

Study Report
on
The Project
for
Grant Aid for Child Health,
Promoting Child Health (Phase II)
in
The Republic of Nicaragua

May 2000

Japan International Cooperation Agency

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PREFACE

In response to a request from the Government of the Republic of Nicaragua, the Government of Japan decided to conduct a study on the Grant Aid for Child Health, the Project for Promoting Child Health (Phase II) and entrusted the Japan International Cooperation Agency (JICA) to conduct the study with the assistance of the Japan International Cooperation System (JICS).

JICA sent to Nicaragua a study team from December 12 to 19, 1999.

I hope that this report will contribute to the promotion of the project and to the enhancement 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 Nicaragua for their close cooperation extended to the team.

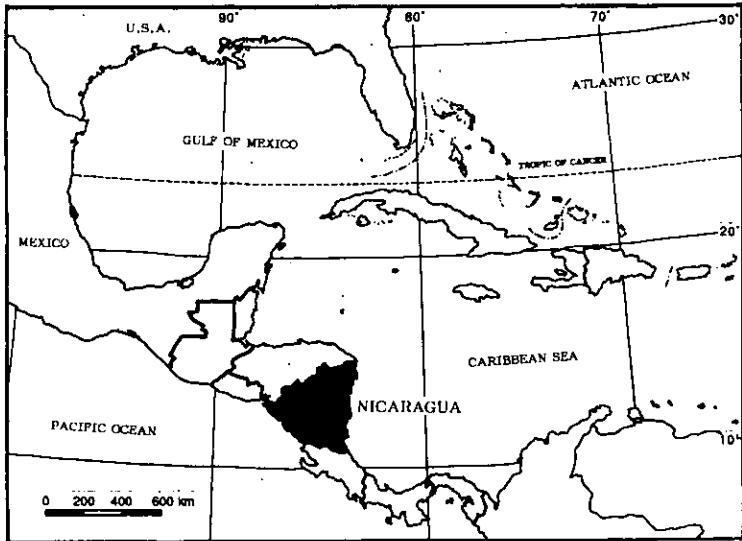
May 2000

A handwritten signature in black ink, appearing to read 'Kimio Fujita', written in a cursive style.

Kimio Fujita

President

Japan International Cooperation Agency



Location Map

Abbreviations

Abbreviations / Acronym	English/ Spanish
BCG	Bacille de Calmette and Guerin
CFC	Chloro Fluoro Carbon
<i>CIPS</i>	<i>Centro de Insumos para la Salud</i>
<i>C/S</i>	<i>Centro de Salud</i>
<i>DGNIM</i>	<i>Dircción de Normalización Insumos Médicos</i>
DPT	Adsorbed Diphtheria-Purified Pertusis-Tetanus Combined Vaccine
EPI (<i>PAI</i>)	Expanded Programme on Immunization (<i>Programa Ampliado de Inmunización</i>)
GMP	Good Manufacturing Practice
HB	Hepatitis B
Hib	Haemophilus influenza type b
IMCI (<i>AIEPI</i>)	Integrated Management of Childhood Illness (<i>Atención Integral a las Enfermedades Prevalentes de la Infancia</i>)
MMR	Measles Mumps and Rubella Combined Vaccine
OPV	Oral Poliomyelitis Vaccine
PAHO (<i>OPS</i>)	Pan American Health Organization (<i>Organización Panamericana de la Salud</i>)
<i>P/S</i>	<i>Puesto de Salud</i>
<i>RAAN</i>	<i>Región Autónoma Atlántico Norte</i>
<i>RAAS</i>	<i>Región Autónoma Atlántico Sur</i>
<i>SILAIS</i>	<i>Sistemas Locales de Atención Integral a la Salud</i>
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development

Note: Italics indicate Spanish.

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Chapter 1 Background of the Project

Following the end of the 10-year civil war (1979~1989) between the government of Daniel Ortega supported by the Frente Sandinista de Liberacion Nacional (FSLN) and right-wing antigovernment guerrillas (Contras), the Republic of Nicaragua (hereafter called "Nicaragua") turned to the task of rebuilding the country under former President Chamorro, introducing democracy, shifting to a free market economy, reducing the size of the army and improving relations with western countries. Economically, it succeeded in bringing under control the hyperinflation which had reached 10,000% by the end of the 1980s and stabilizing the currency. The Aleman Government which came to power in January 1997 continued to pursue steady economic recovery while dealing with issues such as foreign liabilities that stood at 5.9 US billion dollars (as of the end of 1997), high unemployment rate and the growing number of poor. The country, however, remains the poorest in Central America (with GNP per capita of US\$410 in 1997), and according to data from the Pan American Health Organization (PAHO)*¹, 50% of the total population is living in poverty and 19% in dire poverty, with the disparity particularly striking in the cities and in the country.

The cooperation of many international and bilateral aid organizations has been obtained in the field of health, and the total aid from such organizations between 1993 and 1997 amounted to around 177 million US dollars. However, according to Nicaraguan health indicators, although the infant mortality rate fell from 140 per 1,000 births in 1960 to 44 in 1996 and the under 5 mortality rate from 206 to 57, with the exception of Haiti (where the respective rates are 130 and 91 in 1988), it remains the worst in the Central American region where the respective averages are 35 and 43. The main causes of infant mortality are epidemic diseases and parasitic diseases caused by poor sanitary conditions.

In the face of many problems particularly in the maternal and child health sector, in 1996 PAHO/UNICEF introduced Integrated Management of Childhood Illness (IMCI)*² in Nicaragua as a strategy for controlling illness among children, and directed its efforts at preventing diarrhea and pneumonia, supplying micronutrients, improving nutrition, promoting

*¹ One of the 6 regional offices of WHO (World Health Organization) with jurisdiction over the whole of the American continent. Headquarters in Washington D.C.

*² The aim is to provide all-round treatment for sick children who come for examination, not just treating the individual disease, but including the child's physical and mental development, inoculations, family environment, etc.

immunization and providing training courses for medical workers as a means of improving medical services. Regular immunization is provided against the six EPI illnesses: tuberculosis (BCG), diphtheria, tetanus, pertussis, poliomyelitis and measles. According to PAHO statistics for 1998, the immunization coverage rate in Nicaragua was comparable with the average for Central and South America (Refer to Table 1-1).

Table 1-1 Immunization Coverage Rate

	(unit:%)			
	DTP	Polio	Measles	Tuberculosis
Nicaragua	86	91	99	91
Average of Central and South America	86	88	85	99

As a result, no cases of poliomyelitis, measles or neonatal tetanus have been reported in recent years. The next aim of the Ministry of Health in Nicaragua (hereafter called MINSA) after eradicating poliomyelitis is to eradicate measles and neonatal tetanus, and as the next stage in this effort, it introduced MMR vaccine*³ (measles-mumps-rubella combined vaccine) two years ago and pentavalent vaccine*⁴ recommended by PAHO last year.

In the wake of Hurricane Mitch which devastated Nicaragua in October 1998, epidemic diseases raged in the mountainous region in the north, inland from the Pacific coast and in the northwest, and attempts were made to restrain the spread of disease with the cooperation of donor countries through the dispatch of emergency medical teams and the supply of medicines, etc. However, supplies were unable to keep pace with a demand, and many health centers and health posts still lack stocks of medicines. According to MINSA, Under 5 Mortality Rate (U5MR) in 1998 rose 10% compared with the previous year (Refer to Table 1-2). This is attributable to the increase in infectious diseases accompanying the deterioration in sanitary conditions caused by Hurricane Mitch.

*³ A combined vaccine against measles, mumps and rubella given to one-year olds.

*⁴ A vaccine in which hepatitis B (HB) and haemophilus influenza type b (Hib) antigens are added to DTP (diphtheria, tetanus, pertussis). Administered to infants under one 3 times a year.

Table 1-2 Trends in Infant Mortality Rate

	1997	1998 (increasing rate%)	
Infant Mortality Rate (under 12 months)	2,410	2,550	5.8
Mortality Rate (1 to 4 years old)	563	719	27.7
U5MR	2,973	3,269	10.0

In 1998 Nicaragua requested grant aid cooperation from Japan for the procurement of vaccines, syringes and cold chain equipment required for immunization at national level and the essential drugs for the IMCI program, and the request was fulfilled by Japan.

However, following the devastation caused by Hurricane Mitch, with the Nicaraguan government in financial straits and the MINSA no exception, many of the health centers (C/S), which are at the center of primary health care in the provinces and farming areas, and health posts (P/S) which are the end unit, lack basic facilities, medical equipment and drugs and are unable to provide adequate basic services for the local people.

This project (hereafter called the Project) was requested as Phase II of the 1998 Project for Enforcement of Child Health (hereafter called the 1998 Project) to enable the financially straitened MINSA to continue the EPI and IMCI programs.

Chapter 2 Contents of the Project

2-1 Objectives of the Project

In view of the serious financial difficulties facing MINSA in the wake of Hurricane Mitch, the Project aims to support the implementation of EPI and IMCI, promote immunization of children and eradicate measles and neonatal tetanus, and also to encourage overall health management for children through IMCI.

The Project is a follow-up to the 1998 Project which was implemented with the aim of supporting Nicaragua's efforts towards EPI and IMCI, and contributes to:

- supporting immunization activities through the procurement of EPI-related goods such as MMR and pentavalent vaccines (excluding the share allotted to the Nicaraguan government and PAHO) for the implementation of EPI in 2001
- reducing the infant mortality rate (target: 30 deaths per 1000 births) and improving the health of mothers and children, including maternals, through the supply of essential drugs to 9 SILAIS for the implementation of IMCI.

Goods procured under the 1998 Project are at the delivery stage, but the damage caused by Hurricane Mitch is more serious than expected and long-term pressure on the finances of MINSA appears unavoidable. Such is the background to the Project.

2-2 Basic Concept of the Project

1) Goods related to EPI activity

The original request for EPI-related goods was for 250,000 doses*⁵ each of pentavalent and MMR vaccines, but the appropriateness of the items and quantities was investigated as explained below, resulting in Table 2-1.

1) Pentavalent vaccine

Use of pentavalent vaccine enables the number of inoculations to be reduced from nine a year to three a year, as three vaccines, DTP (diphtheria-tetanus-pertussis combined vaccine), HB (hepatitis B) and Hib (haemophilus influenza type b), intended for administration three times

*5 Unit indicating the amount of vaccine administered in one inoculation. In the case of pentavalent vaccine and MMR, one dose is 0.5cc.

a year to children under the age of one, can be administered simultaneously.

This is expected to lead to a major improvement in the immunization coverage rate. In addition, it is cheaper than purchasing the three vaccines separately and the use of pentavalent vaccine is actively encouraged by PAHO. Therefore it has been used in Nicaragua since 1999.

Table 2-1 Original request for EPI-related goods and results of study

No.	requested items	major specifications	unit	procured quantity under the former Project	requested quantity	result of study	priority
10	pentavalent vaccine	mono-dose	doses	500,000	250,000	150,000	A
11	MMR vaccine	mono-dose	doses	700,000	250,000	182,000	A
12	autodestruct syringe	0.5ml 23Gx25mm	pics.	1,200,000	650,000	332,000	A
13	safety box	5 liters	pics.	12,000	40,000	3,400	A
14	solar refrigerator system (regular type)	power source: DC 12V, vaccine capacity: at least 30 liters	sets	30	34	34	A
					15	0	B
15	solar refrigerator system (large type)	power source: DC 12V, vaccine capacity: at least 80 liters	sets	—	3	0	B
16	vaccine carrier	vaccine capacity: at least 1.5 liters	pics.	—	2,000	0	B
17	Ice pack	—	pics.	—	8,000	0	B

MINSAs calculated the necessary quantities of vaccine as shown below on the assumption of three inoculations a year.

$$\begin{aligned}
 &\text{Required quantity of pentavalent vaccine} = \text{Population under age one} \times 3 + 1 \times (1 + \text{loss rate} + \text{margin}) \\
 &= 169,884 \text{ persons}^{*6} \times 3 + 1 \times (1 + 0.1 + 0.07) \\
 &= 596,293 \Rightarrow 600,000 \text{ doses}
 \end{aligned}$$

Previously multi-dose vials*7 (10 or 20 doses per vial) were commonly used in Nicaragua, resulting in a 20~60% loss. Pentavalent vaccine, however, comes in a mono-dose vial*8, so a much lower loss rate can be expected. However, allowing for immunization in remote areas

*6 Estimated population in 1998 based on the 1995 census

*7 Vial containing enough vaccine for two or more inoculations

without adequate cold chain systems, errors in population statistics, artificial causes and other physical factors, loss during storage and inoculation will be unavoidable and a 10% loss rate, the same percentage as in the 1998 Project, is considered appropriate.

MINSa fears that, in addition to the loss rate, there will be a blank period until the supply of the next year's vaccine, and to cover this a further margin of 7% is taken into consideration.

This is an unprecedented multi-valent vaccine combining five vaccines, and if there were a blank period due to a delay in procurement, it would be a major hindrance, therefore this margin is considered unavoidable.

In the original request, the shortfall of 250,000 doses was requested as grant aid cooperation from Japan, but as Nicaragua has undertaken to supply 100,000 doses, the final amount requested from Japan was 150,000 doses (Refer to Table 2-2). MINSa will receive aid for procurement of the vaccine from PAHO until 2003 and is currently considering a means of funding the difference between the amount procured with PAHO aid and the total amount required.

Table 2-2 Procurement plan for pentavalent vaccine

	(unit: dose)		
	1999	2000	2001
MINSa	100,000	100,000	100,000
Request to Japan	0	500,000	150,000
PAHO	500,000	0	350,000
Total	600,000	600,000	600,000

2) MMR vaccine

This vaccine combines three vaccines used for immunization against measles, mumps and rubella, and procurement of 700,000 doses for National Immunization Days in 2000 was included in the 1998 Project.

In the Project, vaccine will be supplied for routine immunization of one-year-old children

*8 Vial containing vaccine for one inoculation

(aged 12~23 months) in 2001 after the end of the campaign. MINSA estimated the amount of vaccine required as 250,000 doses as shown below and requested the total amount from Japan.

Table 2-3 Procurement plan for MMR vaccine

(unit: dose)			
	1999	2000	2001
MINSAs	250,000	0	0
Request to Japan	0	700,000	250,000
Total	250,000	700,000	250,000

Population of children (aged one) to be vaccinated: 164,745

Loss during storage and inoculation (10% of target population) :

164,745 (target population) x 1.10 (loss rate) = 181,219.5 ⇒ 182,000

Revaccination in the case of loss of vaccination card (30% of target population) : 49,000

2~4 year-olds who were not vaccinated at age one (10% of target population) : 16,474

Total 247,474

⇒ 250,000 doses

A loss rate of 10% is considered appropriate for the same reasons as those put forward for the pentavalent vaccine.

However, 30% revaccination in the event of loss of the vaccination card is unwarranted and should be reduced by the self-help efforts of MINSA through better education in the 2000 campaign. 10% has been added for revaccination of two to four year-olds who were not vaccinated at age one, but in view of the fact that the 2000 campaign targets one to four-year olds, it is unreasonable to allow for revaccination of one to three year-olds in 2000.

Physical loss of MMR vaccine is therefore estimated at 10% of the target population (164,745 one-year-old children) and the final number is rounded up to 182,000 doses.

3) Syringes

The original request was for 650,000 auto-disable syringes*⁹, but as explained earlier, the main vaccines administered under EPI in Nicaragua are, in addition to pentavalent vaccine and MMR, OPV and BCG. As OPV is administered orally, it does not require a syringe, and BCG is administered in doses of 0.05 ml, so it does not require this type of syringe either (0.5 ml). The only vaccines requiring syringes under the Project, therefore, are pentavalent vaccine (150,000 doses) and MMR (182,000 doses), making a total of 332,000 syringes.

4) Safety boxes

The original request was for 40,000 boxes. Each safety box has a capacity of 5 liters and can hold 100 (0.5 ml) auto-disable syringes. As 332,000 syringes are procured, divided by 100 gives a figure of 3,320, so 3,400 boxes is considered appropriate when this figure is rounded up to the nearest 100.

5) Solar photovoltaic refrigerator system

This system is installed in regions with no electricity, where access is extremely poor, and gas or kerosene refrigerators cannot be used. Since 1996 MINSA has installed 46 such systems with aid from other donor countries, and it plans to install another 29 in 2000 on its own budget (Social Supplement Fund). 30 systems were supplied to the central and Atlantic coastal regions of Nicaragua under the 1998 Project and were due to be installed by May 2000.

Under the Project, another 34 systems will be supplied to regions with no electricity, ensuring that Nicaragua has enough systems for some time to come.

However, the systems requested as Priority B (second priority) will not be included in the Project for the reasons stated below.

6) Other items requested

In addition to the above, MINSA requested 15 of the above solar photovoltaic refrigerator systems, 3 large systems, vaccine carriers and ice packs.

*⁹ Reuse is prevented by a mechanism that locks the plunger after it has been pushed in. The needle is also fixed and cannot be removed.

These goods were intended to be procured under the PROSILAIS program being implemented with aid from Sweden in 6 SILAIS (RAAS, Chinandega, Esteli, Leon, Madris and Nueva Segovia), but following the suspension of the program in November 1999, the goods were requested from Japan. At the present time, it is not clear what is happening with the Swedish aid, but as there is a good chance of it being reinstated, these items have not been included in the Project.

(2) Goods related to IMCI activity

1) Essential drugs

The following nine SILAIS which are currently implementing IMCI have been selected on the basis of such criteria as:

- high infant mortality rate and population density, and broad distribution of poor who are susceptible to spread of infectious diseases (low-income housing districts and slums)
- farming regions with poor access and high rates of poverty and malnutrition
- regions where infant mortality rates are higher than the national average (53/1,000)

Children under the age of five in these regions account for 73% of the total for the whole country (695,323 persons/950,924 persons).

The SILAIS concerned are Chinandega, León, Managua, Chontales, Jinotega, Matagalpa, RAAN, RAAS and Rio San Juan.

MINSA plans to expand the present 9 SILAIS to a total of 17 in 2001 and has requested the essential drugs shown in Table 2-6. One year's supply of essential drugs to 17 SILAIS nationwide represents an increase of 10~70% compared with 9 SILAIS. In the original request, the 9 SILAIS were accorded priority A (first priority), and the other 8 SILAIS priority B (second priority).

The 1998 Project involving a one-year supply of essential drugs to 9 SILAIS is currently being implemented and has not yet reached a stage that will allow evaluation of distribution and use. As procurement for all 17 SILAIS is therefore considered premature, the regions targeted in the Project are the 9 priority A SILAIS. For the same reason the items involved are the 18 priority A items, and the quantity is one year's supply, as in the 1998 Project (Refer to

Table 2-4).

The amount for one-year supply to the 9 SILAIS differs slightly compared with the 1998 Project. This is mainly because, some NGO are supporting SILAIS with drugs, and MINSA encourages the use of certain drugs in IMCI.

A breakdown of the planned distribution in the 9 SILAIS is shown in Table 2-5.

2) Micronutrients

Micronutrients, especially ferrous and vitamin A, are already supplied to children throughout Nicaragua as one of the key pillars of IMCI. Ferrous sulfate is used in the treatment and prevention of ferrous deficiency, and retinol in for the prevention of vitamin A deficiency which causes nyctalopia and conjunctival xerosis. As a follow-up to the 1998 Project, these micronutrients will be supplied in the Project as well.

① Ferrous sulfate

The dosage of ferrous sulfate differs depending on whether the nutritive supplement is administered as a treatment or for preventive purposes, and also on age. The necessary quantity is calculated as shown in Table 2-6.

② Vitamin A (retinol)

The respective doses for children and women in puerperal*¹⁰ are calculated with an estimated loss of 10%, as shown in Table 2-7.

3) Nebulizers

Nebulizers are used for vaporizing and inhaling anti-asthmatic drugs (bronchodilator: salbutamol sulfate) to treat allergic respiratory diseases. Nebulizers were supplied to 43 health centers in 4 SILAIS under the 1998 Project. For this the Project, nebulizers will be supplied to 60 health centers in another 11 SILAIS with a high number of sufferers (Refer to Table 2-8).

*¹⁰ Puerperal is the period from delivery until the mother's body returns to its state prior to pregnancy. Normally 6~8 weeks.

Table 2-4 Content of request for essential drugs for IMCI

No.	requested items	presentation	indications	priority	requested quantity (for 9 SILAIS)	procured quantity under the 1998 project
101	benzylpenicillin as sodium	vial	Pneumonia, bacteria-borne diseases	A	224,000	251,700
102	procaine benzylpenicillin	vial	Pneumonia, bacteria-borne diseases (containing soothing agents)	A	1,182,000	1,531,600
103	benzathine benzylpenicillin	vial	Pneumonia, bacteria-borne diseases, syphilis	A	208,000	287,400
104	amoxicillin	bottle	Pneumonia, bronchitis, other infectious diseases	A	90,000	16,900
105	chloramphenicol as sodium succinate	vial	Meningitis, typhoid, serious infectious diseases	A	31,000	20,200
106	gentamicin as sulfate	ampoule	Septicemia, peritonitis	A	79,000	102,700
107	sulfamethoxazole + trimethoprim syrup	bottle	Pneumonia, dysentery, typhoid, urinary tract infections	A	500,000	408,100
108	sulfamethoxazole + trimethoprim tablet	tablet		A	4,023,000	3,856,700
109	nystatin	bottle	Gastrointestinal candidiasis	A	34,000	64,500
110	albendazole	bottle	Hydatid diseases	A	99,000	165,700
111	salbutamol syrup	bottle	Bronchial asthma, bronchitis (for internal use)	A	252,000	271,500
112	salbutamol sulfate inhalation (aerosol)	bottle	Bronchial asthma, bronchitis (portable type for inhalation in event of attack)	C	51,000	—
113	salbutamol respirator solution	bottle	Bronchial asthma, bronchitis (for inhalation)	A	13,000	10,800
114	beclometasone dipropionate	bottle	Allergic rhinitis, asthma	C	19,000	—
115	adrenaline (epinephrine)	ampoule	Bronchial asthma, resuscitation after shock, arrest of bleeding during operation	B	38,000	—
116	lactated ringer's solution (Hartman)	bottle or sachet	Supply and correction of extracellular fluid	A	71,000	79,100
117	oral rehydration salts (ORS)	bag	Water and electrolyte supply in event of diarrhoea or dehydration	A	1,677,000	2,524,500
118	ritodrine chloride	ampoule	Imminent premature delivery or miscarriage	A	5,000	4,700
119	tetracycline	tube	Neonatal ophthalmia, conjunctivitis, styes	C	66,000	—
120	paracetamol (acetaminophen) solution	bottle	Anti-inflammatory alleviation of fever, pharyngitis	A	582,000	632,900
121	paracetamol (acetaminophen) syrup	bottle		C	255,000	—
122	paracetamol (acetaminophen) tablet	tablet		B	2,332,000	—
123	dexamethasone injection (as sodium phosphate)	ampoule	Lung disease, allergic diseases	A	59,000	34,400
124	prednisolone *1	tablet	Endocrine disease, collagen disease, allergic diseases	A	757,000	—

note: The columns indicated with thick frame are quantity authorized by Japan.

*1 This has been started to utilize in IMCI.

Table 2-5 Breakdown of distribution of essential drugs

NO	requested items	presen- tation	Chinandega	Leon	Managua	Chontales	Jinotega	Matagalpa	R.A.A.N	R.A.A.S	Pro San Juan	Total	Quantity to be procured
101	benzylpenicillin as sodium	vial	12,258	648	5,400	68,400	27,090	28,710	58,302	19,314	3,312	223,434	224,000
102	procaine benzylpenicillin	vial	162,000	82,800	477,846	72,000	126,000	135,000	45,000	54,000	27,000	1,181,646	1,182,000
103	benzathine benzylpenicillin	vial	24,264	25,650	85,986	13,050	6,966	25,740	8,676	10,188	6,984	207,504	208,000
104	amoxicillin	bottle	10,656	12,978	34,542	8,856	4,446	5,094	3,564	1,890	7,020	89,046	90,000
105	chloramphenicol as sodium succinate	vial	0	18,144	0	3,780	1,530	360	7,164	0	0	30,978	31,000
106	gentamicin as sulfate	ampoule	16,020	3,060	6,534	17,118	7,542	13,608	9,864	2,790	1,944	78,480	79,000
107	sulfamethoxazole+trimethoprim syrup	bottle	72,000	54,000	135,000	45,000	33,984	62,100	33,372	31,500	32,760	499,716	500,000
108	sulfamethoxazole+trimethoprim tablet	tablet	459,594	440,442	1,122,228	297,378	496,116	598,590	39,600	433,116	135,000	4,022,064	4,023,000
109	nystatin	bottle	3,942	3,240	11,574	2,484	1,764	4,824	2,106	2,088	1,386	33,408	34,000
110	albendazole	bottle	6,372	6,876	39,600	7,470	6,300	8,136	8,154	8,154	7,650	98,712	99,000
111	salbutamol syrup	bottle	43,956	44,298	49,860	24,732	15,426	42,606	11,574	15,084	3,528	251,064	252,000
113	salbutamol sulfate inhalation (aerosol)	bottle	1,386	1,656	3,636	1,116	720	2,610	810	324	486	12,744	13,000
115	lactated ringer's solution (Hartman)	bottle or bag	7,200	4,500	9,360	10,800	7,560	12,600	9,000	4,500	4,500	70,020	71,000
117	oral rehydration salts (ORS)	sachet	239,508	153,828	418,824	65,232	175,482	316,998	137,034	91,800	77,958	1,676,664	1,677,000
118	ritodrine hydrochloride	ampoule	540	720	198	684	108	900	900	306	72	4,428	5,000
120	paracetamol (acetaminophen) solution	bottle	67,500	54,846	203,346	29,934	34,758	92,250	35,280	36,630	27,000	581,544	582,000
123	dexamethasone phosphate (as disodium salt) injection	ampoule	36,216	1,098	8,262	4,500	1,044	4,842	2,358	0	144	58,464	59,000
124	prednisolone	tablet	134,766	82,134	247,950	104,220	63,900	42,228	48,510	25,560	7,470	756,738	757,000

Table 2-6 Calculation of quantity of ferrous sulfate

[treatment use for ferrous deficiency]

category	① dosage (drops/day)	② treatment period (day)	③ number of targeted children (coverage*)	④ drops needed (=①×②×③)	⑤ drops per bottle	bottles needed (=④÷⑤)
2 to 3 months old	10	120 (4 months)	2,831 (10%)	3,397,200	600	5,662
4 to 11 months old	20	120 (4 months)	79,279 (70%)	190,269,600	600	317,116
1 to 2 years old	40	120 (4 months)	162,410 (50%)	779,568,000	600	1,299,280
3 to 4 years old	50	120 (4 months)	92,341 (30%)	554,046,000	600	923,410
total	—	—	336,861	—	—	2,545,468

[use for ferrous supplement]

category	① dosage (drops)	② treatment period	③ number of targeted children (coverage*)	④ drops needed (=①×②×③)	⑤ drops per bottle	bottles needed (=④÷⑤)
6 months to 2 years old	15 (daily)	120 (days)	249,638 (100%)	449,348,400	600	748,914
2 to 4 years old	30 (weekly)	20 (weeks)	359,826 (75%)	215,895,600	600	359,826
total	—	—	609,464	—	—	1,108,740

* the rate of population needed to administrate to whole population of each category

Table 2-7 Calculation of quantity of vitamin A (retinol)

[use for vitamin A supplement]

category	① dosage (drops/time)	② dosage times (times)	③ number of targeted children (coverage*)	④ drops needed (=①×②×③)	⑤ drops per bottle	bottles needed (=④÷⑤)
6 to 11 months old	4	2	71,978 (100%)	575,824	600	960
1 to 4 years old	8	2	529,308 (100%)	8,468,928	600	14,115
women in puerperal	8	1	154,598 (80%)	1,236,784	600	2,062
sub-total	—	—	—	—	—	17,137
margin (10%)	—	—	—	—	—	1,714
total	—	5	755,884	—	—	18,851

*1 the rate of population needed to administrate to whole population of each category

*2 Number of drops in a bottle: 30 ml (1 ml = 20 drops), 20 drops × 30 ml = 600 drops

Table 2-8 Nebulizer distribution plan

SILAIS	number of C/S	quantity procured in the 1998 project	projected quantity
Chinandega	15	15	-
Leon	14	-	6
Matagalpa	21	17	-
Nueva Segovia	3	4	-
R.A.A.N	6	-	3
R.A.A.S	7	-	4
Esteli	6	-	3
Jinotega	9	7	-
Rivas	10	-	9
Madriz	9	-	5
Managua	22	-	13
Rio San Juan	7	-	4
Granada	7	-	6
Masaya	10	-	4
Boaco	7	-	-
Carazo	8	-	-
Chontales	14	-	8
total	175	43 (at 4 SILAIS)	65 (at 11 SILAIS)

note1: Hatchings indicate the projected SILAIS for IMCI.

note2: Each 2 stes will be procured for 2 of C/S in Managua, 2 of C/S in Rio San Juan and 1 of C/S in Granada, 5 of C/S in total.

2-3 Basic Design

2-3-1 Design Concept

(1) Specifications and grade of goods supplied

1) Goods related to EPI activity

EPI-related goods supplied under the Project (vaccines, syringes, safety boxes and refrigerators) are required to meet WHO/UNICEF standards.

① Vaccines

For campaigns such as the National Immunization Days, the unit cost of one vial of vaccine containing 10 or 20 doses (multi-dose vial) is low, ensuring efficient immunization. The Project, however, involves routine immunization throughout the year, and if the storage temperature exceeds the permitted range before the multi-dose is used up, it will result in a major loss of vaccine. Mono-dose vaccine will therefore be used in the Project.

As the vaccine must be transported in a controlled temperature ranging from 2~8°C, transportation shall be by air since the travelling time is short and the temperature can be easily controlled.

② Syringes

To prevent blood-borne infection such as HIV, the syringes used for immunization shall be auto-disable syringes recommended by WHO. This type of syringe is made in a way that when the plunger has been pulled out and pushed in, it becomes locked, preventing reuse. As this type was supplied in the 1998 Project, loss through misoperation is not considered as a problem, but it is advisable for the persons concerned to be made aware of this mechanism in advance.

The number of syringes supplied will be the same as the quantity of vaccine including estimated loss. As the vaccine loss rate itself lacks a sound statistical basis, it may be possible to administer all the vaccine supplied. If there is no loss of vaccine and a surplus of syringes arises, they can be used for other vaccines or for immunization the following year and will not be wasted.

③ Safety boxes

The boxes shall have a capacity of 5 liters and be capable of holding 100 syringes.

④ Solar photovoltaic refrigerators

Existing solar refrigerators used in Nicaragua have a storage capacity of 17.5 liters. In view of the fact that the refrigerators will be installed in regions with no electricity and poor access, and allowing for an increase in the types of vaccine used in the future, in order to reduce the burden of transporting the vaccines, the refrigerators shall have a minimum storage capacity of 20 liters. The output of the solar module is calculated on the basis of 3.05 kWh/m² per day in RAAS which has the lowest solar radiation intensity of the project sites.

CFC-free substitute fleon will be used as the refrigerant.

2) Goods related to IMCI activity

① Essential drugs and micronutrients

They shall conform to the composition, dosage forms and contents stipulated in the list of medical equipment. Tablets shall be packed in blister packages*¹¹ for better storage.

Instructions and labels shall be in Spanish.

② Nebulizers

There are two main types of nebulizer, a spray type and an ultrasonic type. The ultrasonic type will be supplied in the Project. This type sprays very small particles of less than 5 microns and has a greater bronchodilatory effect. It was supplied in the Granada Hospital Construction Project carried out with Japanese grant aid cooperation. The nebulizers shall have a capacity of over 30 ml and an inhalation volume of 1~5 ml per spray.

(2) Country of origin of the goods

1) Goods related to EPI activity

① Vaccines

WHO has introduced a pre-qualification scheme for EPI vaccines under which any vaccines

*¹¹ Also known as PTP (Press Trough Package). One sheet contains a specific quantity (usually 10) and the tablets are removed by pressing them out as needed. Merits: hygienic, moisture proof, contents can be checked easily, etc.

supplied by a UN agency must be certified.

Vaccines used in inoculations in Nicaragua have until now been supplied on its own budget through international tender using the PAHO revolving fund. Vaccines that meet WHO standards have therefore been supplied by various countries around the world.

MMR vaccine does not, however, fall under the WHO pre-qualification scheme, so there are no certified manufacturers or products at present. As a result, MMR vaccine shall be supplied by DAC countries due to their procurement record and for the same reasons as those put forward for essential drugs.

On the other hand, pentavalent vaccine was certified by WHO in July 1999, and at present it is made by only one vaccine manufacturer in Belgium. For this reason, it shall be included in the Project on condition that it is offered to several bidders.

② Syringes, safety boxes and solar refrigerators

These items shall meet WHO/UNICEF standards. Syringes (auto-disable type) shall be supplied by the U.S. or Germany, and safety boxes by Germany, Finland, Norway or South Africa.

The solar refrigerator body shall be supplied by U.S. or U.K., and the solar system by Japan, U.S., U.K. or Germany.

2) Goods related to IMCI activity

① Essential drugs

The composition and dosage form of many drugs manufactured and sold in Japan differ from the specifications required in the Project, and even for those items that meet the specifications, there is no competition in terms of cost, with prices varying from a few times to several times more expensive than third country products. Pharmaceutical manufacturers in Japan lack a business strategy that takes into consideration the markets of developing countries, with the result that the instructions and labels are only in Japanese and there are none in Spanish, French, or even English.

There are only two drug manufacturers in Nicaragua that conform with GMP standards*¹², and only one item required for the Project can be supplied by one of these companies.

Procurement from third countries must therefore be considered. There are many low-priced drugs manufactured in Mexico, India and China, but many are also reported to have poor quality and the specified quality is not assured.

From the viewpoint of quality assurance, supplies shall therefore be obtained from DAC countries where GMP standards are properly observed.

② Nebulizers

Nebulizers that meet the specifications are produced by two or more Japanese manufacturers and shall be supplied by Japan.

*¹² Standards relating to drug manufacture and quality control. Starting from receipt of raw materials, facilities, equipment and environment suited to each manufacturing process must be maintained, and production control and quality control carried out.

2-3-2 Result of Basic Design Study

(1) Goods related to EPI activity

Table 2-9 Goods related to EPI activity

NO	items	major specifications	unit	purpose	quantity
10	pentavalent vaccine	mono dose	dose	immunization for diphtheria, tetanus, pertussis, hepatitis B and haemophilus influenza	150,000
11	MMR vaccine	mono dose	dose	immunization for measles, mumps and rubella	182,000
12	autodisable syringe	0.5 ml, 23Gx25mm	pieces	administration of above-mentioned vaccine	332,000
13	safety box	5 liters	boxes	disposal for above-mentioned contaminated syringes and needles	3,400
14	solar refrigerator system	DC 12V, vaccine storage capacity: no less than 30 liters	sets	vaccine storage at the area without electricity	34

(2) Goods related to IMCI activity

Table 2-10 Goods related to IMCI activity

NO	items to be procured	剤形	composition/ concentration	presentation	indications	contents	quantity
101	benzylpenicillin as sodium	powder for injection	1.0 MIU	vial	Pneumonia, bacteria-borne diseases	-	224,000
102	procaine benzylpenicillin	powder for injection	0.8 MIU	vial	Pneumonia, bacteria-borne diseases (containing soothing agents)	-	1,182,000
103	benzathine benzylpenicillin	powder for injection	1.2 MIU	vial	Pneumonia, bacteria-borne diseases, syphilis	-	208,000
104	amoxicillin	powder for oral suspension	250 mg / 5 ml	bottle	Pneumonia, bronchitis, other infectious diseases	100 ~ 120 ml	90,000
105	chloramphenicol as sodium succinate	powder for injection	1 g / vial	vial	Meningitis, typhoid, serious infectious diseases	-	31,000
106	gentamicin as sulfate	solution for injection	20 mg / 2 ml	ampoule	Septicemia, peritonitis	2 ml	79,000
107	sulfamethoxazole + trimethoprim syrup	syrup	200 mg + 40 mg / 5 ml	bottle	Pneumonia, dysentery, typhoid, urinary tract infections	100 ~ 120 ml	500,000
108	sulfamethoxazole + trimethoprim tablet	tablet	400 mg + 80 mg	tablet		ブリストア	4,023,000
109	nystatin	oral suspension	100,000 IU	bottle	Gastrointestinal candidiasis	30 ~ 60 ml	34,000
110	albendazole	oral suspension	100 mg / 5 ml	bottle	Hydatid diseases	10 ~ 20 ml	99,000
111	salbutamol syrup	syrup	2 mg / 5 ml	bottle	Bronchial asthma, bronchitis (for internal use)	100 ~ 150 ml	252,000
113	salbutamol respirator solution	respirator solution	5 mg / ml	bottle	Bronchial asthma, bronchitis (for inhalation)	20 ml	13,000
116	lactated ringer's solution (Hartman)	solution for infusion	NaCl 0.6%, KCl 0.03%, CaCl ₂ 0.02%, NaHCO ₃ 0.31%	bottle or bag	Supply and correction of extracellular fluid	1,000 ml	71,000
117	oral rehydration salts (ORS)	powder for oral suspension	27.9 g / 1,000 ml	sachet	Water and electrolyte supply in event of diarrhoea or dehydration	-	1,677,000
118	ritodrine chloride	solution for injection	10 mg / ml	ampoule	Imminent premature delivery or miscarriage	5 ml	5,000
120	paracetamol (acetaminophen) solution	solution	100 mg / ml	bottle	Anti-inflammatory alleviation of fever, pharyngitis	15 ml	582,000
123	dexamethasone injection (as sodium phosphate)	solution for injection	4 mg / 2ml	ampoule	Lung disease, allergic diseases	2 ml	59,000
124	prednisolone*1	tablet	5 mg	tablet	Endocrine disease, collagen disease, allergic diseases	blister	757,000
125	ferrous sulfate	oral suspension	15 mg / 0.6 ml	bottle	ferrous deficient anemia	30 ml	3,655,000
126	vitamin A (retinol)	oral suspension	25,000 IU / drop (1 ml = 20 drops)	bottle	prevention and treatment for vitamin A deficient disease (nyctalopia, conjunctival xerosis)	30 ml	19,000
200	nebulizer	-	ultrasonic	-	inhalng anti-asthmatic drugs (salbutamol)	-	65

* IU is an abbreviation of International Unit. MIU is million IU. IU means weight unit which is arranged in order to indicate active moiety as international standard.

Chapter 3 Implementation Plan

3-1 Implementation Schedule

3-1-1 Implementation schedule

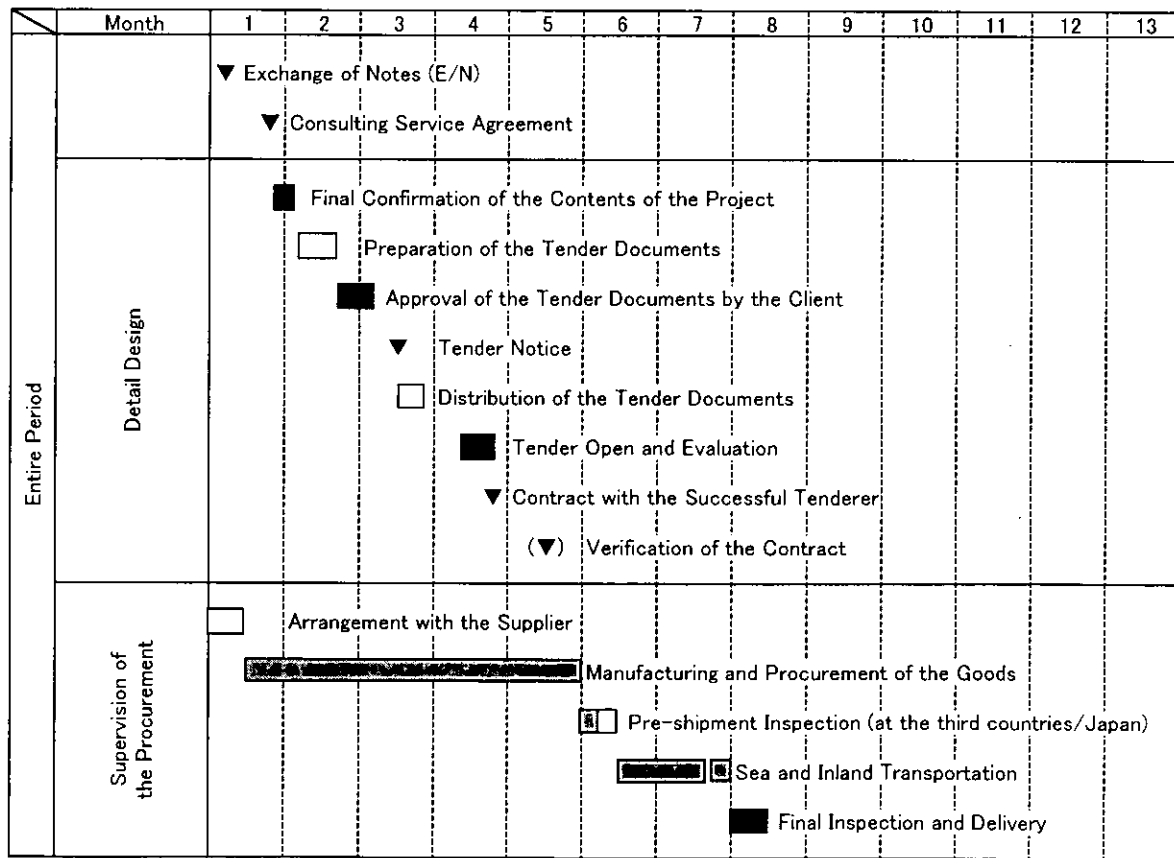
Budgetary year: Single year (F/Y 2000)

Work schedule:

Entire work period (from E/N to delivery): 12.0 months

From E/N to contract with supplier: 4.5 months

Delivery (from contract with supplier to delivery): 7.5 months



the Work in the Recipient country
 the Work in Japan
 the Works in the third countries

3-1-2 Obligations of recipient country

The obligations of Nicaragua in the implementation of the Project are as follows.

- (1) To ensure all the expenses and prompt execution for unloading, customs clearance at the port of disembarkation and internal transportation of the products purchased under the Grant Aid.
- (2) To exempt Japanese nationals from customs duties, internal taxes, and other fiscal levies which will be imposed in the recipient country with respect to the supply of the products and services under the Verified Contracts.
- (3) To accord Japanese nationals whose services may be required in connection with the supply of the products and services under the Verified contracts, such facilities as may be necessary for their entry into the recipient country and stay therein for the performance of their work.
- (4) "Proper Use"

The recipient country is required to maintain and use the facilities constructed and the equipment purchased under the Grant Aid properly and effectively and to assign the necessary staff for operation and maintenance of them as well as to bear all the expenses other than those covered by the Grant Aid.

- (5) "Re-export"

The products purchased under the Grant Aid should not be re-exported from the recipient country.

- (6) Banking Arrangement (B/A)

- a) The Government of the recipient country or its designated authority should open an account in the name of the Government of the recipient country in a bank of Japan (hereinafter referred to as "the Bank"). The Government of Japan will execute the Grant Aid by making payment in Japanese yen to cover the obligations incurred by the Government of the recipient country or its designated authority under the Verified Contracts.
- b) The payments will be made when payment requests are presented by the Bank to the Government of Japan under an authorization to pay issued by the Government of the recipient country or its designated authority.

(7) Obligations of the recipient country specific to this Project

a) Solar photovoltaic refrigeration systems

1) Installation of equipment according to the distribution plan

b) Vaccines and essential drugs

1) Appropriate distribution based on drug distribution plan

2) Reliable procurement of Nicaragua and PAHO's share of pentavalent vaccines

3) Report to Japanese government through JICA Nicaraguan office every 3 months on state of distribution after delivery

3-2 Project Cost Estimation

Nicaragua shall not be liable for any incidental capital.

3-3 Operation and Maintenance Plan

Of the equipment to be procured for the Project, only the solar photovoltaic refrigeration system requires maintenance. Nicaragua has already introduced 46 such systems with USAID aid. Installation was carried out by MINSA itself and to date the refrigerators are working without breakdown. A full-time cold chain engineer has been appointed in about half of the SILAIS to carry out maintenance. In places where there is no full-time engineer, 4 centrally based engineers make regular visits. Health workers are trained in temperature control and maintenance of the refrigerators with PAHO aid, and Nicaragua's cold chain and maintenance system is highly regarded outside the country.

Chapter 4 Project Evaluation and Recommendation

4-1 Project Effect

(1) Verification of appropriateness

1) Items and quantities

① Solar photovoltaic refrigerators

15% of the health facilities with no refrigerators are distributed in the north and on the Atlantic side of Nicaragua. As these regions not only lack electricity but are not easily accessible and fuel transportation is difficult, gas or kerosene refrigerators cannot be used. In these regions, the immunization teams must carry vaccine in vaccine carriers from the nearest health facilities and assemble people in a centrally located village for vaccination every 3~6 months.

Vaccine, however, can only be kept cool reliably in a vaccine carrier for 72 hours, and immunization is less than complete in places that cannot be reached in that time. The immunization rate in such regions is less than 30%, far behind the 90% of other regions.

Through implementation of the 1998 Project and the Project, a total of 139 solar photovoltaic refrigeration systems have been installed in these regions, leading to major improvement in the immunization coverage rate in isolated districts and contributing to close on 100% immunization.

② Essential drugs (including micronutrients)

The essential drugs including micronutrients were selected on the basis of a list of essential drugs drawn up by MINSA. The list contains items such as antibiotics, insect repellent, antipyretics, painkillers, bronchodilators, uterine contraction reductant, parenteral fluid, oral fluid replacement, water for injections and micronutrients (ferrous and vitamin A). All of these are essential drugs for which there is great demand and the contents of the list conform to the concept of the Project.

③ Nebulizers

As a follow-up to the 1998 Project, nebulizers will be supplied to health centers which do not have them, regardless of the fact that many children suffer from acute allergic respiratory

diseases. One nebulizer per health center is not sufficient, and in order to reduce patients' waiting time, many places need one more. By supplying nebulizers to 60 health centers through the Project, patients will be able to receive prompt treatment at their local health center.

(2) Beneficial effects

1) Direct effects

Immunization activities will be reinforced by the supply of EPI-related goods, including in isolated regions with no electricity and lacking a cold chain system, and the high immunization coverage rate in Nicaragua will be maintained. At the same time, the main infectious diseases will be prevented among children by means of vaccination, thereby contributing to eradication of measles and neonatal tetanus. In addition, secondary infection will be prevented, including among health workers, by use of auto-disable syringes. Pentavalent vaccine will directly benefit 169,884 children under the age of one nationwide and MMR vaccine 164,745 one-year-olds nationwide, and the current immunization coverage rate of DTP 86% and measles 99% (as of 1998) can be further improved with a target of 100%.

The supply of essential drugs and other IMCI-related goods will contribute to treatment of the principal children's diseases, such as acute respiratory disease and diarrhea, and to a lower mortality rate in the 9 target SILAIS. It can improve the health condition of women and contribute to overall disease control among mothers and children. The supply of nebulizers will enable children suffering from allergic respiratory disease in the target regions (11 SILAIS, 60 health centers) to be treated. It will directly benefit 695,323 infants, or 73% of the infants in the country, with the aim of bringing the infant mortality rate (44, as of 1996) down to 30.

2) Indirect effects

By implementing EPI through grant aid cooperation, pre-school children will obtain immunity against the infectious diseases targeted by immunization, and children will be prevented from infecting their families when the diseases become prevalent in schools, etc. If a woman in the early months of pregnancy catches rubella, there is a high risk of the fetus contracting congenital rubella syndrome which brings with it the risk of miscarriage or handicap. EPI will

contribute greatly to preventing this situation.

Cooperation on IMCI will relieve the financial burden on MINSA in its aim to develop a nationwide IMCI program, and will facilitate expansion of the program to the remaining 8 SILAIS which are not included in the Project.

As acute respiratory infectious diseases can be tackled at regional level, by equipping primary level facilities with nebulizers, inquiries and referrals to secondary level hospitals are reduced and consequently relieving their burden of patients. The risk of secondary infection in hospitals will also be reduced, freeing hospitals to concentrate on medicine of a higher order.

The Project will indirectly benefit at least 950,924 infants nationwide, and the infant mortality rate can be expected to fall from its current level of 57 to around the Central American average of 43.

4-2 Recommendation

Under the 1998 Project, Nicaragua monitors consumption of expendable supplies, such as drugs, every quarter. In addition, major significance is placed on analysis of immunization coverage rates, the number of persons infected with the diseases targeted by immunization, the number of infant with a disease and the cause, and the mortality rate, by SILAIS, and on grasping the effectiveness of the aid. Similar monitoring is also considered to be necessary under this Project.

[Appendices]

1. Member of the Study Team

Equipment Planning

SUGAWARA Toshio

General Grant Aid Division,

Grant Aid Management Department,

Japan International Cooperation System

2. Survey Schedule

No.	Date	Day of the week	Activities	Where to stay
1	December 12	Sunday	Tokyo 11:00 (NH010) → New York 9:15	New York
2	December 13	Monday	New York 13:29 (CO1977) → Houston 16:21 17:35 (CO1263) → Managua 20:43	Managua
3	December 14	Tuesday	8:30 Courtesy call to JICA office 14:00 Discussion with the Ministry of Health of Nicaragua 16:00 Courtesy call to Embassy of Japan and discussion	Managua
4	December 15	Wednesday	(AM) Examination of the answers to the questionnaire (PM) Discussion with the Ministry of Health	Managua
5	December 16	Thursday	(AM) Examination of the answers to the questionnaire (PM) Discussion with the Ministry of Health 18:00 Report to Embassy of Japan and JICA	Managua
6	December 17	Friday	Managua 8:45 (CO1262) → Houston 12:05 13:10 (CO1970) → New York 17:29	New York
7	December 18	Saturday	New York 11:00(NH009) →	on the plane
8	December 19	Sunday	→Tokyo 14:50	

List of Party Concerned in the Recipient Country

1. Japanese Embassy in Nicaragua

Masaru Ito: Ambassador extraordinary and plenipotentiary

Yasuhisa Suzuki: Councilor

Satoshi Uematsu: Secretary

2. JICA Nicaragua Office

Kozaburo Yonezawa: Resident Representative

Minoru Arimoto: JICA expert

3. Ministry of Health

Annamaria Cerulli: Chief Advisor of General Division of Foreign Cooperation

Mario Ortiz: Staff of General Division of Foreign Cooperation

Omar Malespin: Staff of Expanded Program on Immunization (EPI)

Edgard Narvaez: Staff of Department of Pharmaceutical Products Procurement