



Partnering with The Vaccine Fund

# Progress Report

to the  
Global Alliance for Vaccines and Immunization (GAVI)  
and  
The Vaccine Fund

by the Government of the

People's Republic of China

First annual progress report

Date of submission: 30 September 2003

Reporting period: 15 December 2002 to 30 September 2003

*Unless otherwise specified, documents may be shared with the GAVI partners and collaborators*

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## 1. Progress made during the previous calendar year

NOTE: (for continuity, information from the inception report submitted in December 2002 has been retained in lighter font color, and new activities and information since then are presented in **bold**).

### 1.1 Immunization Services Support (ISS) (Not applicable to China)

### 1.2 GAVI/Vaccine Fund New & Under-used Vaccines Support

#### 1.2.1 Receipt of new and under-used vaccines during the previous calendar year

*Please report on receipt of vaccines provided by GAVI/VF, including problems encountered.*

- GAVI disbursement was received on 8 October 2002. Since that time, procurement for the first year of the project and other project activities have been underway. As of 15 December 2002, competitive negotiation among suppliers of hepatitis B vaccine has been completed. Hepatitis B vaccine will start to be supplied to provinces by the end of 2002.
- **Since the date of the inception report (15 December 2002), the contract for the first year supply of hepatitis B vaccine was signed. There are two suppliers of hepatitis B vaccine, Beijing Tiantan Biological Products Co., and Shenzhen Kangtai Biological Company Co. Hepatitis B vaccine is supplied to the provinces quarterly; to date, three quarters supply of hepatitis B vaccine has been distributed, and the fourth quarter supply is pending.**
- Procurement of hepatitis B vaccine for the second year of the project is planned for October 2003.

#### 1.2.2 Major activities

*Please outline major activities that have been or will be undertaken, in relation to, introduction, phasing-in, service strengthening, etc. and report on problems encountered.*

- **Integration of Hepatitis B Vaccination into EPI**
  - Joint Ministry of Health/Ministry of Finance regulation was issued in December 2001, calling for financial integration of hepatitis B vaccination into EPI
  - “Technical Guidelines for Hepatitis B Immunization of Children” were issued by China CDC in early 2002
- **Project Launch**
  - Memorandum of Understanding (MoU) was signed on 1 June 2002, and the Project was officially launched in a ceremony.
- **Project Office**
  - Project Office was established, and project co-managers were named
  - **Three additional staff were assigned by China CDC to work part-time in the Project Office**
  - **The Children’s Vaccine Program at PATH hired a staff person, based at China CDC, to work half time on GAVI-related activities and half time on a project evaluating use of hepatitis B vaccine outside the cold chain (see below).**
  - **In January 2003, the Project Office held a national meeting in Beijing of provincial EPI staff to introduce the Project, and review the project implementation plan**

- **Project Implementation Plans:**
  - A detailed project implementation plan (national level) has been prepared and is being cleared by the Ministries of Health and Finance, and will be issued to the provinces in the first quarter 2003
  - The national project implementation plan (PIP) was formally issued to the provinces on 12 February 2003. The national PIP differs from the MoU regarding the relative distribution of central vs. provincial funds covering the China 50% portion of funding for procurement of AD syringes. According to the PIP, GAVI and central financing will provide for 70% of the injection equipment used for hepatitis B vaccine and other EPI vaccines in 12 Western provinces, and in national poverty counties in Shanxi, Anhui, Jiangxi, Henan, Hubei and Hunan provinces, with provincial funding providing the remainder. And GAVI will provide 50% injection equipment used for hepatitis B vaccine and other EPI vaccine to national poverty counties in Helongjiang, Hainan, Hebei and Jilin provinces, with provincial funding providing the remainder.
  - **Provinces have prepared provincial PIPs along with progress reports regarding activities conducted in preparation for the Project. These plans and reports have been reviewed and approved by the Project Office. Most provincial PIPs have followed national guidelines. All provinces have established pricing policies according to the MoU, with the hepatitis B vaccine price <3 RMB per dose (see Table 1). In some provinces, the price varies within the province according to the geography or income level. In Nei Menggu, the average price in the province is 3 RMB per dose, but it is higher in some counties due to the increased cost of providing EPI services to hard-to-reach population. Discussions are underway with Nei Menggu to revise this policy to be consistent with the MoU.**
- **Procurement:**
  - Activities related to procurement of hepatitis B vaccine and Auto-disable syringes are underway:
    - Provinces have been surveyed regarding updated target population estimates
    - Technical specifications for hepatitis B vaccine and AD syringes have been prepared
    - Procurement Coordinating Committee has been established and has met on 16 October 2002 and 9 December 2002 to decide procurement process
    - Tendering Agency has been selected and prepared the tendering documents, in collaboration with Ministry of Health, China CDC, and the Project Office
    - Tendering documents were issued
    - Competitive negotiation with hepatitis B vaccine manufacturers has been conducted
  - **Activities related to procurement of hepatitis B vaccine and AD syringes since the date of the inception report (15 December 2003)**
    - **Contracts were signed with two manufacturers for procurement of hepatitis B vaccine (7,099,341 person-doses) for the first year of the Project.**
    - **An additional meeting of the Procurement Coordinating Committee (PCC) meeting was held to reach consensus among national and international partners on the procurement mechanism for AD syringes.**
    - **Competitive negotiation with AD syringe manufacturers was conducted, and MOH contracted with two AD syringes manufacturers for procurement of AD syringes for hepatitis B vaccine (a total of 21,298,022 AD syringes for the first year of the Project).**
    - **MOH contracted with one manufacturer for procurement of a total of 150,155 safety boxes for the first year of the project.**
    - **Procurement for AD syringes for EPI vaccines other than hepatitis B was delayed due to the SARS epidemic; procurement of these syringes (and safety boxes for these syringes) will occur in October 2003.**
    - **In July 2003, each province reported to the Project Office updated target population estimates for the second year of the Project.**
    - **New plans for the next rounds of procurement have been developed and discussed with the Operational Advisory Group (OAG) at an OAG meeting in 1 August, 2003 (see attached meeting summary).**
    - **Another meeting of the PCC, to discuss the next rounds of procurement, will be held in the near future (planned in October 2003).**
- **Supervision**
  - **In March 2003, supervision visits were carried out in 11 of the 12 MOH/GAVI western project provinces.**

- The supervision visits for the remaining western province and the 10 middle provinces, which were planned for June 2003, was delayed due to SARS, and will be conducted in the fourth quarter 2003 and the first quarter 2004.
- The SARS epidemic had a major impact the national immunization program activities. Most provinces originally planned to begin the MOH/GAVI Project in the first quarter of 2003. Because of the SARS epidemic, most provinces had to delay starting province-wide Project activities until June or July 2003 (see Table 1).
- A national EPI review was conducted in September 2003 by the government. One focus of the review was the MOH/GAVI Project. The review report is in preparation; when completed, relevant results will be shared with the OAG.
- A review of the MOH/GAVI Project, including international partners, is planned for 2004.
- **Training**
  - Cascade training on hepatitis B immunization and injection safety has been initiated, and conducted by MOH and China CDC (with support of partners, including UNICEF, WHO and JICA) at the provincial level in all provinces.
  - Provinces have been surveyed regarding further progress regarding training activities. To date, most 22 GAVI provinces have conducted training to the county level, and training to lower levels (township and village) is ongoing. Assessment regarding the effectiveness of training, and the need for additional training and updates, will be conducted in the first quarter, 2003.
  - **During Project Office supervision visits in March 2003, the extent of implementation of training on hepatitis B and injection safety to the lower levels (e.g. township and village) was reviewed. As of that time, training to the village level had been completed in 7 of 11 western provinces, and substantially undertaken in the other 4 provinces (see Table 1).**
  - UNICEF has provided support for an evaluation of training on hepatitis B and injection safety, to be conducted in the fourth quarter of 2003. This evaluation will review the extent and quality of the training that has been conducted, and provide guidance for additional training activities.
  - The MOH/GAVI Project Office continues to work with other partners (WHO, UNICEF, World Bank, JICA, AusAID, Government of Luxembourg, others) to coordinate ongoing training activities on hepatitis B and injection safety. To the extent possible, information regarding hepatitis B and injection safety is incorporated into training activities of international partners' projects (for example, the WHO/U.S. CDC supported the Guizhou measles project supported by WHO, training in Tibet on hepatitis B control supported by WHO, training in Qinghai on injection safety supported by Luxembourg, training of grass roots level EPI health workers in Ningxia and Chongqing supported by UNICEF)
  - Through an AusAID/WHO supported project, a new model for EPI training of grass roots level EPI health workers, using interactive methods, has been developed. A training workshop for this model was held at China CDC in September 2003. Implementing this model more extensively for future training activities is being explored.
- **Financing**
  - Central funding: Year 2002 funding (36 million RMB = 4.35 million USD) received by Ministry of Health from Ministry of Finance in February 2002
  - GAVI/Vaccine Fund funding: GAVI disbursement received in China on 8 October 2002
  - Provincial funding: Some provinces have already obtained from their Departments of Finance funding for operations and for co-funding of AD syringe procurement for EPI vaccines other than hepatitis B vaccine, and others are in the process of mobilizing funds. Provinces will be surveyed in the near future (after issuance of the project implementation plan) to confirm the amount of funding received.
  - **Second year national funding was received on 30 December 2002**
  - **Second year GAVI disbursement was received on 31 May 2003**
  - **Regarding procurement of AD syringes, among 22 project provinces, 12 provinces (7 of 12 western provinces, although for one funding is not sufficient, and 5 of 10 middle provinces) have received co-funding from provincial governments (see Table 1).**
  - **Regarding operational funds, 12 provinces (6 western provinces and 6 middle provinces) have received from provincial governments funds for provincial level activities (see Table 1).**
- **Information, Education and Communication (IEC)**
  - Advocacy and communication activities (supported by UNICEF) for integration of hepatitis B vaccine into EPI have been conducted, including meetings in selected provinces to sensitize

policy makers, the development and broadcast of television programs, and the development and printing of posters.

- Initial meeting to be held in near future with the National Health Education Institute to prepare an overall IEC plan for MOH-GAVI project
- **The theme of the National EPI Day in April 2003 was Hepatitis B Immunization. The Project Office participated in a briefing on hepatitis B prevention activities, which was sponsored by the Ministry of Health and the China Foundation for Hepatitis Prevention and Control, and attended by 30 journalists from 20 mass media organizations. The MOH called for all the provinces to organize advocacy activities on hepatitis B immunization to increase more attention from society and awareness among the public. - Social mobilization activities, using a variety of approaches, were carried out in most Project provinces.**
- **Three staff from the Project Office attended the GAVI Communication for Immunization Workshop held in Bangkok, Thailand, June 30 – July 1, 2003**
- **A MOH/GAVI Project Newsletter was initiated, and two issues have been distributed to provinces and other interested parties**
- **A grant was received from the Children's Vaccine Program at PATH to support the development of a website for the MOH/GAVI Project. A website developer has been selected, and the website ([www.Chinagavi.org.cn](http://www.Chinagavi.org.cn)) is currently under construction.**
- **Initial meetings were held with the National Health Education Institute in February 2003, at which plans were made to develop a national action plan for IEC. Work on this plan was delayed, and will be reinitiated in the near future, with the assistance of ICC and other international partners.**
- **Monitoring and Evaluation**
  - The routine immunization reporting form has been modified to require information regarding timing of the hepatitis B vaccine birth dose
  - An international consultant is currently evaluating methods to improve the routine immunization reporting system, to improve its usefulness as a management tool
  - Plans are to collaborate with the World Bank Health Project VII end-of-project review, which involves a multi-province immunization coverage survey (in 2003), to obtain baseline data for the MOH-GAVI project
  - **The World Bank Health Project VII end of project coverage surveys are being conducted by Health Project VII provinces in 2003 (although only 6 provinces are MOH/GAVI Project provinces).**
  - **Other possibilities to obtain baseline coverage data are being explored.**
  - **In 2002, the Institute of Nutrition at China CDC conducted a nationwide nutrition survey (all age groups), including the collection of the sera from >80,000 persons. Plans are underway to use these sera for hepatitis B serologic testing to obtain a baseline HBsAg prevalence.**
  - **In 2004, surveys will be conducted to determine the impact of price on coverage.**
- **Operational Advisory Group (OAG)**
  - The OAG was convened, and had its inaugural meeting on 12 December 2002
  - **An OAG meeting was held on 1 August 2003 to review project progress and discuss outstanding issues related to the second round of procurement (see attached minutes)**
  - **Another OAG meeting is planned in the near future to decide on use of savings from the first year of the project. After procurement of AD syringes for EPI vaccines other than hepatitis B vaccine (expected during October 2003), the total amount of savings for the first year of the Project can be determined. Potential savings may result from a lower price of hepatitis B vaccine than was budgeted; a smaller birth cohort than was estimated; a decision to not purchase AD syringes for JE vaccine and meningococcal vaccine in all provinces.**
- **Project unmet needs**
  - An assessment of unmet needs regarding all aspects of the project, including training, IEC, injection safety, monitoring and other activities, will be conducted in February 2003
  - **The results of the assessment were presented at an ICC meeting in early 2003 (see attached meeting summary). Additional work needs to be conducted to specify unmet needs and to identify potential sources of funds, including surveying provinces to develop provincial specific estimates, and developing standards ways to estimate unmet needs.**

Hopefully, activities related to developing the Financial Sustainability Plan, due in 2004, can also be used to identify unmet needs.

- **Relevant activities in collaboration with partners**
  - **Timeliness of the hepatitis B vaccine birth dose**
    - A study is planned to evaluate factors related to timeliness of the hepatitis B vaccine birth dose (WHO)
      - **Implementation of this study was delayed due to the SARS epidemic, and will be conducted in the last quarter of 2003.**
    - A study is planned to evaluate improving timeliness of the birth dose using the Uniject device outside the cold chain (PATH-CVP, UNICEF, U.S. CDC)
      - **This study has been initiated in Hunan Province, as a collaboration between the National Vaccine and Serum Institute, PATH-CVP, U.S. CDC, the Hunan Bureau of Health and the Hunan CDC**
  - **Strengthening of the National Regulatory Authority**
    - A WHO team will visit China on 16-20 December 2002 to assess progress
      - **The team found that the State Food and Drug Administration had met four NRA critical functions, but that improvements were needed in GMP and in post-marketing surveillance for adverse events following immunization (AEFI).**
    - **Another WHO team visited China in early September 2003. Results of the visit showed substantial progress in NRA strengthening, especially in GMP and AEFI. SFDA has met all six NRA critical functions.**
- **Injection safety activities** (please see section 1.3)

Table 1. Status of MOH/GAVI Project in Twelve Western Provinces, by Province (from Provincial Progress Reports submitted August 2003)

Province	Hepatitis B vaccine price per dose (RMB)	Date of Province-wide Project Start (2003)		Training to village doctor level
		Planned	Actual	
Guangxi	3	March	June	Completed
Chongqing	3	April	August	Completed
Sichuan	3	April	June	75% of townships completed
Guizhou	1-2	April	June	Not finished, Ongoing
Yunnan	3	March	June	Most finished
Tibet	1-3	March	August	Ongoing
Shanxi	3	April	August	Completed
Gansu	3	April	June	Completed
Qinghai	1	March	July	Completed
Ningxia	3	June	June	Completed
Xinjiang	3	May	July	Completed
Nei Menggu	2-5	April	August	Most finished

### 1.2.3 Use of GAVI/The Vaccine Fund financial support (US\$160,000) for the introduction of the new vaccine

*Please report on the proportion of 160,000 US\$ used, activities undertaken, and problems encountered such as delay in availability of funds for programme use.*

- The additional financial support from GAVI/VF is for Project Office activities. An overall budget has been prepared containing elements of personnel, equipment and supplies, and activities (including supervision and monitoring), staff are being recruited, and equipment and supplies will be purchased in the near future. To date, funds have been used for: 1) publication and distribution of a newsletter to provinces and other groups regarding inauguration of the Project and 2) local travel to AD syringe manufacturers to review operations, in preparation for procurement
- **To date, total US\$ 153,320 has been expended, the detailed information lists as following:**

- Project staff	25,000
- Project office rent	25,000
- Consultation by domestic experts	1,717
- Equipment for project office (including computers, copy machine, fax, etc.)	42,528
- Supervision visits	47,907
- National Project Meeting	9,968
- Newsletters (printing and distribution)	1,200

## 1.3 Injection Safety

### 1.3.1 Receipt of injection safety support

*Please report on receipt of injection safety support provided by GAVI/VF, including problems encountered*

- GAVI disbursement was received on 8 October 2002. Since that time, procurement for the first year of the project and other project activities have been underway. As of 15 December 2002, suppliers for AD syringes for hepatitis B vaccine and for safety boxes have been prequalified, the invitation to bid has been issued, and evaluation of bids is planned before the end of 2002.
- Procurement for AD syringes for other EPI vaccines for which a 0.5 mL syringe is used (e.g. DPT vaccine) will occur in 2003. While GAVI and central level funding for these purchases are secured, provincial level co-funding is still being mobilized.
- **The contract for the first year's supply of AD syringes used for hepatitis B vaccine was signed. There are two suppliers of AD syringes, Becton, Dickinson, and Co., and Linyang Medical Instrument Co. AD syringes are supplied to the provinces quarterly; to date, three quarters supply of AD syringes has been distributed, and the fourth quarter supply is pending.**
- **The contract for the first year's supply of safety boxes was signed. All procured safety boxes have been distributed to the provinces (in July).**
- **Second GAVI disbursement was received on 31 May 2003**
- **Procurement of AD syringes for other EPI vaccines, for the first (delayed due to the SARS epidemic) and second year of the Project, is planned for October 2003.**



### 1.3.2 Progress of transition plan for safe injections and safe management of sharps waste.

*Please report on the progress based on the indicators chosen by your country in the proposal for GAVI/VF support.*

Indicators	Targets	Achievements	Constraints	Updated targets
<p><i>The following are indicators as specified in the Project Implementation Plan. The injection safety action plan has not been finalized, therefore, targets and methods for measuring progress toward targets have not been finalized.</i></p> <p>Percentage of immunization sites using AD syringes for hepatitis B vaccination</p> <p>Percentage of counties using AD syringes for hepatitis B vaccination</p> <p>Percentage of immunization sites using AD syringes for other EPI vaccines</p> <p>The percent of counties using AD syringes for other EPI vaccines.</p> <p>The percent of immunization sites that conduct appropriate collection and disposal of AD syringes.</p>				

### 1.3.3 Statement on use of GAVI/The Vaccine Fund injection safety support (if received in the form of a cash contribution)

*The following major areas of activities have been funded (specify the amount) with the GAVI/The Vaccine Fund injection safety support in the past year:*

- An action plan has been prepared, and is currently under review. The plan calls for use of AD syringes for all immunization injections by 2005.
- Activities to date include:
  - Training at the provincial level in all provinces regarding injection safety and AD syringe use has been conducted. Training at lower administrative levels is ongoing
  - A pilot study is being conducted looking at collection of used immunization injection equipment (with JICA)
  - An evaluation of introduction of AD syringes into immunization services is being conducted (with UNICEF)
  - WHO-supported consultants, including from the Safe Injection Global Network (SIGN), have visited China to assist with the action plan and the development of technical materials

- Activities for next year (2003-4) include:
  - Procurement of AD syringes for EPI vaccines other than hepatitis B vaccine
  - Continuation of training and education activities, and evaluation of training activities.
  - Continuation of the JICA management of used injection equipment pilot study
  - Initiation of a costing study (with World Bank) for introduction and long-term sustainability of AD syringe use for immunization injections
- Main constraints
  - Availability of provincial co-funding for purchase of AD syringes for immunization injections other than hepatitis B vaccine
  - Availability of funding for training, especially at the lower levels
  - Syringes needed for measles vaccine and BCG vaccine include 0.2 mL and 0.1 mL syringes, respectively, and reconstitution syringes. Discussions are being held with syringe manufacturers regarding the availability of these products, with expected procurement sometime during 2003. Two companies produce 0.1 mL AD syringes which are registered by the State Food and Drug Administration in China. Consideration is being given to change the measles vaccine dosage from 0.2 mL to 0.5 mL, so that the volume conforms to international standards; therefore, it may not be necessary for the Project to purchase 0.2 mL syringes.

## 2. Financial sustainability

As specified in the Memorandum of Understanding, a financial sustainability plan will be prepared for submission in November 2004. In the near future, the Ministry of Health will begin working with the ICC and other international partners, the Operational Advisory Group, and the MOH/GAVI Project Office on developing a financial sustainability plan. The guidelines for preparing a national immunization program financial sustainability plan issued by GAVI will be reviewed and adapted for the China situation.

## 3. Request for new and under-used vaccines for year 2003

*Section 3 is related to the request for new and under used vaccines and injection safety for the **forthcoming year**.*

### 3.1. Up-dated immunization targets

Confirm/update basic data (surviving infants, DTP3 targets, new vaccine targets) approved with country application:

(please see Table 2 next page)

## 5.. Table 2: Baseline and annual targets for MOH/GAVI Project

(Project area: 12 western provinces and poverty counties in non-western provinces)

Number of	Baseline and targets			
	2001	2002	2003	2004
<b>DENOMINATORS</b>				
Births <sup>a</sup>	6,561,819	5,902,463		
Infants' deaths <sup>b</sup>	211,290	177,074		
Surviving infants	6,350,529	5,725,389		
<b>Infants vaccinated with DTP3</b>				
Infants vaccinated with DTP3: administrative figure reported in the WHO/UNICEF Joint Reporting Form	6,189,225	5,371,241 <sup>c</sup>		
<b>NEW VACCINES</b>				
Infants vaccinated with hepatitis B vaccine	2,206,935	3,364,404 <sup>c</sup>	6,561,819	5,902,463
Wastage rate of hepatitis B vaccine <sup>d</sup>				
<b>INJECTION SAFETY</b>				
Pregnant women vaccinated with TT				
Infants vaccinated with BCG		5,548,315 <sup>c</sup>		
Infants vaccinated with Measles		5,312,217 <sup>c</sup>		

a: Provincial Statistic Bureau estimates

b: Calculated based on 2001 infant mortality estimate (30.0 per 1000) (MOH Health Statistics Summary, June 23, 2003)

c: China did not provide an overall coverage estimate in 2002 on the WHO/UNICEF Joint Reporting Form. The numbers in the 2002 column are estimated from coverage surveys conducted in five provinces (Qinghai, Sichuan, Guizhou, Shanxi, Hubei) during the EPI review in September 2003 (DTP3 91%, HepB3 57%, BCG 94%, MV 90%), and applied to the MOH/GAVI Project birth cohort (which includes the western provinces and poverty counties in other provinces).

d: Wastage for hepatitis B vaccine is not known

*Please provide justification on changes to baseline, targets, wastage rate, vaccine presentation, etc. from the previously approved plan, and on reported figures which differ from those reported in the WHO/UNICEF Joint Reporting Form in the space provided below.*

The denominator data in this table is based upon data provided to the MOH/GAVI Project office in June 2003 from Project provinces, which in turn obtained the data from the provincial statistics bureaus. The official birth rate in China continues to decline, and this is reflected in these estimates. Wastage for hepatitis B vaccine is not known, but will be evaluated in future studies. For procurement purposes, it has been estimated to be 10%.

**4. Please report on progress since submission of the last Progress Report based on the indicators selected in the proposal for GAVI/IF support**

Indicators	Targets	Achievements	Const raints	Updated targets
<p>1. Indicators for management Indicators for management include organization, allocation of co-funds, monitoring/supervision, training and social mobilization.</p> <p>2. Indicators for vaccine management</p> <p>2.1 System for recording vaccine distribution and immunization</p> <p>2.2 Wastage factor</p> <p>2.3 Range of recipients of hepatitis B vaccine (determining the percentage of hepatitis B vaccine used to immunize newborns through review of distribution records, immunization records, sampling survey and other methods)</p> <p>2.4 Service fee: percentage of infants who were charged an amount equal to or less than the maximum fee (3 RMB, including all service fees).</p> <p>3.1 Safe injections See section 1.3.2</p> <p>4. Immunization working indicators</p> <p>4.1 HepB3 coverage rate in children less than 12 months old</p> <p>4.2 Percentage of infants receiving first dose of hepatitis B vaccine within 24 hours of birth</p> <p>4.3 Percentage of counties carrying out bimonthly reports on immunization coverage rates</p> <p>4.4 The accuracy and completeness of each year's previous population data from routine immunization reporting</p> <p>4.5 Percentage of counties meeting hepatitis B immunization coverage objectives</p> <p>4.6 The HBsAg carrier rate in children under 3 years old: combining project mid-term review and end of project review. Certain regions can carry this out themselves if conditions allow.</p> <p>5. Data reporting</p> <p>5.1 Timeliness of reported data.</p> <p>5.2 Completeness of reported data.</p>	<p>4.1 85% at county level by end of project</p> <p>4.2 75% timeliness of first dose by end of project</p> <p>4.6 2% by province among children under 3 years of age</p>	<p>These indicators were developed for the project implementation plan. Targets still need to be determined., and most need to be measured by special surveys and studies, which have not been conducted yet</p>		

## 5. Checklist

Checklist of completed forms:

<b>Form Requirement:</b>	<b>Completed</b>	<b>Comments</b>
Date of submission	30 September, 2003	
Reporting Period (consistent with previous calendar year)	15 December 2002 to 30 September 2003	Inception report submitted 15 December 2002 covered most of the previous calendar year
Table 1 filled-in		Not applicable to China
DQA reported on		Not applicable to China
Reported on use of 160,000 US\$	See section in report	
Injection Safety Reported on	See section in report	
FSP Reported on (progress against country FSP indicators)	See section in report	FSP for China due 2004
Table 2 filled-in	See section in report	
New Vaccine Request completed		Not applicable (China is procuring hepatitis B vaccine)
Revised request for injection safety completed		Not applicable (China is procuring AD syringes)
ICC minutes attached to the report	See section in report	
Government signatures	See section in report	
ICC endorsed	See section in report	

## 6. Comments

*ICC comments:*

The ICC considers hepatitis B prevention, and the MOH/GAVI Project, as one of the highest priority immunization activities in China. Progress during this first year of Project has been substantial. The SARS epidemic had a major impact on Project activities, as it did on all immunization and public health activities in China. Priority activities in the near future include finalization of recommendations regarding immunization injection safety, development of reliable methods to accurately determine coverage, and ensuring through supervision and advocacy that provincial level cofunding for AD syringe procurement is mobilized in all provinces.

ICC members will work actively with the Ministry of Health to carry out the GAVI requirement of preparation of a financial sustainability plan (FSP), which for China is due in 2004. Given the special situation of immunization financing in China, the format of the FSP will have to be adapted so that the FSP will be most useful for the government.

## 7. Signatures

For the Government of the People's Republic of China .....

Signature: .....

Title: .....

Date: .....

We, the undersigned members of the Operational Advisory Group of the MOH/GAVI Hepatitis B and Injection Safety Project (a subgroup of the Inter-Agency Co-ordinating Committee) endorse this report. Signature of endorsement of this document does not imply any financial (or legal) commitment on the part of the partner agency or individual.

Financial accountability forms an integral part of GAVI/The Vaccine Fund monitoring of reporting of country performance. It is based on the regular government audit requirements as detailed in the Banking form. The ICC Members confirm that the funds received have been audited and accounted for according to standard government or partner requirements.

Agency/Organisation	Name/Title	Signature	Date
Ministry of Health, China Department of International Cooperation	Dr. Ren Minhui Deputy Director General		
Ministry of Health, China Department of Disease Control	Dr. Yu Jingjin, Deputy Director General		
Chinese Center for Disease Control and Prevention	Dr. Bai Huqun Deputy Director		
World Health Organization (WHO)	Dr. Henk Bekedam WHO Representative, China		
United Nations Children's Fund (UNICEF)	Dr. Christian Voumard Representative, UNICEF-China		
U.S. Centers for Disease Control and Prevention (CDC)	Dr. Craig Shapiro Medical Epidemiologist		
The Children's Vaccine Program at PATH	Dr. Mark Kane Director		

~ End ~

## **Interagency Coordinating Committee (ICC) Meeting Record**

**Date and location:** 27 February 2003, 9:00 a.m. at Chinese Center for Disease Control and Prevention (CCDC).

**Participants:** Please see the attached Name List.

Liang Xiaofeng, Director of the National Immunization Program, CCDC and Deputy Director of MOH/GAVI Project Office, chaired the meeting.

**Review of the GAVI project activities and work plan:** Wang Xiaojun gave a progress report on the GAVI project to date. The project year one funding arrived in February and October from China Central Government and GAVI, respectively. An impressive amount has been done in the five months of the project, including completion of the vaccine and AD (for Hep B vaccine) procurement. The “Project Implementation Plan” and the “Notice on AD syringes distribution” will be issued soon. An AD syringes tracking monitor will be conducted to monitor the management and distribution of the project syringes. Studies such as “feasibility of using vaccine out of the cold chain” and “factors impact the timeliness of the birth dose of the HB vaccine” are necessary to be conducted. The challenges remaining are the AD syringes procurement for other EPI vaccines, and the project needs still to be funded. The project plans to standardize supervision requirements.

**GAVI project unmet needs:** The GAVI Project was launched in 2002. Project funding for hepatitis B vaccine, autodisable syringes, safety boxes, and establishment of the Project Office was provided by both the government of China and GAVI. Project implementation activities for which funding had not been specifically provided include: training; information, education and communication (IEC); supervision; monitoring and evaluation. Janet Vail of the Program for Appropriate Technology in Health (PATH) was invited to review unfunded needs for MOH/GAVI Project implementation, and to assist in identifying potential sources of funds to meet those needs. After meeting or talking with people from provincial Health Bureau and CDC, CCDC, GAVI Project Office, WHO, UNICEF, JICA, China Foundation for Hepatitis Prevention and Control (FHPC), CSY Foundation, Rotary Club District 3540, and National Health Education Institute, it was concluded that it was very difficult to estimate a new budget for the unmet needs based on field level information. This is because each program had a different idea of how the system should work, and also because official guidance has still not been issued yet on how the system it to operate. This guidance is about to be issued in the implementation plan from the Ministries of Health and Finance. Rather than focusing on building a budget all the project counties, it was recommended to focus on a few key priorities such as the birth dose at home.

**Overlapping work:** Janet Vail presented that many different international agencies have been conducting overlapping work in different provinces, and therefore, not all provinces and

levels are starting with the same needs. Efficiencies may be gained by eliminating overlapping (and sometimes conflicting) training materials.

**Funding identification:** Procurement savings has already been realized, which should be applied to these needs. New funders can be mobilized, such as CSY and Rotary. International partners can address gaps in their future program planning to see how they might fit with the GAVI project.

**Standard of management of hepatitis B vaccine:** Lisa Lee briefly discussed the World Bank 7 mission. She said that management of hepatitis B vaccine should be standardized so that it is similar to other EPI vaccine—for example, there is confusion about who reports what, how the vaccine is delivered, and fee collection.

MOH/GAVI Project Office

Attachment: Name List of the Participants



### **Name List of the Participants**

Dr. Lei Zhenglong	Deputy Director, EPI Division, DDC, MOH Deputy Director, MOH/GAVI Project Office
Dr. Bai Huqun	Deputy Director, CCDC Director, MOH/GAVI Project Office
Dr. Liang Xiaofeng	Director, NIP, CCDC Deputy Director, MOH/GAVI Project Office
Dr. Craig Shapiro	MOH/GAVI Project Manager
Dr. Wang Xiaojun	MOH/GAVI Project Manager
Dr. Lisa Lee	WHO, Beijing
Ms. Saba Mebrahtu	UNICEF, Beijing
Dr. Zhu Xu	UNICEF, Beijing
Dr. Toru Chosa	JICA, Beijing
Ms. Janet Vail	PATH, Seattle, USA
Dr. Wang Lixia	PATH, Beijing
Dr. Feng Zijian	Deputy Director, NIP, CCDC
Ms. Zhou Yuqing	MOH/GAVI Project Office
Dr. Yang Zhenyu	MOH/GAVI Project Office
Dr. Li Junhong	MOH/GAVI Project Office
Dr. Li Yixing	NIP, CCDC
Dr. Chen Yuansheng	NIP, CCDC
Dr. Yang Junfeng	NIP, CCDC
Dr. Zuo Shuyan	NIP, CCDC
Dr. Wen Ning	NIP, CCDC
Dr. You Xuedan	NIP, CCDC

## Minutes of the ICC Meeting

.1. Date: 2003/5/22

.2. Time: 1:30pm

Venue: 7<sup>th</sup> floor meeting room in China CDC

Participants:	Bai Huqun	Vice director-general of CDC
	Cui Gang	Director of department of IP, MOH
	Liang Xiaofeng	Director of NIP, CDC
	Craig Shapiro	Manager of GAVI project office
	Saba Mebrathu	Officer of Unicef
	Zhu Xu	Officer of Unicef
	Li Ailan	Officer of WHO
	Toru Chosa	Chief Advisor of JICA
	Naoko Ishikawa	Officer of JICA
	Ryuji Iriyama	Officer of JICA
	Yang Junfeng	NIP, CDC
	Wang Xiaojun	Chinese Manager of GAVI project office
	Li Yixin	NIP, CDC
	Xu Wenbo	Institute of Virology, CDC
	Li Jie	Institute of Virology, CDC
	Wang Lixia	GAVI Project coordinator of PATH/Beijing
	Zuo Shuyan	NIP, CDC
	Wen Ning	NIP, CDC
	You Xuedan	NIP, CDC
	Sheng Li	NIP, CDC
	Li Junhong	NIP, CDC
	Zhou Yuqing	NIP, CDC
	Yang Zhenyu	NIP, CDC
	Cao Lei	NIP, CDC
	Guo Biao	NIP, CDC
	Hao Lixin	NIP, CDC
	Li Hongming	NIP, CDC
	Zhang Lanxiang	NIP, CDC

### Major topics:

1. AFP cases report in China in 2002 and the first season of 2003.
  - In 2002, AFP surveillance system is fine.
  - However, in a few provinces the provincial non-polio AFP rate is less than the minimum level (1 AFP case per 100,000); The percentage of collecting AFP case stool specimens is less than 80% required by WHO.
2. NT analysis of surveillance system in 2002 and 2003(1-3).

- Rate of home delivery is much higher for NT cases than normal infants.
  - Male-Female Rate of Confirmed Cases is not similar with any other countries.
  - Many cases were not reported and some cases were not investigated.
  - There are many discordant codes that have a great effect on determination of high-risk county.
3. Status of coverage surveillance system, 2002, China
    - The reporting coverage of routine vaccine is high in all over the country.
    - Accuracy and timeliness of report need to be improved.
  4. Measles analysis of surveillance system in 2002
  5. Report the results of poliovirus lab in 2002.
  6. GAVI project progress recently.
    - Finish the GAVI supervision in the western provinces
    - Baseline information for GAVI project
    - HBV serosurvey draft, coverage survey)
    - Procurement of afety boxes
    - Prepare for the next round procurement of AD syringes for other EPI vaccines
    - Management of vaccine and syringes and collect and summarize the progress reports from the GAVI province progress.
  7. Vaccine supply in every province in 2002.
    - There are several provinces whose vaccines ( including DTP, DT, measles) are not enough for their requirement.
  8. Recent work plan of department of IP.
  9. Recent work plan of NIP.

## **Summary: Operational Advisory Group Meeting, August 1, 2003**

The third MOH/GAVI Project Operational Advisory Group (OAG) Meeting was held on August 1, 2003 in National Immunization Program (NIP) meeting room, China Center for Disease Control (CCDC). Staff from Department of Disease Control (DDC), Ministry of Health (MOH), CCDC, MOH/GAVI project office, and World Health Organization (WHO), Beijing participated in the meeting (The list of participants is attached.) Dr. Lei Zhenglong, Deputy Director, Vaccine Preventable Disease Division, DDC, MOH and Deputy Director, MOH/GAVI Project Office, chaired the meeting.

The objectives of this meeting were to update participants on the status of the Project, and to discuss several outstanding issues related to the next round of procurement.

The Project Office reviewed Project activities since the last OAG meeting (held 20 December, 2003), including hepatitis B (HB) vaccine and AD syringe for HB vaccine procurement in 2002-2003. The following issues related to the Project were discussed in detail:

### **1. Project Implementation Plan**

The Project Implementation Plan (PIP) was finalized and issued to the Provinces in February 28 (a translation of the PIP is attached). The PIP and the Memorandum of Understanding (MOU) differ according to the relative distribution of central vs. provincial level funding for the portion of the Project funding provided by China. In the MOU (Article 5, Section 3), China funding for injection equipment (AD syringes and safety boxes) for hepatitis B vaccine would come predominantly (with some exceptions) from the central level, and for EPI vaccines other than hepatitis B vaccine, would come predominantly from the provincial level. According to the PIP (Section 5.1), funding provided for AD syringe procurement totally will be 70% central (central government and GAVI) and 30% provincial.

Since the China funding for procurement of injection equipment (for AD syringes and safety boxes for hepatitis B vaccine) to date has been fully from the central level, the amount of central-level funding for procurement of injection equipment for the remainder of the first year, and for the second year, the procurement for all the AD syringes would be accomplished and the relative distribution of central vs. provincial funds will correspond to the PIP.

### **2. Syringes for Japanese Encephalitis (JE) vaccine and meningococcal vaccine**

In the original Project proposal, AD syringes for JE and meningococcal vaccines were to be procured, and funding was received from GAVI for this purpose. However, a recent review of the status of JE vaccine and meningococcal vaccine use shows that while JE and meningococcal vaccines are available in many Project provinces, most provinces have not integrated these vaccines into EPI. Participants at the OAG meeting decided that a survey would be conducted to obtain more precise information on JE and meningococcal vaccines at

the provincial level, including the schedule used; the number of doses for each procured last year; and the coverage among infants achieved, and use this information to estimate the number of AD syringes needed for the current level of JE and meningococcal vaccine use. Based on this information, AD syringes will be procured.

### 3. Measles vaccine

Currently, in most provinces the standard dose for measles vaccine is 0.2 mL. Currently, there are no domestic or international manufacturers make a 0.2 mL AD syringe (and availability in the future is uncertain). In addition, draft EPI technical regulations are currently under review by MOH and CCDC, to be issued sometime in the near future, which specify that the dose for measles vaccine should be 0.5 mL. Therefore, participants at the OAG meeting suggested for the Project, AD syringes to be procured for measles vaccine should be 0.5 mL.

### 4. Reconstitution syringes

Measles and BCG vaccines in China are lyophilized, and need to be reconstituted with diluent before use. When the MOH/GAVI Project was originally developed, funding for reconstitution syringes was not specified, and funding for these syringes was not received from GAVI or the central government. Furthermore, there is no WHO/UNICEF specification for reconstitution AD syringes. Because of these reasons, participant at the OAG meeting decided that for the first year MOH/GAVI Project would not procure syringes for reconstitution, but that this decision would be reevaluated in subsequent years, based on information collected from lower levels on methods and types of syringes used for reconstitution of measles and BCG vaccines.

### 5. Provincial cofunds for procurement

The bidding at national level will principally for the central funding. To use the existing resource well, during the bidding negotiation, the manufactory will be requested to provide the same price to provinces procuring the syringes using the co-funding. Regarding the question about how to ensure that the provinces mobilize the co-funding for AD syringes, MOH/MOF joint issued documents: “Note for integrating Hepatitis B vaccine into children routine immunization” and “MOH/GAVI project implementation plan”. These documents stated clearly about the co-funding. The OAG suggested enhancing supervision, learning the progress actively and reporting the situation frequently. Other mechanism will be considered to improve functioning the co-funding.

### 6. Timetable for upcoming procurement

The year 2 funding from Central government (36 million RMB) and GAVI (\$7.73 million) has been disbursed. It was suggested at the meeting that the year 2 bidding should be done with the upcoming bidding for the AD syringes, and that the Project Office modify the procurement plan based on the above suggestions.. According to the MOF’s requirement for

use of central government funds, the bidding and procurement needs to be completed by the end of September.

#### 7. Other items

The wastage rate (both for hepatitis B vaccine and for AD syringes) will be 10% for the year 2 procurement

#### NEXT STEPS

According to the meeting, a PCC meeting are proposed to held to address all the relevant issues related to bidding and procurement.

MOH/GAVI Project Office

Attachment:

Project Implementation Plan, Official Translation

#### **Name List of the Participants**

##### **OAG members**

Dr. Yu Jingjin	Deputy Director, DDC, MOH
Dr. Cui Gang	Director, EPI Division, DDC, MOH
Dr. Lei Zhenglong	Deputy Director, EPI Division, DDC, MOH
	Deputy Director, MOH/GAVI Project Office
Dr. Bai Huqun	Deputy Director, CCDC
	Director, MOH/GAVI Project Office
Dr. Feng Zijian	Deputy Director, NIP, CCDC
Dr. Craig Shapiro	MOH/GAVI Project Manager
Dr. Wang Xiaojun	MOH/GAVI Project Manager
Mr. Alan Schnur	WHO, Beijing
UNICEF	Could not attend
Dr. Mark Kane	PATH (could not attend)

##### **Other persons at the meeting**

Mr. Yoshihiro Takishima	WHO, Beijing
Dr. Wang Lixia	PATH, Beijing
Ms. Zhou Yuqing	MOH/GAVI Project Office
Dr. Yang Zhenyu	MOH/GAVI Project Office
Dr. Li Junhong	MOH/GAVI Project Office
Dr. Chen Yuansheng	MOH/GAVI Project Office

# **Ministry of Health, Global Alliance for Vaccines and Immunization (GAVI) and Vaccine Fund**

## **Hepatitis B Vaccination Project Implementation Plan**

Issued to Provinces: February 11, 2003

Final version (pip2003final3)

To ensure that each newborn has access to hepatitis B immunization services, the government of China has made a decision to integrate hepatitis B vaccine into the Expanded Programme on Immunization (EPI) starting in 2002. To accelerate the timetable for achieving control of hepatitis B and ensure the safety of immunization injections, the central government has provided special funds to strengthen hepatitis B immunization and safe injection activities in western provinces and poverty regions, and has sought to collaborate on this project with GAVI and The Vaccine Fund.

### **Part I Project Areas, Target Population, and the Project Duration**

#### 1.1 Project Areas:

12 Western provinces includes Sichuan, Guizhou, Yunnan, Xizang, Chongqing, Shaanxi, Gansu, Qinghai, Ningxia, Xinjiang, Guangxi, and Inner Mongolia. 10 provinces with national poverty counties includes Hunan, Hubei, Shanxi, Jiangxi, Anhui, Henan, Heilongjiang, Hainan, Hebei and Jilin.

#### 1.2 Target Population:

All new born children in the project areas during the project period.

#### 1.3 Project Duration:

5 years. From 2002 to 2007.

### **Part II Goals and Objectives**

#### 2.1 Goal

Implementation of this Project will accelerate the integration of hepatitis B vaccine into EPI in 12 western provinces and in national poverty counties; provide hepatitis B vaccine to all infants in the Project area; promote safe infection practices for all routinely administered immunizations; reduce the hepatitis B surface antigen (HBsAg) prevalence rate and hepatitis B incidence; and strengthen hepatitis B control work in the Project area.

#### 2.2 Detailed objectives

To integrate hepatitis B vaccine into EPI by the conclusion of the Project:

- To increase the three dose coverage rate in children under 12 months to 85% (at the county level)
- To increase the rate of timely first dose delivery to higher than 75% (at the county level)
- To reduce the HBsAg carrier rate to less than 2% in children under three years of age (at the county level)
- To ensure the safety of immunization injections through the comprehensive use of autodisable (AD) syringes

## **Part III Organizational Structure and Responsibility**

### **3.1 National**

1) The Ministry of Health is responsible for overall planning, leadership, Project implementation, and coordination with relevant ministries, committees, and international agencies, and submitting progress reports.

2) The Ministry of Finance is responsible for providing specified funds, monitoring the use of project funds using and procurement of vaccines and injection equipment.

3) The State Drug Administration is responsible for carrying out quality control work on hepatitis B vaccine and injection equipment on the basis of Project requirements.

4) The Chinese Centers for Disease Control and Prevention (China CDC) will provide technical support, carry out field monitoring, supervision and evaluation and assume responsibility for day-to-day activities carried out by the Project Office.

5) The EPI Interagency Coordinating Committee consists of members of the Ministry of Health, China CDC and international agencies. Its responsibilities include guiding the development of the Project Implementation Plan, coordinating related activities, helping raise funds for Project operation, carrying out consultations and providing advice on Project progress.

6) The Project Office will be responsible for the following activities:

- Project implementation and management of day-to-day activities
- Review and approval of the Project Implementation Plan and work plans for Project areas
- Organization of monitoring, supervision and evaluation activities
- Provision of technical support
- Preparation of annual progress reports
- Other related work.

7) The Procurement Coordinating Committee consists of the members from the Ministry of Health, Ministry of Finance, State Drug Administration, the Project Office, UNICEF, WHO and the World Bank. Its responsibilities include reviewing the vaccine needs of each province, selecting qualified bidding agencies, reviewing bids, supervising the bidding process, approving winning bids and coordinating the procurement process.

8) The Operational Advisory Group will consist of two persons appointed by MOH, one from China CDC, one from the MOH/GAVI Project Office, one representative of GAVI from the global level and two persons selected by the ICC. Its responsibilities include providing advice and guidance on project implementation and the use of leftover GAVI funds as well as endorsing progress reports. Members of the Operational Advisory Group will meet at least twice per year.

### **3.2 Project Areas**

1) Health Bureaus

- Responsible for the implementation, coordination and management of the Project.
- Establishing detailed implementation regulations
- Ensuring the provincial co-funds through coordination with provincial departments of finance

2) CDC's at all levels

- Follow the requirements of the "Technical Guidelines for Hepatitis B Immunization of Children (draft)"
- Developing detailed implementation plans for the project in their project areas



- Conducting training activities
- Vaccine management and AD syringe surveillance
- Supervision, monitoring, surveillance and evaluation activities
- Preparing periodic reports

### 3) Immunization sites

All sites providing immunization services must be responsible for hepatitis B vaccination in their responsible areas and strictly adhere to the requirements listed in "EPI Technical Regulations" and "Technical Guidelines for Hepatitis B Immunization of Children (draft)."

## **Part IV Activities**

### **4.1 Procurement and Delivery of hepatitis B vaccine and injection equipment:**

#### 4.1.1 Development and revision of procurement plans for vaccines and injection equipment

Each province must develop an objective and realistic vaccine and safe injection device needs-assessment plan and submit it to the national Project Office for review before 30 June of each year. The plan will be implemented after receiving approval from the Ministry of Health.

During the process of implementation, appropriate adjustment of each province's vaccine needs-assessment plan will be carried out on the basis of actual conditions, such as birth rate data, progress of immunization work, population mobility and vaccine wastage.

#### 4.1.2 Procurement of the vaccine and injection equipment

The vaccine used for hepatitis B immunization will be 5µg recombinant vaccine (yeast). As for syringes, 0.5ml AD syringes will be used exclusively. For injection of other EPI vaccines, AD syringes of different fixed specifications will be used.

Vaccine and injection equipment to be used in this project will be centrally procured by the central government and bidding documents will be developed uniformly at the central level. The central government will select qualified suppliers. Each province will sign a contract with a supplier to use provincial co-funds for procurement. Contract documents will be photocopied by the provinces and sent to MOH for review and filekeeping. After reviewing each province's contract, MOH will sign a contract with suppliers to use the funds allocated by the central government and GAVI to complete procurement. Central government and GAVI funds will be sent directly from the central government to the supplier.

#### 4.1.3 Management of distribution of vaccines

The hepatitis B vaccine and injection equipment will be transported to provincial CDCs as stipulated in the signed contracts and the periodic needs assessments. The vaccine will be kept between 2 and 8 degrees Celsius throughout the shipping process. From the provincial level, the vaccine will be distributed to immunization sites through the existing cold chain.

Hepatitis B vaccine, AD syringes and safety boxes will be distributed to lower levels in appropriate quantities. Each level must establish a systematic and complete system for managing and recording distribution of vaccine, AD syringes and safety boxes. During distribution from county level to rural immunization site, one dose of hepatitis vaccine must be paired with an AD syringe and an appropriate number of these must be accompanied by a safety box. The wastage factor must be taken into consideration.

The hepatitis B vaccine and AD syringes will be distributed to the facility which approved by provincial health administration agency. The vaccine and syringes for the first year will be provided by manufactures through 4

times. The quantity of the vaccine and syringes will be notified by project office. Each province should check the vaccine and syringes carefully and return the receipt announcement to the project office.

#### **4.2 Training and Social Mobilization**

##### 4.2.1 Training of staff

The central level is responsible for carrying out training of provincial level professional and technical staff. Each province and lower administrative level must carry out training according to uniform national requirements; uniform teaching materials prepared at the central level will be used. The content of the training includes primarily: program management, monitoring/supervision and reporting, safe injection information, administration of hepatitis B vaccine, use of safety boxes, collection and disposal of AD syringes and so on. Training work runs throughout the entire duration of the Project.

##### 4.2.2 Health Education

Health administration departments at all levels should actively coordinate and communicate with relevant sectors, seek understanding and support for integration of hepatitis B vaccine into EPI and mobilize all sectors of society to participate in the effort to prevent and control hepatitis B. They should organize multiple forms of health education activities through multiple channels and raise public awareness of the importance of disease prevention, health maintenance and proactive participation in the prevention of hepatitis B. Medical and public health units at all levels should undertake hepatitis B prevention education work as a long-term project and make education, counseling and guidance services routinely available to the public.

## **Part V Financing, Implementation and Management**

### **5.1 Funds for procurement of hepatitis B vaccine and injection equipment**

Funds for procurement of hepatitis B vaccine and injection equipment come from GAVI, Central financing and provincial financing.

#### 5.1.1 Project financing (Central-level and GAVI):

During the Project, from 2002 to 2007, GAVI and Central financing will provide Hepatitis B vaccine to 12 Western provinces and national poverty counties in Shanxi, Anhui, Jiangxi, Henan, Hubei and Hunan provinces. At the same time, 70% of injection equipment used for the Hepatitis B vaccine and other EPI vaccine will be provided to above areas.

GAVI will provide 50% Hepatitis B vaccine, injection equipment used for hepatitis B vaccine and other EPI vaccine to national poverty counties in Helongjiang, Hainan, Hebei and Jilin provinces.

#### 5.1.2 Local government financing:

Departments of Finance in the 12 western provinces and Shanxi, Anhui, Jiangxi, Henan, Hubei and Hunan provinces, which have national poverty counties, will provide co-funding for purchasing 30% of injection equipment used for the Hepatitis B vaccine and other EPI vaccine.

Departments of Finance in Helongjiang, Hainan, Hebei and Jilin provinces, which have national poverty countries, will provide co-funding for purchasing 50% of the hepatitis B vaccine, and the injection equipment used for hepatitis B vaccine and other EPI vaccine.

According to the "Notice about Integration of Hepatitis B Vaccine into EPI" (MOH Department of Disease Control Document 339 [2001]) issued by the Ministry of Health and the Ministry of Finance, provincial Departments of Finance are responsible for guaranteeing uniform allocation of funds required at each level for carrying out hepatitis B immunization and safe injection activities among newborns.

### **5.2 Financial management**

5.2.1 The specified funds should be used only for the Project and cannot be appropriated for any other purposes or any expense not relevant to the Project.

5.2.2 Each province should arrange co-funding according to the requirement of this implementation plan. The provincial implementation plan should clarify the provincial financial management and requirements according to the local situation.

5.2.3 GAVI and the central government will reduce or terminate their provision of funds to any province that is not able to provide required co-funds or has significant problems implementing the Project.

5.2.4 The Ministry of Health and the Ministry of Finance will carry out monitoring of procurement and use of provincial matching funds

## **Part VI Project Management**

### **6.1 Hepatitis B vaccine Immunization management**

6.1.1 During the project implementation period, if subsidization for immunization service has been provided, the service fee associated with delivery of hepatitis B vaccine should not be charged. If no subsidization for immunization service is provided, the service fee for hepatitis B vaccine may be charged according to the pricing standards established by the pricing departments.

6.1.2 Every administrative level in the project area should strive to establish accurate population records in the project areas and keep such records on file. In addition, the latest population data from the government should be collected, and the situation of the floating children must be mastered. At the same time, administrative levels should report population estimates every year as determined by the routine immunization coverage reporting system, following the requirement of "the national surveillance plan of routine immunization coverage".

6.1.3 A system and management record must be established at all levels for recording the flow of vaccine and injection equipment (refer to Annex1). Immunization sites must establish an immunization recording system; after carrying out immunization of age-appropriate infants, immunization personnel, a parent or guardian should sign the immunization card. It is strictly forbidden for Project vaccine or injection equipment to be used for vaccinating other populations - violations will be dealt with according to the severity of the violation.

6.1.4 Health administration departments at all levels should standardize management of hepatitis B immunization according to the requirements outlined in "Technical Guidelines for Hepatitis B Immunization of Children (draft);" clarify the responsibilities of medical staff, health workers and CDC staff engaged in hepatitis B immunization work; improve the immunization record system; foster linkages between each branch of China CDC and other bodies in the health system in the area of hepatitis B vaccination; follow the principle of "the person who makes the delivery is responsible for giving the first dose of vaccine;" ensure that the first dose has been given; confirm that the newborns have been given the vaccine in a timely manner; and ensure that floating children have the same immunization rights as resident children.

6.1.5 Routine immunization cards, certificates and forms should be revised according to the requirements of the "Technical Guidelines for Hepatitis B Immunization of Children (draft)." Immunization coverage should be reported bimonthly according to the modified national uniform table 3-1 of the Technical Guidelines; annual coverage of the previous year should be reported each February according to table 3-2 of the Technical Guidelines; and timeliness of delivery of the first dose of hepatitis B vaccine should be reported.

6.1.6 Hepatitis B immunization services should be standardized to prevent the occurrence of accidents in delivery of vaccine. At the same time, it is necessary to be serious about monitoring, reporting and treating adverse reactions.

## **6.2 Injection safety**

6.2.1 In each provincial implementation plan, it is necessary to clarify the safe injection requirements for routinely administered vaccines and to establish corresponding work and management procedures.

6.2.2 When carrying out immunization work, staff in grass roots immunization sites should check packaging of injection equipment and expiration dates. If the packaging has been damaged or the expiration date has been reached, the product cannot be used. After vaccination has been carried out, placing the needle cap back on the tip of the needle is forbidden. Used AD syringe equipment should be placed directly in a safety box for centralized disposal.

6.2.3 After used AD syringes are collected, they are to be taken to the township or county level for centralized disposal. The first option for syringe disposal is high-temperature incineration, in which case the temperature in the incinerator must exceed 800 degrees Celsius; the next best option is disinfection followed by shredding and recycling; disposal centers that have neither incinerators nor shredding machines may adopt burial as a method of disposal.

## **6.3 Supervision, Evaluation and Review**

### **6.3.1 Supervision**

During project implementation, each level must carry out supervision on a periodic basis. Supervision should be carried out in the following areas: leadership, organization, implementation and management, status of hepatitis B vaccination work, service fees, management of vaccine and injection equipment and so on.

The national level will carry out supervision of Project Provinces at least once per year; the provincial level will carry out supervision of prefectures at least once per year; prefectures will carry out supervision of counties at least twice per year; counties will carry out supervision of townships, local hospitals and first-dose delivery sites at least twice per year.

### **6.3.2 Evaluation**

The evaluation indicators refer to Annex 2.

### **6.3.3 Reviews**

6.3.3.1 A review meeting will be convened each year with relevant personnel to evaluate and discuss methods for solving existing problems and to provide suggestions regarding ensuing phases of the Project.

6.3.3.2 Project mid-term review: before the conclusion of the third year of the Project, the MOH Operational Advisory Group will organize a mid-term review. GAVI-approved international specialists will participate in the mid-term review. Review work can be combined with a review of EPI. The review protocol will be developed by the Project Office.

6.3.3.3 End of Project review: before the conclusion of the fifth year of the Project, the end of Project review will be conducted in the same format as the mid-term review.

## **Part VII Project Progress Report**

### **7.1 Reporting period**

The progress report covering the period from June to December 2002 will be submitted before 15 March 2003. The first annual report (covering 1 June 2002 to 30 June 2003) will be submitted by 31 August 2003. Afterward, semi-annual progress reports (covering July to December) will be submitted before 15 March of

each year and completed annual progress reports (covering July of the previous year to June of the current year) will be submitted by 31 August of each year.

#### 7.2 Content of progress reports (refer to Annex 3)

- Plan/distribution/usage of hepatitis B vaccine and injection equipment at the province and county level
- Data on DPT3 and full course hepatitis B (HepB3) vaccination coverage rate in 12 month old infants (routine data and coverage survey data)
- Coverage rate of timely delivery of first dose (routine data and coverage survey data)
- Injection safety
- Status of monitoring and supervision
- Status of training
- Social mobilization
- Use of project funding.

Annex 1. Record Sheets for Vaccine and Injection Equipment Receipt and Distribution (for use at the province, prefecture, county and township level)

Province _____ Prefecture _____ County _____ Township _____										
Date	Name of vaccine or equipment	Manufacturer	Number of vaccines or equipment	Specification (mL/syringe)	Lot Number	Expiration date for Vaccine	Number Received	Number Distributed	Number in Storage	Remark

1. Indicators for management

Indicators for management include organization, allocation of co-funds, monitoring/supervision, training and social mobilization.

2. Indicators for vaccine management

2.1 System for recording vaccine distribution and immunization

2.2 Wastage factor

2.3 Range of recipients of hepatitis B vaccine (determining the percentage of hepatitis B vaccine used to immunize newborns through review of distribution records, immunization records, sampling survey and other methods)

2.4 Service fee: percentage of infants who were charged an amount equal to or less than the maximum fee (3 RMB, including all service fees).

3. Safe injections

3.1 Percentage of immunization sites using AD syringes for hepatitis B vaccination

3.2 Percentage of counties using AD syringes for hepatitis B vaccination

3.3 Percentage of immunization sites using AD syringes for other EPI vaccines

3.4 The percent of counties using AD syringes for other EPI vaccines.

3.5 The percent of immunization sites that conduct appropriate collection and disposal of AD syringes.

4. Immunization working indicators

4.1 HepB3 coverage rate in children less than 12 months old

4.2 Percentage of infants receiving first dose of hepatitis B vaccine within 24 hours of birth

4.3 Percentage of counties carrying out bimonthly reports on immunization coverage rates

4.4 The accuracy and completeness of each year's previous population data from routine immunization reporting

4.5 Percentage of counties meeting hepatitis B immunization coverage objectives

4.6 The HBsAg carrier rate in children under 3 years old: combining project mid-term review and end of project review. Certain regions can carry this out themselves if conditions allow.

5. Data reporting

5.1 Timeliness of reported data.

5.2 Completeness of reported data.

**GAVI Progress Report Form**

**Explanation:**

Project progress reports must be reported twice a year by level. The twelve provinces in western China should submit provincial-level reports to the national project office. Enshi prefecture in Hubei province, Xiangxi prefecture in Hunan province and Yanbian prefecture in Jilin province, and officially designated poverty counties in other areas are required to submit county-level progress reports through the provincial level.

**Submitted By:**

**Submitted Date:**

**Project Period:** \_\_\_\_\_ Year \_\_\_\_\_ Month to \_\_\_\_\_ Year \_\_\_\_\_ Month

**1. The Organization of the Activities (description)**

**2. Details of Co-Funds/Operation Funds and the Flow of Funds (description and forms)**

Please give the answers for the following questions and describe the details of co-funds /operating funds and the flow of the funds of your province:

- 1) Has your province established a maximum allowable service fee for hepatitis B immunization? Yes or no?  
If yes, what is the maximum fee? \_\_\_\_\_ RMB
- 2) How many project counties / prefectures are in your province?
- 3) How many GAVI project counties/prefectures are in your province which charge less than the maximum allowable service fee for hepatitis B vaccination?
- 4) The co-funds used provided by your province for procuring the hepatitis B vaccine are \_\_\_\_\_ RMB.
- 5) The co-funds provided by your province for procuring the injection equipment for hepatitis B vaccination are \_\_\_\_\_ RMB.
- 6) The co-funds provided by your province for procuring the injection equipment for other vaccines \_\_\_\_\_ RMB.
- 7) The number of hepatitis B vaccine doses provided to your province by the central government is \_\_\_\_\_.
- 8) The number of AD syringes provided to your province for hepatitis B vaccination is: \_\_\_\_\_.
- 9) The number of AD syringes provided by the central government for other vaccines is:  
The number of 0.5 mL AD syringes: \_\_\_\_\_  
The number of 0.2 mL AD syringes: \_\_\_\_\_  
The number of 0.1 mL AD syringes: \_\_\_\_\_



### 3. Population estimates for determining the number of vaccines and injection equipment needed:

Province /prefecture/ national poverty county \_\_\_\_\_ GB code \_\_\_\_\_ Year \_\_\_\_ Month \_\_\_\_ Day

Statistic Department	Resident		Floating	
	Total population	Annual newborn population	Total Population	Annual newborn population
EPI Division				
Statistic Bureau				
Family Planning Department				

\*Please also provide data regarding 1) vaccine delivery: the proportion of immunization services provided house to house vs. at the immunization site, and 2) the proportion of newborns born at home.

### 4. Management of Vaccines and Injection Equipment

Describe the details of receipt, distribution, and use (including wastage) for hepatitis B vaccine and injection equipment. Required information must based on data, and declare the source of the data. In addition, please describe the management policy for vaccines and syringes at each level, and the accomplishments, challenges and remaining problems.

(Because of the MOH GAVI Project, more specific and timely data should be provided)

**5. Safe Injection Management**

Please complete the following reporting form on injection safety management and report to each respective higher administrative level.

Safe Injection Management Reporting Form

(to be used by province/prefecture/county/township)

\_\_\_\_\_ Province \_\_\_\_\_ Prefecture \_\_\_\_ County Period: \_\_\_\_ Year \_\_\_\_ Month \_\_ Day to \_\_\_\_ Year \_\_\_\_  
Month \_\_\_\_ Day

Unit	Total no.	No. immunization	No. immunization		The means of disposal of used AD syringes
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	immunization sites	sites using AD syringes for hepatitis B vaccination	sites using AD syringes for all EPI immunizations			No. immunization sites returning AD syringes to township level for centralized disposal	No. immunization sites returning AD syringes to county level for centralized disposal
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					Burning (using incinerator)	Collecting	Burning and burial (no incinerator used)		

\*Burning: means the destruction of AD syringes by incineration  
Collecting: means the returning of AD syringes to disposing unit.  
Burning and burial: means no incinerator was used

## **6. Vaccination reporting**

Analyze and review results of routine immunization coverage reporting for hepatitis B vaccine. Describe the results and methods for determining coverage, and results of studies to address the rate of timeliness of the first hepatitis B vaccine dose and the three dose coverage.

## **7. The Reporting for Training**

The Reporting for Training should include the content, frequency, level, number of training sessions, methodology, inputs and the like.

## **8. Social Mobilization Reporting**

The social mobilization reporting should include subject, frequency, methodology, inputs and the like.

## **9. Monitoring and Supervision Reporting**

Monitoring and supervision should include contents, frequency, methodology, problems, solutions, effectiveness, and input.

## **10. Problems and Suggestions (describe)**