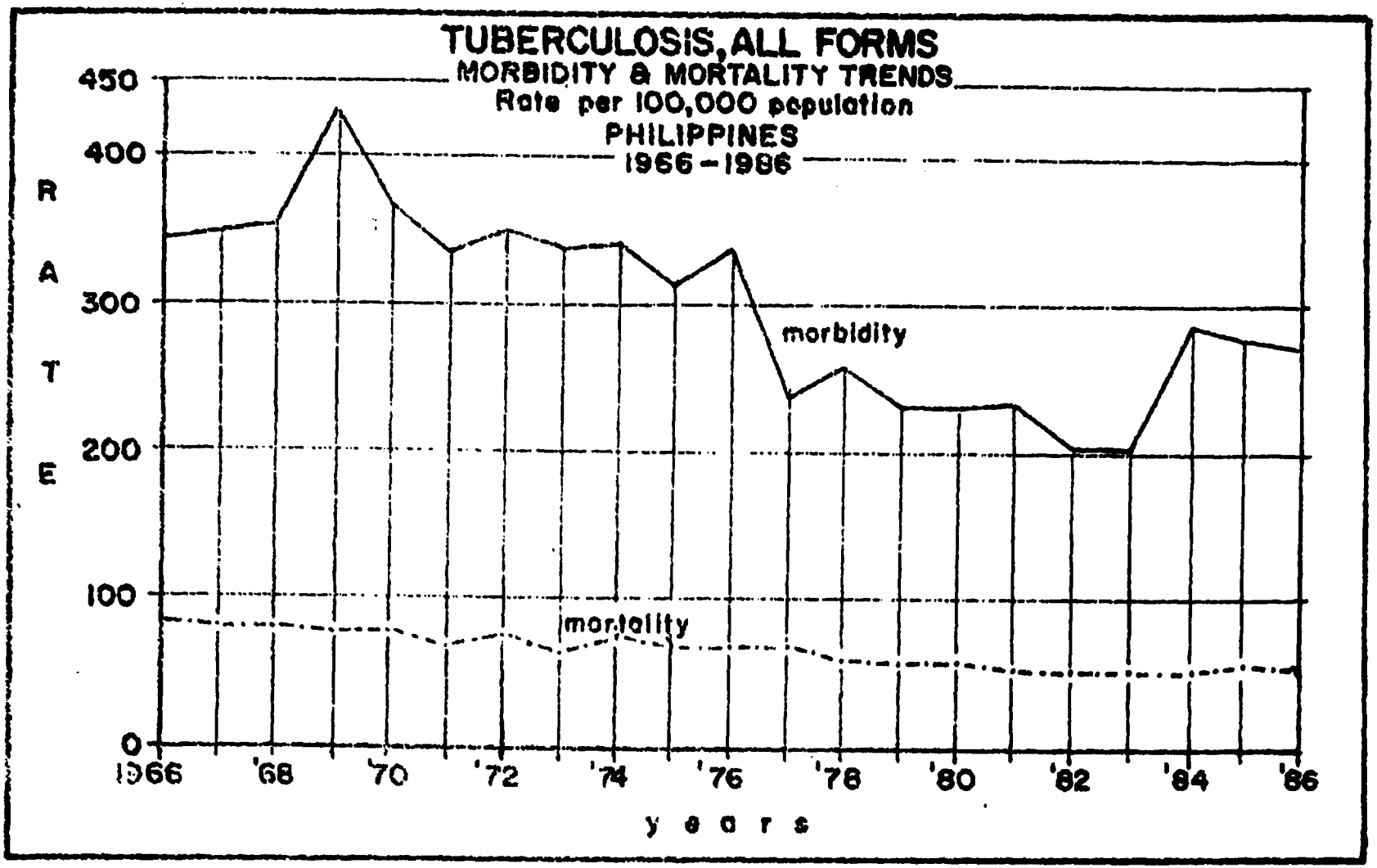


MORBIDITY: 538,849

MORTALITY: 9,815

Source: Philippine Health Statistics 1986

FIGURE 4

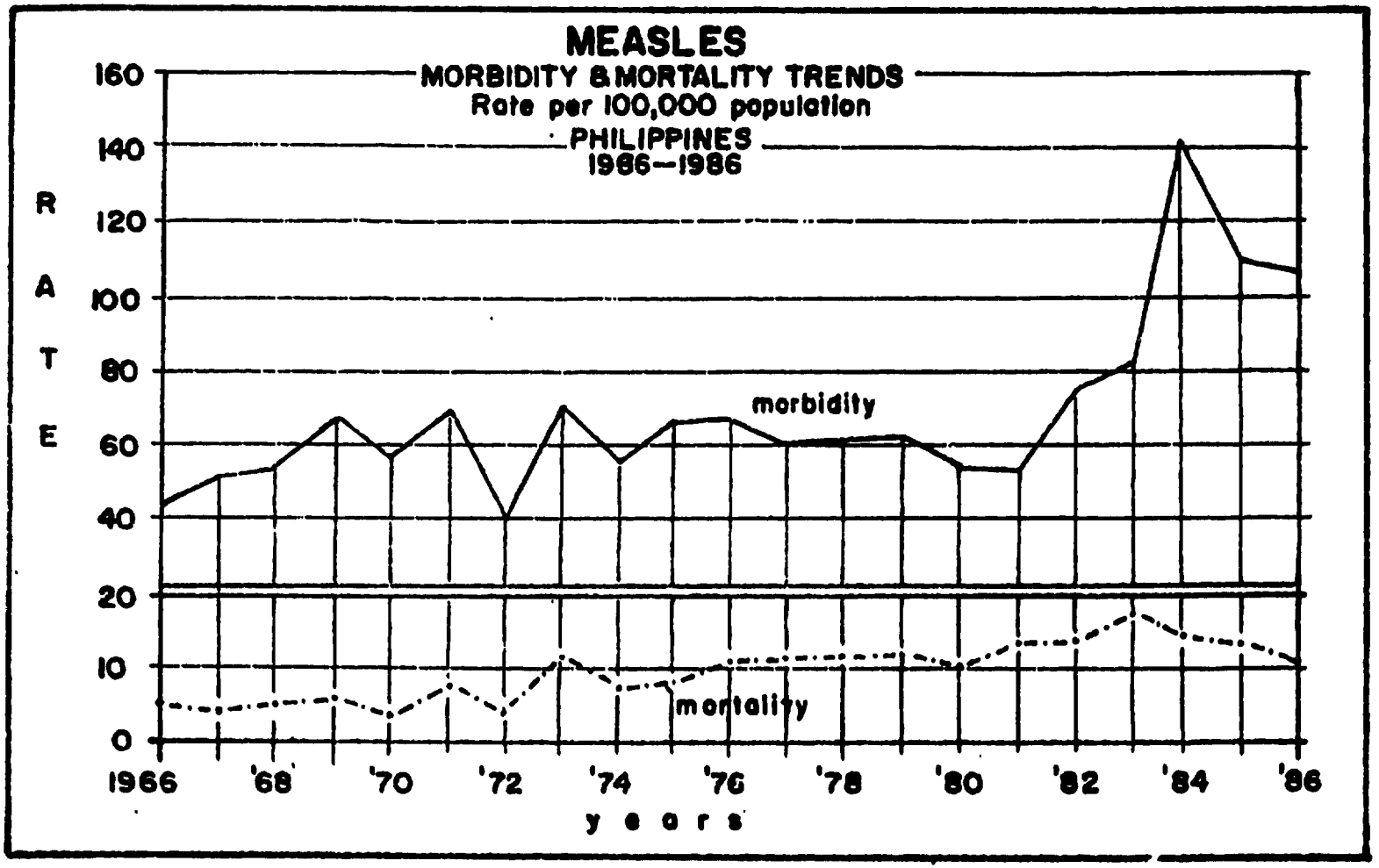


MORBIDITY: 153,129

MORTALITY: 30,604

Source: Philippine Health Statistics 1986

FIGURE 5

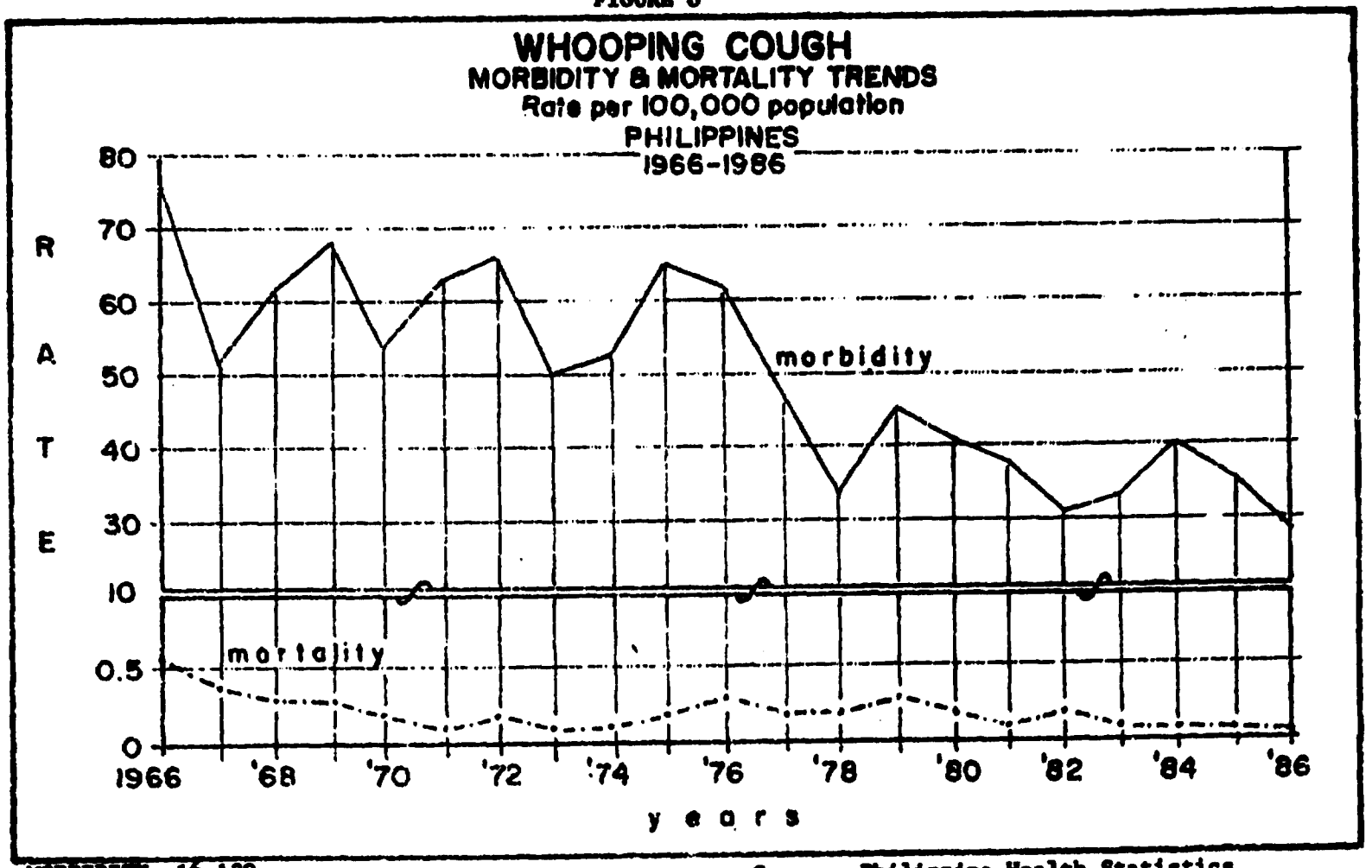


MORBIDITY: 59,375

MORTALITY: 6,249

Source: Philippine Health Statistics 1986

FIGURE 6



MORBIDITY: 16,139
MORTALITY: 28

Source: Philippine Health Statistics 1986

FIGURE 7

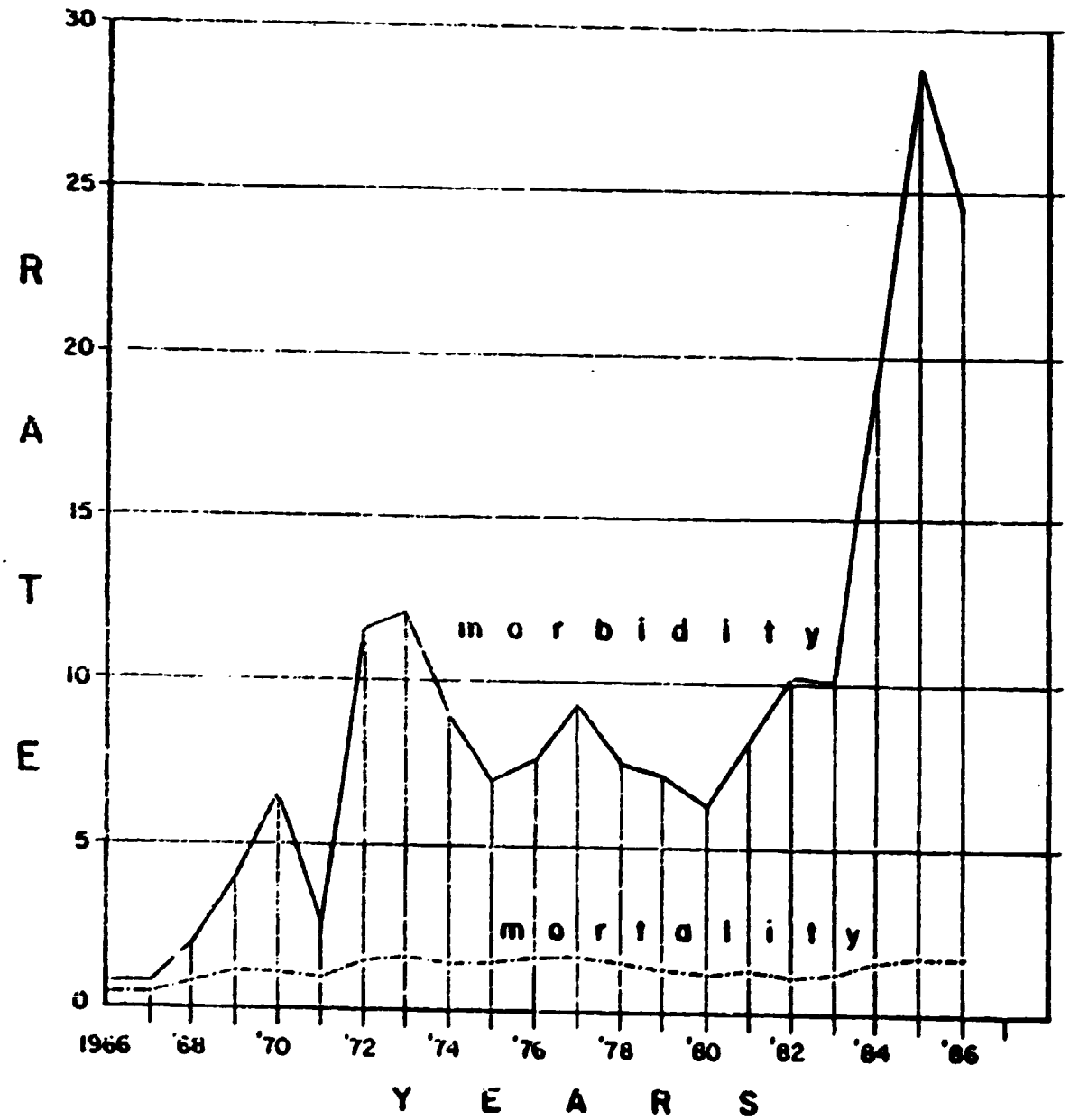
TYPHOID & PARATYPHOID & OTHER SALMONELLA INFECTIONS

MORBIDITY & MORTALITY TRENDS

Rate per 100,000 population

PHILIPPINES

1966-1986

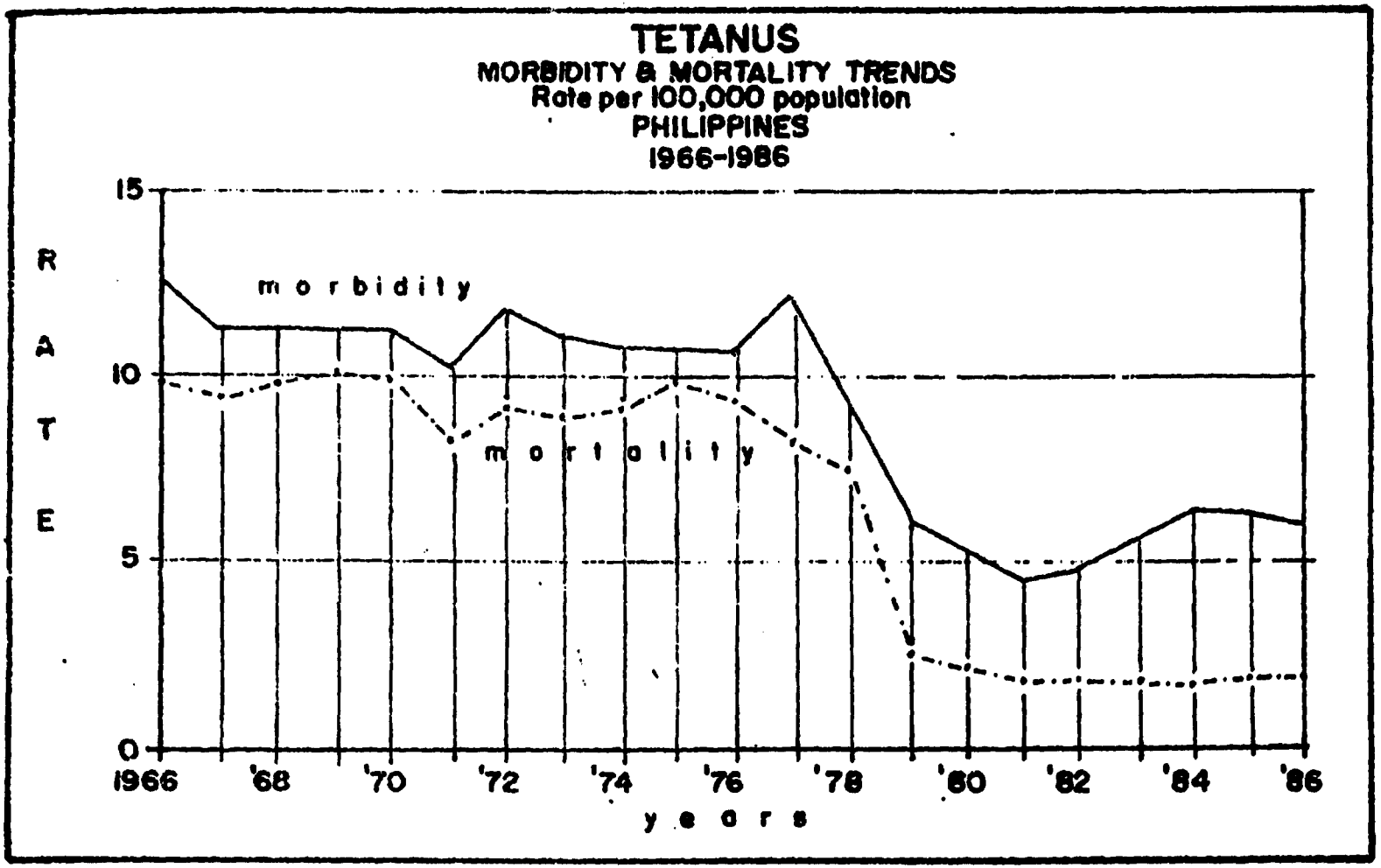


MORBIDITY: 13,764

MORTALITY: 1,024

Source: Philippine Health Statistics 1986

FIGURE 8

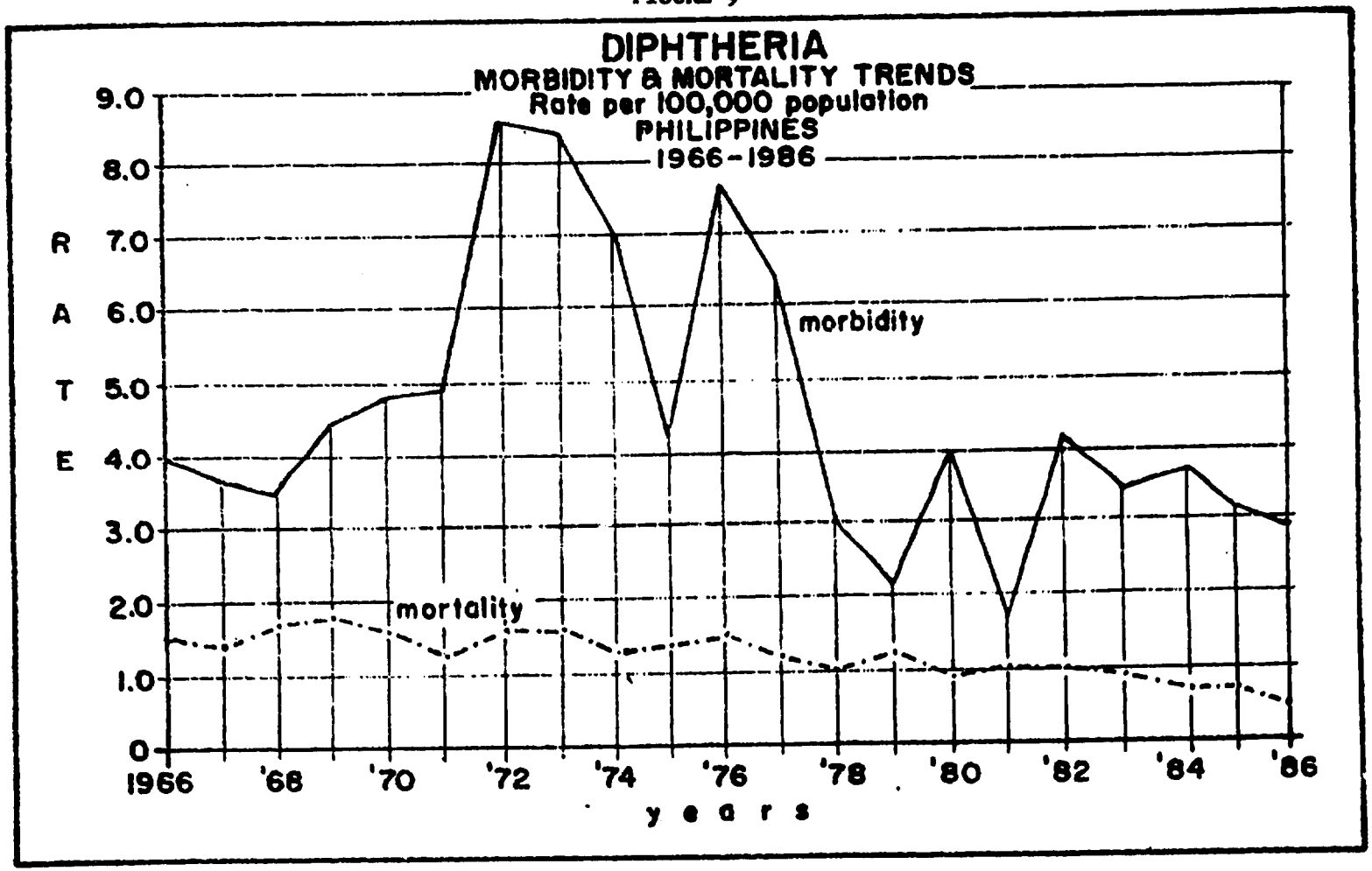


MORBIDITY: 3,381

MORTALITY: 1,034

Source: Philippine Health Statistics 1986

FIGURE 9

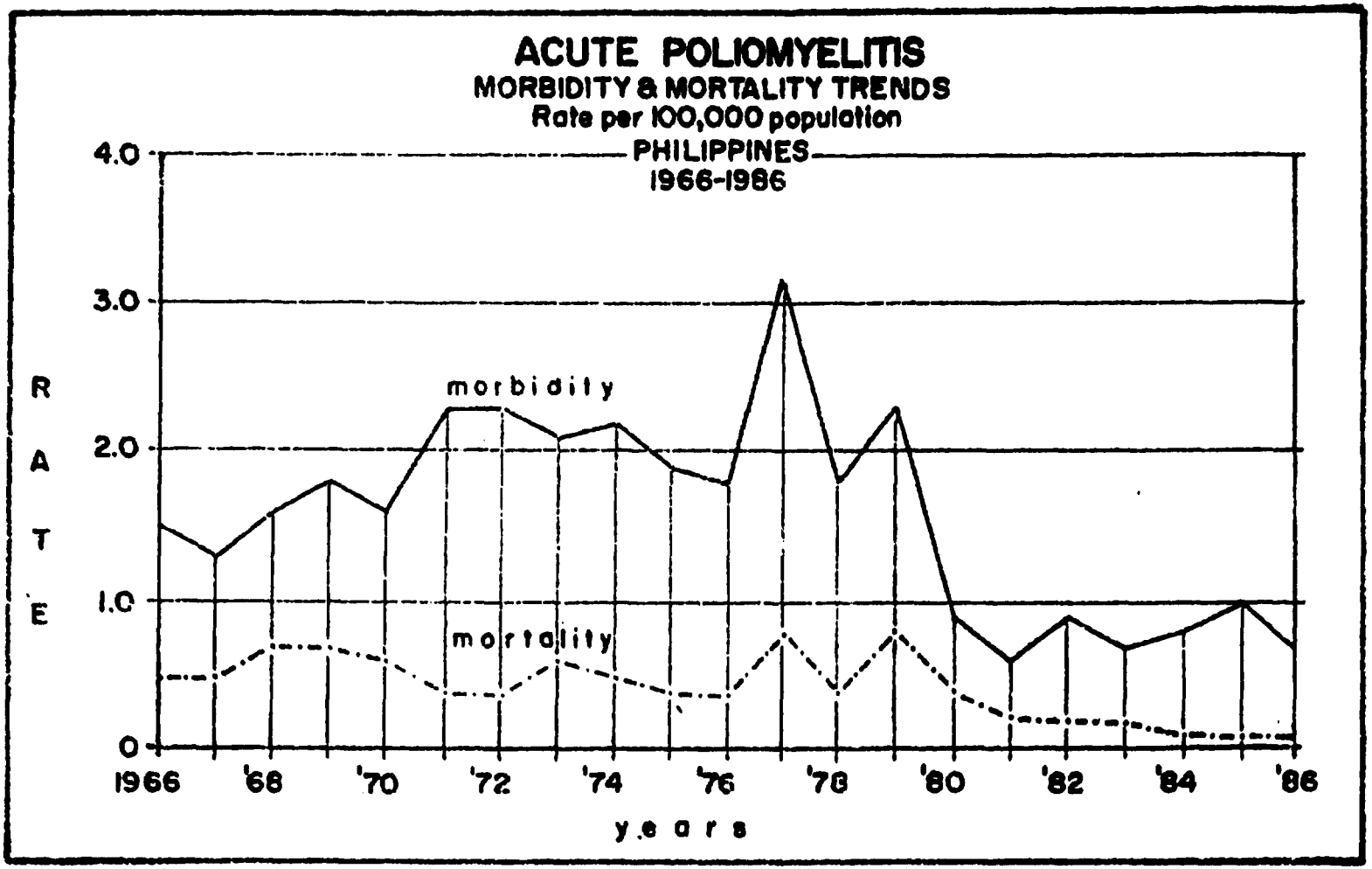


MORBIDITY: 1,630

MORTALITY: 261

Source: Philippine Health Statistics
1986

FIGURE 10



MORBIDITY: 375

MORTALITY: 45

Source: Philippine Health Statistics 1986

Vaccine Needs by Region for 1989 (Doses)

Region	Target (0-12)	BCG Infants	BCG Sch.Entr.	DPT	OPV	Measles	Tetanus Toxoid
I	126,375	221,156	157,968	473,906	473,906	157,968	368,595
II	83,351	145,864	104,188	312,566	312,566	104,188	243,107
III	180,054	315,094	225,067	675,202	375,202	225,067	525,157
IV	236,922	414,613	296,152	888,457	888,457	296,152	691,022
V	128,777	225,359	160,971	482,913	482,913	160,971	375,600
VI	166,667	291,667	208,333	625,001	625,001	208,333	486,112
VII	135,935	237,886	169,918	509,756	509,756	169,918	396,477
VIII	99,307	173,314	123,796	371,388	371,388	123,796	288,857
IX	93,829	164,200	117,286	351,858	351,858	117,286	273,667
X	105,783	185,120	132,228	396,686	396,686	132,228	308,532
XI	126,974	222,204	158,717	476,152	476,152	158,717	370,342
XII	86,153	150,767	107,691	323,073	323,073	107,691	251,280
NCR	233,047	407,832	291,308	873,926	873,926	291,308	679,722
PHIL.	1,802,909	3,155,090	2,253,636	6,760,908	6,760,908	2,253,636	5,258,485

Figure 11

TOTAL QUANTITY OF EPI VACCINE DISTRIBUTED
(IN DOSES)

YEAR	DPT	BCG	POL		TETANUS TOX	MEASLES	
	20 DOSE	20 DOSE	20 DOSE	5 DOSE	20 DOSE	10 DOSE	50 DOSE
1984	5,020,100	4,021,200	5,339,780	-	2,267,840	1,606,050	-
1985	3,135,340	3,213,920	3,491,360	1,009,800	1,376,480	1,330,300	-
1986	3,741,520	3,867,120	4,316,400	514,600	1,779,140	1,344,830	
1987	6,579,320	5,329,480	6,669,980	-	3,702,420	2,111,470	99,850
		223,040 *	7,041,900	-	4,018,160	2,247,710	-
	6,772,760	5,052,820					
		413,600 *					

* BCG supplied by Japan

BIOLOGICALS PRODUCTION SERVICE
TARGET FOR 1989

	ACTIVITIES	#DOSES
1.	BCG	7,000,000
2.	TUBERCULINE DILUTION	300,000
3.	TETANUS TOXOID	5,000,000
4.	COBRA ANTIVENIN	1,200
5.	CHOLERA TYPHOID	1,500,000
6.	BL TOR VACCINE	300,000
7.	TYPHOID VACCINE	[illegible]
8.	DIPHTHERIA	720,000
9.	EL BABIES	240,000
10.	LEP BABIES	20,000
11.	ORESOL	4,000,000 packets
12.	ANTISERA	2,700 ml
13.	ANTIGEN	4,000 ml
14.	DPT VIRAL PROD.	1,000,000
15.	FERMENTER UNIT PRODUCTION CAPACITY BY FERMENTION:	

50,000 DOSES/RUN at [illegible] (20 YEARS)
at 20 runs/year = 50,000 x 20 = 1,000,000 DOSES

*

Increase in production can be achieved only by the procurement of needed equipment, training of personnel and hiring of maintenance personnel.

Annex VII

LIST OF THE MEETING OF UNIDO ADVISORY PANEL ON PREVENTIVE MEDICINE

1st Meeting	Vienna, Austria	27-28 February 1984
2nd Meeting	Bogota, Colombia	22-23 November 1984
3rd Meeting	Bilthoven, The Netherlands	6-7 June 1985
4th Meeting	Ottawa, Canada	11-12 March 1986
5th Meeting	Dakar, Senegal	28 September - 1 October 1987
6th Meeting	Manila, The Philippines	4-6 April 1989

LIST OF UNIDO SYMPOSIA BLOOD AND ITS DERIVATIVES

1st Symposium	Stockholm, Sweden	27 September - 1 October 1982
2nd Symposium	Cartagena, Colombia	25 - 30 November 1984
3rd Symposium	Macau	1-4 December 1986
4th Symposium	Paris, France	11 - 15 December 1987

List of Participants
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	President Fondation Marcel Merieux Lyon, France
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List of Participants To the Advisory Panel Meeting To Validate the Intercare Study on the Alabang Vaccine Plant

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