

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

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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

- 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 provides funds to China for procurement of hepatitis B vaccine. Hepatitis B vaccine is procured domestically in China for the China MOH/GAVI project, which is funded by both the Chinese governments and GAVI.
- There are two large-scale suppliers of hepatitis B vaccine in 2003, Beijing Tiantan Biological Products Co., and Shenzhen Kangtai Biological Company Co.
- Contracts for hepatitis B vaccine were signed in December 2002 and in December 2003 respectively for the first two years of the Project (2003, 2004). (please see Table 1 and 2, section 1.2.2 for more details on number of doses procured)
- It was found that the Hepatitis B vaccine was overstocked in some counties because of delays starting implementation of the project and differences between estimated doses needed and actual coverage levels. Ministry of Health has issued a document to call for actions from each project province to address the current problems, including carrying out large-scale supervision activities to identify the low performances/issues, working closely with the relevant government departments to mobilize the resources including operational funding, developing effective strategies to improve coverage and birth dose timely coverage. It is also recommended to conduct catch-up campaign for the missed children born before the launch of the project in 2003 or even older children. However, it is expecting that some challenges would exist and the additional operational funds will be needed to fully implement these recommendations.

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.

a. Two National Workshops held in 2003

- In 22-23 January 2003, the national MOH/GAVI workshop was held in Beijing to introduce the Project, and review the project implementation plan. Participants included the officials from the provincial health authorities and EPI managers/staff from the provincial CDCs in the 22 project provinces.
- In 29-30 December 2003, another national MOH/GAVI working meeting was held in Beijing to review progress, identify problems and determine the tasks and major areas and issues to be addressed in 2004.

b. Project Implementation Plans:

- The national project implementation plan (PIP) was formally issued to the provinces on 12 February 2003. 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 6 central 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 4 central 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 3). The pricing policy was approved by the pricing authorities in the 15 provinces, and the relevant regulations on user fee were issued by the health Department in the other 7 provinces. Administrative costs for immunization services are financed through local government subsidies and user-fees. In one province, the hepatitis B vaccine is given free of charge without user fees.

c. Procurement:

- An meeting of the Procurement Coordinating Committee (PCC) was held on 8 January 2003 to reach consensus among national and international partners on the procurement mechanism for AD syringes.
- Procurement of AD syringes used for hepatitis B vaccine was conducted in 9-10 January 2003, and contract was sighed in February.
- 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 and unavailability of 0.1 AD and 0.2 AD syringes in the domestic market.
- New plans for the next rounds of procurement were 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, was held on 31 October 2003.
- One working meeting was organized in 17 November 2003 to determine the mechanism to assess AD syringes produced by the different manufactures.
- The negotiations were carried out in December 2003 for procurement of hepatitis B vaccine and AD syringes used for all the EPI vaccine for the second project year, also including the AD syringes for the EPI vaccines rather than Hepatitis B vaccine for the first year project.
- The procurement mechanism for safety boxes was different due to multiple manufactories available in the domestic markets. The process is ongoing and it is expected that the procurement would be done in June 2004.
- Detailed information for procurement as table 1.

Table 1 Amount of Hepatitis B vaccine and injection Equipment procured

Procurement	Hepatitis B vaccine	AD s	syringes	Safaty havas**	
Frocurement	(person-dose)	0.1ml	0.5ml	Safety boxes**	
Dec. 2002-Jan. 2003	7,099,340	-	21,298,022	150,154	
Dec. 2003	6,325,925	8,504,281	65,874,430		

^{**}To date, only small part of safety boxes have been procured, the next procurement for about 750,000 safety boxes will occur in the near future.

d. Supervision

- In March 2003, supervision visits were carried out in 11 of the 12 MOH/GAVI western project provinces. Supervision for the reminding western province was done in November 2003.
- Supervision visits were also done in 5 of the 10 central provinces combining with other purposes in 2003.
- The SARS epidemic had a major impact on 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, some provinces delayed starting province-wide Project activities until June-August 2003 (see Table 3).
- A national EPI review was conducted in September 2003 by Ministry of Health. One focus of the review was the MOH/GAVI Project.
- A full round review of the MOH/GAVI Project is planned for 2004. The work in all the 22 MOH/GAVI project provinces will be assessed by the end of June 2004.

e. Training

• 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. By the end of 2003, training to the village level had been completed in 7 of 12 western provinces, and substantially undertaken in the other 5 provinces (see Table 3).

- With the support from UNICEF, an evaluation of training on hepatitis B and injection safety was conducted in the November and December 2003 in the 8 provinces. The result showed that the quality of training for lower level staff was inadequate and there is need in particular for another round of training in all GAVI project areas on correct use of AD syringes. Surveys have found in some areas poor acceptance of AD syringes with high breakage rates due primarily to improper use. Intensified training courses were carried out in the areas after the assessment.
- 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, 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 Ningixa 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.
- With the cooperation with the AD syringe manufactories, the additional training courses were done in 15 of 22 provinces in 2003, focusing on improving the skill to use of AD syringes at grass root level.

f. Financing

- According to MOU, it is planned to provide 7,735,784 USD annually to China from GAVI, among which 7,575,784 USD would be used for procuring Hepatitis B vaccine, AD syringes and safety boxes and 160,000 USD would be allocated for supporting project office activities at the national level.
- The second year GAVI disbursement was received on 31 May 2003. The third year funding from the central government was received on 30 December 2003.
- Every year, the overall budget is prepared containing elements of personnel, equipment and supplies, and activities, staff are being recruited, and equipment and supplies will be purchased.
- By the end of 2003, totally 15,471,762 USD was received from GAVI for procurement. Detailed amounts are shown in table 2.
- Expenditures and cost savings. Procurement of AD syringes for JE vaccine (JEV)and meningococcal vaccines(MMV), and the procurement of safety boxes for 2004 is still not finalized, therefore an exact accounting of savings is currently not available. However, there are approximately 4million USD that will not be expended after completion of procurement for the first two project years (2002 and 2003).

These savings have resulted from the continued reductions of birth rates in project areas in the first two project years and a lower than budgeted price for hepatitis B vaccine. The estimated target population dropped from 6,945,648 in budget to 6,561,819 in the first project year, then to 5,843,662 in the second year. The average price for Hepatitis B vaccine dropped from 1 USD for three doses in budget to 0.97 USD in the first year and continuously to 0.86 in the second year.

In addition to financial savings, hepatitis B vaccine, AD syringes and safety boxes were procured for the entire 12-months of 2003. Because of unanticipated delays due to the SARS epidemic, implementation was delayed until the 3rd quarter of 2003 in many areas with resultant less than expected utilization rates of vaccines and safe injection supplies.

- Co-funding. 18 of 22 GAVI project provinces, (10 of 12 western provinces and 8 of 10 central provinces) have received co-funding for purchase of AD syringes from provincial governments (see Table 3). This includes one province, Guizhou, where the funding was only partial. Four provinces, Yunnan, Guansu, Shaanxi and Hunan have not allocated counterpart funds for purchase of AD syringes to date. MOH/GAVI office has been making efforts to urgent the provinces to address the issues.
- Operational funding. 16 provinces of 22 (10 western provinces and 6 central provinces) have
 received some additional operational funding to support integration of hepatitis B vaccine and
 introduction of AD syringes (see Table 3). At the county-level, however, EPI operational funds
 have not been increased to support integration of hepatitis B vaccine into EPI and this is a
 major constraint to further increasing coverage and timeliness of the hepatitis B birth dose.

Table 2 The detailed information regarding GAVI procurement funds for the two project years(USD) (Excluding the 320,000 USD for the project office activities during the two project years)

_	Fu	ands Received	l		Expenses			Savings	
Items -	I st Year	2 nd Year	Total	Ist Year	2 nd Year	Total	Ist Year	2 nd Year	Total
Hepatitis B vaccine(Hep B)	3,655,604	3,655,604	7,311,208	3,453,018	2,845,356	6,298,374	202,586	810,248	1,012,834
AD for Hep B	658,239	658,239	1,316,478	669,806	601,169	1270975	-11,567	57,070	45,503
Safety boxes for Hep B	76,795	76,795	153,590	57,019	<u>50,778</u> *	<u>107,797</u> *	19,776	26,017	45,793
AD for BCG, DPT, Measles	1,535,891	1,535,891	3,071,782	1452143**	1452143	2904286	83,748	83,748	167,496
Safety boxes for BCG, PT, Measles	179,187	179,187	358,374	<u>118,483</u> *	<u>118,483</u> *	<u>236966</u> *	60,704	60,704	121,408
AD for JEV and MMV	1,316,478	1,316,478	2,632,956	-	-	-	1,316,478	1,316,478	2,632,956
Safety boxes for JEV and MMV	153,590	153,590	307,180	-	-	-	153,590	153,590	307,180
Difference btw budget and the received	-11	205	194	-	-	-	-11	205	194
Total	7,575,773	7,575,989	15,151,762	5,750,469	5,067,929	10,818,398	1,825,304	2,508,060	4,333,364

^{*}To date, only safety boxes used for the 1st year Hepatitis B vaccine have been procured, all the others safety boxes needed will be procured in July 2004. The numbers are estimated ones. **Procurement for those AD syringes and safety boxes occurred in the Dec. 2003, together with procurement of AD syringes and safety boxes for the second year.

g. Information, Education and Communication (IEC)

- 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 the project provinces, prefectures, counties and the international parties.
- With the support from UNICEF, IEC material has been developed including one poster, six booklets and "pocket book" for village doctors.
- A grant was received from the Children's Vaccine Program at PATH to support the development of a website for the MOH/GAVI Project. The website (www.Chinagavi.org.cn) is in use.
- 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. As planned, the IEC meeting was organized to share experiences and build partnerships with other departments and institutes in March 2004. A national IEC plan has been developed with the support of one international consultant in April 2004. The actions are planned.

h. Monitoring and Evaluation

- The World Bank Health Project VII end of project coverage surveys have been done by Health Project VII provinces in 2003 (although only 6 provinces are MOH/GAVI Project provinces).
- 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. Actions are underway to use these sera for hepatitis B serologic testing to obtain a baseline HBsAg prevalence.
- In 2004, national wide coverage survey is planned, which could provide baseline coverage data by province for the project.

i. Operational Advisory Group (OAG)

- 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)
- A pre-OAG meeting was held in March 2004 to discuss reprogramming of project savings. An OAG meeting to decide how to use project savings and unused hepatitis B vaccine accumulated during the first two years of the project is planned for July 2004. Potential use of the savings include: 1) support for activities to enhance integration of hepatitis B vaccine and introduction of AD syringes such as training and IEC; 2) support for catch-up campaigns to utilize excess hepatitis B vaccine prior to expiration; 3) extending the duration of the GAVI project to 2008 or 2009.

j. Project unmet needs

- A crude assessment of unmet needs regarding all aspects of the project, including training, IEC, injection safety, monitoring and other activities, was done 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 done to specify unmet needs and to determine how to apply the savings to address the needs of project.

k. Relevant activities in collaboration with partners

• Timeliness of the hepatitis B vaccine birth dose

- A study was carried out to evaluate factors related to timeliness of the hepatitis B vaccine birth dose in 2003 with the support from WHO.
- A study on acceptability of UNIJECT was conducted in Chongqing and Ningxia. (Ministry of Health, China CDC, Two provincial Health Departments and CDCs, UNICEF, PATH-CVP, US CDC)

- Strengthening of the National Regulatory Authority. A 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)

I. Problems and Challenges

- Funding issues. Operational funds for training, supervision, monitoring, IEC to support full integration of hepatitis B vaccine and introduction of AD syringes are insufficient in many GAVI project counties. This is a major constraint affecting implementation of the project, increasing coverage and improving injection safety.
- First Dose of Hepatitis B vaccine. Methods for ensuring a timely birth dose of hepatitis B that can be effectively scaled-up, particularly in poor and remote areas of China, need to be improved.
- Lack of effective monitoring mechanisms. Currently the quality of routine reporting system does
 not provide reliable data on immunization coverage in China. China has been struggling to
 develop the reliable methodologies to allow routine monitoring of coverage.
- The impact of application of the user-fee for hepatitis B immunization on access and coverage has not yet been evaluated. A focused study to address this issue is planned 2004.
- Vaccine management. Vaccine delivery and supplies in China are based on a push-down method where all vaccine supplies are distributed downward for each pulsed round (usually 6 per year in rural areas). There is inadequate information on actual doses needed, and estimates of vaccine needs are not part of the vaccine delivery mechanism. Because of delayed implementation in many provinces by as much as 6-8 months -- there is likely considerable excess hepatitis B vaccine distributed to county and township levels. Information on numbers of doses of vaccine currently in storage at different levels, the expected utilization rate of that vaccine, and the vaccine's expiration dates is urgently needed prior to additional shipments of hepatitis B vaccine. The higher cost of hepatitis B vaccine compared with other EPI vaccines highlights the need for development of a vaccine forecasting system to guide vaccine deliveries.
- Staffing. The international GAVI co-project manager funded by CDC/Atlanta departed in May 2004 and has not been replaced. There is urgent need to increase the number of staff at central and provincial levels to support the project.
- Much of the cost-savings has accrued due to delays in purchase of AD syringes. In 2003, the Japanese encephalitis vaccine and meningitis vaccine were not fully integrated into EPI in the most GAVI project provinces. However, in March 2004, Ministry of Health issued the documentations to strengthen the prevention of JE and meningitis through improving the vaccination with those two vaccines, and to call for integration of JE vaccine into EPI. So the decisions are needed whether to purchase AD syringes for those two vaccines and/or whether an extension of the project is needed.

Table 3. Status of MOH/GAVI Project in 22 project provinces, by Province (From Provincial Progress Reports submitted in March 2004)

Region	Province	Hepatitis B vaccine price per dose (RMB)	Date implementation started province- wide	Training to village doctor level	Allocation of Co- funding for AD syringes and Safety boxes	Allocation of province-level operational funding*
	Nei Menggu	2-5	August 2003	Completed	Yes	Yes
	Guangxi	3	June 2003	95% Completed	Yes	Yes
	Chongqing	3	August 2003	Completed	Yes	Yes
	Sichuan	3	June 2003	84% completed	Yes	Yes
Western	Guizhou	1-2	June 2003	Completed	Yes (Inadequate)	Yes
Provinces (Entire province	Yunnan	3	June 2003	95% Completed	No	Yes
supported by MOH/GAVI	Tibet	1-3	August 2003	95% Completed	Yes	No
project)	Shaanxi	3	August 2003	Completed	Yes	Yes
	Gansu	3	June 2003	Completed	No	Yes
	Qinghai	1	July 2003	98% completed	Yes	Yes
	Ningxia	3	June 2003	Completed	Yes	No
	Xinjiang	3	July 2003	Completed	Yes	Yes
	Hebei	3	December 2002	Completed	Yes	No
	Shanxi	3	March 2003	Completed	No	No
Middle Provinces	Jilin	3	April 2003	Completed	Yes	Yes
(Only National Counties	Heilongjiang	2	July 2003	Completed	Yes	Yes
supported by MOH/GAVI	Anhui	3	December 2002	90% completed (Whole provinces)	Yes	Yes
project)	Jiangxi	Free in charge	April 2003	Completed	Yes	Yes
	Henan	3	September 2003	98% completed (Whole provinces)	Yes	Yes
	Hubei	3	April 2003	99% completed (Whole provinces)	Yes	Yes
	Hunan	3	February 2003	93% completed (Whole provinces)	No	No
	Hainan	2	May 2003	Completed	Yes	No

^{*} In most counties, no additional operational funds have been allocated by local governments.

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.

By the end of 2003, total 320,000 USD was received for the two project year2 and 128,114 USD was expended.

All the long-term staff, who are part time staff for GAVI project, have been paid by China CDC as the routine CDC staff. The above expenses excluded the payment for CDC staff. The second year funds would due to June 2004. A lot of project activities, such as large-scale supervision activities and FSP preparation, are on process in 2004.

The detailed information lists as following(USD):

Table 4 Expenses of MOH/GAVI Project Office funding

Items	Expenses
Renting	40,000
Equipments	49,879
Supervision	14,926
Consultants	7,450
Conference	6,804
Telecommunication	4,079
Stationery	2,346
Newsletter	1,507
Transportation	719
Others	404
Total	128,114

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

- a. Procurement for AD syringes for EPI vaccines other than hepatitis B was delayed due to the SARS epidemic and unavailability of 0.1 mL AD and 0.2 mL AD syringes in the domestic market in 2003. The procurement of 0.1 mL syringes (and safety boxes for these syringes) occurred December 2003.
- b. 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.
- c. 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 2003.
- d. The negotiation for procurement was carried out in December 2003 for AD syringes used for all EPI vaccines for the second project year, also including the AD syringes for the other EPI vaccines rather than Hepatitis B vaccine for the first year project.
- e. The contracts for AD syringes were signed at the end of 2003. (See table 1)

f. The procurement mechanism for safety boxes was different due to multi manufactories available in the domestic markets. The process is ongoing and it is expecting the procurement would be done in June 2004.

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.

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.

Indicators	Targets	Achievements	Constraints
Percentage of immunization sites using AD syringes for hepatitis B vaccination	100%	100%	The national action plan on safe injections has still not been finalized and no
Percentage of counties using AD syringes for hepatitis B vaccination	100%	100%	national recommendations for collection and destruction of used injection materials at
Percentage of immunization sites using AD syringes for other EPI vaccines	100%	100% *	village and township levels have been issued. Training for introduction of AD
The percent of counties using AD syringes for other EPI vaccines.	100%	100 *	syringes was inadequate for health workers to master basic skills in use of
The percent of immunization sites that conduct appropriate collection and disposal of AD syringes.	100%	Unknown	the syringes, and another round nationwide training is needed.

^{*} AD syringes were procured for DPT, BCG and MV for the two project years. Procurement for AD syringes for JE and meningitis vaccine is under discussion.

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:

- a. An action plan has been prepared, and is currently under discussion. The plan calls for use of AD syringes for all immunization injections.
- b. Activities done in 2003 include:
 - Training at the provincial level in all provinces regarding injection safety and AD syringe use has been conducted. Training at lower administrative levels accomplished in the most areas.
 - A pilot study is being conducted looking at collection of used immunization injection equipment (with JICA)
 - The needs for additional training on introduction of AD was evaluated and the second round large-scale training is planned in 2004.
 - WHO-supported consultants, including from the Safe Injection Global Network (SIGN), visited China to assist with the action plan and the development of technical materials.

- c. Activities for next year (2004) include:
 - To continue the training and education activities, and evaluation of training activities.
 - To continue the JICA management of used injection equipment pilot study main constraints.
 - To track the allocation of provincial co-funding for purchase of AD syringes for immunization injections other than hepatitis B vaccine.
 - An evaluation on introduction of AD syringes into immunization services is being conducted in 2004. (with support from UNICEF)
 - Availability of funding for training, especially at the lower levels.
 - Solution needed urgently for reconstitution 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. (Note: in calendar year 2004, China has begun working with international partners and GAVI consultants to conduct an immunization financing review and policy assessment).

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. <u>Up-dated immunization targets</u>

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

(please see Table 5 next page)

5.. Table 5: 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				
Number of	2001	2002	2003 ^e	2004 ^e		
DENOMINATORS						
Births ^a	6,561,819	5,843,662				
Infants' deaths ^b	211,290	165,960				
Surviving infants	6,350,529	5,677,702				
Infants vaccinated with DTP3						
Infants vaccinated with DTP3: administrative figure reported in the WHO/UNICEF Joint Reporting Form	6,189,225	5,126,965°				
NEW VACCINES						
Infants vaccinated with hepatitis B vaccine	2,206,935	3,423,654 ^c				
Wastage rate of hepatitis B vaccine ^d						
INJECTION SAFETY						
Pregnant women vaccinated with TT						
Infants vaccinated with BCG		5,427,883°				
Infants vaccinated with Measles		5,115,610°				

- a: Provincial Statistic Bureau estimates
- b: Calculated based on 2000 infant mortality estimate (28.4 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 90.3%, HepB3 60.3%, BCG 95.6%, MV 90.1%), 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 in the field is not known. The first two project years, it was decided to apply 10% wastage of hepatitis B vaccine for estimation on needs of the vaccines.
- e: 2003 birth data will be available in June 2004. It is difficult to project birth data due to the lack of good methodologies.

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% for the first two year of the project.

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

Indicators	Targets	Achievements	Const raints	Updated targets
 Indicators for management Indicators for management include organization, allocation of co-funds, monitoring/supervision, training and social mobilization. Indicators for vaccine management 2.1 System for recording vaccine distribution and immunization Wastage factor 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) Service fee: percentage of infants who were charged an amount equal to or less than the maximum fee (3 RMB, including all service fees). 	100% ≤3 RMB / dose	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		
 3.1 Safe injections See section 1.3.2 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 	4.1 85% at county level by end of project 4.2 75% timeliness of first dose by end of project 4.6 2% by province among children under			
out themselves if conditions allow. 5. Data reporting 5.1Timeliness of reported data. 5.2 Completeness of reported data.	3 years of age			

5. Checklist

Checklist of completed forms:

Form Requirement:	Completed	Comments
Date of submission	30 May, 2004	
Reporting Period (consistent	1 January o	
with previous calendar year)	31 December 2003	
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	See section in report	FSP for China due 2004
against country FSP		
indicators)		
Target Table filled-in	See section in report	
New Vaccine Request		Not applicable (China is
completed		procuring hepatitis B
		vaccine)
Revised request for injection		Not applicable (China is
safety completed		procuring AD syringes)
ICC minutes attached to the	See section in report	
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 disease control priorities in China. Progress during the two years of the Project has been substantial. The SARS epidemic had a major impact on delaying start of the Project in many provinces, 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 methods to accurately determine coverage, and ensuring through supervision and advocacy that provincial level co-funding for AD syringe procurement is mobilized in all provinces, improving the financing of the routine immunization program, and strengthening management of the Project, include decision on use of cost savings and stored vaccine.

ICC members will work actively with the Ministry of Health to carry out the GAVI requirement for a financial sustainability plan (FSP) due in 2004. Given the special situation of immunization financing in China, the format of the FSP has been adapted with agreement from the GAVI Financing Task Force (FTF) to improve it's use to the government.

7. Signatures

For the Gov	vernment 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	Not available

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: 7th 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:

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