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THE INTEGRATION OF HEPATITIS B IMMUNIZATION INTO EPI IN THE PHILIPPINES

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Resources for Child Health Project

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The Integration of Hepatitis B Immunization into EPI in the Philippines

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LIST OF ACRONYMS

BCG	Bacillus of Calmette and Guerin vaccine
BHS	Barangay Health Station
BHW	Barangay Health Worker
DOH	Department of Health
DPT	Diphtheria-pertussis-tetanus toxoid vaccine
EPI	Expanded Program on Immunization
FIC	Fully Immunized Child
FHSIS	Field Health Service Information System
HB	Hepatitis B
HBeAg	Hepatitis B "e" antigen
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B Virus
HIS	Health Intelligence Service
HMDTS	Health Manpower and Development Training Services
IEC	Information, education, and communication
MCH	Maternal and Child Health
MCHS	Maternal and Child Health Services
NGO	Non-Governmental Organizations
OPV	Oral Polio Vaccine
PATH	Program for Appropriate Technology in Health
PHC	Primary hepatocellular carcinoma
PIHES	Public Information and Health Education Services
REACH	Resources for Child Health Project
RHU	Rural Health Unit
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization
WPRO	Western Pacific Regional Office of WHO

I. EXECUTIVE SUMMARY

The Maternal and Child Health Service (MCHS) of the Department of Health (DOH), Government of the Philippines, requested that USAID/Manila provide a team of consultants to assist with planning for national integration of hepatitis B vaccine into the government's EPI. The Resources for Child Health Project (REACH) provided a four-person team which included two REACH staff members and two staff from the Program for Appropriate Technology in Health (PATH), a sub-contractor on the REACH Project. The team leader was from PATH and serves as Executive Director of the International Task Force for Hepatitis B Immunization. The team arrived in Manila on August 19, 1990 and stayed until August 31. They made field trips to Regions III and VII. The team met with staff at all levels of the DOH and with the World Health Organization (WHO). At the end of the consultancy they held debriefing meetings with Secretary Bengzon, other DOH staff, and USAID.

Hepatitis B is hyperendemic in the Philippines. The only means to achieve significant control and prevention is through integration of hepatitis B immunization into the EPI.

Working closely with EPI staff of the DOH, the team looked at all aspects of the current immunization program. They found that coverage levels for all vaccines were high, that staff were motivated and competent, and that integration of the new vaccine had a high probability of success. Based on experiences introducing hepatitis B vaccine elsewhere, the team raised a number of issues for discussion including appropriate vaccine specifications and procurement, effective delivery strategies, requirements for the cold chain and vaccine logistics, training programs, and public information, education, and communication approaches.

The result of the discussions and observations were the following recommendations as stated in Section V. of this report:

1) **General Considerations:** The integration of hepatitis B vaccination into the EPI in the Philippines constitutes the most feasible method to reduce the incidence of chronic carriage of hepatitis B and its sequelae. The existing EPI in the Philippines is performing at an extremely high level and is capable of absorbing an additional antigen into its delivery services. With proper planning, this can be accomplished with a minimum of disruption to the health services. All infants in the Philippines should be vaccinated as early in life as possible with three doses of hepatitis B vaccine as part of EPI. The minimum interval between each dose is four weeks.

2) **Delivery Strategies:** Hepatitis B vaccination at scheduled EPI sessions in fixed facilities and as part of outreach services is the most immediate and feasible strategy for quickly raising hepatitis B vaccination coverage.

3) **Target Groups and Vaccine Requirements:** In order to calculate vaccine requirements for the first year of hepatitis B introduction, the DOH will need to decide whether all infants alive at the time of hepatitis B vaccination start-up are eligible to begin the three dose series, or if immunization should be limited to babies born after the launch.

A pragmatic and epidemiologically sound compromise which should be considered for the first year is to limit the first dose of hepatitis B to infants less than three months old.

4) **Phase In:** Clear guidelines for phased implementation need to be developed. It may be politic to start up in each region. But within regions, selections will still need to be made according to some neutral and objective criteria.

5) **Vial Size:** Both single- and multiple-dose hepatitis B vials will be needed. Available information suggests that about 10% of all needed doses should be supplied in single-dose vials, and the remaining 90% should be supplied in 10-dose vials. While single dose vials are particularly useful in giving the first dose, either at home or in smaller hospitals, subsequent doses will be given at scheduled EPI sessions where multiple dose vials are preferred because many infants will be vaccinated per session.

6) **Storage and Shipping Volumes:** Storage volumes (vial + packet containing the vial + any other packaging) per dose for hepatitis B must be specified on tenders. Storage volumes should be no more than 10 cm^3 per dose for single-dose vials and 3 cm^3 per dose for 10-dose vials.

7) **Cold Chain and Vaccine Logistics:** Required and available storage at all levels of the cold chain, and capabilities for making and storing ice for cold boxes, must be assessed and re-analyzed at all levels. The analysis should be based on the models in Tables 5 and 6 and take into consideration a <u>50% increase in total storage volume</u> due to introduction of hepatitis B vaccine, as well as the size of the population actually supplied and the exact frequency of re-supply. These calculations are especially important at district level. The Alabang Laboratories authorities need to be included in discussions regarding the introduction of hepatitis B vaccine so that they can be prepared for a projected 50% increase in air shipping costs.

Increases in vaccine volume, ice, and shipping cartons will add to the cost of vaccine shipments at various levels. Additional or more frequent supply trips may be required in some areas, depending on existing cold chain equipment and on the type of conveyance being used. At some levels, shipment schedules may need to be staggered to allow sufficient ice to be made and stored between each shipment.

8) **Vaccine Packaging:** The number of vials to be packaged together should also be included in specifications for tenders. Hepatitis B multiple-dose vials should be supplied with 10 vials to the packet and 10 packets to the box (total 100 vials per box) for ease of storage and handling at all levels of the cold chain.

9) **Vaccine Inventory and Ordering:** If hepatitis B vaccine will be ordered in both single-dose and 10-dose vials, it will be essential that stock balances of each kind of vial be kept and stored separately to avoid confusion.

10) **Freezing of Vaccine:** Because hepatitis B vaccine is inactivated by freezing, it is important that icepacks be allowed to sit at room temperature for 5-10 minutes prior to use in vaccine carriers and cold boxes.

11) **Vaccine Security:** As the current market price for hepatitis B vaccine is $10 per dose, it is crucial that government vaccine supplies be securely stored. There will be great temptation to divert the vaccine for use in the private sector. Vaccine tenders should specify that vials are labelled "Pediatric Dose" and "Property of the Department of Health" to discourage pilferage.

12) **Vaccine Labeling:** Vaccine should be labeled as property of the DOH and for pediatric use only. Package and carton inserts should give recommendations related to pediatric use only, with dosage and intervals between doses specified according to recommendations for use in the Philippines EPI.

13) **Quantity of Syringes and Needles Required:** Approximately 25% more disposable syringes and needles than in 1990 will be needed during the first year of hepatitis B introduction. The incremental requirement for 1991 due to hepatitis B vaccine is 2.3 million syringes and needles, assuming disposables will be used exclusively. As hepatitis B vaccinations reach 90% coverage in the following years, approximately 50% more disposable syringes and needles than in 1990 will be required. As steam sterilization becomes more common, supplies of reusable syringes and needles must be replaced more frequently. Future orders of steam sterilizers need to specify larger sizes with more racks.

14) **Monitoring:** The DOH may like to monitor the specified indicators by province or district on a quarterly basis to identify any problems related to startup. Serological surveys may be chosen to monitor program impact.

15) **Reporting:** All the forms used by EPI will need to be reviewed and many will require revision to include information about hepatitis B.

16) **Hepatitis B Vaccine Specifications and Procurement:** A number of hepatitis B vaccines are currently licensed in the Philippines. However, none of them are packaged appropriately for the new program. Because the Philippines is pioneering mass immunization of infants, and because the potential market in the Philippines for the vaccine is so large, manufacturers will be motivated to supply

their vaccines according to specifications laid down by the DOH. The Philippines is in position to play a key role in formulating specifications for hepatitis B vaccine which meet their own requirements and set the standard for EPI globally.

Vaccine should be procured by official tender and bid process, and all manufacturers currently licensed to sell hepatitis B vaccine in the Philippines should be invited to bid. If procurement regulations permit, international tender and bid is preferable to local tender and bid, because this mechanism will ensure that vaccine meeting all necessary specifications can be procured in the shortest period of time and at the lowest cost. This, in turn, would allow larger numbers of infants to be immunized within a given budget than would be possible under conditions of local tender and bid. Sample specifications appear in section IV, part R of this report.

17) **Health Staff Training and Public IEC Programs:** During the first year of hepatitis B introduction, the DOH should concentrate on training/informing their staff nationwide about the disease and the vaccine. Training programs should include all levels of staff and volunteers, from administrators in Manila to barangay health workers. Public information programs using mass media may be needed to respond to misinformation during the first year.

Immediate action should be taken to update the EPI Manual and the Household Teaching Guide with hepatitis B information. A short EPI Manual supplement on hepatitis B was created during the consultancy and is included as Annex 4 of this report. It could be sent with the next issue of the EPI newsletter. The supplement could also be adapted for insertion into copies of the Household Teaching Manual prior to distribution.

As soon as possible, resources (financial, personnel, technical assistance) should be identified to assist with systematic planning of training and IEC programs. Needs assessments, including audience research, are required to create a comprehensive training and IEC strategy.

Every opportunity should be used to inform DOH staff about the new hepatitis B program (see the training opportunities list in Section IV., Part S). Activities will have to be coordinated between EPI, PIHES, and HMDTS.

After DOH staff have been well-informed about the program, consider planning and implementing appropriate public information activities. Ideas for IEC activities are also included in Section IV., Part S of this report.

II. INTRODUCTION

In June, 1990, the Maternal and Child Health Service (MCHS) of the Department of Health (DOH), Government of Philippines, contacted the International Task Force on Hepatitis B Immunization for technical assistance with introduction of hepatitis B vaccine into the national Expanded Program on Immunization (EPI). A team of specialists in hepatitis B control, vaccine logistics, communication, and training were requested.

USAID/Manila requested that the Resources for Child Health Project (REACH) support the mission through the USAID "buy-in" to REACH. The purpose of this consultancy was for the REACH team to:

1) collaborate with the DOH, WHO, and other appropriate organizations in the development of a detailed implementation plan for integrating hepatitis B immunization into EPI in the Philippines;

2) provide technical assistance in the planning and development of a national information, education, communication (IEC) and training strategy for hepatitis B vaccination;

3) evaluate options for procuring hepatitis B vaccine including local production;

4) assess cold chain and logistics requirements and related operational issues involved in the introduction and integration of hepatitis B into EPI; and

5) determine the appropriate use of service statistics and indicators for this effort.

The team members included, as team leader, Dr. James Maynard, International Task Force on Hepatitis B Immunization and an employee of the Program for Appropriate Technology in Health (PATH); Mr. Robert Steinglass, REACH; and Mr. Scott Wittet, also of PATH. PATH is a sub-contractor on the REACH Project. Mr. Alasdair Wylie, the REACH resident technical advisor in Manila, was also an active team member. The team collaborated closely with Dr. Elvira Dayrit, Director of MCHS, Dr. M. Costales, EPI Manager, and their associated staff throughout the consultancy.

Two field visits were made during the two-week visit. A day was spent in Bulacan, near Manila, and another was spent on the island of Cebu. The team discussed hepatitis B introduction with many DOH staff at the central, provincial, regional, municipal, and barangay levels. They also met with WHO and with staff at the Alabang Laboratories.

Final debriefings were held with Honorable Secretary Dr. A. Bengzon, Dr. M. Roxas, Mr. M. Taguiwalo, Mr. R. Gamboa, Dr. E. Dayrit, and Dr. E. Voulgaropoulos and Ms. P. Moser of USAID. The team would like to thank all of the people mentioned above, and other DOH staff, for their kind support, assistance, and hospitality. A complete list of persons contacted appears in Annex 1.

III. SITUATION ANALYSIS

A. BACKGROUND

The Philippines is an archipelago consisting of some 7,100 islands in the Pacific Ocean lying off the coast of China and stretching some 17,000 kilometers from the Celebes Sea in the South to the South China sea in the North. The country lies in proximity to the equator and has a tropical climate. Three major island groups - Luzon, Visayas, and Mindanao - dominate the geography of the country, which is predominantly rural in nature. Approximately 2 percent of the land is classified as urbanized, with 35 percent of the land under cultivation and the rest lying as forest and open land.

The population of the country numbers 60 million people according to the 1990 census. The ethnic background of the people is mixed, mainly Malay, Chinese, and Arabic. One-quarter of the population lives in the urban area of metro Manila, comprising 4 cities and 13 municipalities. Another 15 percent of the population resides in urban centers outside of Metro manila, of which Cebu in the Visayas island group is the largest. Sixty percent of the population lives in rural areas.

Since the revolution of 1986 the Philippines has been under the administration of a democratically elected government headed by President Corazon Aquino. The administrative structure of the national government closely parallels the US model and there is a bicameral legislature consisting of a senate and house of representatives. The national infrastructure is subdivided into 14 administrative regions. Local government is vested in 75 provinces.

The Philippines shares many of the problems of the developing world. Crude birth rates remain high and decreased only moderately from 39/1000 population in 1970 to 32/1000 population in 1985. Infant mortality rates remain high, declining from 82/1000 live births in 1970 to 57/1000 live births in 1985. The period of the 1970s and 1980s has been economically difficult for the Philippines. Early economic growth in the 1970s was slowed by a decline in economic productivity, which in 1985 witnessed GNP returning to the 1975 level. Nonetheless, the Philippine government, particularly in the health sector, is extending the levels of access of its citizens to adequate services.

B. THE HEPATITIS B PROBLEM IN THE PHILIPPINES

The Philippines Department of Health (DOH) has stated its intention to launch a national program to integrate hepatitis B immunization into EPI in 1991. Preparatory efforts are underway including the request of 65 million pesos (US$ 2.6 million) for procurement of vaccine. An Operational Plan and Implementing Guidelines have been drafted by the Government.

Hepatitis B is highly endemic in the Philippines. Community-based serological surveys in rural populations show an average carrier rate for the hepatitis B virus of 12 percent[1]. In volunteer blood donors this rate is 13 percent. Thus, there are over seven million Filipinos who are now carrying the hepatitis B virus in their blood. Of these, approximately two million will die from one of the primary sequelae of this infection, cirrhosis, or primary hepatocellular carcinoma (PHC). Indeed, PHC is the most common cause of cancer mortality in Filipino males and is second only to lung cancer overall[2].

Transmission of hepatitis B in the Philippines is largely a problem of early childhood. The majority of infections occur before the age of six and these are responsible for the great majority of chronic carriers. Because of the relatively low frequency of high level virus carriage (HBeAg positivity) among chronic carrier mothers, the relative contribution of perinatal transmission (transmission from the carrier mother to the baby during birth) to the overall carrier rate in the Philippines is low. It may be inferred that no more than 15 percent of the chronic carriers in the population result from perinatal transmission, with another 5 to 10 percent induced by infection in adulthood. **Therefore 75 to 80 percent of the carriers in the population result from infection by horizontal transmission (typically from child to child or mother to child) occurring between the ages of three months and five years. Any national immunization program in the Philippines aimed at significantly reducing the pool of future chronic carriers must be aimed at infants as early as possible after birth.**

C. HEALTH CARE ORGANIZATION

At the national level, health services are provided by a Department of Health (DOH) headed by a Secretary of Health, Dr. Alfredo Bengzon. The Secretary is served by a group of five Under Secretaries, including four Under Secretaries who head programmatic offices and one Under Secretary who serves as Chief of Staff, Mr. M. Taguiwalo. Responsibility for health care planning, public information and education, and health intelligence resides with the Chief of Staff. The four programmatic offices are the Public Health Service, Hospital and Facilities Service, Standards and Regulation Service, and Management Services. Responsibility for communicable disease control and maternal and child health resides within the Public Health Service Office. Responsibility for the Expanded Program on Immunization resides within the Division of Maternal and Child Health Services headed by Dr. Elvira Dayrit who is responsible to Undersecretary Dr. Manuel Roxas. Functions related to vaccine procurement, biologicals production, health manpower development and training

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[1] Domingo, E.O., A.L. Lingao, M.A. Langson, et al. "Hepatitis B Infection in the Philippines: Epidemiology and Prospects for Control." Asean J. Clin Sciences, Monograph No. 11, 81-86, 1990.

[2] Lingao, A.L. "The Relationship of Hepatocellular Carcinoma and Liver Cirrhosis to Hepatitis B Infection in the Philippines." Gastoenterol Jpn, 4:425-433, 1989.

reside in the Office for Management Services headed by Undersecretary Rhais Gamboa. Vaccine procurement is the responsibility of Attorney N. Tayao. Biologicals production takes place at the Alabang Laboratories located in the suburbs of Manila and under the direction of Dr. B. Mora.

The activities of the DOH are distributed within 14 Regional Health Offices, each headed by a Regional Director. Within the 14 Regions there are 75 Provincial Offices of Health, each headed by a health officer with two assistants, one responsible for hospital services and another for public health. Within each Province there are several Districts, usually represented by a district hospital headed by a surgeon or obstetrician. This individual with relevant staff is responsible for a series of rural or municipal health units (RHU), headed by a rural health physician, a dentist, one or more trained midwives, and a sanitarian. The RHUs do not usually have hospital beds. There are approximately 3,000 RHUs in the Philippines. On average, each RHU serves a population of 20,000 to 30,000 people. Each RHU is responsible for several barangay health stations (BHS). These health stations exist at the village level and serve populations of about 3,000 to 5,000 people. The BHS is usually staffed by a trained midwife who is assisted by a group of volunteer barangay health workers (BHW). Each health worker is given responsibility for health activities including maintaining demographic information for 20 families. The health infrastructure in cities is similarly organized, with responsibility for health under a city health officer and assistant health officer paid by the DOH. Other city health office employees are paid by the city government. The equivalents of District hospitals exist within the city, and they exercise responsibility over municipal health units, which in turn administer urban barangay health units.

D. MATERNAL AND CHILD HEALTH (MCH) SERVICES

MCH services are provided at all levels of the health care infrastructure from the Provincial, City, and District hospitals down to the RHU and BHS level. However the vast majority of pre-natal, post-natal, and well baby services are provided at the RHU level and below, reflecting the essentially rural and home-based nature of these services in the Philippines.

With a crude birth rate of 3.2 percent, there are approximately 2 million births per year in the country. Approximately 75 percent of deliveries take place at home. Of these 36 percent are attended by DOH midwives, 36 percent by traditional birth attendants (hilots), and the rest by others (usually privately trained midwives). Of the 25 percent of births that take place in hospitals, the proportion that take place in DOH vs. private hospitals or maternities varies greatly according to socioeconomic conditions and level of private practice of medicine in the communities served.

The Philippines does not have a health policy of encouraging hospital deliveries. A DOH goal is to provide domiciliary MCH services, including immunization after the home birth. The implication of this fact relates clearly to the earliest time after birth when hepatitis B immunization can be performed. In order for vaccines and other MCH services to be delivered at or near birth, a mechanism must be found to access

mothers and their infants in the home within the first few days after birth. The government is committed to the eventual replacement of hilots with trained DOH midwives. This bodes well for delivery of services, such as immunizations, that can be performed by these midwives in the home, either at the time of delivery, or at post-natal visits.

Approximately 65 percent of pregnant women in the Philippines receive some form of prenatal care from the DOH and 47 percent of women receive some post-natal care. DOH midwives are supposed to make three postnatal visits to the home, the first within 48 hours of birth, and the second and third within the second and third weeks following birth. Well-baby services are delivered statically at BHS and RHUs as well as at district and provincial hospitals.

E. STAFF TRAINING AND PUBLIC INFORMATION, EDUCATION, AND COMMUNICATION (IEC)

Responsibility for DOH staff training rests at several levels. Most initial staff training is organized by the Health Manpower and Development Training Service (HMDTS). The HMDTS works closely with national and regional resource persons (clinicians, midwives, health educators, etc.) to plan and implement training programs. Some in-service training is organized by the DOH itself. Other staff training opportunities exist at regular, national, provincial, or regional staff meetings, weekly clinical management training, or consultative meetings.

IEC activities are also carried out at all levels. Health educators are placed in central, provincial, and regional DOH offices to provide support to the RHUs and barangay health stations. At the grassroots level, it is the midwives and barangay health workers who provide the interpersonal IEC. Radio and TV messages about health are frequently broadcast. Since literacy is high in the Philippines, newspapers, magazines, brochures, and comics are common sources of health information, even in rural areas.

A high-visibility, well-planned, immunization marketing campaign is now expanding in the Philippines. Begun as an urban-centered project, it is being conducted nationwide. The TV spots, banners, and other IEC products of the campaign should contribute to a stronger EPI.

Non-governmental organizations (NGOs) are also important health service providers in the Philippines. In order to implement a national hepatitis B program, their staff must also be well-informed about the disease, the vaccine, and its relation to the rest of EPI. NGO fieldworkers will need to become effective interpersonal communicators.

F. EPI IN THE PHILIPPINES

The EPI in the Philippines was officially launched in 1976 with the administration of BCG to school entrants. By 1979, BCG and DPT were administered nationwide and oral polio immunization was initiated in areas reporting polio outbreaks. By 1980, OPV for infants and tetanus toxoid for pregnant women were being administered nationwide. In 1982, measles immunization was introduced in selected areas and in 1983 the 6 EPI antigens became available to all infants nationwide.

Overall EPI performance has improved markedly since the inception of the program. According to routine service statistics, by 1985 BCG coverage had increased to 67 percent, DPT 3 and OPV 3 to 52 and 54 percent respectively, and measles to 49 percent. In 1989, nationwide coverage surveys revealed that BCG coverage of infants had reached 96 percent, DPT3/OPV3 85 percent; and measles 83 percent. These are among the highest EPI coverage rates to be found in the developing world and a testimony to the perseverance and dedication of DOH and city health staff.

Coverage surveys usually report immunization completeness during a period of time, most often by the end of the first year of life. Scheduling recommendations in the Philippines call for administration of BCG at birth or any time after birth; DPT and OPV at 6 weeks, with second and third doses at monthly intervals thereafter. Measles is recommended to be given at 9 months. In fact, very little vaccine is given at birth in the Philippines, even to babies born in DOH hospitals. The vaccine (BCG) which could be given to babies before discharge from maternity wards is often not given then. The reasons stated for this low early coverage are that too few babies are born in a 24 hour period to warrant the opening of a 20-dose ampoule of BCG, responsibility for BCG storage and administration is not conveniently located near the maternity ward, and hospital staff prefer that the mother register with her local health facility in the interest of better record-keeping.

The vast majority of EPI immunizations are given at fixed immunization sites, either at the RHU or BHS levels. At most RHUs and at many BHSs, vaccines are administered on at least one day of the week (usually Wednesday), though at some BHSs vaccines are administered on one day each month. **Any attempt to administer the first dose of hepatitis B vaccine at or near birth would require the creation of new outreach mechanisms for babies within the first several days of birth.**

In the Philippines a variety of trained DOH staff perform vaccinations. In addition to doctors and nurses in hospital, midwives at the RHU and BHS levels also administer vaccines, including BCG. This capability is of key importance in devising strategies for early administration of the first dose of hepatitis B vaccine.

With regard to vaccine production, the Philippines is primarily self-sufficient in BCG and tetanus toxoid (TT). National requirements for TT are met through production by the Alabang Laboratories, the state vaccine production institute. In 1990 Alabang produced 85 percent of the national requirements for BCG, with the remaining 15 percent provided by UNICEF. Measles and DPT vaccines are provided to the Philippines by the Canadian International Development Agency (CIDA), and OPV is provided by Rotary International.

G. WHO POLICIES AND HEPATITIS B ACTIVITIES IN THE PHILIPPINES

In 1987, the WHO Hepatitis Technical Advisory Group encouraged implementation of global programs to control hepatitis B infection. Mass immunization of infants was stressed as the most important means to control infection and reduce mortality from its sequelae (Annex 2). For countries with chronic carrier rates of hepatitis B of over 2% and with the resources to initiate and sustain hepatitis B immunization programs, the 1987 WHO EPI Global Advisory Group recommended introduction of hepatitis B immunization as an integral part of existing childhood immunization programs (Annex 3).

According to the Weekly Epidemiological Record (v. 64, no. 38, 1989), as of December 1988, 20 countries/areas in the Western Pacific Region of WHO had begun hepatitis B control programs. Model programs to demonstrate the feasibility of integrating hepatitis B vaccination into the EPI had begun in the Gambia, Indonesia and Thailand, and immunization activities for high-risk populations were under way in Colombia and Venezuela.

During the last two years, the Regional Office for the Western Pacific of WHO (WPRO) has cooperated with the Philippines government in exploring possibilities for procurement of hepatitis B vaccine. A consultant from Japan has been provided to assess the possibility that the Alabang Laboratories might undertake local production of hepatitis B vaccine. The consultant was able to report that it was possible, in principle, for technology to be transferred to Alabang, but that considerable improvement of facilities would have to take place. However, a formal feasibility study relating to hepatitis B vaccine production at Alabang has not yet been undertaken.

WPRO has also facilitated an interaction between the Philippines and Japan where 20 liters of plasma collected in the Philippines has been sent to the Kitasato Institute in Japan for processing into hepatitis B vaccine. This exchange will yield approximately 20,000 adult doses of vaccine which will be sent back to the Philippines before the end of 1990. It is not clear whether this vaccine will be used for further research or placed directly into a national immunization program. In any case, the production capacity of this plasma exchange system falls far short of the annual vaccine requirements for a sustainable national program in the Philippines.

IV. A STRATEGIC PLAN FOR INTRODUCTION OF HEPATITIS B IMMUNIZATION IN THE PHILIPPINES

A. GENERAL CONSIDERATIONS

Because the Philippines is a country in which hepatitis B is highly endemic and where the majority of infections leading to the state of chronic virus carriage occur in the first five years of life, it follows that the only strategy capable of significantly reducing and finally eliminating this disease is a program of mass vaccination aimed at infants. **The integration of hepatitis B vaccination into the EPI in the Philippines constitutes the most feasible method to achieve this objective. The existing EPI in the Philippines is performing at an extremely high level and is capable of absorbing an additional antigen into its service delivery. With proper planning, this can be accomplished with a minimum of disruption to the health services.**

All infants in the Philippines should be vaccinated as early in life as possible with hepatitis B vaccine as part of EPI.

B. DELIVERY STRATEGIES

The DOH will use three delivery strategies to reach newborns and infants with hepatitis B vaccine:

1. Vaccination of <u>newborns</u> at home;
2. Vaccination of <u>newborns</u> before discharge from a health facility; and
3. Vaccination of <u>infants</u> at scheduled EPI sessions.

The DOH should encourage health workers to vaccinate all babies as soon as possible after birth, within 48 hours if possible. For babies born in the hospital, vaccination should be given before discharge. For babies born at home, and attended by a DOH midwife, the midwife should try to immunize the child during the first post-partum home visit recommended within 48 hours of birth. Midwives are the principal care providers in each of the 12,000 BHS. They have additional outreach duties in approximately 30,000 neighboring barangays without health stations. Midwives provide integrated curative and preventive services and are responsible for prenatal, partum and post-partum care. Their services are much in demand and travel to homes, and to RHUs to pick up vaccine is difficult in some areas. Nevertheless, inclusion of hepatitis B immunization on post-partum visits should be strongly encouraged.

1. <u>Vaccination of newborns at home</u> presents new challenges to the EPI system. Each RHU will need to determine which BHS's are close enough to the RHU to allow BHS midwives to collect vaccine and ice before visiting the home to immunize. Some of the prerequisites for providing hepatitis B vaccine within the first 48 hours of life during home visits include:

- motivated RHU and BHS staff and receptive communities
- timely notification ("masterlisting") of births
- sufficient transportation allowance
- cold chain integrity
- availability of single dose vials of hepatitis B vaccine.

2. Vaccination of newborns before discharge from hospital presents an opportunity which should not be missed. Only a small minority of births occur in hospital. In addition, many hospitals prefer to refer newborns to local RHUs and BHS's for immunization (including BCG) in order to have them enter into the ongoing primary health care system. While in hospital, vaccination could theoretically be offered at a fixed time daily to catch all deliveries within the past 24 hours. This is not being done in many hospitals. Single-dose vials and/or multiple-dose vials could be used, depending on the volume of births.

3. **Hepatitis B vaccination at scheduled EPI sessions in fixed facilities and as part of outreach services is the most immediate and feasible strategy for quickly raising hepatitis B vaccination coverage.** Approximately 90% of all EPI doses are administered at EPI sessions held at RHUs and BHS's. Inclusion of hepatitis B vaccine at EPI sessions will result in a rapid increase in coverage which will soon approximate high levels achieved with the other antigens. Immunization of infants within the first several weeks of life, through the standard EPI system, will result in a very significant decrease in chronic carriage rates for hepatitis B. Most likely, all three strategies will be implemented to some extent.

The logistical and cold chain requirements of each strategy needs to be carefully anticipated, so that potential problems can be averted. These issues are addressed in this report.

C. TARGET GROUPS AND VACCINE REQUIREMENTS

All infants should be vaccinated as early in life as possible with three doses of hepatitis B vaccine as part of EPI. The minimum interval between each dose is four weeks.

The Department of Health uses a population-based method of calculating requirements for vaccine. The method is described in their EPI Manual. The population-based approach to planning vaccine requirements is well-suited to the Philippines because of prevailing high levels of immunization coverage and because immunization is available on only one or two fixed days per week (or per month at peripheral levels of the health system).

Requirements for hepatitis B vaccine for the country by year (1991 to 1996) are given in Table 1. The 1991 population is estimated at 62 million and assumed to grow at an annual rate of 2.3%. The crude birth rate is fixed at 30/1000 or 3%.

The DOH has established targets of 40% for the third dose of hepatitis B vaccine in the first year of introduction, rising in increments of 10% annually to 90% by 1996. The average wastage multiplier for 10-dose and single dose vials is estimated to be 1.2, which corresponds to a wastage rate of about 17%. (The wastage rate for single dose vials can be assumed to be less than 10%, while wastage for 10-dose vials would be higher). This 17% wastage rate is lower than the rate assumed by the DOH for 20 dose vials, which is estimated at 25%. A 10-dose vial such as hepatitis B can be expected to have lower wastage than a similarly sized vial of measles vaccine, since practically every child at an EPI session would be eligible for hepatitis B vaccine.

In 1991, the DOH plans to provide 2,857,000 doses of hepatitis B vaccine. Annual requirements increase to 6,752,000 by 1996.

The 2,857,000 doses needed for 1991 will allow a 40% target to be reached - but only if a single cohort (3% of the population) is to be immunized. In fact, in the year of start-up, one cohort 0-11 months of age is already present (a "backlog") and is replaced by a second cohort of babies born during the following 12 months. In effect, the start-up year has a two-year cohort leading to important implications for vaccine procurement. This is a situation peculiar to the first year of any EPI. In subsequent years, only a single cohort passes through.

The DOH will need to decide whether all infants alive at the time of hepatitis B vaccination start-up are eligible to begin the three dose series, or if immunization should be limited to babies born <u>after</u> the launch (creating a single cohort for the first year).

To vaccinate both cohorts would require twice as much vaccine in the first year if the DOH wanted to be sure to vaccinate 40% of both cohorts. In any phased EPI, some children will receive vaccine and some will not. **However, given limited vaccine, it is better from an epidemiological perspective to limit the target only to babies born after the introduction of hepatitis B vaccination.** This will set the program on the right footing in terms of emphasizing immunization at as early an age as possible. Midwives will need the support of supervisors to apply this criterion during EPI sessions.

If immunization is limited to children born after project start-up, it may be difficult initially for midwives to refuse to vaccinate the older infants. This is especially true since there will be a seeming excess of vaccine in the first few months. This "excess" is due to the fact that the health facility will have a 1-3 month ration of vaccine but only a very narrow target at first, consisting exclusively of babies born during the month of start-up. The apparent surplus of vaccine at the beginning of the program, combined with pressure from parents, may cause considerable difficulty for the midwife.

Table 1
Hepatitis B Vaccine Requirements

Year	Total Pop. A	Eligible Percent B	Eligible Pop. C (AxB)	Target Percent D	Target Pop. E (CxD)	No. Doses F	Wastage Factor G	Total annual doses required (ExFxG) [a]	Annual Doses Required in single dose vials	Annual Doses Required in 10 dose vials
1991	62,000,000	.03	1,860,000	40%	744,000	3	1.2	2,678,400	267,840	2,410,560
1992	63,426,000	.03	1,902,780	50%	951,390	3	1.2	3,425,000	342,500	3,082,500
1993	64,804,800	.03	1,946,544	60%	1,167,926	3	1.2	4,204,500	420,450	3,784,050
1994	66,377,200	.03	1,991,316	70%	1,393,921	3	1.2	5,018,100	501,810	4,516,290
1995	67,903,900	.03	2,037,117	80%	1,629,694	3	1.2	5,866,900	586,690	5,280,210
1996	69,465,700	.03	2,083,971	90%	1,875,574	3	1.2	6,752,100	675,210	6,076,890

[a] Wastage of single dose and 10 dose vials will be less than the customary 25% (1.33 multiple) calculated for 20 dose vials

Consequently, a pragmatic and epidemiologically sound compromise which should be considered for the first year is to limit the first dose of hepatitis B to infants less than three months old. This will make it easier for the midwife to make good use of her vaccine stocks, which at district and RHU levels might quickly start to choke available refrigerator space. Community pressure would be partially relieved, and rapid use of the vaccine would in itself stimulate further demand in the community for hepatitis B vaccination for the appropriate age groups.

In the second year, if it is felt that stocks are still insufficient, the DOH could continue to restrict demand to the most epidemiologically appropriate age group by requiring the series to be begun before the child reaches three months of age. This policy may serve as a "hook" to bring eligible babies into the EPI system earlier than is now occurring. (While immunization coverage in the Philippines is high, the mean age of immunization by antigen is still too old).

D. PHASE-IN

The DOH will need to decide how to phase implementation of the hepatitis B vaccination program. It may be politic to start up in all regions. But within regions, selections will still need to be made according to some neutral and objective criteria.

Sero-epidemiological data do not now exist to guide this selection. Criteria will need to be formulated so that the selection does not appear arbitrary. Possible criteria to consider are:

- Existing designation as a priority province/city (e.g. as a Child Survival Program Priority province);
- Provinces/cities with high coverage, since their staff have already demonstrated an ability to manage EPI;
- Provinces/cities representing a variety of administrative, geographic, population settlement, urban/rural, and health service organization parameters;
- Selected regions and all administrative units within;
- Expected ease of start-up;
- Availability of cold chain with special attention to district levels (see part G);
- Likelihood of reaching babies in the first 48 hours; and
- Equity and social justice.

Whenever hepatitis B vaccine is introduced, staff should be encouraged to exceed their target, if possible. To select areas in which only 40% of the nation's population lives in order to meet the 40% national target would be doomed to failure, since it would then be necessary to immunize all infants in that area. Table 2 shows this relationship of targets, coverage, and size of operational areas. **For example, the DOH might like to select areas in 1991 in which 70% of the population lives and provide vaccine to allow a coverage target of 57% to be reached in those areas. (70% x 57%=40% national target.)**

Table 2

Coverage (%) Required to Meet Nation's Hepatitis B Vaccination Targets by Size of Operational Area

National Population in Operational Areas	Coverage required to achieve % of national target of 40% (1991)	50% (1992)	60% (1993)	70% (1994)	80% (1995)	90% (1996)
40%	100%	--	--	--	--	--
50%	80%	100%	--	--	--	--
60%	67%	83%	100%	--	--	--
70%	57%	71%	86%	100%	--	--
80%	50%	63%	75%	88%	100%	--
90%	44%	56%	67%	78%	89%	100%
100%	40%	50%	60%	70%	80%	90%

E. VIAL SIZE

Hepatitis B vaccine is often packaged in single adult dose vials (1.0 ml per dose). This is equivalent to two pediatric doses (0.5 ml per dose). However, the various strategies appropriate for hepatitis B immunization in the Philippines require two vial sizes - both a single pediatric dose and a multiple pediatric dose.

A vial containing a single pediatric dose will be useful for home visits by midwives and in hospitals delivering 1-2 babies during each 24 hour period. Single dose vials for home and hospital use will reduce some missed opportunities to immunize, since staff may be reluctant to open multiple dose vials to vaccinate one or two infants. In the case of BCG, which is in 20-dose ampoules, more than 60 coverage surveys have shown that considerably less than 5% of BCG vaccinations are given as recommended in the first week of life, even though coverage by 12 months reaches 96%. Clearly, the babies born in hospital and those attended by DOH staff at home are not now being vaccinated as early as possible with 20-dose BCG ampoules, most likely because of wastage concerns and the desire to link hospital-born children with their local health systems.

While single dose vials are particularly useful in giving the first dose, either at home or in smaller hospitals, subsequent doses will be given at scheduled EPI sessions where multiple dose vials are preferred because many infants will be vaccinated per session. Larger hospitals (seeing more than two births per day) may also use multiple dose vials. Even if each baby born in hospital or attended at home by DOH staff (40% of all births) is immunized with the first dose using single dose vials, only about 10% of all hepatitis B doses would need to be packaged in single dose vials. For cost and storage reasons, multiple dose vials are preferred for second and third EPI encounters.

The recommendation to have 10% of doses in single dose vials is based on the assumption that only 40 of each starting cohort of 100 newborns can be reached in a hospital or at home with a dose within 48 hours of birth. These 40 infants then continue to receive second and third doses at scheduled EPI sessions, where multiple dose vials are used. The remaining 60 newborns receive all their doses at scheduled EPI sessions where multiple dose vials are used. Therefore, with 100% coverage, a maximum of 40 doses are needed in single dose vials. All subsequent doses for the cohort of 40 and all three doses for the cohort of 60 newborns are delivered in multiple dose vials. Of the approximately 350 doses required (when wastage is considered) to vaccinate each of the 100 newborns with three doses, only 44 (wastage included) -- or about 13% -- are needed in single dose vials.

There are many unpredictable factors which could change the ratio of single to multiple dose vials. In a more elaborate model, one could factor in the effect of different levels of coverage (i.e., less than 100% as above), or of variable drop-out rates or wastage rates, or of the proportion of babies born in hospitals who might be vaccinated with mulitple dose vials, etc.

The need for single dose vials may not be the same throughout the country, but available data do not permit more precise calculations by geographic area. As experience is gained, the relative need for single dose vials will become apparent. For example, in terms of early vaccination, Baguio City surpasses other districts by reaching 44% of infants with BCG in the first week of life, probably because 67% of all births there take place in hospital. Unlike areas which have a smaller population and fewer daily births in hospital, Baguio City clearly does not require as high a proportion of doses in single dose vials.

Clear guidelines will need to be given regarding use of single dose vials. In order of priority, <u>single dose vials could theoretically be used in three situations</u>:

1. when one or two newborns are born in a hospital per day or are to be vaccinated at home within 48 hours;

2. at scheduled EPI sessions when an extra one or two doses is required after a multiple dose vial is emptied (the exact trade-off can be calculated once CIF - cost, insurance, freight - per dose of single and multiple dose vials is known); and

3. when infants present on a day between scheduled EPI sessions.

The size of multiple dose vials most appropriate for the Philippines is 10 doses. This is the most economical size given the expected attendance at weekly or monthly fixed and outreach sessions. Wastage will be lower than if the vial held twenty doses. **Until more experience comes to light, 90% of all doses should be supplied in ten dose vials, and 10% in single dose vials.**

Single dose vials are important to provide timely protection at the first opportunity. However, if hepatitis B vaccination before six weeks is not included by the DOH as recommended policy, then the percentage of all doses needed in single dose vials would drop from 10% to about 5%.

F. STORAGE AND SHIPPING VOLUMES FOR HEPATITIS B VACCINE

The following discussion gives approximate storage requirements for hepatitis B vaccine for sample population sizes based on the current fixed center strategy combined with outreach services. The step by step approach makes implicit assumptions (frequency of re-supply, vaccine wastage, etc.) for which actual conditions at various levels in different parts of the country should be substituted. The reader interested in a more complete discussion of the approach is referred to the 1985 edition of The Cold Chain: Product Information Sheets, a periodic series of publications co-published by WHO and UNICEF also known as SUPDIR 55, Amt. 5. A more detailed description is also available in a WHO paper, "A Guide to Estimating Capacity of Equipment for Storage and Transporting EPI Vaccines" (WHO/EPI/CCIS/86.3).

Once vaccine requirements are determined, the capacity of existing cold chain equipment for storage and transport must be calculated. **Because of the presence of cold chain experts in Manila, this paper does not attempt to calculate storage requirements at each level based on the population. However, such calculations at each level are urgently needed and should consider the population actually supplied by each higher level and the exact frequency of re-supply. This is especially needed at the district level.**

This section emphasizes issues specific to hepatitis B vaccine and its introduction into EPI. Of particular concern is the storage volume per dose of hepatitis B vaccine which varies enormously depending on the manufacturer. For example, 1000 pediatric doses of vaccine from one manufacturer may be packaged in a box the size of a small pizza box. One thousand pediatric doses from another manufacturer may be packaged in a box big enough to hold a basketball!

Storage volume, also known as packaging or shipping volume, includes the vaccine vial, the packet containing the vial, and any intermediate parcelling of vaccine packets. **The storage volume of hepatitis B vaccine for use in the Philippines should be no more than 10cm^3 per dose for single dose vials, and 3cm^3 per dose for 10 dose vials.** (For comparison, the WHO standard storage volume per dose for current EPI vaccine is 1.0 cm^3 for BCG, 1.5 cm^3 for polio, 2.5 cm^3 for DPT in 20 dose vials, and 3.0 cm^3 for each of measles, TT and DPT in 10 dose vials.)

Procurement of a vaccine with a greater storage volume could overwhelm the current capacity of the cold chain - tripling or quadrupling volumes to be refrigerated. While excess cold chain capacity probably exists at higher and lower levels of the cold chain, intermediate levels of the cold chain would be unable to cope with the volumetric requirements. Faced with a mountain of vaccine to store, cold chain managers would likely transfer the stock to lower levels, where it would also exceed existing refrigerator space, and might be piled from ceiling to floor.

The importance of selecting a hepatitis B vaccine supplier carefully can be illustrated by a "best case" and "worst case" scenario which faithfully reflects the current ten-fold difference in storage volume among the different manufacturers (6 cm^3 per dose to 60 cm^3 per dose). Table 3 shows how a "typical" district of 100,000 population which receives a 3 month vaccine supply would be able to accommodate the addition of hepatitis B vaccine into its current EPI/USAID "Kelvinator" refrigerator if the storage volume per dose is 6 cm^3. The required net storage volume doubles from 37 to 78 liters. **However, if the bulkiest hepatitis B vaccine (60 cm^3/dose in storage volume) was supplied, six additional "Kelvinators" would be needed in each "typical" district.**

Table 3

NET STORAGE VOLUME REQUIRED* FOR DISTRICT WITH 100,000 POPULATION FOR 3 MONTH SUPPLY

Using Current EPI Vaccines	BEST CASE Adding hepatitis B Vaccine at 6 cm^3/dose	WORST CASE Adding hepatitis B Vaccine at 60 cm^3/dose
1.3 ft^3 or 37 liters (1 x EPI/USAID "Kelvinator" refrigerator)	plus 1.5 ft^3 or plus 41 liters (existing "Kelvinator" refrigerator can be used)	plus 14.5 ft^3 or plus 405 liters (6 additional EPI/USAID "Kelvinator" refrigerators required)

* at 2° to 8°C

- Note: Currently available hepatitis B vaccine ranges from 5 to 70 cm^3 per dose in storage volume.

It should be possible to specify an even better hepatitis B storage volume than 6cm^3/dose in multiple dose vials. Based on recent (incomplete) WHO data, a storage volume of 3cm^3/dose for vaccine in 10-dose vials and 10cm^3/dose for vaccine in single dose vials has been assumed for the calculations which follow. Procurement of 10% of all hepatitis B doses in single-dose vials, and 90% of all doses in 10-dose vials, has also been assumed as the ideal mix for the Philippines. Any change in this mix of vial sizes must be carefully considered, as it will change storage requirements in the cold chain.

Table 4

Net Storage Volume Requirements per 1000 doses at different mixes of single and 10-dose vials.

% of doses in vials (and no. of vials) of: One-dose	10-dose	Net Storage Volume Required[a] in liters by vial size: One-dose	10-dose	Total
0% (0)	100% (100)	0.0	3.0	3.0
10% (100)	90% (90)	1.0	2.7	3.7
20% (200)	80% (80)	2.0	2.4	4.4
30% (300)	70% (70)	3.0	2.1	5.1
40% (400)	60% (60)	4.0	1.8	5.8
50% (500)	50% (50)	5.0	1.5	6.5
60% (600)	40% (40)	6.0	1.2	7.2
70% (700)	30% (30)	7.0	0.9	7.9
80% (800)	20% (20)	8.0	0.6	8.6
90% (900)	10% (10)	9.0	0.3	9.3
100% (1000)	0% (0)	10.0	0.0	10.0

a Assumes storage volume per dose of 3.0 cm^3 and 10.0 cm^3 for 10-dose and single-dose vials, respectively.

Table 4 illustrates this concept. For example, a thousand single dose vials require 3.3 times the amount of net storage volume (10 liters for 1000 vials) as a thousand doses in 10-dose vials (3 liters for 100 vials).

Table 5 shows the **gross refrigerated storage volume** required per 100,000 population, assuming 100% coverage and quarterly supply. Similar calculations are needed at each level of the cold chain based on known populations, relevant grossing factors, and frequency of re-supply. A gross volume of 62 liters, or 2.2 ft^3., is required at 2°C to 8°C to store 3 months' vaccine supply (with a 25% buffer stock) for a population of 100,000. A population of 300,000, with a monthly supply period, would require the same gross volume as a population of 100,000 with a quarterly supply. The grossing factor allows for air circulation space and maneuverability and is estimated for front-opening refrigerators at 2.0, for top-opening refrigerators/freezers at 1.2, and for cold rooms at 3.5.

Typical **net shipping volumes** required for vaccines per 100,000 population with monthly and quarterly supply periods to permit 100% coverage are shown in Table 6. A cold box with nearly 11 liters of net, or 12 liters of gross capacity, would be needed to transport this volume of vaccine. The currently used Polyfoam cold box (E4/36) would barely suffice, assuming no additional buffer stock is required and diluents are not shipped inside the cold box. A quarterly supply would require at least three Polyfoam cold boxes.

Table 5

Gross Refrigerated Storage Volume Per 100,000 Population
With 100% Coverage and Quarterly Supply

Vaccine	Pop.	Eligible Percent	Elig. Pop.	No. Doses	Wastage Factor	Total annual doses CxDxE)	Net quarterly doses (F/4)	Buffer Stock	Grossing Factor	Volume Per dose (cm^3)	Conversion Factor	Required Volume (liters)
	A	B	C (AxB)	D	E	F	G	H	I	J	K	(GxHxIxJxK)
BCG	100,000	.03	3000	1	2.0	6000	1500	1.25	2	1.0	.001	3.75
DPT	100,000	.03	3000	3	1.33	12000	3000	1.25	2	2.5	.001	18.75
TT	100,000	.035	3500	2	1.33	9310	2320	1.25	2	2.5	.001	14.5
HepB	100,000	.03	3000	3	1.2	10800	2700:					
							270	1.25	2	10.0	.001	6.8
							2430	1.25	2	3.0	.001	18.3
								Total Gross volume required at 2 to 8°C:				62.1
OPV	100,000	.03	3000	3	1.33	12000	3000	1.25	1.2	1.5	.001	6.75
Measles	100,000	.03	3000	1	1.33	4000	1000	1.25	1.2	3.0	.001	4.5
								Total Gross volume required at -20°C:				11.25

Diluent - Small quantities to be kept cold at all times.

Table 6

Typical Net Shipping Volumes Required for Vaccines Per 100,000 Population with Monthly and Quarterly Supply Periods to Permit 100% Coverage

Vaccine	Monthly Doses (vials) Required[a]	Net Shipping Volume (liters)	Quarterly Doses (vials) Required[a]	Net Shipping Volume (liters)
BCG	500 (25)	.5	1500 (75)	1.5
DPT	1000 (50[b])	2.5[b]	3000 (150[b])	7.5[b]
TT	775 (39)	1.9	2325 (117)	5.8
HepaB[c]	900 (90 single dose) (81 ten dose)	.9 2.4	2700 (270 single dose) (243 ten dose)	2.7 7.3
OPV	1000 (50)	1.5	3000 (150)	4.5
Measles	333 (34)	1.0	1000 (100)	3.0
		10.7 liters (11.8 gross)		32.3 liters (35.5 gross)

Note: Additional storage volume is required for a small buffer stock, and for diluents in case these are to be shipped with ice.

a. Wastage multiplier of 1.33 used for DPT, TT, OPV and Measles; 2.0 for BCG and 1.2 for HepaB vaccine.

b. DPT shipping volume calculations assume 20 dose vials supplied.

c. Calculations assume that WHO's proposed shipping volume specification of 3 cm^3 per dose in 10 dose vials can be met. Author has assumed that a shipping volume of 10cm^3 per dose in single dose vials can be met.

G. COLD CHAIN AND VACCINE LOGISTICS

Central Level

The Alabang Laboratories of the Biological Production Service store all the EPI vaccines at the central level. Alabang also manufactures BCG in 20-dose ampoules and TT vaccine in 20-dose vials. All other EPI vaccines are imported.

Vaccines are stored in eight cold rooms at Alabang. An additional three cold rooms are not in working order. One cold room each is used for cholera/typhoid, rabies, TT, BCG, and anti-venom. DPT is stored in 3 cold rooms. Polio and measles vaccines are stored in large chest freezers.

The gross storage capacity has not been computed. It is likely that sufficient capacity exists to store a four month supply of all vaccines under the worst case scenario - i.e., if all vaccines arrived at the same time. **Whether or not hepatitis B vaccine and 1991's increased requirement of tetanus toxoid can be stored, in addition to six months'**

stock of vaccines, should be determined urgently. MCHS needs to coordinate procurement closely with Alabang, so that the laboratories have a list of scheduled vaccine arrivals for the year.

The MCHS presents Alabang with the quotas of each vaccine to be supplied quarterly to specified regions and to selected provinces. Alabang uses its own budget to dispatch vaccines by air to the regions. Some regions and nearby provinces collect vaccine by land. Alabang uses cardboard boxes with styrofoam panels and icepacks for shipping vaccine.

The Alabang authorities need to be included in discussions regarding the introduction of hepatitis B vaccine so they can be prepared. Inclusion of hepatitis B vaccine will increase the bulk of shipments by 50% (given eventual 100% coverage levels). This will translate into a 50% increase in air shipping costs for Alabang, but less by land if excess capacity exists within the DOH vehicles.

The icepack freezing and storing capacity at Alabang also needs to be calculated in light of a 50% increase in numbers of shipment cartons due to the introduction of hepatitis B vaccine.

Regional and Provincial Levels

Alabang supplies vaccine quotas to the regions on a quarterly basis. These exact quotas are fixed unless a region specifically requests more or less vaccine based on their balances in stock.

Twelve of the fourteen regions store vaccines in cold rooms. The two remaining regions are due to get cold rooms shortly. Regions keep a three months' stock of vaccine with an additional fourth month as a buffer.

The 75 provinces use refrigerators and freezers for vaccine storage. One province has a cold room. Provinces receive a quarterly quota of vaccine from the regions. Provincial stores are scheduled to receive up to 25% buffer stock, as well. Like the regions, provinces automatically receive the quota unless they specifically request more or less depending on their balances.

Based on earlier calculations by MCHS and REACH cold chain staff, 135 top-opening refrigerators, each with 12 ft^3 gross capacity, are being purchased locally by the DOH with funds from the DOH/USAID Primary Health Care Financing Project. These are required mostly at provincial and city levels.

As with the central (Alabang) level, the additional 50% refrigerated storage volume needed at $+2^0$ to $+8^0$C once hepatitis B vaccine is introduced will add to the cost of vaccine shipments to regions and provinces. More shipment cartons and more icepacks will be needed. The ability of each level of the cold chain to freeze and store 50% more icepacks should be evaluated. Shipment schedules may need to be staggered to allow sufficient ice to be made and stored between each shipment.

District Level

Most of the 383 Districts collect their quarterly or monthly allocations from the provinces. A front-opening "Kelvinator" (or similar) refrigerator is typically used to store the vaccine. An urgent assessment is needed, district by district, to determine requirements for additional refrigerators. In some districts, unutilized storage capacity exists, but more refrigerators will be needed in other districts. Voltage stabilizers, spare parts and thermometers will be required, as well. Some districts will need to be issued more cold boxes for vaccine shipments. **By substituting actual catchment populations and re-supply periods, the models in Tables 5 and 6 can be used to calculate district requirements for additional refrigerators and cold boxes.**

Icepack freezers at most districts are used to make ice for transporting vaccines in cold boxes down to RHU level. Excess capacity for making and storing ice probably exists in most district icepack freezers. However, more icepacks may be required in some districts given the expected 50% increase in vaccine volume to be shipped.

Rural Health Units and Municipal Health Centers

These approximately 3000 units are the lowest level of the health system with refrigerators for vaccine storage. Refrigerators typically have 5 ft^3 of storage space, which should be sufficient to hold a monthly supply of all the EPI antigens plus hepatitis B vaccine.

An RHU with a population of 50,000 collecting a month's supply of all EPI vaccines requires a cold box with only six liters of gross shipping volume. For most RHU's and MCHS', a single large Polyfoam cold box (E4/36), which has 11.1 liters of net capacity, should continue to be sufficient for collecting vaccines from the district. **However, those RHUs which presently rely for vaccine collection only on Polyfoam vaccine carriers (E4/19), with a net capacity of 1.7 liters, will need 50% more vaccine carriers to accommodate hepatitis B vaccine. This may require additional supply trips in some areas.**

A "rule of thumb" when collecting vaccine from the districts is that an RHU requires one 10-dose vial of hepatitis B vaccine per 1,000 population per month OR 1 vial per planned immunization session, whichever is greater.

Barangay Health Stations

Vaccine is not stored at this level. Each midwife has been issued a vaccine carrier and icepacks, which are exchanged at RHU's or municipal health centers for frozen icepacks at the time of vaccine collection. The vaccine carrier can easily accommodate hepatitis B vaccine vials.

As each BHS midwife has been issued a vaccine carrier and icepacks, no additional cold chain equipment is needed to permit home vaccination at the first post-partum visit. RHU's will need to have icepacks frozen at all times, as is now the standard

requirement. A typical RHU serves a catchment population of 10,000 to 30,000, which means 1-3 births occur daily. Even if these births are located in different BHS catchment populations, daily ice-making requirements can be handled by the current upright refrigerators at RHU's.

For the midwife to add vaccination to her duties at the domiciliary post-partum visit, she will need first to travel to the RHU for vaccine and ice. A transportation allowance is already being provided in many areas (but not always in cities) irrespective of the extent and cost of travel required. Requirements for additional transportation allowance are best calculated and budgeted locally.

H. VACCINE PACKAGING

When multiple dose vials are packed 100 vials to the box as with current DPT and TT vaccines, the box is frequently opened at provincial level (and always at district level) so that vials are supplied loose to lower levels which require fewer than 100 vials. This frequently leads to loose vials not being segregated by expiry date or by "first in, first out" in the refrigerators and freezers, with the result that individual vials may be stored for too long at the weakest levels of the cold chain and may expire before use.

Therefore, hepatitis B vaccine vials should be supplied 10 to the packet and 10 packets to the box. A typical RHU would require 1 to 4 packets (10 to 40 vials of ten-dose vials) each month to serve a population of 10,000 to 40,000. Boxes of 100 vials (10 packets of 10 vials each) are useful for ease of storage and handling at higher levels of the cold chain.

I. VACCINE INVENTORY AND ORDERING

Vaccine is ordered and supplied in the Philippines by numbers of vials, not doses. **Because hepatitis B vaccine is supplied in single-dose and ten-dose vials, it is essential that stock balances be kept separately.** Orders should separately specify numbers of vials required in single-dose and ten-dose vials. An arrival of single dose instead of 10-dose vials by accident, or through failure to specify separate requirements of each, would be uneconomical and result in vaccine stock-out. **Re-order points should be calculated separately for single and 10-dose vials at each level.**

J. FREEZING OF HEPATITIS B VACCINE

Freezing of hepatitis B vaccine inactivates the vaccine by causing dissociation between vaccine and adjuvant.

At each level of vaccine distribution according to the Philippines EPI Manual (p.55-56), icepacks should be kept for 5-10 minutes at room temperature before loading into vaccine carriers or cold boxes. This practice should be continued for hepatitis B vaccine as it is with DPT and TT. **Particularly at higher levels of the cold chain,**

where chest freezers and icepack freezers are capable of freezing icepacks down to minus 20°C, and where any accidental freezing would be catastrophic as greater numbers of vials would be affected, letting icepacks sit at room temperature for 5-10 minutes before packing the cold boxes is essential.

Freezewatch indicators should be included in international vaccine shipments to the Philippines; however, these indicators may give a false sense of security. They indicate that freezing may have occurred if temperatures are -4°C or colder. However, some hepatitis B vaccine may freeze at temperatures warmer than -4°C.

K. SUPPLYING HEPATITIS B VACCINE TO PRIVATE PRACTITIONERS

Although other antigens are supplied free of charge by the DOH to private practitioners, there is a strong possibility that, if also supplied to them, hepatitis B vaccine intended for infants will be administered to adults instead. The current market price for hepatitis B vaccine is said to be $10/dose. Private physicians should be encouraged to refer infants to DOH facilities for free hepatitis B vaccination. Non-availability of DOH hepatitis B vaccine through private practitioners would not affect coverage, as less than 5% of other EPI antigens are now given by the private sector.

DOH staff will also need to refer ineligible infants and older children to private practitioners. With increasing IEC from the DOH and advertising by vaccine manufacturers, it is possible that private practitioners will start to play a relatively greater role in covering older infants with hepatitis B vaccine. Because they will not receive free hepatitis B vaccine from the DOH, private practitioners will not be as likely to report their monthly achievements to the DOH.

L. VACCINE SECURITY

As the market price for hepatitis B vaccine is $10 per dose and given heightened adult demand due to publicity, **vaccine stocks must be made secure.** This may include refrigerators with locks and keys, or refrigerators in locked rooms. Inventories need to be compared frequently against ledgers to detect discrepancies.

Tenders for vaccine procurement should specify that labels and boxes must be stamped with "Pediatric Dose" and "Property of Department of Health." This will help discourage diversion of vaccine to the private sector.

M. QUANTITY OF SYRINGES AND NEEDLES REQUIRED

Disposable syringes and needles are being widely used in the Philippines. They are distributed based on a calculation of population and targets. Table 7 shows the number of disposable syringes and needles required per 100,000 population, assuming that disposables are used exclusively and that a sterile syringe and sterile needle are used one time only. Approximately 25% more syringes/needles (3600) are required

per 100,000 population in the first year of hepatitis B vaccination, compared to the 17,100 required for other subcutaneous and intramuscular vaccinations. **By 1996, when the hepatitis B target is also 90%, 50% (8100) more syringes/needles will be needed.** Of course, syringes/needles for BCG and for reconstitution of BCG and measles will continue to be needed.

Table 7
Requirements for Syringes and Needles
Suitable[a] for Administering DPT, TT, Measles and Hepatitis B Vaccines

Vaccine	Per 100,000 Population	Eligible Population	No. Doses	Target	Required Amount[b]	
DPT	100,000	.03	3	.90	8100	17,100
TT	100,000	.035	2	.90	6300	
Measles	100,000	.035	1	.90	2700	
HepaB	100,000	.035	3	.40	3600 (1991)	
				.50	4500 (1992)	
				.60	5400 (1993)	
				.70	6300 (1994)	
				.80	7200 (1995)	
				.90	8100 (1996)	

a: Assumes disposable syringes and needles are used exclusively.
b: Additional syringes/needles would be needed as a buffer stock.

The syringe and needle characteristics suitable for hepatitis B vaccination will be the same as for DPT, TT and measles. A 23g x 1" needle and a 1 ml. or 2 ml. syringe are most appropriate.

Managers at each level are responsible for ensuring that adequate supplies are available at all times to permit each injection to be given with one sterile needle and one sterile injection. It is understood that, at least for 1991, the DOH in Manila is planning to provide sufficient funds to cover requirements for syringes and needles. **The incremental requirement for 1991 due to hepatitis B vaccine is 2.3 million syringes and needles, assuming disposables will be used exclusively.**

When planning their annual budgets, Regions, Districts and Provinces do not know how many needles and syringes that they can expect to receive from the central level. Discussions between the DOH in Manila and these levels will be needed to ensure a sufficient stock, so that districts can estimate the additional quantities to purchase with their own funds.

Inappropriate re-use of disposable injection equipment has been raised as a concern by EPI reviews in the past. Steam sterilizers (pressure cookers fitted with racks) and re-usable syringes and needles are scheduled to be distributed to each RHU and midwife. Of the 12,000 steam sterilizers needed, 4000 are already in the country. In the Philippines, the sterilizers are mostly used as back-up in case of insufficient stocks of disposable injection devices, although it is understood that sterilizers are to become the main method for ensuring sterile injection devices.

As the number of injections per session will increase by 25% in the first year of hepatitis B vaccine use and by 50% within 5 years, some facilities already using steam sterilizers will need to graduate to a larger size (e.g., from 1 to 2, or 2 to 3 racks). Alternatively, more than one sterilization cycle may be needed per session. This can only be calculated locally. Future orders of steam sterilizers will need to specify larger sizes. Re-usable needles and syringes will need to be replaced more frequently given their increased use once hepatitis B vaccine is introduced.

N. INDICATORS

Program managers will want to monitor progress particularly closely during the introductory period. Monitoring can be accomplished using routine service statistics and special surveys. As cases of hepatitis B in infants are generally asymptomatic and the consequences of infection are not seen for 30-40 years, disease surveillance is impractical for monitoring impact.

Service Statistics

a) hepatitis B 3 coverage vs Eligible Population

This is the standard measure used by EPI.

b) hepatitis B 1 vs hepatitis B 3

This monitors drop-out and should not be higher than the drop-out rates with DPT or polio vaccines.

c) hepatitis B 1 vs BCG

This measures early start of the series by comparing the first dose of hepatitis B against the vaccine which is given earliest and for which coverage is highest (96%). With the availability of single dose vials of hepatitis B for the first dose, hepatitis B coverage will approximate BCG coverage after a few years.

d) hepatitis B 3 vs DPT3

This monitors completion. By the time 3 doses of DPT can be given, the infant should also have received 3 doses of hepatitis B. A difference of more than 5% signifies missed opportunities for immunization which require investigation. For example, staff might be reluctant to give the same infant multiple injections on the same day.

The DOH may like to monitor these indicators by province or district on a quarterly basis to determine whether there are any problems. The EPI Monitoring Chart could be used to monitor graphically cumulative monthly coverage of hepatitis B 1 vs BCG, and hepatitis B 3 vs DPT3. Feedback to lower levels in graphic form would stimulate interest.

Coverage surveys

Surveys will play an important role in monitoring coverage since greater numbers of hepatitis B vaccinations (relative to other EPI antigens) will be administered to infants by private practitioners, who may not report accomplishments to the DOH.

Standard questionnaires used on 30-cluster surveys will need to be modified to include the 3 doses of hepatitis B. COSAS (Coverage Survey Analysis System), already in use in the Philippines, can help provide computer-generated information on mean and median age of each dose, mean intervals between doses, coverage levels, and missed opportunities. The coverage survey data can also be used to correlate hepatitis B vaccine with place or attendant at delivery, which will help identify strengths and weaknesses in early notification and referral.

Serological Surveys

In order to monitor the effectiveness of the immunization effort in reducing the level of hepatitis B virus carriage (HBsAg positivity) and increasing the protective level of anitbody against the virus (anti-HBs positivity), serologic surveys in selected areas should be undertaken. An effective survey methodology is to collect baseline serologic information on HBsAg and anti-HB levels on children aged 0-4 in an operational area prior to vaccination. Similar information on fully immunized and partially immunized children in the same age groups can be collected 2-4 years after introduction of immunization. Detailed protocols on serologic surveys utilized in immunization programs in Indonesia and Thailand are available from the International Task Force on Hepatitis B Immunization.

FIC (Fully Immunized Child)

By 1996, the DOH intends to expand the definition of FIC to include a child who received three doses of hepatitis B vaccine at minimum one month intervals before the age of 12 months.

O. SUPERVISION

The EPI Target/Client List very easily allows a supervisor to examine immunization records by date of birth and date of vaccination. Supervisors will be able to assess whether vaccinators are properly limiting the vaccine to the target group or whether all children are being offered it. At a glance, one can also determine whether hepatitis B vaccine is systematically not being given under certain circumstances - e.g. 6-12 week old children on their first EPI encounter are being given only BCG and DPT 1 but are inappropriately denied hepatitis B 1.

P. REPORTING

The Field Health Service Information System (FHSIS) administered by the Health Intelligence Service (HIS) has recently reviewed and revised forms for all DOH projects. These have been printed in sufficient quantities to last until October 1990, at which time provinces will print them using their own funds. The forms will not be reviewed and revised again by central level staff in the HIS until 1992. DOH criteria for including forms into FHSIS are that the health program should be implemented nationwide and that the program can demonstrate a use for the information.

All the forms in use by EPI will need to be reviewed and most will require revision due to the introduction of a new antigen. The EPI Target/Client List, EPI monthly accomplishment report, and various stock inventory and ordering forms need attention. All vaccine stock forms and cards need to be modified. **Single dose and multiple dose vials of hepatitis B should be tallied separately.** These revisions should begin now, since the process of gaining approval and pre-testing may take some time. The MCHS will need to review all existing forms and consult with the HIS on how to proceed - either by designing new forms or trying to revise the FHSIS forms.

Q. HEPATITIS B VACCINE PROCUREMENT

Hepatitis B vaccine requirements for the first year of the program will be about 3 million pediatric doses. **The only practical and efficient way to obtain this vaccine is through a process of tender and bid.** The purpose of the tender and bid process should be to acquire a highly safe and effective hepatitis B vaccine that meets the specific requirements of the Philippines at the lowest possible cost.

There are currently five vaccines licensed for use in the Philippines. Three of these are plasma derived vaccines and two are produced by recombinant DNA (rDNA) technologies. All of these vaccines are highly safe and effective, and there is no superiority of the rDNA products over the plasma derived vaccines in respect of these characteristics. However, the vaccine which will meet all the specifications peculiar to the needs of the Philippines does not yet exist on the shelves of any commercial company and will have to be prepared and packaged through negotiations with the manufacturers themselves. For this reason, and because of the ability to obtain lower concessionary prices through direct interaction with the manufacturers, international tender and bid is preferable to local tender and bid and should be undertaken if local regulations permit. Also because of the current contentious nature of the competion between the companies which produce hepatitis B vaccines, particularly in respect of unwarranted claims and counter-claims regarding safety and efficacy, it would be wise for the DOH to avail themselves of the assistance of an unbiased group of international experts in the field of hepatitis B, such as the International Task Force on Hepatitis B Immunization, in the tender and bid process.

R. SPECIFICATIONS FOR HEPATITIS B VACCINE SUITABLE FOR THE PHILIPPINES

Considerable variation exists from manufacturer to manufacturer in the formulation and packaging of hepatitis B Vaccine (See Table 8). Existing vaccine products are primarily geared for use in developed countries and are packaged and targeted for selective vaccination of high risk groups, such as adult drug-users or medical practitioners exposed to the virus. Manufacturers of hepatitis B vaccine do not now package vaccine according to requirements for use in large-scale public health programs in developing countries. Most of the hepatitis B vaccines listed in Table 8 are licensed for use in the Philippines. However, the packaging must be changed by the manufacturers to meet the needs of the EPI.

Table 8: Characteristics of Some Currently Available Hepatitis B Vaccines*

Company	Concentration Per Pediatric Dos	Pediatric Doses	Pediatric Doses per Vial	Vials Per Box	(Boxed) Storage vol. per dose (cc)
**Chiel USA	1.5 mcg	0.5 cc	2	20	18.0 cc/dose
**Smith Kline BEL	10.0 mcg	0.5 cc	2	10	5.2 cc/dose
**Smith Kline BEL	10.0 mcg	0.5 cc	2	25	10.9 cc/dose
Kitasato JAP	10.0 mcg	0.25 cc	2	3	30.4 cc/dose
**Green Cross KOR	10.0 mcg	0.5 cc	2	5	14.6 cc/dose
**Pasteur FRA	5.0 mcg	1.0 cc	1	1	70.0 cc/dose
**Pasteur FRA	5.0 mcg	1.0 cc	10	1	5.1 cc/dose
**Merck Sharp & Dohme		Data not available			
Bikan		Data not available			

* Data from WHO/Geneva as of June 25, 1990.
** Manufacturer is licensed to sell Hepatitis B vaccine in the Philippines

The specifications for hepatitis B vaccine suitable for the Philippines should reflect its intended use for newborns and infants and consider logistic and epidemiological factors in delivering health services. Unlike the other antigens used in the EPI, global standards and specifications for hepatitis B vaccine have not yet been determined. The packaging of vaccine most suited for the Philippines' EPI is not now available, not because of production difficulties, but because of insufficient demand for pediatric dose packaging from public health programs in the past.

The bioactivity of hepatitis B vaccine, that is, its ability to induce a protective antibody response, is related to the antigenic mass of HBsAg protein contained in a dose of vaccine specific to the production process of each manufacturer. This antigenic mass is specified in micrograms (mcg) of HBsAg protein. Because of differences in the production processes between manufacturers, a given quantity of HBsAg protein of one manufacturer may provide more or less bioactivity than that of another manufacturer. For example, a pediatric dose of vaccine from one company which contains 2.5 mcg of HBsAg protein may have the same bioactivity as the pediatric dose of another manufacturer which contains 10 mcg of HBsAg protein. For this reason, there is no international standard of vaccine potency expressed in mcg of HBsAg protein, and the relative efficacies of the different vaccines cannot be inferred on the basis of differences in HBsAg content between them. Vaccine procurement must be based on appropriate evaluation of the adult or pediatric dose with the HBsAg content as specified by each manufacturer.

SPECIFICATIONS OF HEPATITIS B VACCINE FOR THE PHILIPPINES SHOULD INCLUDE THE FOLLOWING POINTS:

Method of preparation:	Plasma or rDNA (yeast) derived
Dose:	micrograms of HBsAg protein established as efficacious by manufacturer in 0.5 ml per pediatric dose
Doses per vial:	Single dose and 10-dose
Overfilling:	Vials to be overfilled 10% per dose
Maximum packaging volume[3]:	10 cm^3 per dose for single dose vial
	3 cm^3 per dose for 10-dose vial
Freezing point:	Manufacturers will specify freezing point of vaccine and methods of determination.
Storage Temperature:	2^0 to 8^0C

[3] Includes vaccine vial, the packet containing the vaccine vial and any intermediate parcelling of vaccine packets.

Stability:	Stable for 3-7 years at 0-8°C Stable for several months at 22-25°C Stable for more than 6 weeks at 35°-37°C Stable for 2 weeks at 45°C Loss of potency after a few days at 53°C and after a few hours at 60-65°C. (Manufacturers to specify stability characteristics.)
Minimum time from arrival in country to expiry:	2 Years
Vials/Packet:	For single dose vial: Consistent with maximum packaging 10 cm^3 per dose For 10 dose vial: 10 Vials/Parcel
Packets/Box:	For single dose vial: Consistent with maximum packaging of 10 cm^3 per dose For 10 dose vial: 10 parcels/box
Vaccine Insert:	Messages should include: "Pediatric Dose;" "For pre- and post-exposure vaccination;" indications according to epidemiology in developing countries; "Intramuscular injection in anterolateral thigh; "Shake well before use; "Vaccine schedule according to Philippines EPI Recommendations;" "Need for booster has not been established;" "Precautions;" "Contraindications;" "Reactions;", etc.
Other:	"Securité Generale Suisse (SGS): Inspection requirements at port of embarkation" "Master file information on safety, immunogenicity and efficacy."

Additional specifications

The vaccine shall meet all national regulations concerning hepatitis B vaccine and WHO biological requirements. Master file information may be sent to the International Task Force on Hepatitis B Immunization, a WHO Collaborating Center, for analysis and verification of vaccine quality, safety, and effectiveness.

Insulated packaging standards

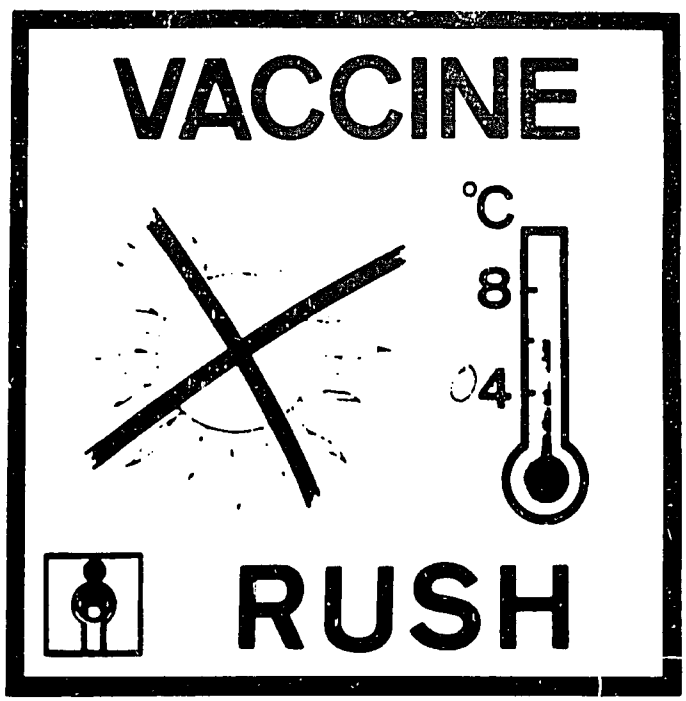
Class B: Hepatitis B Vaccine shall be packed to assure that the storage temperature of the vaccine does not rise above +30°C in continuous outside ambient temperatures of +43°C for a period of at least 48 hours and that the vaccine will not freeze. Suitable cold chain monitor cards should be packed with each 3000 doses of vaccine. Temperature indicators should be packaged with each vaccine shipment to show that freezing did not occur. Manufacturers shall specify package materials used to insulate against freezing.

Storage volume standards

Vaccine manufactures shall state the storage volume occupied per dose of vaccine in trade literature and in tender documents submitted to the purchaser. Maximum recommended volume per dose are as follows:

- For single dose hepatitis B vaccine vials: 10.0 cm^3/dose
- For 10-dose hepatitis B vaccine vials: 3.0 cm^3/dose

Figure 1: Vaccine shipment label



Labeling and packaging standards

The external surface of vaccine packaging shall be white. A label of the design specified in Figure 1 shall be affixed to every outside face of each vaccine package giving clear warning in English about:

- Need for urgent handling of vaccine contents;
- Need to keep continuously refrigerated at between $+2^0$ to $+8^0C$ ($+36^0F$ to 46^0F);
- Need to avoid freezing.

Labels on each vaccine vial shall be fixed with water-resistant adhesive. The expiry date shall be printed on each vial or vial label in indelible ink.

Labels on single-dose and 10-dose vials and packages shall be distinguished by different color printing or highlights.

Labels on each vial, parcel, and box shall state: "Property of the Department of Health, Government of Philippines" and "For pediatric use only."

Labels and instructional inserts are to be in English.

Standard shipping procedures

Vaccines shall travel by a direct route whenever possible. If transhipment is unavoidable the journey shall be planned, whenever possible, through airports with a temperate climate and cold store facilities. Shipments shall be scheduled to arrive on Monday, Tuesday, Wednesday or Thursday ONLY.

Vaccine consignments shall be booked well ahead of the date of departure. At least ONE WEEK before the date of despatch, telexes or cables shall be sent to the consignee stating the following:

1. Number of doses
2. Type of vaccine
3. Number of cartons
4. Gross weight, kgs
5. Flight Number
6. Date at final destination
7. ETA
8. Air Waybill (AWB) number
9. PLEASE ARRANGE IMMEDIATE COLLECTION OR TELEX IMMEDIATELY IF VACCINE DOES NOT ARRIVE.

The following shall be stated on the Air Waybill:

A. Consignee's name, address and TELEPHONE NUMBER;
B. Type of vaccine and quantity;

C. "HIGHLY PERISHABLE, Telephone consignee upon arrival: (Repeat telephone number);"

D. Handling information:

"MEDICINES - VACCINE - FOR HUMAN USE - HIGHLY PERISHABLE - NOT TO BE DELAYED - CONNECTION BY BOOKED FLIGHT - PENDING RESHIPMENT OR COLLECTION STORE AT +2°C TO +8°C (36°F TO 46°F). DO NOT FREEZE."

Two copies of the invoice or pro-forma invoice with packing details shall be attached to the Air Waybill for customs clearance at destination. At the time of shipping the following shall be sent to the consignee by airmail:

- Copy of the Air Waybill;
- Copy of the invoice with packing details.

All invoices shall quote the vaccine batch numbers and the dates of expiry of the lots included in the consignment.

S. HEALTH STAFF TRAINING AND PUBLIC IEC PROGRAMS

In order for hepatitis B vaccine to be effectively integrated into EPI, comprehensive training programs must be implemented for all health staff, including DOH administrators, doctors, nurses, midwives, barangay health workers, and NGO fieldworkers. The general public must also be informed about the disease, its consequences, and the hepatitis B vaccination program. Without a strong training/information, education, communication (IEC) component, misinformation and confusion will abound, vaccine will be administered inappropriately, and public concern could create a negative impression of the entire EPI.

There are many ways that training and IEC can be planned and carried out. In the following pages basic strategic issues relevant to potential program activities are discussed. These strategies are based on findings from meetings with national, regional, provincial, district, and local DOH staff. Possible target audiences are listed, along with broad definitions of the kinds of information needed by each audience. Comprehensive listings of potential ways to reach each audience, and issues specific to training and IEC programs, are also presented. The information in this section is meant to stimulate debate in the DOH about the most appropriate ways to initiate training and IEC activities, and how they should evolve as hepatitis B vaccination activities expand and the program matures over the next few years.

1. Strategic Issues to Consider

- **While awareness about hepatitis B is high, there is considerable confusion about the disease among health professionals, fieldworkers, and the general public.**

  At all levels, individuals are confused about the differences between hepatitis A and B, the primary routes of transmission of the virus in the Philippines, the importance of adult versus infant immunization, vaccine dosage versus vaccine concentration, the safety and effectiveness of the various vaccines, and other issues.

- **It is important to create a strong foundation of knowledge about hepatitis B and the vaccine among health workers and volunteers before building public information IEC campaigns.**

  Health workers are the primary source of health information for the public. Only health workers can answer individual questions and address specific confusions and concerns.

  Top priority: Educate/train DOH administrators, doctors, nurses, midwives, BHWs, and NGO vaccinators and fieldworkers about hepatitis B so that they understand the national program, are able to correctly explain the disease and the vaccine, and can immunize appropriately.

  Second priority: Increase public awareness and demand for the vaccine. Due to the public relations efforts of drug companies and other media coverage, there is already considerable awareness of hepatitis B among the population. However, misinformation is rampant and must be corrected. The most effective means of doing this is by informing health staff. Later, public information campaigns targeting a variety of audiences can be implemented.

  A phased approach, focussing first on medical staff, will allow the DOH to effectively complete high priority tasks before moving on to less crucial activities.

- **Immediate action should be taken to update the EPI Manual and the Household Teaching Manual with hepatitis B information.**

  The EPI Manual can be updated by including a supplement with the EPI Newsletter being mailed soon. A draft supplement is attached as Annex 4. The EPI Manual is due to be revised sometime in 1991, but since the hepatitis B program will begin before that time, it is important to distribute the supplement now. Hepatitis B information should be included in the revised manual.

  The English version of the Household Teaching Manual is currently being printed at the Public Information and Health Education Service (PIHES). It contains no information about hepatitis B. A supplement should be added to the printed manuals before they are distributed. The dialect versions of the manual, to be printed later this year, should also be updated.

- **While some actions should be taken immediately, it is important to plan overall training and IEC activities in a methodical, systematic way and to develop a final strategy based on field data.**

  As soon as possible, DOH should determine how best to fund and implement standard training and IEC research and planning. These activities would include:

  * Qualitative audience research to investigate specific information needs of DOH staff and the general public. The data generated through these studies will be useful for finalizing training and IEC strategies and developing messages and materials for training and IEC programs.

  * Pretesting all messages and materials prior to production and distribution.

  * Evaluation of training and IEC activities.

- **New training and IEC initiatives must minimize the burden placed on current EPI systems.**

  In other words, no special, extra hepatitis B training courses for midwives and BHWs should be planned. Hepatitis B information should be integrated into all standard EPI training courses and IEC materials.

- **DOH should use every opportunity to reach health workers, even if some individuals might receive the same information more than once.**
  Training opportunities will include distribution of the manual supplements mentioned above, regular staff meetings, newsletters, and in-service training, among others. Not all staff will be reached through any one channel. Repetition helps people remember hepatitis B information.

- **When the time comes for public campaigns, DOH should use a mix of media to reach the public.**

  No single medium (posters, brochures, radio, TV, etc.) will reach all the people. A strong campaign carefully chooses the most appropriate media and reaches audiences from many different "angles."

- **The vaccine will be introduced in phases and may not be available in all areas for several years.**

  HB vaccination should not be actively promoted in areas where it is not generally available.

- **Some drug companies may initiate campaigns of "misinformation" and false rumors may be broadcast by the mass media** (e.g., "Plasma-derived vaccines can spread AIDS" or "Some vaccines are better than others" - both untrue!).

  Public information activities (such as press releases correcting misinformation in the media) should be implemented when the need arises. Responses to such campaigns must be made in a timely manner.

- **In order for the hepatitis B training and IEC programs to be effective, EPI, PIHES, and the HMDTS will need to coordinate activities.**

- **Some hepatitis B program issues have not yet been resolved - as decisions are made, information should be passed on to field staff.** For example, it is not yet known what size vials will be purchased, where the vaccine will be available, or what the selection criteria will be for eligible children, among other policy issues.

2. Target Audiences and Information Needs

There are a number of different target audiences requiring hepatitis B information. Many of them have differing information needs. The chart below specifies the needs of each audience. The information needs are defined at the bottom of the chart.

Target Audience	Information Needs
1) DOH Administrators, Doctors (including private doctors), Nurses	Technical information* Practical information*
2) Midwives NGO vaccinators	Basic information* Practical information
3) BHWs, NGO fieldworkers	Basic information
4) Parents, Community leaders Development workers	Basic information

* Definitions:

Basic information

What is hepatitis B?
Common modes of transmission in Philippines
Priority target clients for immunization (infants)
Consequences of HB infection
Advantages of HB immunization
HB vaccination schedule
How hepatitis B differs from hepatitis A
Side effects of HB immunization (none)

Note: Many of the basic messages about hepatitis B are included in the draft EPI Manual supplement attached as Annex 4.

Technical information:

Basic information +
Epidemiological data
Technical information about the various vaccines available

Practical information:

How to handle HB vaccine
How to immunize with HB vaccine

Note: Many of the practical messages about hepatitis B are included in the draft EPI Manual supplement attached as Annex 4.

3. Implementation of Training Programs for DOH and NGO staff

There are many different ways that health staff can be informed about hepatitis B. Every opportunity should be taken to disseminate accurate information, even if there is a chance of repetition. The chart below lists target audiences and possible opportunities for informing them about hepatitis B. Following the chart is a list of training issues to consider before beginning training activities.

Target Audience	Training Opportunities
1) Administrators, Doctors, Nurses, Health Educators, Training Officers, Local Development Officers (Regional, Provincial, District, and RHU levels)	Medical Specialist Training Weekly Clinical Management Training Other in-service training DOH Staff Meetings Consultative workshops NGO staff training (through coordination with the Community Health Development Service) Meetings of the Philippines Pediatric Society, Philippines Medical Association, Philippines Public Health Association, Organization of Public Health Educators and other professional associations EPI Manual supplement EPI Newsletter (20,000 distribution) DOH Newsletter published by PIHES (5,000 distribution) Other DOH departmental newsletters NGO newsletters Medical and nursing school curricula Mass media (radio, TV) Press releases

2)	Midwives, NGO vaccinators	DOH refresher training Staff meetings at RHU and District NGO staff training Annual meeting of the Integrated Midwives Association of the Philippines EPI Manual supplement EPI Newsletter Hepatitis B insert in the Household Teaching Manual Family Health Guide (if it is revised to include hepatitis B information) Midwifery school curricula New handout being developed by MCHS Mass media (radio, TV) Comic books, posters, other print media Press releases
3)	BHWs, NGO fieldworkers, Government of Philippines (GOP) fieldworkers	Training by midwives during regular staff meetings NGO training programs GOP fieldworker training New handout by MCHS Hepatitis B insert in the Household Teaching Manual Family Health Guide (if it is revised to include hepatitis B information) Mass media (radio, TV) Comic books, posters, other print media Press releases

Training Issues to Consider

- **Integration of hepatitis B information.** How can we ensure that hepatitis B information is integrated into all routine training programs for administrators, doctors, nurses, midwives, and BHWs? How can we integrate it into NGO training? Medical and midwifery school curricula?

- **BHW Training.** How can we ensure that the BHWs get adequate hepatitis B training from the midwives?

- **Technical accuracy of materials.** How can we guarantee the technical accuracy of training and IEC materials? The International Task Force for Hepatitis B Immunization would be happy to review English language materials at the request of the DOH.

- **Systematic training program design.** It is impossible to know whether training programs are appropriate without first conducting audience research and later pretesting and evaluating the curricula and training materials. Are there resources for systematically designing training programs that include hepatitis B information?

- **Communication skills training.** Health educators at all levels reported that midwives and BHWs do not have adequate interpersonal communication, or teaching, skills. Many have never received training in this area. Would it be possible to incorporate this topic into future refresher training? Improved communication skills will benefit all development programs, not only hepatitis B and EPI.

4. Implementation of IEC Programs for Community Leaders and the Public

IEC programs can take many forms. Usually, a comprehensive IEC strategy is developed based on audience research and an analysis of needs and resources. An attempt is made to reach target audiences by matching understandable messages with appropriate communication channels (media). The most important information channel is the local health worker who provides interpersonal communication. Well-informed community leaders (barangay council members, church figures, teachers, etc.) can also serve this purpose. Other media may include printed materials like posters, brochures, or flipcharts; broadcast media like radio and TV; performances; audio cassettes; printed t-shirts; or any number of additional possibilities. Each medium has advantages and disadvantages, so it is important to use more than one channel to reach target audiences.

The chart below links hepatitis B program target audiences with potential information channels. Following the chart is a list of IEC issues to consider while planning the communication program.

Target Audience	IEC Channels/Materials
1) Parents	New flyers being developed by MCHS Press releases Radio, TV (if appropriate) PTA meetings Slides in cinema halls "Parent's classes" organized by BHWs and midwives Performances/puppet shows/taped dramas to be organized through schools and performed by school children during Health Week Comic books produced by commercial publishers Contests with prizes

2)	Community leaders, Teachers, Development workers	All above + Various government and NGO newsletters and publications Informational briefings with local leaders Teacher's Association meetings and newsletters Meetings between barangay health committees and local health staff Meetings between local service organizations (Rotary, Kiwanis, Lions, etc.) and health staff

IEC Issues to Consider

- **Systematic development of a communication strategy and IEC materials.** Standard methods (audience research, pretesting, etc.) should be used to create a comprehensive strategy and to develop materials. How could these be funded? Would staff have time to work on these activities? When?

- **Responses to misinformation in the mass media.** How can PIHES and EPI stay abreast of false or misleading information about hepatitis B in the media? How can they respond to it in a timely manner?

- **Community outreach.** Can the various ideas listed above for outreach to parents, teachers, and community leaders be implemented? How?

- **IEC materials for the community.** In addition to the brochures currently being developed by EPI, what other types of materials are needed for parents and community leaders? What sort of materials for parents are affordable? Is it possible to guarantee distribution beyond the district level? Will midwives and BHWs receive supplies of IEC materials? Will they use them? Ideas for additional materials are included in the list above.

- **Use of mass media.** When (if ever) will it be appropriate to use mass media (radio, TV) for the hepatitis B program, given that the vaccine will not initially be available in all areas? How does hepatitis B fit into current EPI mass media campaigns being conducted by PIHES? Is it possible that hepatitis B can be an additional "hook" once the measles campaign has lost its novelty?

  Until the vaccine is available nationwide, promotion by mass media may not be advisable. After the phase-in is nearly complete, EPI and PIHES can formulate plans for coordinating hepatitis B messages with other EPI promotion.

V. RECOMMENDATIONS

See Executive Summary.

ANNEX 1

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ANNEX 2

RECOMMENDATIONS OF THE NOVEMBER 1987 HEPATITIS TECHNICAL ADVISORY GROUP (WHO)

"HEPATITIS B VACCINES AND IMMUNIZATION STRATEGIES"

1. The TAG notes that over 30 million doses of plasma-derived HB vaccine have been distributed worldwide and that there are now more than 10 manufacturers of these vaccines globally. The vaccines have an impressive record of safety. In addition, several vaccines manufactured by rDNA technology are now on the market and additional manufacturers are expected to enter the market in the next two or three years. These rDNA vaccines are equivalent to plasma derived vaccines in respect to safety, immunogenicity and efficacy and neither offers any advantage over the other in these respects. Plasma-derived vaccines will continue to play an essential role in Hepatitis B control programmes worldwide for the foreseeable future.

2. There has been a dramatic decrease in the price of HBV vaccines to the level where many countries in Hepatitis B hyperendemic areas may now begin the development and implementation of large scale vaccination programmes. WHO should encourage their implementation and monitor their progress.

3. The TAG encourages the establishment of programmes and liaising with relevant groups within and without the Organization and encourages continued and increasing close collaboration between WHO and such bodies in the development and implementation of the global programme on HBV control.

4. The TAG emphatically reiterates that the most important means to control HB on a global scale and to reduce mortality due to chronic sequelae of this infection, including cirrhosis and HCC, is the large scale immunization of infants. It therefore recommends that HB vaccination be integrated into EPI as soon as possible. For incorporation into EPI, it is recommended that three doses of HBV vaccine will be given and that administration should be intramuscular into the thigh of infants. The first dose (HBV-1) should be given as soon as possible after birth. Although programmes should aim at administration of HBV-1 within the first week of life, it should be initiated at any time if it cannot be given so early. It is also desirable that HBV-1 be given simultaneously with the first EPI immunization.

The second dose (HBV-2) should be given 4 to 12 weeks after HBV-1, as it best fits into the EPI schedule of the particular Region.

A third dose (HBV-3) is currently needed to achieve high levels of antibody and prolonged protection. There is considerable latitude regarding timing of this dose. Countries can adopt schedules with 2 to 12 months following HBV-2, at a time when it best fits into the EPI schedule of the particular Region.

HBIG may be of additional value in HB immunization programmes for infants, but cost of its inclusion into large scale immunization programmes precludes its use in most countries.

5. The TAG encourages operational research to define methods for an optimal integration of HB vaccination into EPI through the establishment of immunization projects in selected countries in hyperendemic areas of the world, and that WHO monitor the results of these projects. In particular the effectiveness of Hepatitis B vaccination in a variety of EPI settings and according to differing schedules of delivery of other EPI immunogens should be evaluated. Also thermal stability of HB vaccines should be further evaluated in order to adapt them to EPI cold chain characteristics.

Model immunization projects in Indonesia, Thailand and China are being established in collaboration with the International Task Force of Hepatitis B Immunization. These projects should be closely monitored and evaluated on an ongoing basis.

Source: R. Palmer Beasley, "Hepatitis B Immunization Strategies." Expanded Program on Immunization, World Health Organization. 1988. (WHO/EPI/GEN/88.5).

ANNEX 3

RECOMMENDATIONS ON HEPATITIS B VACCINATION FROM THE 1987 WHO EPI GLOBAL ADVISORY GROUP

Chronic infection with hepatitis B virus is common in many countries. Such infection is a cause of hepatocellular carcinoma and other chronic liver disease. Hepatitis B vaccine is safe and effective in preventing infection, and its cost is now decreasing. Its use early in infancy can reduce chronic carrier rates by over 75%.

Hepatitis B immunization programmes should primarily aim at the prevention of chronic carriage of hepatitis B virus and should be considered in all population groups with chronic carrier rates of hepatitis B virus of over 2%; they become a major public health priority for populations with carrieer rates above 10%.

Countries with chronic carrier rates of hepatitis B of over 2% and with the resources to initiate and sustain hepatitis B immunization programmes should introduce hepatitis B immunization as an integral part of existing childhood immunization programmes. This vaccine should be used in ways which strengthen existing programmes.

A minimum of 3 doses of hepatitis B vaccine is recommended, given by the intramuscular route. The first dose is recommended at birth or as soon as possible thereafter, the second dose 4-12 weeks after the first and the third dose 2-12 months after the second dose. While intramuscular administration is the only recommended route at this time, further studies on other modes of delivery which could contribute to further reductions in vaccine costs, including intradermal administration, should be encouraged.

Immunization schedules should be integrated so that the use of hepatitis B vaccine does not require any extra contacts with the health system beyond those already needed for vaccines included within national childhood immunization programmes.

While the use of hepatitis B immune globulin is effective in complementing the use of hepatitis B vaccine in preventing perinatal infection, its high cost and the need to administer it within hours of birth will preclude its use in most developing countries.

Source: Weekly Epidemiological Record, No. 3, 1988.

ANNEX 4

EXPANDED

PROGRAM ON

IMMUNIZATION

MANUAL -

HEPATITIS B SUPPLEMENT

This supplement to your EPI Manual informs you about a new vaccine soon to be available throughout the country, hepatitis B vaccine. The vaccine will protect children against a disease which can often be fatal, hepatitis B.

Please read this information carefully and keep it with your EPI Manual for future reference.

HEPATITIS B

Hepatitis is a generic term meaning "inflammation of the liver." Different kinds of hepatitis are caused by different hepatitis viruses (such as hepatitis A, B, C, D, and others). The symptoms of hepatitis can include enlarged and painful liver, jaundice, darkening of urine, nausea, severe loss of appetite, weakness, and fever.

The most dangerous hepatitis virus is hepatitis B. The hepatitis B virus is a major cause of acute and chronic hepatitis, cirrhosis, and liver cancer in the Philippines. Liver cancer is one of the most common cancers in our country. Most hepatitis B related deaths are due to cirrhosis and liver cancer.

About 80% of cases of liver cancer are caused by hepatitis B. Liver cancer has a long latency period. Even though most carriers were infected as children, they usually do not develop cirrhosis or liver cancer until they reach 30 to 50 years of age, during the most productive period of life!

Because immunization against hepatitis B protects individuals against infection which can lead to liver cancer, hepatitis B vaccine can be thought of as the world's first anti-cancer vaccine!

Both hepatitis B and hepatitis A are very common in the Philippines. Unlike hepatitis A, hepatitis B usually does not make people ill right away. Instead, it causes liver problems later in life. Though hepatitis A can make an individual very ill, it does not cause liver cancer and is rarely fatal. There is no vaccine to protect against hepatitis A. Luckily, there is a vaccine to protect against hepatitis B.

OCCURRENCE

It is estimated that there are more than 280 million hepatitis B carriers worldwide. Hepatitis B is common in parts of East and Southeast Asia, Sub-Saharan Africa, the Amazon Basin, and many of the Pacific Islands.

Most Filipinos are infected before the age of six years. Most of us are able to fight the infection and become immune for life. However, some of the infants infected are not able to develop immunity. They become chronic carriers of hepatitis B. In the Philippines, approximately 12% of the population are chronic carriers. Most of them will eventually develop serious liver problems. Chronic carriers can spread infection throughout life.

Adults infected for the first time are less likely to become chronic carriers. Hepatitis B is especially dangerous for children.

MODE OF TRANSMISSION

Hepatitis B is spread:

1) from mother-to-child during birth. About 15% of chronic carriers in the Philippines were infected during birth. If babies can be vaccinated within 48 hours after birth, most of them will be protected against the disease;

2) from child-to-child or mother-to-child after birth (through cuts or sores). About 75% of chronic carriers in the Philippines were infected during the first few months and years of life. Even if babies are not vaccinated until the first month or two of life, most of them will still be protected against the disease;

3) through blood transfusion;

4) through sharing of unsterilized needles, knives, or razors;

5) through sexual intercourse. About 10% of chronic carriers were infected through these three routes. In other countries (such as the U.S. and Europe), these are the most common routes of infection.

SUSCEPTIBILITY/RESISTANCE

Everyone is susceptible to infection by hepatitis B, unless they have already been infected. Most adults in our country have already been infected in childhood, so it is not necessary that they be vaccinated against the disease. Children, however, must be vaccinated as early as possible in order to avoid becoming chronic carriers.

HEPATITIS B IMMUNIZATION SCHEDULE

Three vaccinations are needed for full coverage.

HB1: As soon as possible after birth. Within 48 hours, if possible. If not possible, then during the first vaccination encounter (for example, along with BCG).

HB2: At the second vaccination encounter (for example, along with DPT1). However, not less than four weeks after HB1.

HB3: At the third vaccination encounter (for example, along with DPT2). However, not less than four weeks after HB2.

It is safe and effective to vaccinate children against hepatitis B and other diseases at the same time.

CONTRAINDICATIONS

The same as for all other EPI vaccines. The vaccine should be given on schedule except in the case of a fever over 38.5°C or other signs of a very serious illness.

HEPATITIS B VACCINES

There are a number of different brands of hepatitis B vaccine available. Some are made from human blood products (plasma- derived vaccines), some from yeast (DNA-recombinant vaccines).

All hepatitis B vaccines licensed in the Philippines are equally safe and effective. There is no practical difference between plasma-derived vaccines and DNA-recombinant vaccines. Some drug companies claim that their vaccines are better than others, but it is not true.

HANDLING HEPATITIS B VACCINE

Hepatitis B vaccine should always be stored in the refrigerator at a temperature between 2° and 8°C. It should be treated like DPT.

Store hepatitis B vaccine on the second shelf of the refrigerator. Do not allow the vaccine to touch the sides or back of the cabinet or to come into direct contact with ice in the vaccine carrier. Place frozen icepacks at room temperature for 5 to 10 minutes before loading them with hepatitis B vaccine into cold boxes or vaccine carriers. Never allow hepatitis B vaccine to freeze. Freezing destroys the vaccine.

Discard open vials of hepatitis B vaccine at the end of the day.

DOSAGE

The pediatric dosage for hepatitis B vaccine is 0.5 ml. The vaccine is liquid and is ready for use from the vial.

HOW AND WHERE TO INJECT

Prior to immunization, remove the vaccine from the refrigerator or vaccine carrier and leave it at room temperature for at least three minutes. This will make the immunization sting less.

Shake the vial of vaccine well before use.

Hepatitis B vaccine is given intramuscularly (90 degree angle) in the upper and outer portion of the thigh (same technique as for DPT).

When giving hepatitis B immunization at the same time as DPT, use the thigh opposite that used for DPT.

Be sure to use a sterilized needle and syringe for each injection.

SIDE EFFECTS

The hepatitis B vaccine has almost no side effects.

Some infants may develop mild soreness at the immunization site, but this will go away within 24 hours. No treatment is necessary.

When the vaccination is given along with DPT, the child may have some mild side effects due to the DPT. Be sure the BHWs know how to manage DPT side effects.

TEACH YOUR BARANGAY HEALTH WORKERS ABOUT HEPATITIS B

When your BHWs come to the Health Station, explain about the hepatitis B virus and how parents can protect their children now from liver disease in later life.

Make sure that the BHWs understand:

1) What hepatitis B is, and how it is different from hepatitis A and other diseases that cause jaundice. The hepatitis B vaccine can only protect against hepatitis B, not against other forms of hepatitis or other diseases that cause jaundice.

2) The dangers of hepatitis B infection and how it can cause liver cancer many years after a baby is infected.

3) Hepatitis B is a disease attacking children in the Philippines. Most adults and children over 6 years of age are already immune to hepatitis B and do not need to be vaccinated.

4) Hepatitis B can be prevented through vaccination.

5) The first dose of hepatitis B vaccine should be given as soon after birth as possible.

6) The hepatitis B vaccination schedule.

7) The importance of making sure that the child receives all the EPI and hepatitis B vaccinations (full coverage).

8) Hepatitis B vaccine is safe and effective.

9) Hepatitis B vaccine has no side effects.

10) BHWs must tell parents about hepatitis B and the vaccine.