



TECHNOLOGY MISSION ON VACCINATION AND IMMUNIZATION OF VULNERABLE POPULATION, PARTICULARLY CHILDREN

1987



Department of Biotechnology
Ministry of Science and Technology
Government of India
New Delhi

Department of Family Welfare
Ministry of Health and Family Welfare
Government of India
New Delhi

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**TECHNOLOGY MISSION ON VACCINATION
AND IMMUNIZATION OF VULNERABLE
POPULATION, PARTICULARLY CHILDREN**



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GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NEW DELHI-110011

FOREWORD

The Universal Immunization Programme, an effective intervention to prevent mortality and morbidity of children and mortality of pregnant women, was launched on the 19th November, 1985 as a "Living Memorial to the memory of our late Prime Minister, Smt. Indira Gandhi". The Programme made a modest beginning by covering 30 districts in the country and catchment areas of 50 Medical Colleges. The Programme is being extended in phases and, at present, we are covering 182 districts and catchment areas of all the 108 Medical Colleges. We hope to cover the entire country by 1990. Having realised the tremendous impact this Programme can have on the health status of the pregnant women and children of this country, the Government decided to have a "Technology Mission on Vaccination and Immunization of Vulnerable Population specially children."

Broadly, the objectives of the Mission are to reduce morbidity and mortality of children due to the six vaccine-preventable diseases, reduce mortality of pregnant women due to Tetanus and to achieve self-sufficiency in vaccine production. Under the umbrella of the Mission, all aspects connected with the delivery of services, research and development on improved and new vaccines, are also intended to be covered.

The Mission has been divided into two parts viz., Part-I, dealing with implementation of the Programme and, the Part-II, dealing with the research and development of vaccines. The first part is being implemented by the Ministry of Health and Family Welfare is charged with the nodal responsibility for this Mission.

This booklet on the "Technology Mission on Vaccination and Immunization of Vulnerable Population specially children" is intended to give brief information on the components of the Mission and this will form the basis for detailed write-ups on each component, later.

(P. K. Umashankar)
Special Secretary

New Delhi
Dated: 1st September, 1987

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TECHNOLOGY MISSION ON VACCINATION & IMMUNIZATION OF
VULNERABLE POPULATION, PARTICULARLY CHILDREN

NODAL AGENCY : MINISTRY OF HEALTH & FAMILY WELFARE

MINISTRY OF HEALTH & FAMILY WELFARE

SUB-MISSION-I ADMINISTRATION OF VACCINES, MONITORING AND EVALUATION

SUB-MISSION-II STORAGE AND DISTRIBUTION OF VACCINES

DEPARTMENT OF BIOTECHNOLOGY

SUB-MISSION-I VACCINE PRODUCTION

SUB-MISSION-II VACCINE RESEARCH AND DEVELOPMENT

OUTLINE

- * OBJECTIVE
- * COVERAGE
- * BASIC INFORMATION
- * STRATEGY
- * MANAGEMENT STRUCTURE
- * TARGETS
- * METHODOLOGY
- * SUBMISSIONS-ACTION CALENDER
- * ACCOMPLISHMENT
- * RESOURCES

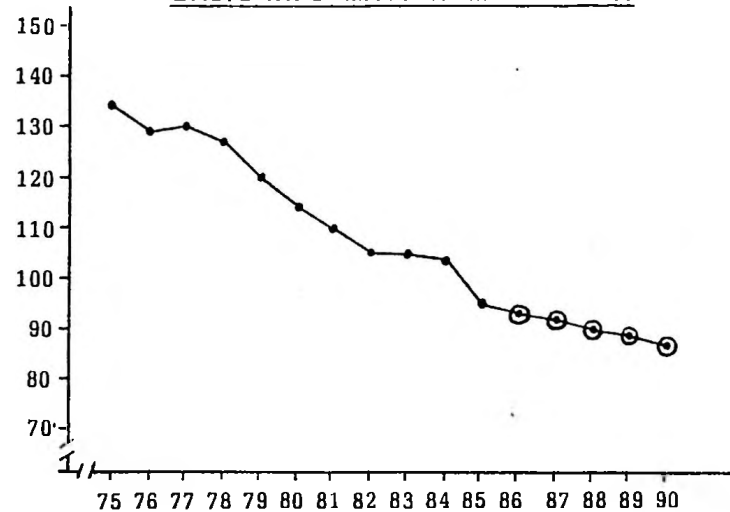
MISSION OBJECTIVES

- * REDUCE MORBIDITY AND MORTALITY DUE TO DIPHTHERIA, PERTUSSISS, TETANUS, POLIOMYELITIS, TUBERCULOSIS, MEASLES AND TYPHOID AMONG CHILDREN
- * ACHIEVE SELF SUFFICIENCY IN VACCINE PRODUCTION

COVERAGE

- * 100% OF PREGNANT WOMEN WITH TETANUS TOXOIDE BY 1990
- * 85% OF INFANTS WITH DPT, POLIO, MEASLES, BCG AND TYPHOID BY 1990.

BASIC INFORMATION IMR IN INDIA



INTERVENTIONS TO REDUCE IMR

- * ANTENATAL CARE - PERTINATAL CARE
- * IMMUNIZATION
- * FAMILY PLANNING + HIGHER AGE AT FIRST PREGNANCY
SPACING OF CHILDREN
SMALL FAMILY NORM
- * BREAST FEEDING AND INFANT NUTRITION
- * DRINKING WATER AND BETTER SANITATION
- * CONTROL OF DIARRHOEA AND ORT
- * IMPROVED RURAL HEALTH CARE
- * HEALTH EDUCATION AND FUNCTIONAL LITERACY

DEMOGRAPHIC ESTIMATES 1985

*	POPULATION	-	7488 LAKHS
*	BIRTH RATE	-	32.7 PER 1000
*	DEATH RATE	-	11.7 PER THOUSAND
	IMR	-	95 PER THOUSAND LIVE BIRTHS
*	NUMBER OF PREGNANT WOMEN	-	258 LAKHS
*	NUMBER OF INFANTS	-	245 LAKHS
*	ESTIMATED NUMBER OF INFANT DEATHS IN ONE YEAR	-	22 LAKHS

INCIDENCE OF TARGET DISEASES - YEAR 1984

*	NEONATAL TETANUS (TETANUS)	-	29718
*	POLIO	-	18040
*	MEASLES	-	190881
*	PERTUSSIS	-	189287
*	TUBERCULOSIS	-	987013
*	DIPHTHERIA	-	13111
*	TYPHOID	-	306639

SOURCE - CBHI (REPORTED)

VACCINE PRODUCTION AND REQUIREMENT

(IN LAKHS)

VACCINE	PRODUCTION						REQUIREMENT			
	PUBLIC SECTOR			PRIVATE SECTOR (ANNL)			1987-88	1988-89	1989-90	BUFFER
	1987-88	1988-89	1989-90	1987-88	1988-89	1989-90				
D.P.T.	360	410	450	600	600	800	861	1046	1104	100
POLIO	-	-	10	-	-	-	861	1040	1104	100
BCG	600	600	600	-	-	-	215	261	276	25
T.T.	420	450	480	1000	1000	1200	738.40	1150	1171	100
D.T.	260	260	260	200	200	400	375	379	383	33
T.A.	74	74	74	-	-	-	376	379	383	33
MEASLES	UNICEF ASSISTANCE						220	313	331	-

* OPV IS PRODUCED IN HBPCL, BOMBAY FROM IMPORTED BULK CONCENTRATE
** WASTAGE FACTOR - 25% FOR DPT, POLIO, TT, DT, TA AND BCG
- 50% FOR MEASLES

*** PRIVATE SECTOR MANUFACTURER IS ONLY SERUM INSTITUTE OF INDIA LTD,
PUNE.
THE OTHER PRIVATE MANUFACTURER, BIOLOGICAL E. WILL BE PRODUCING
DPT FROM 1987.

FACTORS AFFECTING IMMUNIZATION

1. HUGE SIZE OF THE COUNTRY
2. SIZE OF THE POPULATION
3. POLITICAL WILL
4. POOR SOCIO ECONOMIC CONDITIONS
5. LOW LITERACY
6. DIVERSE CLIMATE
7. LACK OF ADEQUATE RESOURCES
8. QUALITY OF VACCINES

PROBLEM AREAS

MAJOR STATES

UTTAR PRADESH

RAJASTHAN

MADHYA PRADESH

BIHAR

ORISSA

- LOW COVERAGE

- HIGH DROPOUT

MINOR STATES

ARUNACHAL PRADESH

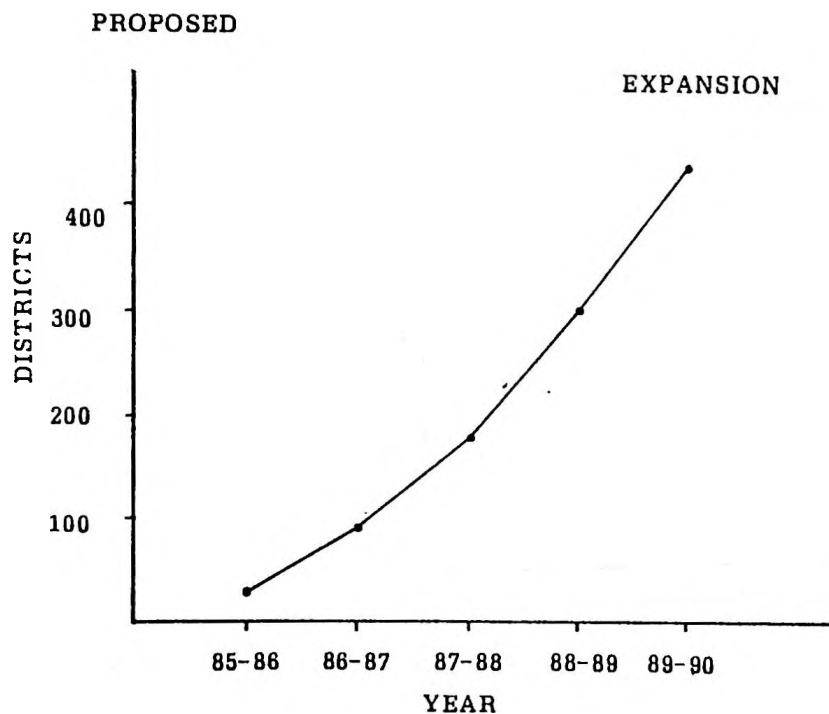
MIZORAM

NAGALAND

SIKKIM

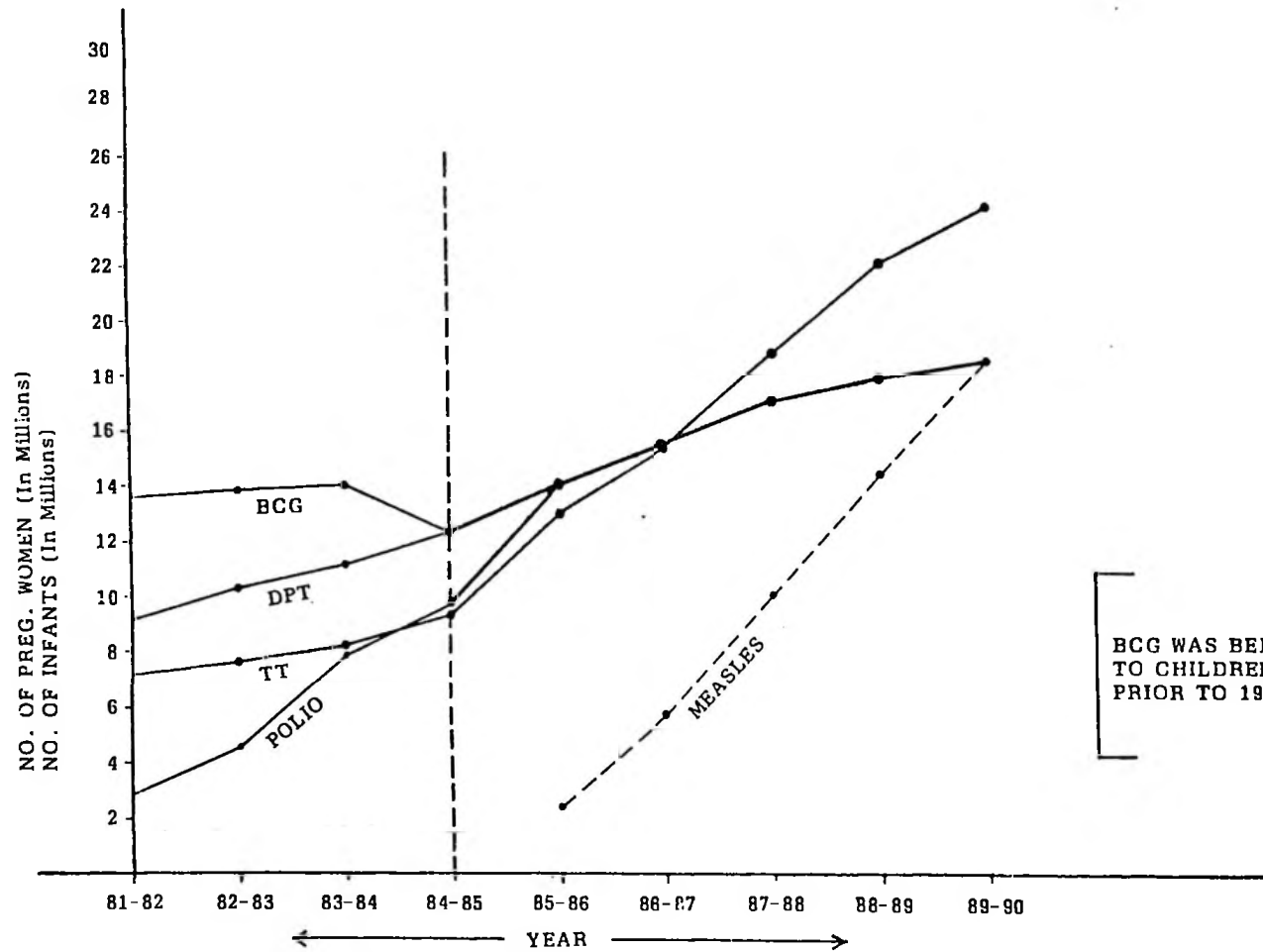
STRATEGY

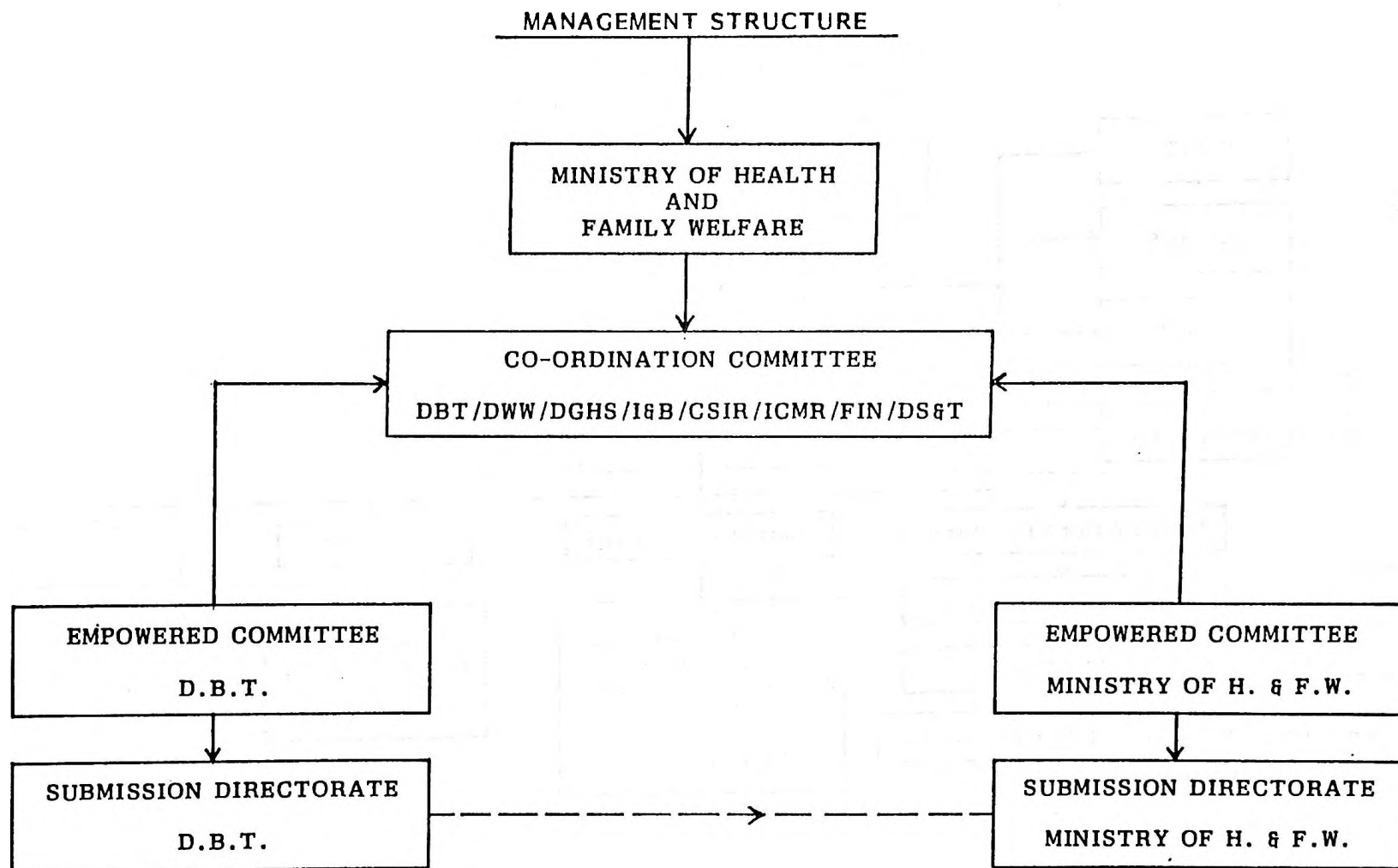
- * AREA SPECIFIC APPROACH - DISTRICT WISE EXPANSION
- * ACHIEVE 100% COVERAGE FOR PREGNANT WOMEN WITH T.T. VACCINE AND 85% COVERAGE FOR INFANTS WITH DPT, BCG, POLIO, MEASLES AND TYPHOID VACCINE IN THE DISTRICT WHICH IS TAKEN UP UNDER UNIVERSAL IMMUNIZATION PROGRAMME IN THAT PARTICULAR YEAR



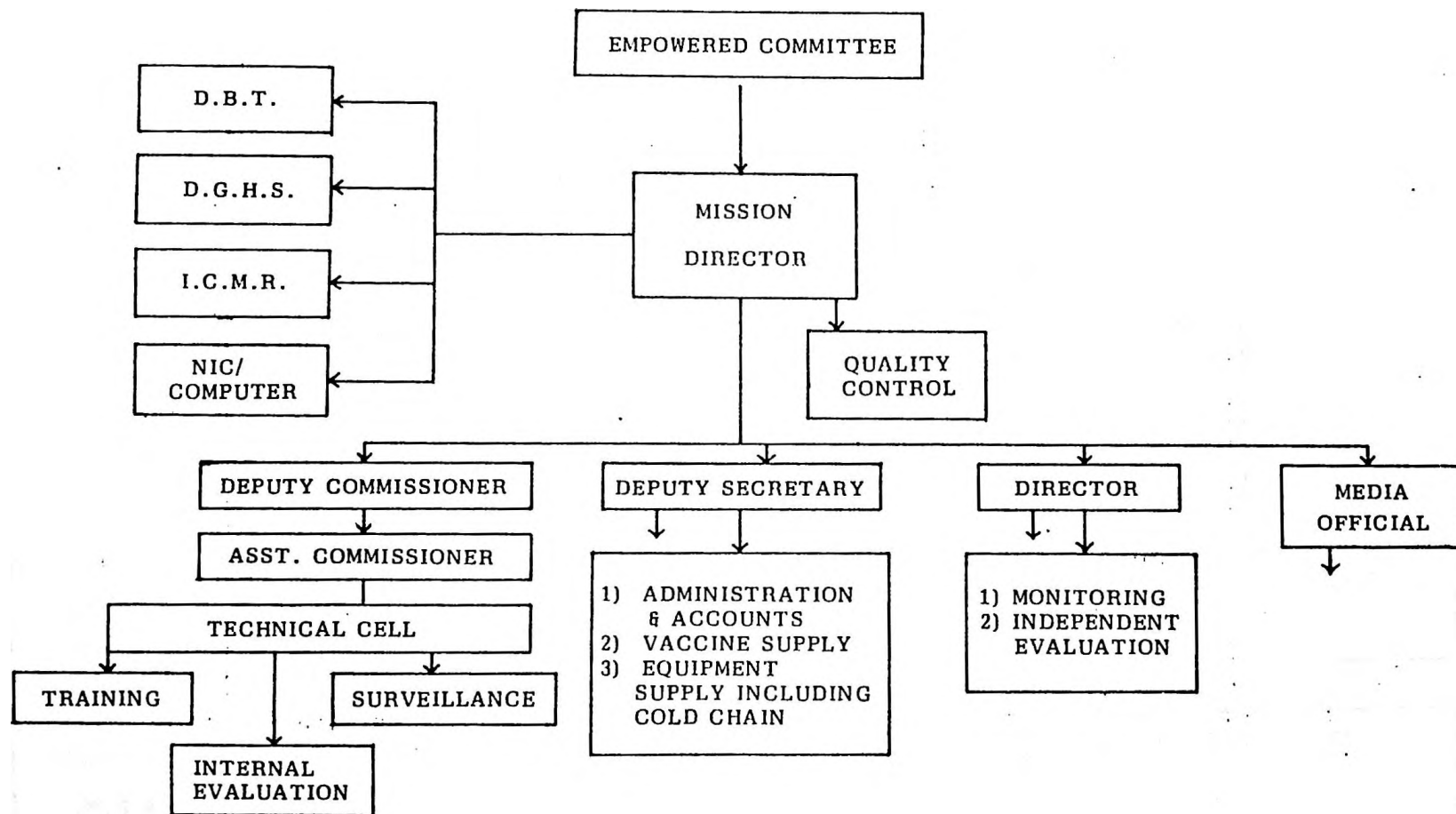
SR. NO.	YEAR	COVERAGE OF DISTT.
1	1985-86	30
2	1986-87	92
3	1987-88	182
4	1988-89	302
5	1989-90	435 +

TARGETS

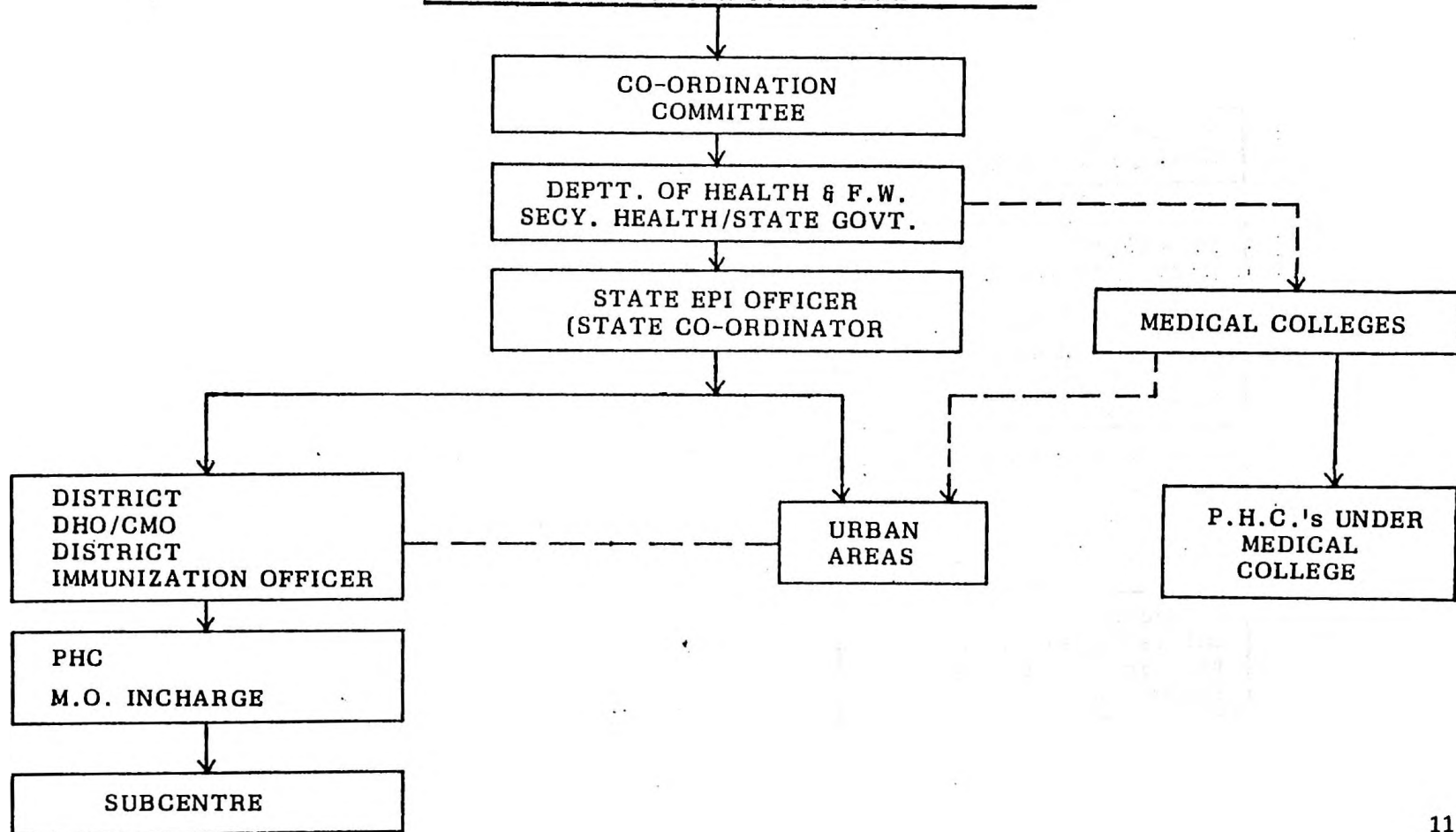




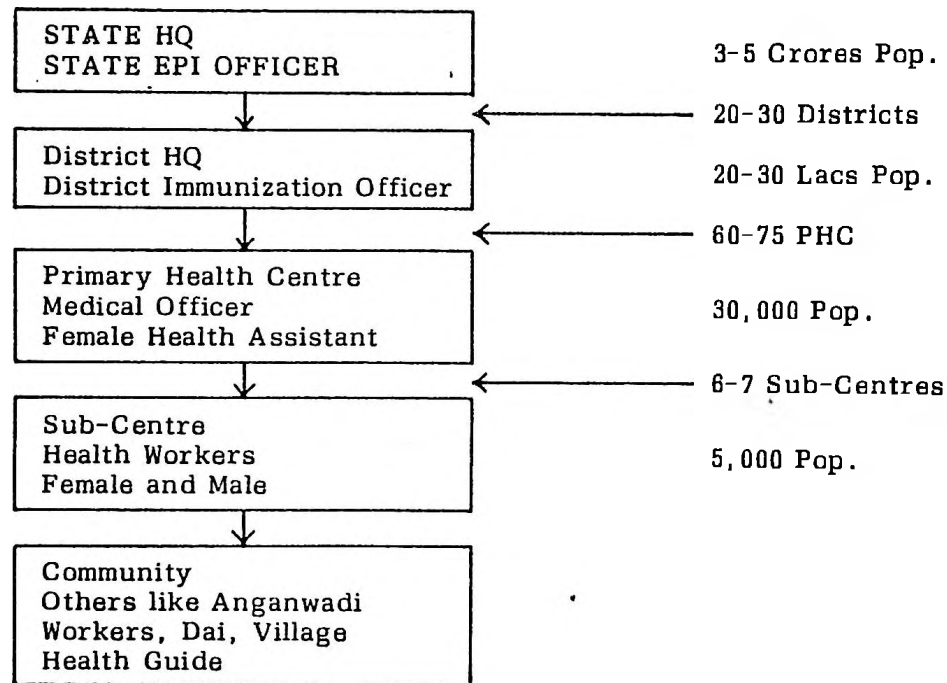
ORG. STRUCTURE - MISSION DIRECTORATE (MINISTRY OF H. & F.W.)



ORGANISATIONAL
STATE LEVEL STRUCTURE



STRUCTURE OF FIELD ORGANISATION (STATE)



OPERATIONAL CONSTRAINTS

1. INSUFFICIENT MOTIVATION
2. INADEQUATE HEALTH INFRASTRUCTURE
3. POOR LOGISTIC SUPPORT
4. DEFICIENCY IN TRAINING
5. WEAK SUPERVISION AND MONITORING
6. IRREGULAR FLOW OF FUNDS
7. CLASHING PRIORITY OF VARIOUS PROGRAMMES
8. INACCESSIBILITY

METHODOLOGY

- * ENSURE SUPPLY OF FULL REQUIREMENT OF VACCINE
- * ENSURE SUPPLY OF REQUIRED EQUIPMENT i.e. NEEDLES, SYRINGES, STERILIZING EQUIPMENT
- * ENSURE PROPER TRANSPORTATION AND STORAGE OF VACCINE AT AMBIENT TEMPERATURES
- * STRENGTHEN INFRASTRUCTURE
- * TRAINING STAFF
- * MONITORING OF THE QUALITY OF VACCINATION
- * ENCOURAGE INDIGENISATION OF EQUIPMENT
- * PRODUCTION OF REQUIRED VACCINES
- * CONCURRENT EVALUATION/INDEPENDENT EVALUATION
- * INVOLVE VOLUNTARY AGENCIES IN ENUMERATION AND ACTUAL VACCINATION
- * COMMUNITY MOBILIZATION
- * DEVELOP EFFECTIVE I.E.C. ACTIVITY
- * RESEARCH/DEVELOPMENT FOR IMPROVED VACCINES

SUBMISSION-I

ADMINISTRATION OF VACCINES, MONITORING AND EVALUATION

1. PLANNING IMMUNIZATION
2. IMMUNIZATION IN THE FIELD
3. TRAINING
4. MONITORING
5. EVALUATION
6. SURVEILLANCE
7. COMMUNITY PARTICIPATION

1. PLANNING IMMUNIZATION

Selection of districts to be taken
up under UIP for the years 1987-88,
1988-89, 1989-90

November, 1986/
May, 1987/
November, 1987

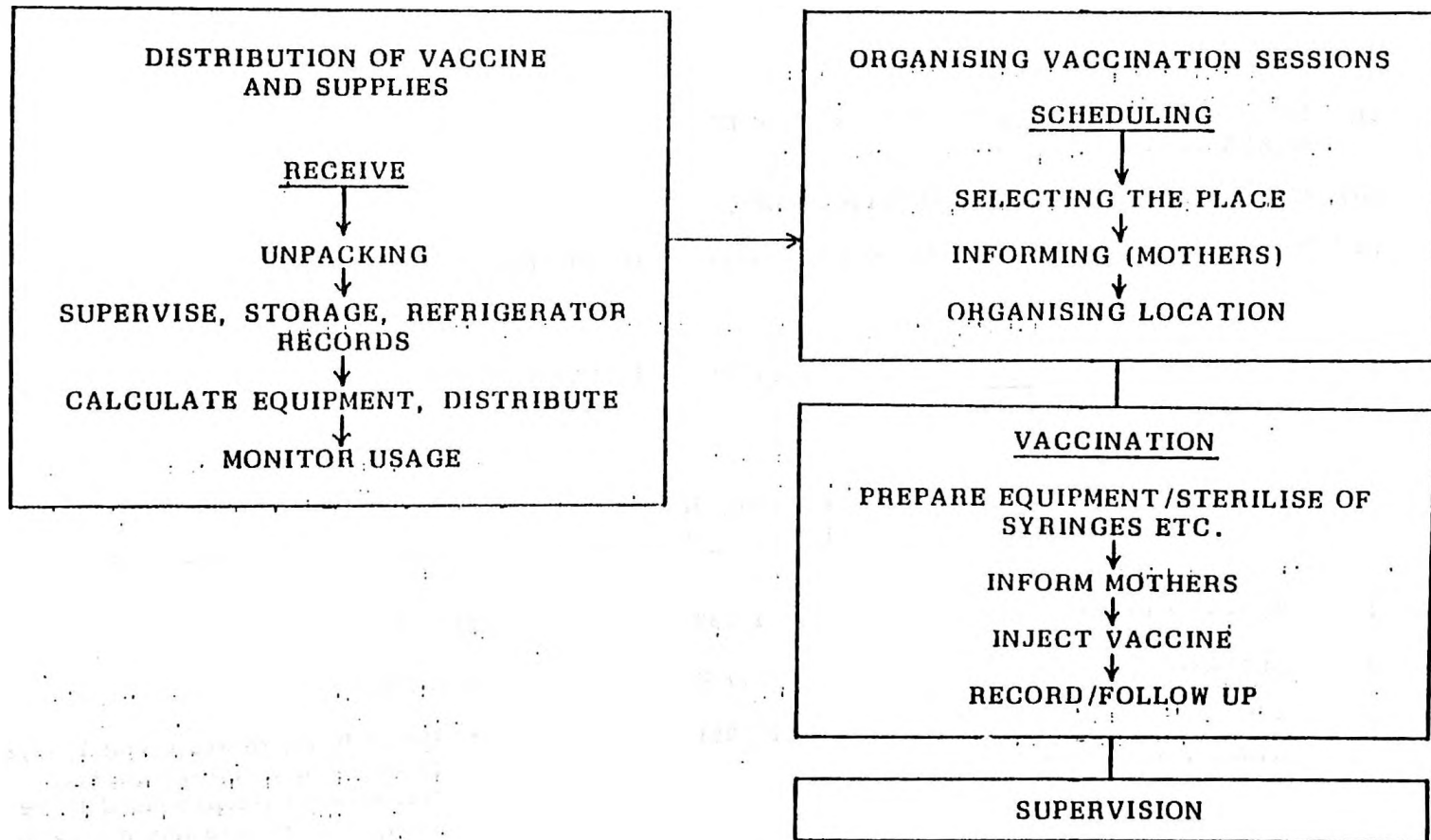
Estimation of targets for Infants
and Pregnant Women, district-wise
for 1987-88, 1988-89 and 1989-90

March, 1987/
June, 1987
December, 1987

Identify districts for special
consideration depending upon the
constraints for 1987-88, 1988-89
and 1989-90

May, 1987/
August, 1987/
June, 1988

IMMUNIZATION IN THE FIELD



3. MONITORING

- (i) MONITORING OF PERFORMANCE IN UIP DISTRICTS EVERY MONTH
- (ii) PERFORMANCE FOR IMMUNIZATION (EPI)
- (iii) FIELD VISITS - TECHNICAL/ADMINISTRATIVE OFFICERS

TRAINING PROGRAMME DURING VII-PLAN (1985-1990)

	Training during *		Total to be Trained during
	1985-86	1986-87	
1. M.O's of PHC's	1,988		21,666
2. M P W's	25,780		303,000
3. Others (Dias V.H. Guide Anganwadi Worker etc.)	20,051		* Other Workers are given 2 days orientation training course. No. of workers proposed to be given this course has not been fixed. States have been given the discretion.

* Figures Provisional

4. TRAINING SCHEDULE

- | | | | |
|-------|--|---|----------------------|
| (i) | Training to District Health Officer
for 1987-88 UIP Districts | - | April, 1987 |
| (ii) | National Planning Management
Course of EPI | - | April/November, 1987 |
| (iii) | National Refrigerator Repair
Technical Course | - | May/October, 1987 |
| (iv) | Training to District Health Officer
for 1988-89 UIP District | - | February/March, 1988 |

EVALUATION

I. CONCURRENT EVALUATION

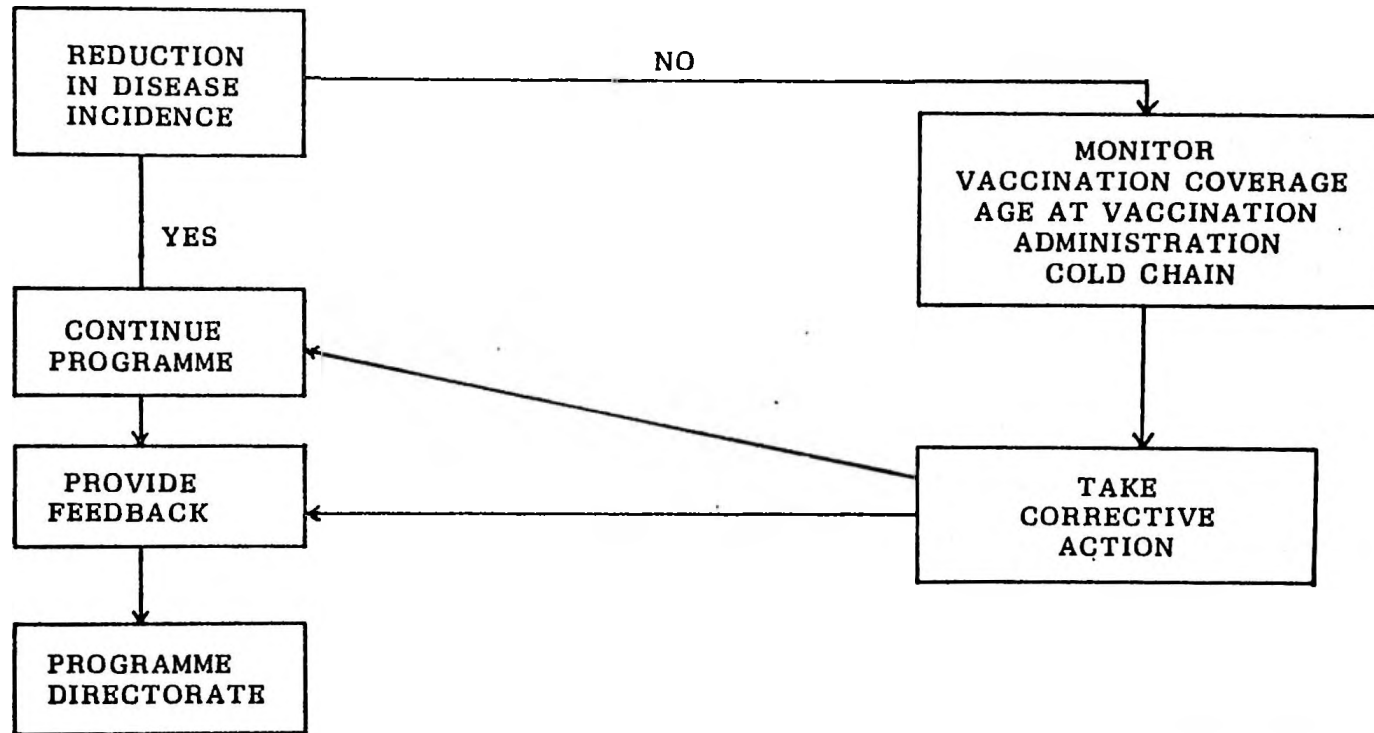
INTERNAL

II. EVALUATION BY INDEPENDENT BODY

CONCURRENT EVALUATION

- * IDENTIFY THE INSTITUTE/BODY WHICH WILL TAKE UP THIS EVALUATION
- * FORMATION OF CORE GROUP FOR EVALUATION
- * SELECTION OF DISTRICT
- * DETERMINATION OF SAMPLE
- DISTRIBUTION OF PROFORMA AND COLLECTION OF INFORMATION, COMPILATION AND TABULATION
- * ANALYSIS

SURVEILLANCE



6. COMMUNITY PARTICIPATION

Increased community participation By Method and Group based approaches (requires consideration at both levels, community and individual)

(i) Method adopted:

- Mass Media
- Inter-personal efforts
- Inter-personal communication

(ii) Group based approach:

- (1) Health Workers and ICDS workers
- (2) Political and Social Leaders
- (3) Primary School Teachers and personnel of other Government Welfare Departments
- (4) Medical Students and Medical professionals
- (5) Organised and Co-operative Sectors

SUBMISSION - II

STORAGE AND DISTRIBUTION OF VACCINES

1. PROCUREMENT OF VACCINES
2. SUPPLY OF VACCINES
3. STRENGTHENING OF COLD CHAIN
4. PROCUREMENT AND DISTRIBUTION OF COLD CHAIN EQUIPMENTS
5. MONITORING SUPPLY OF VACCINES COLD CHAIN EQUIPMENTS
6. MONITORING OF COLD CHAIN

1. SUPPLY OF VACCINES

VACCINES

- | | |
|--|--|
| (i) Monthly review of the Vaccines supply | - Every Month |
| (ii) Procurement of Vaccines from Private Sector for 1987-88 | - April/July/October/December, 1987 |
| (iii) Review supply of Polio Vaccine from Public/Private Sectors for 1987-88 | - April/July/October/December, 1987/February, 1988 |
| (iv) Assessment of requirement of Vaccines for 1987-88 | - September, 1987 |
| (v) Statewise allocation of Vaccines for 1988-89 | - January, 1988 |
| (vi) Procurement of Vaccines from Private Sector for 1988-89 | - January, 1988 |

2. STRENGTHENING OF COLD CHAIN

- | | |
|---|--|
| (1) Assess requirement of VIC's | - February, 1987 |
| (2) Assess requirement for icelined refrigerators for 1987-88/1988-89 and 1989-90 | - January, 1987/
May, 1987/
December, 1987 |
| (3) Assess requirement of cold boxes, vaccine carriers, ice packs for 1987-88/1988-89 and 1989-90 | - January, 1987/
May, 1987/
December, 1987 |
| (4) Assess requirement of refrigerated vans and Mopeds for Institutes/ States for 1987-88/1988-89 and 1989-90 | - January, 1987/
May, 1987/
December, 1987 |

3. PROCUREMENT, DISTRIBUTION OF EQUIPMENT

- | | |
|--|---------------------------|
| 1. Supply of ILRs, Vehicles, Health Education material etc. to districts under UIP for 1987-88 | - April/June, 1987 |
| 2. Supply of ILRs, Vehicles, Health Education material etc. to districts under UIP for 1988-89 | - November/December, 1987 |
| 3. Supply of ILRs, Vehicle, Health Education material etc. to districts under UIP for 1989-90 | - May/July, 1988 |
| 4. UNICEF Assistance-requirement of 1988-89 | - May, 1987 |
| 5. UNICEF Assistance-requirement of 1989-90 | - November, 1987 |
| 6. UNICEF Assistance-Supply of Equipment of 1988-89 | - November/December, 1987 |
| 7. UNICEF Assistance-Supply of equipment of 1989-90 | - May/July, 1988 |

MONITORING SUPPLY OF VACCINES, EQUIPMENT INCLUDING COLD CHAIN

- | | |
|---|------------------------------|
| 1. Despatch of Equipment from M.S.D., Bombay, Madras and Calcutta | - Every Month |
| 2. Despatch of equipment directly as UNICEF assistance to districts | - Every Month |
| 3. Arrival report of equipment from districts | - One time report on receipt |
| 4. Report on installation of icelined refrigerators districtwise | - As and when installed |
| 5. Monthly return from districts regarding working condition of refrigerators, iceliners, Walk-in-Coolers | - Every Month |
| 6. Collection of information and computerising inventory control. | |

MONITORING OF COLD CHAIN - FOR VACCINES MANUFACTURED IN
PUBLIC SECTOR UNDERTAKINGS IN INDIA

- * SYSTEM FOR RECORDING TEMPERATURE AT VARIOUS POINTS OF TIME IN TRANSIT FROM THE MANUFACTURER TO STATE HEADQUARTERS
- * SYSTEM FOR MONITORING COLD CHAIN TO BE DEVISED AT THE STATE LEVEL
- * GOVERNMENT OF INDIA WILL MONITOR COLD CHAIN UPTO STATE LEVEL
- * STATE GOVERNMENT WILL MONITOR MAINTENANCE OF PROPER COLD CHAIN FROM THE STATE HEADQUARTERS TO THE PHC LEVEL
- * - VACCINE PROCURED FROM PRIVATE SECTOR THROUGH DGS&D -
- * THE SUPPLIER WILL GIVE INFORMATION IN PRESCRIBED PROFORMA FOR TEMPERATURES AT VARIOUS POINTS OF TIME DURING TRANSIT FROM THE DISTRIBUTION POINT TO STATE HEADQUARTERS
- * BEYOND THE STATE HEADQUARTERS THE COLD CHAIN MONITORING WILL BE DONE BY STATE GOVERNMENT

RESOURCES

1. FINANCIAL OUTLAY

YEARWISE ESTIMATES EXPENDITURE

(RUPEES IN MILLION)

	<u>1985-86</u>	<u>1986-87</u>	<u>1987-88</u>	<u>1988-89</u>	<u>1989-90</u>	<u>Total</u>
Non-Recurring	55	89	101	142	148	535
Recurring	185	238	304	390	486	1603
Towards vaccine production						262
\$\$	<u>240</u>	<u>327</u>	<u>405</u>	<u>532</u>	<u>634</u>	<u>2400</u>

(Say Rs.240.00 Crores)

2. INFRASTRUCTURE

INFRASTRUCTURE FOR DELIVERY OF SERVICES (1986)

<u>FORMATION</u>	<u>OPERATIONAL</u>	<u>TO BE SET UP BY 1990</u>	<u>TOTAL</u>
C.H.C.	767	1941	2708
P.H.C.	12314	9352	21666
SUB-CENTRE	89819	40181	130000
POST PARTUM CENTRE	1118	636	1754
MEDICAL COLLEGES	106	-	106
HOSPITAL-GOVERNMENT	3575	-	3575
OTHER	3459	-	3459
DISPENSARIES	21226	-	21226

3. HUMAN RESOURCES

STAFF POSITION : KEY HEALTH WORKERS

STAFF	REQUIRED (By 1990)	APPOINTED (till 1986)
Multipurpose Worker (Female)	130,000	100,558
Multipurpose Worker (Male)	130,000	84,598
Female Health Assistant	21,666	16,894
Male Health Assistant	21,666	25,208
Dais	580,000	545,214
Village Health Guide	500,000	390,188
Anganwadi Workers		124,915

4. UNICEF COOPERATION*

Incremental Capital and Operating Costs for UIP District Programme

Figures in '000'
(In US Dollars)

Year	Capital	Operating Cost	Total
1985	30 x 216 = 6,480	-	6,480
1986	60 x 216 = 12,960	30 x 26 = 780	13,740
1987	90 x 216 = 19,440	90 x 26 = 2,340	21,780
1988	120 x 216 = 25,920	180 x 26 = 4,680	30,600
1989	120 x 216 = 25,920	300 x 26 = 7,800	33,720
GRAND TOTAL	420 x 216 = 90,720	600 x 26 = 15,600	106,320

*The Governments of Canada and Sweden have made available supplementary funds for UIP through UNICEF as follows:

CIDA - US\$ 26 million

SIDA - US\$ 33 million

Moreover, Rotary International has agreed to supply Oral Polio Vaccine with a value of US\$ 19 million, but this is not included in this Table 4.

ACCOMPLISHMENTS

YEARWISE TARGETS AND ACHIEVEMENTS DURING 1981-82 TO 1989-90

(Figures in Millions)

Year	T.T. (PREG.WOMEN)			INFANTS			POLIO		
	Target	Achv.	% Achv. of Tg.	Target	Achv.	% Achv. of Tg.	Target	Achv.	% Achv. of Tg.
1981-82	7.96	7.11	89.5	15.97	9.23	57.9	2.40	2.93	123.8
1982-83	9.00	7.64	84.9	13.97	10.34	74.00	5.24	4.55	87.00
1983-84	11.50	8.19	71.3	15.0	11.13	76.70	7.30	7.90	105.9
1984-85	13.0	9.27	71.3	14.5	12.34	85.10	12.00	9.78	81.33
1985-86	12.85	9.31	72.5	14.04	13.34	95.0	14.04	11.98	85.3
1986-87 (upto Jan.87)	15.20	7.99	74.2	15.30	3.41	76.6	15.30	7.96	71.8
1987-88	18.6			18.9					
1988-89	21.9			17.7					
1989-90	23.9			17.0					

YEARWISE TARGETS AND ACHIEVEMENT DURING 1981-82 TO 1986-87

(Figures in Million)

Year	BCG			D.T.			TYPHOID			T.T. (SC)		
	Tg.	Achv.	% Achv.	Tg.	Achv.	% Achv.	Tg.	Achv.	% Achv.	Tg.	Achv.	% Achv.
1981-82	15.0	13.58	90.53	12.57	10.81	86.10	10.0	2.63	26.6	3.5	1.81	51.7
1982-83	15.0	13.93	92.87	12.50	10.25	82.0	10.0	5.02	50.8	5.0	3.11	62.2
1983-84	15.0	13.96	93.07	13.0	10.53	81.0	10.0	6.17	61.7	6.5	4.42	63.0
1984-85	14.3	12.32	84.97	13.0	11.33	87.2	11.0	7.27	66.1	8.0	6.12	76.5
1985-86	14.04	12.89	91.9	11.19	11.10	99.2	11.9	6.99	62.5	8.84	6.70	75.8
1986-87	15.30	8.80	80.3									

(upto Jan., 87)

Contd.....

Contd.....

Yearwise Targets and Achievement during 1986-87 to 1989-90

Year	MEASLES		
	Tg.	Achv.	% Achv. of Tg.
1986-87 (upto Jan., 87)	5.70	1.11	30.2
1987-88	10.0		
1988-89	14.2		
1989-90	18.3		

TESTING AND QUALITY CONTROL OF VACCINES

- | | |
|--|-----------------|
| (i) IDENTIFY INSTITUTIONS/MEDICAL COLLEGES/LABORATORIES WHICH CAN TAKE UP TESTING OF FIELD SAMPLES | May, 1987 |
| (ii) ASSESS THE ADDITIONAL REQUIREMENT OF THESE CENTRES FOR MAKING SUITABLE TO TAKE UP TESTING OF VACCINES | July, 1987 |
| (ii) IDENTIFY THE STATES TO BE ASSOCIATED WITH THE SPECIFIC IDENTIFIED INSTITUTE | August, 1987 |
| (iv) DEVELOP REPORTING SYSTEMS OF TESTING OF FIELD SAMPLES IN THESE IDENTIFIED INSTITUTES | July, 1987 |
| (v) USE COMPUTERISED M.I.S. FOR ANALYSIS OF TESTING RESULTS | September, 1987 |

INVOLVEMENT OF VOLUNTARY AGENCIES

- IDENTIFY VOLUNTARY AGENCIES IN EACH DISTRICT
- TO SELECT SUCH AGENCIES WHICH CAN HELP IN DEMAND GENERATION, ENUMERATION AND ACTUAL VACCINATION
- IDENTIFY MAJOR VOLUNTARY AGENCIES SPARED OVER ACROSS THE COUNTRY/STATES NUMBER OF DISTRICTS
- IDENTIFY SUITABLE AGENCIES TO WORK IN URBAN SLUMS
- PROVIDE FINANCIAL ASSISTANCE WHEREVER UNAVOIDABLE

MANAGEMENT INFORMATION SYSTEM

- COMPUTER TO BE USED FOR COMPILATION OF DATA AND INVENTORY CONTROL
- MONITORING OF IMMUNIZATION
- SURVEILLANCE
- LOGISTICS OF EQUIPMENT INCLUDING COLD CHAIN
- FINANCIAL CONTROL
- SUPPLY OF VACCINES
- EVALUATION REPORTS

Computer is needed at the State Headquarters/District Headquarters.

TECHNOLOGY MISSION ON
VACCINATION AND IMMUNIZATION OF
VULNERABLE SECTIONS OF POPULATION
ESPECIALLY CHILDREN

SUB-MISSIONS

- I. VACCINES PRODUCTION
- II. R&D FOR NEW VACCINES

DEPARTMENT OF BIOTECHNOLOGY
MINISTRY OF SCIENCE AND TECHNOLOGY

SUB-MISSION - I

PRODUCTION OF VACCINES

OBJECTIVES

- Modernization and capacity expansion in major public sector units to meet the EPI demands for DPT, DT, TT, BCG and Typhoid vaccines.
- To establish indigenous production capacities before 1990 for Measles, Polio and tissue culture Rabies vaccine employing advanced technologies.
- To undertake detailed evaluations including field trials of R-DNA hepatitis-B vaccine and new pertussis vaccine and to set up indigenous production capacities for those vaccines by 1990 or soon thereafter.

**SOME DESIRABLE CHARACTERISTICS OF VACCINES CONSIDERED
IN THE CHOICE OF VACCINES/PROCESS TECHNOLOGIES**

High efficacy

(Minimum number of doses to ensure long lasting immunity, better sero-conversion etc.)

safety and minimum side effects.

Long shelf life.

Heat stability.

Distribution through common cold chain.

Ease of application.

Adequate availability.

Ability to combine with other vaccines as vaccine "Cock tails" and

Low cost.

DROP-OUT AND VACCINATION COVERAGE

DOSES/ VISITS	DROP-OUT RATE	<u>NUMBER OF RECIPIENTS</u>	
		FIRST VISIT	LAST VISIT
3	25%	100	56.25
3	20%	100	64.00
3	10%	100	81.00
3	7.5%	100	85.50
4	5%	100	85.70

MINIMUM VACCINATION VISITS DURING FIRST YEAR - 4

Note: The drop out rate in India is about 25%. Vaccines requiring multiple doses calls for multiple visits/recalls, which results in a large cumulative drop out and low coverage. Vaccines requiring fewer doses (ideally single shots) would greatly help improve the coverage.

SOME SALIENT FEATURES OF VACCINE PRODUCTION STRATEGY

- Number of doses manufactured and schedule of production and supply to match the estimated annual requirements of the EPI.
- Quality of the products to meet strictly the standards set by the World Health Organisation.
- Quality of the products to be certified by a independent National Quality Control and Standardization Laboratory.
- The cost of indigenously producted vaccine to be internationally competitive and to enhance the cost-effectiveness of the national programme.
- The production units should have strong in house R & D component.

TECHNOLOGIES FOR PRODUCTION OF VACCINES

MEASLES VACCINE

- I. CHICK EMBRYO FIBROBLAST TECHNOLOGY
- II. HUMAN DIPLOID CELL BASED CELL CULTURES

ORAL POLIO VACCINE

PRIMARY MONKEY KIDNEY CELL CUTURES

KILLED POLIO VACCINE

&

RABIES VACCINE

CONTINUOUS VERO CELL MICROCARRIER FERMENTATION
TECHNOLOGY

HEPATITIS-B VACCINE

R- DNA BASED YEAST/CHO CELL TECHNOLOGY

NEW PERTUSSIS VACCINE

- MONO COMPONENT - TOXOID VACCINE (SUB UNIT VACCINE)
- OR TWO COMPONENT - TOXOID AND FILAMENTOUS
HAEMAGLUTININ VACCINE (SUB UNIT VACCINE)

PRODUCTION OF VACCINE - INDUSTRIAL PROJECT

STAGE - I

-	Live attenuated measles vaccine	25 Million doses
-	Oral Polio vaccine	100 Million doses
-	Killed polio vaccine	50 Million doses
-	Tissue culture rabies vaccine	5 Million doses

STAGE - II

-	R-DNA Hepatitis-B Vaccine	2 Million doses
-	Acellular pertussis vaccine	50-80 Million doses

EXPECTED DATES OF BULK INDIGENOUS PRODUCTION OF VACCINES

Measles vaccine	-	April 1989
Polio vaccine	-	January 1990
Rabies vaccine	-	January 1990
Hepatitis-B vaccine	-	December 1990 or soon thereafter.
New Pertussis vaccine	-	December 1990 or soon thereafter.

CAPACITY EXPANSION IN EXISTING UNITS

VACCINE	INSTITUTE	PRODUCTION 85-86	PLANNED CAPACITY 89-90	% EXPANSION
DPT	CRI, KASAUJI	13	20	54
	PI, COONOR	9	15	67
	HPCL, BOMBAY	6	10	67
	TOTAL	28	45	61
TETANUS TOXOID	CRI, KASAUJI	22	22	-
	PI, COONOR	6	10	67
	HPCL, BOMBAY	8	14	75
	TOTAL	36	46	21
BCG	BCG VACCINE LABORATORY MADRAS	16	22	27

PROGRESS MADE

- Two technical expert committees studied the vaccine requirements, state of the art of technologies for vaccine production and recommended urgent steps to set up indigenous R&D cum production facilities through transfer of most advanced and appropriate technologies for:
 - Hyper attenuated measles vaccine
 - Injectible polio vaccine (Vero)
 - Inactivated tissue culture rabies vaccine &
 - R-DNA Hepatitis - B vaccine.
- An inter-ministerial negotiating committee finalised the technologies and terms and conditions of transfer of technologies for, measles, rabies and polio vaccines.
- Evaluation of technologies for hepatitis-B vaccines, oral polio vaccine and new pertussis vaccines are in progress.

SUB-MISSION - II

R&D FOR NEW AND IMPROVED VACCINES

SELECTED DISEASES FOR VACCINE R&D

- a) Urban rabies with special reference to oral vaccine baits for canine rabies control.
- b) Diarrhoeal diseases : Cholera, Shigellosis, Rotaviral diarrhoea, Salmonellosis.
- c) Typhoid
- d) Hepatitis-B
- e) hepatitis-NANB
- f) Malaria and
- g) Pneumonia

OBJECTIVES

- To set up, promote, undertake and monitor highly competitive R&D activities in vaccinology with a view to develop new process technologies for new or improved vaccines and vaccine cock tails such as:
- R&D, prototype development and field evaluation of oral vaccines against cholera, typhoid etc.
- Development of stable and environmentally safe vaccine baits for canine rabies control in India.
- Epidemiological and etiological studies as well as vaccine development and validation against hepatitis NANB and streptococcal pneumonia. †
- R&D and evaluation of new sub unit vaccines such R-DNA based and synthetic vaccines.
- Development of polyvalent vaccines and vaccine 'cock tails'.

RABIES - PROJECTS AND INSTITUTIONS IDENTIFIED

- * Development of mass immunizing agents against canine rabies in India - urban and rural.
- * Analytical typing and survey of street virus prevalence in India.
- * Studies on the substitution of the reactogenic equine hyperimmune serum with other safer agents (interferon inducers)

Pasteur Institute, Coonoor.

National Institute of Virology, Pune.

HEPATITIS: PROJECTS AND INSTITUTIONS IDENTIFIED

- * Study of the duration of efficacy & safety of genetically engineered yeast vaccine as compared to plasma derived vaccine.
All India Institute of Medical Sciences, New Delhi.
National Institute of Virology, Pune.
- * Development of new recombinant vaccines for immunization against viral hepatitis-B, rabies and malaria.
National Institute of Immunology, New Delhi.
- * Identification and characterisation of virus particle/particles causing NANB hepatitis-detection of humoral immune responses, and development of reagents and tests for specific diagnosis of NANB hepatitis.
All India Institute of Medical Sciences, New Delhi.
National Institute of Virology, Pune.

PERTUSSIS AND OTHERS

R&D cum production, standardisation and quality control of acellular pertussis vaccine in India.

Central Research Institute, Kasauli.

Pasteur Institute, Coonoor.

* Development of an evaluation unit at AIIMS for vaccines used in children.

All India Institute of Medical Sciences, New Delhi.

DIARRHOEAL DISEASES (CONTD..)

- * Development of new vaccines against S.typhi.
All India Institute of Medical Sciences, New Delhi.
- * Studies on the development of an attenuated cholera vaccine.
Banaras Hindu University, Varanasi.
- * Studies on development of an effective vaccine against shigellosis caused by Shigella dysenteriae.
National Institute of Cholera and Enteric Diseases, Calcutta.

DIARRHOEAL DISEASES: PROJECTS AND INSTITUTIONS IDENTIFIED

- * Study of rota viral infection and development of vaccines against rota viral diarrhoea.

National Institute of Cholera and Enteric Diseases, Calcutta,
Director General of Health Services, Manipur.
- * Development of improved cholera vaccine (adhensive factor)

Central Drug Research Institute, Lucknow.

Jawaharlal Nehru University, New Delhi.
- * Research and Development of diagnostics and vaccine against diarrhoeogenic E.coli.

National Institute of Cholera and Enteric Diseases.
- * Improved diagnostic facilities for diarrhoeal diseases through DNA probes.

National Cholera and Enteric Diseases, Calcutta.

Banaras Hindu University, Varanasi.

NOTES
