Evaluation of GAVI-Government of China Hepatitis B Vaccination Program

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Acronyms

APR	Annual Progress Reports
AD	Auto-disable
CCDC	Chinese Center for Disease Control and Prevention (also China CDC)
DDC	Department of Disease Control
DALY	Disability-adjusted life-years
EPI	Expanded Program on Immunization
GAVI	GAVI Alliance
GBD	Global burden of disease project
GOC	Government of the People's Republic of China
GDP	Gross Domestic Product
HepB	Hepatitis B
HepB3	Hepatitis B three-dose
HBV	Hepatitis B Virus
Hib	Haemophilus influenza B
HCC	Hepatocellular carcinoma
ICC	Inter-agency Coordinating Committee
MCH	Maternal and Child Health
MOU	Memorandum of Understanding
MOF	Ministry of Finance
MOH	Ministry of Health
NIP	National Immunization Program
OAG	Operational Advisory Group
OECD/DAC	Organization for Economic Cooperation and Development/Development Assistance Committee
PHC	Primary health care
PO	Project Office

RFP	Request for Proposals
SARS	Severe Acute Respiratory Syndrome
TBD	Timely Birth Dose
THE	Total Health Expenditures
UNICEF	United Nations Children's Fund
WHO	World Health Organization

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Our work would not have been possible without support from staff in the provinces, prefectures, counties, districts, and facilities visited. We are grateful for the contributions of the health bureau officials, CDC officials, and health workers in the following localities: Hunan province, Yueyang prefecture, Pingjiang county, Yunxi district; Gansu province, Tianshui prefecture, Qin'an county, Dingxi prefecture, Anding district; Qinghai province, Haidong prefecture, Xunhua county, Xining prefecture, Huangzhong county.

Lastly, we extend our thanks to the key informants who generously provided their time to inform this evaluation, and who provided comments on earlier drafts of this report. In particular, we wish to acknowledge the invaluable contributions of Cui Fuqiang, Stephen Hadler, and Mark Kane.

Disclosure

Grace Chee, principal investigator, was contracted and funded by PATH for 30 days to assist the government of China in preparation of a Financial Sustainability Plan (FSP) for the immunization program in 2004-2005. Ms. Chee's role was limited to drafting sections of the FSP presenting findings from research conducted by a separate entity to estimate the cost of the immunization program; Ms. Chee did not participate in the design, implementation, supervision or coordination of the Hepatitis B vaccination project, which is the subject of this evaluation report. Although the FSP was referred to as a background document in this evaluation report, the FSP was not a subject of this evaluation, and did not materially influence the evaluation findings. On this basis, Abt Associates concluded that there was no conflict of interest in Ms. Chee acting as principal investigator for this evaluation.

1. Executive Summary

Introduction

The Government of the People's Republic of China (GOC) and the GAVI Alliance (GAVI) undertook a co-funded five-year, $76 million project in June 2002 to expand Hepatitis B vaccination and to purchase auto-disable (AD) syringes for infants in 12 western provinces and national poverty counties in ten central provinces. A significant portion of the funds provided by GAVI remained unspent in the first four years of the project, because of lower than expected prices for vaccines and syringes, and lower than projected vaccine needs. Two subsequent no cost extensions were provided so these savings could be applied to additional activities, bringing the project life to 2011.

GAVI's support to China included several unusual features: 1) GOC co-financing of 50 percent of project costs from inception; 2) establishment of a project office in China; and 3) provision of funding for local procurement of locally produced vaccines and injection safety equipment. This evaluation examines the implementation, effectiveness, impact, and sustainability of this project to draw lessons to inform introduction of other vaccines in China[1], as well as future design and implementation of GAVI support to other countries.

Approach and Methodology

GAVI's support to China was evaluated along five criteria – relevance, implementation/efficiency, effectiveness, impact and value-added, and sustainability. Findings generated from these analyses were used to draw lessons learned, and recommendations for future GAVI investments in other countries.

Data for this evaluation was collected from a variety of sources, including:

- Key documents, including project documents such as the project proposal, Memorandum of Understanding, Inception Report, and Annual Progress Reports, meetings minutes, and correspondence between GAVI and the GOC, as well as national strategy documents, regulations, and policies.
- Key informant interviews with representatives of international partner organizations, Ministry of Health (MOH,) Chinese Center for Disease Control and Prevention (CCDC,) and health officials and health workers at provincial, prefecture, county/district, township and village levels. Interviews with international partner informants were largely conducted by telephone, while interviews with Chinese officials were conducted in person. The evaluation team visited three provinces, with visits to lower administrative levels, and health facilities in each.
- Quantitative data related to immunization coverage, national health and immunization budgets, and commodities prices. Some of the data requested were unavailable, particularly in the area of immunization budgets.

[1] It should be noted that China is no longer eligible for future GAVI support.

[2] It should be noted that China is no longer eligible for future GAVI support.

Both quantitative and qualitative data is analyzed to assess performance. Where findings are based on qualitative data, it was triangulated across key informants and compared with available documentary evidence before drawing conclusions. Detailed notes from all interviews were prepared for internal use to facilitate analysis. Quantitative analysis of changes in Hepatitis B coverage rates over the project period, and comparison with original project objectives was conducted. Analysis was conducted for project and non-project areas, and at county level. Analysis of trends in coverage rates, government budgets, user fees, and vaccine availability pre- and post-GAVI was conducted to assess sustainability. The team relied on existing studies that quantitatively evaluated impact, supplemented with key informant data to assess contributions from the project and GAVI's value-added.

Findings

Relevance of Project and Project Design

With support from GAVI, the GOC adopted a policy to fully integrate Hepatitis B vaccine into the EPI in 2002, making the vaccine available free nationwide, although provider service fees were still in effect. Like the traditional EPI vaccines, parents paid service fees to providers of up to RMB 3 per injection, but did not have to pay for the vaccine, which had cost approximately RMB 8-10 per dose in project areas prior to the project. The GAVI-GOC project provided funding for vaccines and AD syringes in 12 western provinces and poverty counties in ten central provinces. Funding for vaccines and syringes in eastern provinces and non-poverty counties of central provinces were supported by provincial governments.

The design and objectives of the project were well-aligned with the GOC and GAVI's needs a priorities. Control of Hepatitis B was a major health concern in China. This project targeted poorer western provinces, with three-dose coverage rates that were much lower than the national coverage rate of 82 percent. The free vaccines represented removal of a serious financial barrier, while the project placed caps on user fees further aimed to ensure affordability and minimize potential negative effects of fees. Support to China was in line with GAVI objectives as control of Hepatitis B infection in China (with one-third of Hepatitis B carriers in the world) was critical to achieving GAVI's global objectives.

The project was designed to increase Hepatitis B vaccination primarily through reducing cost barriers to access in low income areas. Three objectives were specified in the original MOU:

- HepB3 coverage will reach 85 percent at the county level (revised to 90 percent in 2008)
- >75 percent of newborns at the county level will receive the first dose of hepatitis B within 24 hours of birth
- All immunization injections will be with AD syringes.

There appear to be alternative interpretations of whether these objectives were intended for project areas only, or nationwide. Although project support was directed to 12 western provinces and small portions of 10 central provinces, monitoring focused on national level progress throughout the life of the project. These targets reflected high ambitions – it aimed for all 3,000 counties in China to reach the targeted HepB3 and TBD coverage rates. Monitoring reports focused on progress toward objectives at a national level, even though the project supported the poorest provinces only. While syringe procurements funded by the project included only AD syringes, the GOC did not fully

mandate compliance for syringes procured in non-project areas, and few monitoring mechanisms were in place to regularly track progress.

Implementation and Efficiency

Despite some delay due to SARS, implementation occurred as planned. The Project Office (PO) played a critical role in effective implementation. It managed and coordinated procurement, finances, training, supervision, monitoring and evaluation, and provided general oversight and support to the provinces. Co-management by a CCDC staff and an international advisor (funded by US CDC) ensured access both to external technical experience and knowledge, as well as to knowledge, authority and access from within Chinese health system to ensure timely progress. While the PO provided important guidance and leadership, the bulk of the operational work occurred at provincial, prefecture, county/district township and village levels. Project management responded effectively to problems identified, although one problem it could not resolve was one of insufficient co-funding from provincial level and below for AD syringes and to conduct project activities such as training and supervision.

Local procurement of domestically produced supplies occurred smoothly, with no known problems with vaccine supply or quality. Vaccine prices were lower than originally anticipated and well below international prices, allowing for efficient use of GAVI funds and providing savings that were used for additional activities. While all vaccines were procured through the project office, injection supplies that were funded from provincial budgets were procured by provinces. Thus, for central provinces, for whom less than 15% of injection supplies would be funded through this project, syringes procured for non-project areas with provincial budgets may have been a mix of AD syringes and other disposable syringes.

Key partners including WHO, UNICEF, and PATH worked closely together in support of project implementation through the PO. The role of WHO and its contributions to health policy discussions were extremely important to long term sustainability, even though their work was not directly related to this project. US CDC also was critical in funding staff in the position of project Co-manager.

Effectiveness

The project achieved and has since surpassed its stated objectives of increasing HepB3 coverage to over 85% and TBD coverage to over 75%, at both the national and provincial level, except for one province. All provinces achieved HepB3 coverage rates over 95 percent by 2009. TBD coverage across the western provinces was 84 percent in 2009, a 27 percentage point increase from 2004. Further progress was made, and in 2011, TBD coverage in western provinces was 90 percent, with only one province unable to reach the 75% coverage goal. Additionally, substantial coverage gaps between western and eastern provinces were narrowed. For HepB3 coverage, there is no difference between western and eastern provinces currently, while for TBD coverage, the difference has been narrowed to approximately five percentage points – a significant improvement from the 33 percentage point difference reported in 2004. Further, 99% of all 3,000 counties have reached the 85% coverage goal for HepB 3, while 98% of all counties have reached the 75% TBD coverage target.

Although the project MOU specified use of AD syringes for all immunizations, government guidance did not mandate use of AD syringes. While all syringes ordered at central level were AD syringes, syringes procured by provincial governments included both AD and other disposable syringes. Current use of AD syringes for immunization is 53 percentage points higher in project provinces than non-project provinces, with utilization rates of 78%, 73%, and 25%, respectively, in western, central,

and eastern provinces. Sterilizable equipment has been eliminated, and all injections were given with disposable equipment, with nearly no re-use of disposable equipment. Although the project did not achieve its original objective of exclusive use of AD syringes for all immunizations, significant progress has been made, particularly in project areas.

The basic premise of the project (to increase use of Hepatitis B vaccine and AD syringes by removing financial barriers,) as well as the unique project design, clearly proved effective. In addition, we examined elements of GAVI support, implementation, and country context that contributed to effectiveness. There were four factors that were particularly important for attaining the project outcomes:

1) Detailed guidance from the PO to provinces that created a sense of discipline around project activities, and guidance in pursuing health education activities at all levels of the health system;

2) The structure of the health system that supported smooth implementation of national level guidelines down four administrative levels. Not only did staff carry out the work, but all of the supporting infrastructure was in place.

3) High level political commitment that motivated EPI staff, but also ensured collaboration from other actors, such as MCH staff.

4) Supportive government policies, particularly policies to reimburse hospital delivery, leading to significant increases in TBD coverage rates.

Impact and Value Added

The evaluation team relied on other studies for estimates of quantitative project impact, and used qualitative data to evaluate GAVI's contributions against what might have happened otherwise. A forthcoming study finds that 3.82 million chronic infections and 685,000 future Hepatitis B related deaths were prevented in project areas during the project period. However, this estimate includes immunization that would have occurred without the project, and cannot isolate the impact from changes in government health financing and other health programs, including policies like central government funding for vaccines or reimbursement for hospital delivery that also contributed to these outcomes.

A sero-survey conducted in 2006 shows significant decline in HBsAg prevalence in children <5 to 1.0 percent, compared with 9.7 percent in 1992. GAVI and this project contributed to this decrease by securing full integration of Hepatitis B vaccine into the EPI program for children nationwide, emphasizing the importance of TBD, and supporting social mobilization and public education to increase immunization coverage in project areas.

This project contributed to improved injection safety by raising visibility around the issue, and supporting equipment and training in the project areas. Use of AD syringes is 53 percentage points higher in western provinces than eastern provinces. Given central government funding for syringes to all provinces in 2008, the higher use in western provinces could reasonably be considered a result of this project.

GAVI catalyzed central government commitment and coalesced provincial and lower level government inputs to support integration of Hepatitis B vaccine into EPI. While the GOC may have been able to achieve the current results on its own, GAVI support at a minimum sped up the process, reducing disease for several cohorts of newborns. Also a result of this project was a new emphasis on TBD, which was not even part of routine reporting until 2004. The project elevated the importance of TBD targets and introduced a variety of effective strategies to support this goal.

This project also helped to improve management of the immunization program, instilling structured planning for supervision and training, and greater emphasis on social mobilization and public education. Review of reported and survey coverage rates shows that the discrepancy between surveyed and reported coverage decreased substantially during the project period, and particularly in western provinces.

Sustainability and Factors Contributing to Sustainability

Prospects for future sustainability are excellent since the largest cost components for Hepatitis B and other childhood immunizations (vaccines, syringes, provider fees) are now provided for by the central government. This situation is a stark contrast to findings of a 2004 study that showed only 27 percent of the cost of immunization was provided by government funds, and only 0.7 percent from central government funds. Effective supervision, social mobilization, and training activities are well-integrated into routine immunization work. Recent central government decisions to direct funding to primary health care facilities help to alleviate constraints in funding operational costs, but funding at county and prefecture levels remains limited.

While the SARS epidemic initially delayed project implementation, it was instrumental in putting health on the political and development agenda in China, spurring significant increases in public funding for health. Three factors were critical in helping to take advantage of the opportunity presented by SARS: 1) double digit economic growth during this period; 2) engagement of GAVI partners, particularly WHO, in discussions related to government responsibility for public health; and, 3) project experience of central government contributions for vaccines.

Lessons Learned

For the most part, project design and implementation were very effective. Nonetheless, greater recognition of differences between project areas and allowing for flexibility in implementation, advance communication of co-funding requirements, both at provincial level for AD syringes and at lower levels for operational costs, with mechanisms to assist areas with severe constraints, and better monitoring of injection safety, both to document use of AD syringes and potential risks of disposable syringes may have improved project outcomes.

The central GOC has the authority and resources to make enormous changes in health and health policy (and has) if it is convinced of the benefits. Applying this lesson to new vaccine introduction in China means ensuring evidence of disease burden and vaccine effectiveness, and identifying strong champions in order to achieve large scale impact. In addition to strong champions, efforts to develop and ensure a viable domestic market are critical to decisions to add new vaccines to the EPI.

GAVI's experience in China is an example of how a more tailored approach to support might be more effective in leveraging in-country strengths and building ownership. Had the standard approach for new vaccine support been applied to China, GAVI would not have been able to reach as many

children as it did by leveraging 50 percent co-financing and procuring lower priced vaccines. Other countries may also benefit from hands-on management assistance and expert technical input, but the way these inputs are structured must be carefully adapted to the country context. Assessing each country's capacity individually, rather than applying a formulaic approach to support may be more effective. The experience in China also highlights the benefit of a functioning health system in supporting effective implementation.

Conclusions and Recommendations

The GAVI-GOC Hepatitis B project has achieved and surpassed its original objectives. In particular, the breadth of improvements at the county level is a true testament to improvements in the equity of immunization. Although the project supported only lower income and lower performance areas, it was a catalyst for the GOC to fully integrate Hepatitis B vaccine into the EPI program nation-wide. The success of this project is a validation of the originally-conceived model for GAVI support – time-bound support for country-led programs that generate genuine commitment, and are incorporated both programmatically and financially into the health system.

Based on our findings, the team offers the following recommendations related to future design of GAVI country support:

1. GAVI should review project objectives carefully to ensure they are aligned with the areas of project support. An external review process to ensure data is collected to monitor progress accurately may be useful.

2. GAVI should consider taking a more tailored approach to design of country support. Closer collaboration with in-country implementers during the design phase would help to develop projects that take advantage of in-country strengths to maximize outcomes.

3. GAVI should play a more active role in supporting and coordinating technical assistance and management to support in-country implementation. Although not appropriate in all situations, GAVI should consider project offices with dedicated staff (local or international as appropriate) to provide more attention and prompt problem resolution under special circumstances or for very large projects.

4. Support to countries with stronger health systems better leverages GAVI's investments. GAVI should re-consider broader health system strengthening support to ensure effective implementation of immunization and other health programs.

5. GAVI should consider providing support to higher income countries. While higher income countries may seem to have less need, many have not integrated the newer vaccines into their NIPs. For GAVI, the prospects of time-limited support and transition to long term sustainability are better in higher income countries,

6. GAVI partners can play an important role in advocating for appropriate country level health financing policies. GAVI could be more active in coordinating clear advocacy messages related to national budget financing for vaccines and immunization.

7. For countries with the budget means, substantial co-funding from project inception can ease the transition to self-sustainability.

8. For countries with domestic production capabilities and sufficient market size, GAVI may have an important role to play in facilitating technology transfer or other mechanisms that allow local production of new vaccines. Creation of a viable local market helps to generate interest in new vaccines, and promotes long term sustainability.

9. Since vaccine price is an important cost driver for GAVI programs, efforts to encourage global sourcing from Chinese and other low-priced, high-quality producers can have positive impact on efficient use of GAVI funding.

2. Introduction

The Government of the People's Republic of China (GOC) and the GAVI Alliance (GAVI) undertook a co-funded five-year, $76 million project in June 2002 to expand Hepatitis B vaccination and to purchase auto-disable (AD) syringes for infants in 12 western provinces and poverty counties in ten central provinces. A significant portion of the funds provided by GAVI remained unspent in the first four years of the project, because of lower than expected prices for vaccines and syringes, and lower than projected vaccine needs. Two subsequent no cost extensions were provided so these savings could be applied to additional activities, bringing the project life to 2011.

GAVI's support to China did not follow the standard approach designed for the majority of GAVI-supported countries. Several unusual features of support tailored to China included GOC co-financing of 50 percent of project costs from inception, establishment of a project office in China, and provision of funding for local procurement of locally produced vaccines and injection safety equipment.

The GAVI Alliance commissioned Abt Associates to evaluate the effectiveness of this project and these design features specifically, as well as the project impact and sustainability. This evaluation provides lessons learned to inform introduction of other vaccines in China[2], as well as future design and implementation of GAVI support to other countries. An excerpt from the GAVI Request for Proposal is attached as Annex A.

[2] It should be noted that China is no longer eligible for future GAVI support.

3. Approach and Methodology

3.1 Evaluation Framework

The framework for evaluation is drawn from the Organization for Economic Cooperation and Development/Development Assistance Committee (OECD/DAC) evaluation criteria, with more detailed questions as defined in the Request for Proposals (RFP). GAVI's support to China was evaluated along five criteria – relevance, implementation/efficiency, effectiveness, impact and value-added, and sustainability. Findings generated from these analyses were used to draw lessons learned, and recommendations for future GAVI investments in other countries.

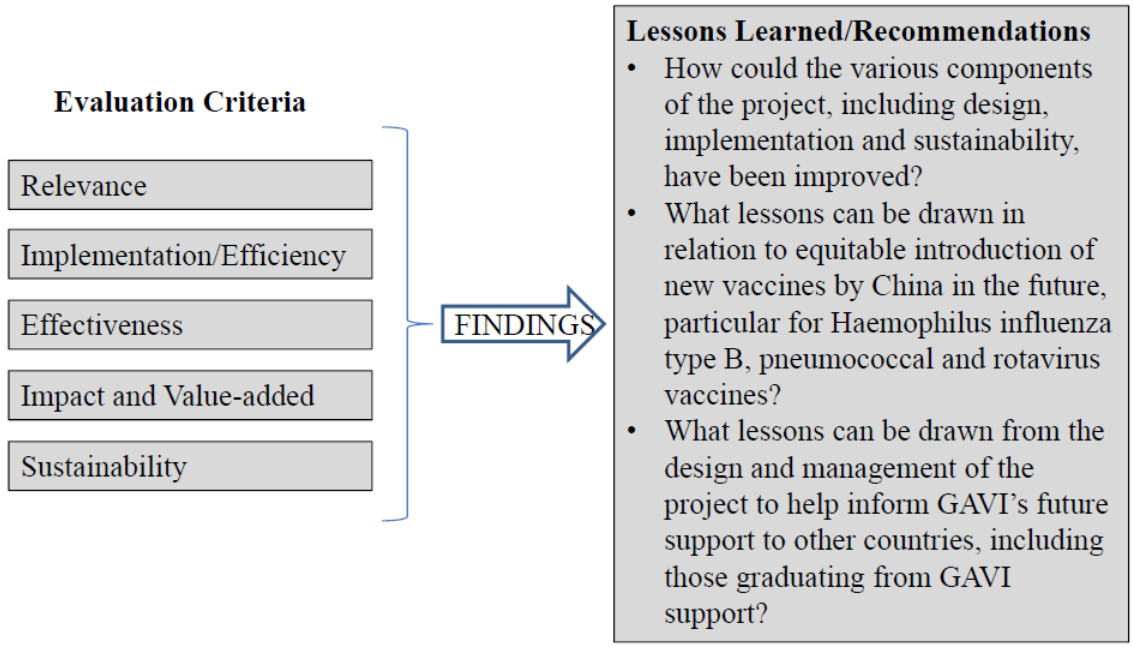
For each of these measures, specific areas of focus within the project in China include:

- **Relevance**. We relied on existing studies of the impact of Hepatitis B infection on morbidity and mortality in China to determine whether this project was suited to the country's health priorities. Additionally, we assessed the relevance of the unique project design in China, in particular, targeting less developed western provinces and poor counties of central provinces only, and requiring 50 percent co-funding from the Chinese government at the project onset. This evaluation addresses whether such design features were relevant given strategic priorities, and the extent to which these design features affected overall project outcomes.
- **Implementation/efficiency**. The main evaluation questions in the RFP showed particular interest in the mode of implementation, and partner contributions. Two elements of the project examined are the functions and effectiveness of the Project Office (PO,) a unique feature to China and the interim design and reprogramming decisions made in light of the extended implementation timeframe. Although the RFP did not pose questions related to technical efficiency, we analyzed vaccine prices, as they are a key driver of immunization program efficiency. Actual vaccine prices are particularly important in this project as GAVI provided financial support for local procurement of vaccines and injection safety equipment, unlike other countries which received in-kind contributions of vaccines and injection safety equipment.
- **Effectiveness**. This evaluation examines whether the GAVI project achieved its objectives. The 2002 Memorandum of Understanding (MOU) between GAVI and the GOC articulated three objectives for the project, which were later adjusted in the 2008 amendment to the MOU. In addition to assessing whether the project achieved these objectives, the project design implies additional unstated objectives related to targeting poorer populations and low coverage populations. Documenting the progress toward these objectives further validates the program design, even if such goals were not formally stated.
- **Impact and value-added**. Examining the extent to which coverage increases during the program period are a result of GAVI support, and determining whether such changes might have occurred without GAVI support are important questions for this evaluation. It is also important to analyze both positive and negative unintended consequences. A quantitative analysis of project and non-project counties in central provinces had been proposed, but the evaluation team learned that a national policy issued end-2001 directed all provincial governments to procure and finance Hepatitis B vaccine, so that this comparison became not meaningful as Hepatitis B vaccine was provided free throughout the country, like the original six EPI vaccines.

- **Sustainability**. Although sustainability was not a stated objective in the project MOU, transition to national funding is an important aim of GAVI support. By the end of the original project life (2007), the GOC had committed to national funding of all childhood vaccines and syringes, including payments to health workers delivering the vaccines. This evaluation examines the extent to which the Hepatitis B vaccination project contributed to this decision, whether the implementation of this mandate proceeded smoothly (including communications to health workers and the general public, reliable funding flows, etc,) and whether coverage rates are maintained or increasing over the short term. The central government policy has effectively resolved the question of sustainability, but the evaluation team will gather evidence on whether the policy is fully implemented and/or whether additional challenges remain for the long term.

Based on the findings along each of these measures, the evaluation team will draw conclusions and provide recommendations to address GAVI's broader lessons learned evaluation questions, as shown in Figure 1.

Figure 1: Evaluation Framework



Addressing the larger lessons learned questions from the China experience is important for GAVI in guiding future funding policies, particularly related to improving equity and increasing national level financing for immunization.

As per the GAVI RFP, the evaluation work was conducted in two distinct phases: 1) Inception Phase; and 2) Core Evaluation Phase. The Inception Phase of work was conducted in July 2012, culminating in the delivery of an Inception Report to GAVI that included a detailed methodology for the evaluation. The core evaluation activities were conducted in August and September 2012.

3.2 Inception Phase Activities

To inform the development of the Inception Report, the Abt team conducted the following activities:

1. **Document review**. The evaluation team reviewed documents provided by GAVI, to guide its preliminary key informant interviews, as well as to develop the evaluation plan. These documents included the MOU and amendment, Inception Report, and Annual Progress Reports (APR).

2. **Chinese language literature search**. The evaluation team began a review of Chinese language articles with information on Hepatitis B immunization and infection. A search was conducted through China National Knowledge Integrated Database (CNKI), a widely used Chinese database of academic literature. The search included seven key words: Hepatitis B (two variations), Hepatitis B virus, immunization, vaccination, vaccine, and GAVI. It resulted in over 2,000 articles, of which approximately 40 were relevant for further review. This work was later completed in the core phase.

3. **Limited interviews with key informants**. The evaluation team conducted telephone interviews with six key informants, representing both GOC and partner organizations, who were closely involved in the design and implementation of the project. Areas of discussion included project design, implementation issues and decisions, project impact, as well as general guidance on other key informants and key evaluation issues. The discussion guide used for these interviews is attached in Annex B.

4. **Quantitative data collection**. The evaluation team reviewed with the National Immunization Program (NIP) the availability of data related to immunization coverage, national and subnational health and immunization budgets, and commodities prices. Based on these initial discussions, some changes and clarifications were made to the initially proposed analyses.

This information fed into the preparation of the Inception Report submitted to GAVI end-July. Comments from GAVI on the planned work were incorporated into the evaluation.

3.3 Core Phase Data Collection

3.3.1 Document Review

The document review began during the Inception Phase was supplemented in the core phase. Overall, the documentation compiled and reviewed included:

- MOU and amendment, between GOC and GAVI
- Project Proposal, Inception Report, and APRs
- Thesis by Cui Fuqiang synthesizing several end-of-project studies
- Communications between GAVI and the GOC
- GAVI staff trip reports, board meeting and teleconference minutes
- Minutes of the Inter-agency Coordinating Committee (ICC) and Operational Advisory Group (OAG) meetings

- National Health Strategy documents and regulations
- NIP strategy documents and regulations

A complete list of the documents consulted is included at the end of this document.

3.3.2 Chinese Language Literature Review

The evaluation team completed its review of Chinese language articles that was begun in the Inception Phase. A list of the most relevant articles with translated abstracts is included in Annex C.

3.3.3 Telephone Interviews with Key Informants

To ensure reliable accounts of design and implementation experience, and to provide greater depth than is available through document review, we interviewed key informants who played critical roles in the design and implementation of this project. Informants based in China were interviewed in person during the in-country visit. The informants interviewed by telephone primarily represented partner organizations and are no longer based in China. These individuals would have participated in initial design discussions, ICC meetings, the OAG, or were directly responsible for project implementation in the position of the international Project Co-Manager. Also interviewed by telephone was the first China Center for Disease Control (CCDC) Project Co-manager, as she is no longer based in China. The interview guide used to conduct these interviews is included in Annex D. The informants interviewed by telephone are shown in Table 1.

Table 1: Key Informants Interviewed by Telephone

Individual	Affiliation/Position	Period of Involvement
Craig Shapiro*	US CDC, Hep B Project Co-Mgr	2000-2004
Stephen Hadler*	WHO, HepB Project Co- Mgr	2005-2008
Yvan Hutin**	WHO, HepB Project Co- Mgr	2009-2010
Wang Xiaojun	CCDC, HepB Project Co- Mgr	2000-2005
Henk Bekedam	World Health Organization (WHO)	2002-2005
Lisa Lee	WHO	2000-2005
Lisa Cairns	WHO	2008-2009
Mark Kane*	PATH and GAVI Rep on OAG	2000-present
Janet Vail	PATH	2001-2002
Wang Lixia	PATH	2003-2005
Tore Godal	GAVI Secretariat	2000-2006
Alex Palacios*	GAVI Secretariat	2002-2007
Ranjana Kumar	GAVI Secretariat	2007-2011
Zhu Xu	United Nations Children's Fund (UNICEF), formerly CCDC	2000-2005
David Hipgrave	UNICEF	2007-2011
Li Wangsheng	Zeshan Foundation	n/a

*These individuals were also consulted during the Inception Phase.
**Inputs were provided through email correspondence.

3.3.4 Quantitative Data Collection

The evaluation team requested key data related to immunization coverage, national and subnational health and immunization budgets, and commodities prices. Not all of the data requested were available. The most challenging data constraints were related to immunization budgets at all levels of the health system, as well as reliable immunization coverage rates pre-2002. Annex E provides a list of the data requested by the evaluation team, and data availability. More discussion of data availability is included in Section 2.4 below.

3.3.5 In-Country Data Collection

The evaluation team spent three weeks in China, conducting interviews with key informants representing GOC, field visits to three provinces, and follow up on quantitative data collection.

The evaluation team met with Ministry of Health (MOH) and CCDC officials involved in project design and implementation. Table 2 shows the key informants representing the MOH and CCDC that the evaluation team interviewed. Interviews were conducted using semi-structured interview guides, with questions tailored to specific individuals interviewed. Interviews were conducted in both Chinese and English, depending on the informants' preference. The interview guide used is shown in Annex F.

Table 2: Key Informants from the MOH and CCDC

Individual	Affiliation/Position	Period of Involvement
Yu Jingjin	MOH, Department of Disease Control (DDC)*, Dir Genl	2003-2007
Lu Ming	MOH DDC, EPI Div	2003
Cui Gang	MOH DDC, EPI Div Dir	2003-2008
Li Quanle**	MOH DDC, EPI Div Dir	2011-2012
Wang Hui	MOH, Dept of Finance	2004
Yang Weizhong**	CCDC, Dep Dir, GAVI Proj Dir	2005-2009
Cui Fuqiang**	CCDC, GAVI Project Co-Mgr	2005-present
Wang Zhao	China Fdtn for Hepatitis Prevention and Control	2000-present

*This office is now called the Bureau of Disease Prevention and Control.
**Also contacted during the Inception Phase.

While in Beijing, the evaluation team also met with WHO staff to provide a briefing of the evaluation progress. Unfortunately, current staff are relatively new, and were not closely involved with this project.

The evaluation team traveled to three provinces – Hunan, Gansu, and Qinghai – to better understand both technical and financial challenges affecting implementation. These provinces were selected in consultation with the EPI program based on three province profiles and criteria proposed at the end of the Inception Phase: 1) central province with delayed co-funding; 2) western province with delayed co-funding and average coverage results; 3) western province with delayed co-funding and weaker coverage results. Hunan is a central province, so project funding was only provided for poverty counties within the province. Gansu and Qinghai are western provinces that faced co-financing

challenges in the early implementation years, and despite achieving project targets, continue to face challenges achieving high timely birth dose (TBD) coverage rates in all counties. Table 3 presents a complete list of the prefectures, counties, and facilities visited within these three provinces. A complete list of individuals met during these visits in presented in Annex G, and the interview guides used are included in Annex H.

Table 3: Field Visit Sites

Province	Province Profile	Prefectures, Counties, and Facilities

Qinghai	• Western province
	• Reported delayed co-funding
		• Xining Prefecture
		  ▪ Huangzhong County
		  ▪ Shangxinzhuang Central Hospital
		• Haidong Prefecture
		  ▪ Xunhua County
		  ▪ Jishi Township Hospital
		  ▪ Tuoba Village Clinic

Gansu	• Western province
	• Reported delayed co-funding
		• Dingxi Prefecture
		  ▪ Anding District
		  ▪ Xigong Township Hospital
		• Tianshui Prefecture
		  ▪ Qin'an County
		  ▪ Xinfeng Central Hospital

Hunan*	• Central province
	• Reported delayed co-funding
	• Visit project and non-project site
		• Yueyang Prefecture
		  ▪ Pingjiang County
		  ▪ Fushoushan Township Hospital
		• Yunxi District
		  ▪ Lukou Township Hospital

* Central province receiving support for poverty counties only.

Table 4 summarizes information on the types of informants and the focus of data collection by type of informant.

Table 4: Summary of Key Informants and Areas of Data Collection

Type of Informant	Focus of Data Collection
National Level	
MOH and CCDC officials • MOH Dept. of Disease Control • MOH Dept. of Finance • NIP Director • Other NIP staff • MOH staff working in the GAVI PO	• National Hepatitis B control strategy (national support for vaccine distribution, vaccine coverage rates, birth dose strategy, user fees, strategies for low coverage populations) from 2000 to present • Role of MOH, GAVI project office, and other partners in implementation • Ability to adapt to implementation challenges within the GAVI partnership • Project outcomes, key project constraints, and success drivers • Unintended consequences of the project, and value added of the partnership • Hepatits B three dose (HepB3) and Hepatitis B timely

Type of Informant	Focus of Data Collection
	birth dose (HepB TBD) coverage data at provincial, prefecture and county levels • Prices paid for vaccine and AD syringes • Current national government commitments to Hepatitis B vaccination
Other partners (mostly interviewed by telephone) • GAVI Int'l Co-Manager • WHO advisor • UNICEF advisor • PATH staff • U.S. Center for Disease Control • Other partners	• Evolution of national support of Hepatitis B vaccination • Role of MOH, the GAVI PO, and other partners in implementation • Ability to adapt to implementation challenges within the GAVI partnership • Project outcomes, key project constraints, and success drivers • Unintended consequences of the project, and value-added of the partnership
Subnational Level (visits to three provinces)	
Provincial health officials • Health Dept Director • Immunization Program Manager • Health Dept Finance office	• Coverage rates up to present • Provincial health and vaccine budgets up to present • Design and implementation experience • Inputs and support received for implementation • Current HepB vaccination strategy • Fees charged during and after GAVI support
Prefecture and County officials • Health Dept Director • Immunization Program Manager • Health Dept Finance office	• Coverage rates up to present • Local health and vaccine budgets up to present • Design and implementation experience • Inputs and support received for implementation • Current HepB vaccination strategy • Fees charged during and after GAVI support
Staff at service delivery facilities • Facility In-charge • Staff conducting immunization	• Implementation experience and support for implementation • Coverage rates and vaccine availability and support since 2010 • Fees charged during and after GAVI support

3.4 Data Analysis Methods

Quantitative and qualitative data from document review, in-country sources, and remote interviews were used to address the evaluation questions posed. The plan included in the Inception Report for evaluating the questions posed in the RFP with data sources, indicators, and analysis methods is shown in Appendix I. Not all the proposed analyses were conducted due to data and other limitations as discussed below.

To address the evaluation questions related to project relevance and implementation/efficiency, much of the evidence was based on qualitative data. Based on data collection during the Inception Phase, key informant interview guides were designed to examine focus questions in depth. All qualitative data was triangulated across key informants and compared with available documentary evidence before drawing conclusions. Detailed notes from all interviews were prepared for internal use to

facilitate analysis. Qualitative data was supplemented by review of data on Hepatitis B coverage rates prior to 2002, and comparison of project vaccine prices with an international benchmark over the project period.

Evaluation of the questions related to effectiveness relied more heavily on quantitative data. Analysis of changes in Hepatitis B coverage rates over the project period, and comparison with original project objectives was conducted. Analysis was conducted for project and non-project areas, and at county level.

Evaluation of the questions related to impact and value-added relied primarily on external studies. The team originally proposed quantitative analysis of GAVI and non-GAVI counties in central provinces, but learned that the differences in these areas were limited. Mostly importantly, the provincial governments began providing Hepatitis B vaccine to all counties in 2002 in response to national policy changes. Instead, the evaluation team has incorporated findings from other studies, and key informant data to assess contributions from the project, and GAVI's value-added.

Analysis of trends in coverage rates, government budgets, user fees, and vaccine availability pre- and post-GAVI was conducted to assess sustainability. Data on coverage rates were available, but data on government budgets were extremely limited. No provincial level comparisons were made because of lack of data, and only very limited summary level data of immunization expenditures at national level were available. The team supplemented this data with publicly available information on health expenditures to assess sustainability. Qualitative data on changes in user fees and vaccine availability were collected through site visits and analyzed.

As suggested by GAVI, we created a ranking system to assess the robustness of our findings, presented in Table 5 below.'

Table 5: Ranking System for Evaluation Findings

Ranking	Definition
A	Finding is supported by a range of reliable data sources, including informant interview data, documentary evidence, other studies or assessments, and/or quantitative data (if quantitative data are relevant to the finding.)
B	Finding is supported by a range of reliable data sources, but relies primarily on qualitative informant interview data.
C	Finding is supported by a single source, with limited supporting data or evidence.

3.5 Methodological Limitations

The evaluation findings presented are based on compiling and analyzing many different sources of information (both current and dated) in a short period of time. Some analyses originally proposed were not able to be conducted due to data constraints; additionally, there are limitations in the methods used:

- Hepatitis B coverage data were less complete in the earlier years. HepB3 coverage data by province is available from 2000, while HepB TBD data is only available from 2004, as that was the first year of required reporting. Thus, there is not a reliable baseline for comparison of TBD in particular. Additionally, we have not made any independent assessment of the accuracy of

coverage data, and rely solely on the data received from CCDC. A comparison of differences between reported and survey data is included in Section 3.4.

- Data on commodities prices was available only for the period when the project conducted national procurement. Once procurement is transitioned to provinces in 2008, there is no data available on prices paid. The evaluation team did make inquiries during field visits, but this is limited to three provinces.
- The team was unable to get accurate data on immunization expenditures at any level of the health system. While anticipating challenges at provincial level and below, the team ultimately was not able to get detailed central government immunization expenditure data either.
- Documentary evidence of progress in the early years was limited, with the APRs as the key source of information. While APRs identified key challenges, they included few details on these challenges and project responses to them.
- Some of our information is based on individuals' recollections of events that occurred up to 12 years ago. Small discrepancies in timing of events are inevitable, and in most cases the team was able to triangulate data from several sources to establish a high degree of reliability. The biggest constraint as a result of the long time span of this project is that recollection of details was limited.
- In the area of project impact, we are unable to provide precise quantitative measures. Instead, project impact is examined using existing studies of the impact of Hepatitis B immunization and the contribution of this project. However, the estimates of benefits cannot be exclusively attributed to the project. Key informant data is used to describe likely developments in the absence of GAVI.

4. Findings

4.1 Overview of Project Design and Implementation

Hepatitis B infection has long been recognized as a major cause of mortality and morbidity in China. Hepatitis B vaccine has been available in China since 1992, managed and distributed through the EPI. Unlike the traditional six EPI vaccines that are funded by provincial governments and available for nominal provider service fees, however, the Hepatitis B vaccine was only available at full cost to the user. This cost created inequities in coverage rates, with much higher coverage rates in urban areas and wealthier provinces.

With support from GAVI, the GOC adopted a policy to fully integrate Hepatitis B vaccine into the EPI in 2002, making the vaccine available free nationwide, although provider service fees were still in effect. Like the traditional EPI vaccines, parents paid service fees to providers of up to RMB 3 per injection, but did not have to pay for the vaccine, which had cost approximately RMB 8-10 per dose in project areas prior to the project. The GAVI-GOC project provided funding for vaccines and AD syringes in 12 western provinces and poverty counties in ten central provinces. Funding for vaccines and syringes in eastern provinces and non-poverty counties of central provinces were supported by provincial governments.

There were three unusual features to GAVI's support in China:

- GOC co-funding of 50 percent of project costs from inception
- Provision of funding for local procurement of domestically produced vaccines and injection equipment
- Establishment of a GOC-GAVI PO

A description of each of these project features is provided below. Because these features were unique to China, in-depth examination of the effectiveness and impact of each of these design features is a key part of this evaluation.

4.1.1 GOC Co-financing

One of the strategies of GAVI in its first phase was to provide time-limited funding to countries to introduce new vaccines, focusing on Hepatitis B, Haemophilus influenza B (Hib), and yellow fever, with a goal of countries taking over responsibility for vaccine financing within a five year period. While countries were expected to make preparations to replace GAVI funding for vaccines at the end of five years, no other GAVI-supported country provided 50 percent co-funding at inception.

Chinese government funding for Hepatitis B vaccination had been considered prior to GAVI, but no firm decision was taken. Coinciding with initial discussions with GAVI, a report was presented by the China Hepatitis B Control and Prevention Foundation suggesting central government funding for vaccines and outlining budget implications. Ultimately, the support of an international organization (GAVI) helped secure agreement from the Ministry of Finance (MOF) to provide funding.

4.1.2 Local Procurement of Domestically Produced Vaccines and Injection Equipment

Hepatitis B vaccine had been produced in China for about a decade before the inception of the GAVI project. There was sufficient domestic capacity to supply vaccines for the whole country at full

coverage rates. Domestically produced vaccines were of high quality, and available at lower prices than from UNICEF procurement. The vaccines were not WHO-prequalified, however, primarily due to reasons related to accreditation of the China FDA. Although GAVI had previously relied on UNICEF for new vaccine procurement, it made an exception in China to allow local procurement of domestically produced vaccine, on the condition that the China FDA also work toward WHO accreditation.

Over the course of the project, all Hepatitis B vaccines and MOH-GAVI funded injection equipment were procured at national level, with manufacturers directly delivering to provincial level. Injection equipment financed by provincial budgets were procured by each of the provinces individually.

4.1.3 MOH-GAVI Project Office

In order to ensure smooth implementation, a dedicated PO was established in China. While the initial idea may have been proposed by GAVI, CCDC recognized the benefits given an understaffed EPI office. All partners were supportive of establishing a dedicated office. At the time of project inception, GAVI did not support country or project offices, instead relying on the NIP and its partners to implement activities proposed. GAVI focused on providing funding support, with little direct involvement in implementation. The PO proved to be critical to implementation of this project for such a large population over such a short time. The PO was co-managed by an international advisor and a CCDC staff person, with responsibility for planning, procurement, training, supervision, and monitoring and evaluation. Initial start-up activities, focused on procurement and training, required significant efforts from project staff. There were approximately 6-8 other CCDC staff that supported project implementation. Funding for three CCDC staff, as well as direct costs related to training, supervision, and communications and dissemination were included as part of GAVI's project support. Other staff were separately provided by the CCDC, while the international advisors were funded by US CDC.

4.2 Relevance of Project and Project Design

Evaluation Question:

1) To what extent were the design and objectives of GAVI's support to China relevant to:
   - China's needs and priorities
   - GAVI's strategic priorities

The relevance of GAVI and GOC focus on Hepatitis B was examined in light of the disease burden and the GOC and GAVI's priorities. In addition to the unique design features described in the previous section, two other design elements – targeting of project support and limitations on user fees – are examined as they suggest interests related to equity of Hepatitis B immunization that are beyond the stated project objectives.

4.2.1 Alignment with China's Health Priorities and GAVI's Strategic Priorities

In its multi-year plan for EPI 2001-2005, the GOC identified control of Hepatitis B as one of four goals for the EPI program:

> *accelerating Hepatitis B control and reducing the prevalence of chronic Hepatitis B virus infection among children <5 years of age*

Hepatitis B control and prevention were recognized as a high priority of the Chinese health system by the GOC given the high disease prevalence. At the time of project design, there were approximately 120 million people in China (10 percent of the population) with chronic Hepatitis B infection, more than 10 million of whom were symptomatic chronic hepatitis patients[3]. Nearly 300,000 deaths related to viral hepatitis occurred annually.

One of the strategies identified in the multi-year plan was to fully integrate Hepatitis B vaccine into EPI, with vaccine for infants financed by provincial finance bureaus. However, the MOH recognized that many provinces would have financial difficulties meeting this obligation. Though the CCDC and MOH were engaged in discussion on how to address these constraints, the integration strategy had not yet been implemented. Thus, the opportunity GAVI funding presented was not only to provide vaccine for the western provinces and poverty counties of central provinces, but also to allow full integration of Hepatitis B into EPI throughout the country.

The focus on Hepatitis B in China was also relevant for GAVI. Increasing use of underutilized vaccines is a key part of GAVI's mission. In its early years, the focus was on three vaccines – Hepatitis B, HiB, and yellow fever. China was one of three special countries for GAVI, along with Indonesia and India. Because of the large populations in these countries, they did not qualify for the standard GAVI funding windows at the time. Given the significant burden of disease in China, and that approximately one-third of the Hepatitis B carriers worldwide lived in China, preventing Hepatitis B infection in China was critical to achieving GAVI's global objectives. Support to China focused on Hepatitis B vaccine strongly supported GAVI's strategic objectives.

4.2.2 Targeting of Project Support

The project targeted support to the poorest regions in China, focusing on 12 western provinces and poverty counties of central provinces. Project funds were used to support these areas specifically, but on a larger scale, project funding allowed the MOH to integrate Hepatitis B vaccine into EPI, requesting that all provinces provide funding for Hepatitis B vaccine.

The evaluation team examined data on coverage in these targeted regions to evaluate the importance of ensuring support for these geographic areas. Table 6 shows the coverage rates for the 12 western provinces supported by GAVI in 2001. As the data show, all but three of these provinces were performing below the national average. Targeting funding to ensure that these provinces had ready access to vaccines and injection equipment was important to achieve overall project goals, and to reduce geographic differences in coverage rates.

Table 6: 2001 Coverage Rates for Twelve Western Provinces

Province	HepB3	HepB TBD
Tibet	1.6	0.9
Guizhou	9.4	2.9
Yunnan	42.0	17.1
Xinjiang	45.8	36.6
Qinghai	51.6	17.8

[3] EPI Multi-year Plan, 2001-2005.

Gansu	57.5	34.9
Sichuan	68.9	56.7
Chongqing	69.3	42.2
Guangxi	73.9	48.9
Shaanxi	81.5	71.9
Ningxia	87.1	77.9
Inner Mongolia	94.8	76.7
National	**82.4**	**63.5**

Source: Survey data from CCDC.

The project also supported vaccines and syringes in poverty counties of 10 central provinces. As shown in Table 7, HepB3 coverage rates in poverty counties were lower than in non-poverty counties in all provinces supported, although in some cases the difference was minimal. County level data were not available on TBD.

Table 7: 2002 Hepatitis B3 Coverage Rates in Central Provinces

Province	Per Capita GDP (USD)	Poverty Counties	Non-Poverty Counties
Anhui	564	99.1	99.3
Hainan	748	83.6	92.6
Hebei	835	96.8	98.5
Henan	n/a	98.7	99.3
Heilongjiang	924	99.8	99.7
Hubei	786	83.1	93.7
Hunan	616	79.9	92.7
Jilin	760	99.1	98.4
Jiangxi	561	84.3	91.1
Shanxi	569	95.2	96.2
Total		**93.7**	**96.7**

Source: Administrative data from CCDC.

Support provided through this project was targeted to areas with lower coverage rates, coinciding with lower income areas, where local governments had limited ability to finance vaccines through provincial government budgets. Table 8 compares per capita Gross Domestic Product (GDP) across western, central and eastern provinces, as well as the scope of project support for different regions.

Table 8: Comparison of GDP and Project Support by Region

Region	Per Capita GDP Range (USD, 1999)	Project Support
Western	297-797	All areas of province
Central	561-924	Only poverty counties
Eastern	1043-3310	None

4.2.3 User Fees

At the time of project design, China's immunization program included the traditional six EPI vaccines, with the addition of Hepatitis B available on a full cost basis. The six EPI vaccines were procured, financed, and distributed by provincial and municipal governments, but users were charged fees by providers for administering the vaccine. These fees generally varied based on the relative incomes in the area, ranging from RMB 1-3 in the project areas. The cost of Hepatitis B vaccine was approximately RMB 8-10 per dose.

With the inception of this project, Hepatitis B vaccine was provided for free and the GOC agreed to establish maximum fees that could be charged by providers for administering the vaccine, varying by province depending on relative incomes. The free vaccines represented removal of a serious financial barrier, while the caps on user fees further aimed to ensure affordability and minimize potential negative effects of fees. Eliminating user fees completely was not considered because village doctors, who were largely responsible for EPI at the time, received limited compensation from government sources and relied on these fees for their livelihood.

4.2.4 Project Objectives

The project was designed to increase Hepatitis B vaccination primarily through reducing cost barriers to access in low income areas. Three objectives were specified in the original MOU:

- HepB3 coverage will reach 85 percent at the county level (revised to 90 percent in 2008)
- >75 percent of newborns at the county level will receive the first dose of hepatitis B within 24 hours of birth
- All immunization injections will be with AD syringes.

There appear to be alternative interpretations of whether these objectives were intended for project areas only, or nationwide. Although project support was directed to 12 western provinces and small portions of 10 central provinces, monitoring focused on national level progress throughout the life of the project. For the GOC, monitoring progress nationally reflected its interest in measuring outcomes in the national policy to fully integrate Hepatitis B into the EPI program and provide free vaccines nationwide. Nonetheless, setting these targets at the county level reflected high ambitions – it aimed for all 3,000 counties in China, including ones in extremely remote and challenging terrains, to reach the targeted HepB3 and TBD coverage rates. While syringe procurements funded by the project included only AD syringes, the GOC did not fully mandate compliance for syringes procured in non-project areas, and few monitoring mechanisms were in place to regularly track progress. Because of the dual interpretation, the evaluation team considers effectiveness both in terms of achievements nationally, as well as achievements in project areas only.

For GAVI, these objectives fully supported its strategic priorities of maximizing Hepatitis B vaccine coverage and reducing future infections. However, given GAVI's geographically targeted support, national level targets were somewhat incongruous with project activities. There did not appear to be more detailed reporting of progress specific to project areas. Ultimately, national progress toward these objectives relied a large part on GOC decisions and policies beyond the scope of the project.

Lastly, though these targets were based on county level coverage, APRs provided to GAVI only reported on coverage at county level in two years (June 2006 and May 2007.) During the evaluation team's visit, there appeared to be challenges with the completeness and reliability of county level

coverage data. Reporting on use of AD syringes in the APRs was limited, and based only on the procurements conducted through the project, which represented only a portion of all syringes used for immunization.

4.2.5 Summary of Findings on Relevance of Project and Project Design

Evaluation Question	Findings	Robustness Ranking*
To what extent were the design and objectives of GAVI's support to China relevant to China's and GAVI's needs and priorities?	Control of Hepatitis B infection was a major health concern in China, and was one of the four key objectives of the EPI program. Project support targeted the poorest provinces, which had low Hepatitis B coverage rates. One-third of Hepatitis B carriers in the world lived in China, so GAVI's support to China was well aligned with its organizational priorities. Monitoring reports focused on progress toward objectives at a national level, even though the project supported the poorest provinces only.	(A) Disease data, differences in provincial incomes, and data on provincial inequities in coverage, all support this finding. Removing financial barriers to HepB immunization and targeting the poorest provinces with lowest coverage rates was appropriate project design.

* See Section 2.4 for definition of robustness rankings.

4.3 Implementation and Efficiency

Evaluation Questions:

2) To what extent was the project implementation plan relevant and appropriate?
3) To what extent were the activities implemented as planned and in a timely manner?
4) To what extent was management appropriately adaptive in response to implementation challenges and evolving circumstances?
5) To what extent were partners and relevant groups involved in the program planning, monitoring and implementation?

To answer these questions, the evaluation team examined the project design features and how they affected implementation, including the effectiveness of the management structure in timely reprogramming of the project savings during the extended implementation timeframe. Although the RFP did not pose questions related to technical efficiency, the evaluation team also analyzed vaccine prices as a measure of program efficiency.

4.3.1 Timeliness of Implementation

The MOU signed in June 2002 presented the overall framework for management and implementation of the project, solidifying structures and agreements that would serve to ensure smooth implementation:

- Creation of a PO co-managed by an international advisor and a CCDC manager
- Establishment of an OAG with representatives from MOH, CCDC, PO, GAVI, and other members of the ICC
- Establishment of a Procurement Coordinating Committee with representatives from MOH, MOF, State Drug Administration, PO, UNICEF, WHO, and the World Bank

- Agreement on equal co-funding from GAVI and central government for Hepatitis B vaccines and injection equipment, and GAVI, central government and provincial government financing for non-Hepatitis B injection equipment

While the MOU contains significant detail around these key agreements, planned activities to support national roll-out, such as social mobilization, training, or supervision are not provided until the Implementation Plan. There was no timeline for completion of specific activities included in the MOU, the Inception Report, or the Implementation Plan against which to compare progress. Further, the outbreak of Severe Acute Respiratory Syndrome (SARS) from January to June 2003 delayed training activities critical to project implementation. Nonetheless, significant progress was made the first year to initiate the project, including procurement and delivery of vaccines, national project initiation meeting held for provincial staff, implementation guidance provided to provinces, and significant progress in sub-provincial training. Further details are provided in Table 9.

Table 9: Implementation Progress in First Year

Area	Activities Completed
Management	• PO was established and staffed with co-managers and support staff in the CCDC • OAG held two meetings
Procurement	• Procurement Coordinating Committee established and met to define procurement process • Provinces updated target population estimates • Completed competitive procurement and signed contracts with two suppliers each for vaccines and AD syringes for HepB • First vaccine shipments to provinces in 1Q 2003
Financing	• First GOC funding disbursement received Feb 2002 • First GAVI disbursement received Oct 2002 • Second GOC funding disbursement received Dec 2002 • Second GAVI disbursement received May 2003
Project initiation	• PO held national meeting in Beijing with provincial EPI staff to introduce project and review the project implementation plan • Project implementation plan was completed and issued to all participating provinces • Provinces completed and submitted provincial implementation plans, including pricing policies in accordance with MOU; also completed the first annual progress reports which were reviewed by the PO
Supervision	• Central PO conducted supervision in 11 of 12 western provinces, including evaluation of training
Training	• Initiated cascade training system with trainings to provincial level • 7 of 11 provinces evaluated had completed trainings down to village level, with ongoing trainings in the others
IEC	• Hepatitis B-themed National EPI Day held • Provinces conducted social mobilization activities
Monitoring and Evaluation	• Modified routine immunization reporting form to include reporting on TBD

Source: 2002 APRs and field visit findings.

There were delays noted, primarily due to the disruption of SARS. One area of delay was in the trainings from provincial level down, as these training would ideally have been conducted in 2Q 2003. One province visited noted that the vaccines had been delivered by the supplier, but because

they were too busy to conduct training, and did not delivered the vaccines to lower levels for several months. The APR also reported that procurement of AD syringes for non-Hepatitis B injections was delayed until October 2003 due to SARS. While SARS may well have caused delays of approximately six months, overall significant progress was made in the first year. More discussion on how implementation proceeded is provided in the remainder of this section.

4.3.2 Relevance of Implementation Plan

Each of the key components of implementation, including the management structure (through the PO and OAG,) procurement mechanism, and co-financing arrangement is examined for their relevance and appropriateness.

Management through PO and OAG

The PO played a critical role in the smooth implementation of this project. It managed and coordinated procurement, finances, training, supervision, monitoring and evaluation, and provided general oversight and support to the provinces. It was widely seen as providing effective management, and a critical factor to the project's success.

Both GAVI and the GOC supported the establishment of a PO during project design. GAVI recognized the potential benefit of dedicated management given such a large project. The GOC was very supportive given past experiences with insufficient central coordination for large health projects. The PO ensured dedicated staff at the central level, particularly important in the context of staffing shortages at the CCDC overall. The PO was located in linked but separate space from the NIP to reduce the extent to which project staff were pulled onto other tasks. Nonetheless, in severe emergencies (SARS, avian flu), it was reported that staff were temporarily reassigned to these pressing issues.

Co-management of the PO by an international advisor and CCDC staff ensured access to both the highest technical expertise and knowledge, as well as to knowledge, authority and access within the Chinese health system. The international co-manager's involvement in day-to-day management was an effective mechanism for knowledge transfer, building capacity at the CCDC centrally and locally. Key informants also noted that, at the political level, the international co-manager increased credibility and visibility of the project, making it easier to raise concerns to higher levels, especially when advocating for additional resources. This credibility was derived not only from the co-manager position, but also the strong relationships that the individuals in these roles built with key MOH officials. These advisors used their position effectively not only to transfer technical knowledge, but also to influence policy discussions. All international co-managers were well respected and worked effectively with country counterparts in the CCDC and MOH.

While the PO provided important guidance and leadership, and served as a critical link to the MOH, the large bulk of the operational work to implement the project occurred at lower levels. The success of this project is very much a result of capacity and dedication at provincial, prefecture, county/district, township and village levels in logistics and management, training, supervision, social mobilization, and ultimately service delivery. The PO provided necessary materials and training in Hepatitis B vaccine management and administration and injection safety, and supervision to ensure adherence to guidelines, but relied on each level of the health system to manage, train and supervise lower levels. For the large part, this cascading system worked well, and any problems that arose were addressed adequately.

The PO office developed detailed guidelines for implementation that were widely disseminated in all project provinces. Many informants at lower level CCDC offices and township hospitals mentioned the importance of having clear targets for management, training, supervision, and social mobilization as well as technical level targets for facilities and village doctors. For example, all health bureaus and CCDC offices created project working groups that managed, coordinated, and provided oversight for reaching project targets. Each level of government was very clear on its responsibilities in terms of the number of trainings and supervision visits to lower levels.

While the detailed guidance provided by the PO was critical, as important was the high level of prioritization given to project objectives by GOC leaders. This is evidenced in the level of collaboration with Maternal and Child Health (MCH) staff who would take on responsibility for birth dosing, as well as collaboration from the local education officials to support social mobilization and education. Despite constraints in funding for implementation (as discussed in the co-financing sub-section,) staff at lower levels were motivated by the potential public health impact of this project, and took pride in reaching targets despite funding constraints.

The OAG, comprised of MOH, CCDC, GAVI and other ICC members, provided oversight and a forum for consensus building. The OAG allowed informal discussions, and was a useful forum to coordinate funding and activities in support of Hepatitis B prevention and to engage individuals outside the PO in technical discussions. Because the OAG focused exclusively on this project, there was sufficient time during biannual meetings for in-depth discussions related to implementation issues. The PO also helped make efficient use of OAG meeting time by preparing "mini proposals" for discussion. While the OAG itself had no direct authority, the OAG members (which included MOH officials) were able to turn decisions into action. Several key informants noted that the role of the OAG, with clear responsibility to GAVI and to the GOC for this project made it more effective than typical ICCs. Overall, the OAG allowed for a productive interplay between technical experts and government decision makers.

Together, the PO and OAG provided effective management and oversight, leveraging international experience and the Chinese health system infrastructure. These dedicated project management mechanisms were critical to effective and efficient project implementation.

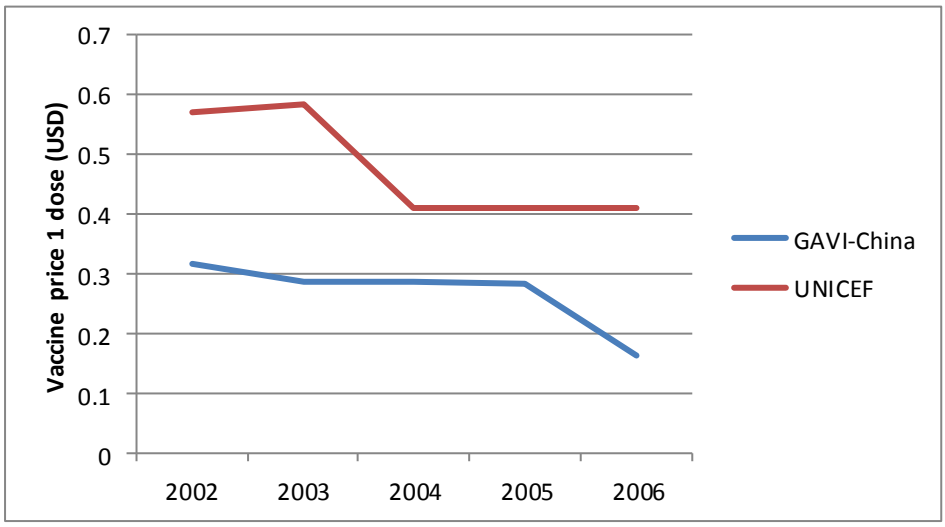
Procurement

The Procurement Coordinating Committee and the PO played a critical role in successful procurement and reliable supplies. Composition of the Committee included a broad range of partners, and there were clear guidelines for selection of suppliers and allocation among the suppliers. Throughout project implementation years, there were no problems found with vaccine supply or quality at any level of the health system. Moreover, with PO oversight, procurement and supplies remained stable during the 2007-2008 transition to provincial procurement with central funding.

Prices for both vaccines and AD syringes under the project were lower than originally anticipated and well below international prices, providing savings that were used for additional activities. As Figure 2 shows, the average price in 2002-2003 for one dose of Hepatitis B vaccine paid by the project was USD 0.32, about half the UNICEF price of USD 0.57. The total doses procured were divided among the two suppliers based on price, using a pre-set formula. This difference narrows until 2006, when one supplier with sufficient capacity substantially underbid its competitor to win the whole

procurement. In 2006, the average price paid per dose was USD 0.16, less than half the UNICEF price that year.

Figure 2: Comparison of Hepatitis B Vaccine Prices 2002-2006



Since 2008, however, the National Development and Reform Commission in China mandated that the price for Hepatitis B vaccine remain at around RMB 7-8 in order to support companies and ensure competition and quality in vaccine production. There was recognition that in 2006 the price paid was likely below cost, and not conducive to healthy vaccine markets.

Local procurement of AD syringes during the project also proceeded smoothly but was managed differently. The PO managed the procurement only for the portion of syringes that were financed with GAVI and/or central GOC funding. The portion of syringes that were to be financed by provincial funds was procured by provincial governments. The central level only procured AD syringes, but provinces had discretion to procure disposable syringes, although they were encouraged to use AD syringes. This distinction may have had impact on injection safety outcomes, as discussed in the next sub-section.

The average price for AD syringes paid by the PO fell from USD 0.06 in 2002 to USD 0.05 in 2007. During the same period, the number of suppliers increased from two to four; this increase is particularly notable as AD syringes were not available from local suppliers before the initiation of the project. These prices are somewhat lower than UNICEF prices.

Co-financing Arrangements

Financing for Hepatitis B vaccine and injection equipment was shared between GAVI, the central GOC, and provincial governments. The expected inputs for provincial governments differed as shown in Table 10.

Table 10: Overview of Co-Financing for Vaccines and Syringes

	Funding for Vaccines			Funding for AD Syringes		
	GAVI	Central GOC	Provincial Govt	GAVI	Central GOC	Provincial Govt
Western Provinces (all counties)	50%	50%	0%	50%	20%	30%
Original Six Central Provinces (poverty counties)	50%	50%	0%	50%	20%	30%
Add'l Four Central Provinces (poverty counties)	50%	0%	50%	50%	0%	50%

Under this arrangement, the western provinces received the highest level of support, recognizing economic differences between provinces. Nonetheless, their expected contributions in terms of financing for syringes still represented a substantial burden. Informants reported that GAVI and central GOC funding was always disbursed in a timely manner (although the evaluation team did not review original financial documentation) but there is documentation of issues with co-financing from provincial governments.

Over the entire project period, nine provinces were identified in various APRs as not having provided co-funding for AD syringes. Most of these reports were in the early years, and the PO with support from the MOH, worked with provincial governments to urge compliance.

The financing and procurement structure, with provincial procurement of syringes that were financed from provincial budgets, may have impacted injection safety outcomes. For western provinces, the financing structure ensured that 70 percent of syringes province-wide were centrally procured and thus were AD syringes. For central provinces, the majority of syringes used would have been procured by the province. For the six original central provinces, the population in poverty counties accounted for 20 percent of the provincial population, so only 14 percent (0.2 * 0.7) of the syringes for immunization would have come from the project. The remaining syringes (for 80 percent of the population in non-project counties and 30 percent of the syringes for the population in project counties) would have been procured at provincial level and may or may not have been AD syringes. For the four additional provinces, the proportion syringes provided by central level would have only represented 3 percent of the syringes for immunization in the province. A recent study found use of AD syringes to be highest in western provinces, where the majority of syringes for immunization has been AD syringes since the inception of this project. Data from key informants and field visits also confirm that use of AD syringes and injection safety practices became connected with Hepatitis B vaccine, rather than general principles for immunization.

In addition to vaccines and injection equipment, other inputs were also needed in order to achieve the project coverage targets, and these were primarily the burden of provincial, prefecture, county and district governments. Provincial and lower level governments were responsible for all operational

costs for immunization, and this project required additional training, social mobilization, and supervision activities.

All informants met during field visits reported that they undertook all the activities required, however, it appears they may have had to cut corners due to budget constraints. For example, local CDCs and township hospitals reported that they might reduce the length of trainings to one day or combine it with another activity to minimize costs. In one county site visit, informants reported that, due to lack of necessary funding, they were unable to meet provincial guidelines for provider subsidies. Informants reported that supervision was always conducted as planned, but may have been combined with other activities. While these were reasonable and practical responses to the budget realities, it is plausible that shorter trainings or supervision visits might have affected the quality and effectiveness of these activities.

During field visits the evaluation team examined the degree to which provincial and lower level governments were involved in project design, or were made aware of their proposed responsibilities. Provincial officials recall broad discussion of a Hepatitis B vaccine project, but no specifics of the level of funding or other resources required from provincial or lower level governments. Those details were spelled out in the Implementation Plan issued in February 2003. This model for implementation is not unusual, however, and staff at all levels reported that they welcomed the project and set out to implement it according to the guidance provided to the best of their ability.

4.3.3 Management Responses to Project Challenges

The PO and the OAG played an active role in managing and addressing implementation challenges. Annual and later bi-annual progress reports from provinces were a key way for the PO to monitor progress and issues at lower levels. The PO conducted regular supervision for this project, and participated in assessments as part of broader EPI work. These other assessments helped to identify issues at all levels. Provinces visited also reported that they had regular communications with the PO beyond scheduled supervision visits or reports.

During field visits and in APRs, the evaluation team found both financial and technical issues that were raised to the project management. Table 11 presents a selection of issues identified and discussed during OAG meetings.

Table 11: Selected Issues Discussed during OAG Meetings

OAG Meeting	Problem Recognized	Solution Recommended/Action Status
Aug 2003	- Concern over making sure provinces provide co-funding	- Note that MOH/MOF issued document notices requiring co-funding of provinces
July 2004	- Insufficient quantitative data to document children immunized - Prevalence of misunderstanding of false contraindications for Hepatitis B	- Suggestion: use savings to improve surveillance mechanisms
Oct 2005	- Lack of co-funding in two provinces - Shortage of operational funding, particularly at lower levels - User fees are still collected - Inadequate reporting of routine immunization data	- Target counties with poor and moderate performance with support for training, supervision, and IEC - Plan GAVI midterm review

June 2006	- Not all provinces and counties have reached targets	- Savings budget to target counties with poor and moderate performance not disbursed - EPI to discuss issue at next meeting
Sept 2008	*2008 International Project Review* - Some hospitals still not reaching TBD targets in large part because of false contraindications - TBD remains problematic for home deliveries - AD syringes always used for HepB and BCG injections but variably for other immunization injections; not used for reconstitution - Unsafe syringe disposal practices observed	*2008 International Project Review* - Continue to support and train MCH staff in TBD - Develop and issue guidelines on false contraindications - Improve home TBD using demonstration project findings - Monitor TBD and hospital delivery rates down to township hospital and village level; identify high risk areas and provide supportive supervision - Issue clear guidance on use of AD syringes for immunization injections, including vaccine reconstitution - MOH/MOF to support hospital delivery with central funding; advice given to include funds for transport and expenses for a few days stay at hospital
Dec 2009	- Insufficient information systems infrastructure at lower levels; overburdening of information system; central government funding insufficient - Some provinces lacking operational funds for catch up campaign work	- New savings budget still includes activities planned in 2008 for catch up, as they were not disbursed - Budget for savings includes operational support for catch up campaign and information system investment
Apr 2010	- Prefectures lagging behind in TBD coverage - Social mobilization activities insufficiently decentralized; not implemented under comprehensive strategy; were not fully documented	- No disbursement of 2009 budget because of H1N1 and challenging integration given increasing central commitment to health - Compile communication package, complete with pilot testing and translation; disseminate on CD

The PO and OAG seemed more able to respond to technical issues than financial management issues. Technical issues could be addressed with new guidance, intensified training, additional studies, etc. The PO and OAG collaborated closely with efforts aimed at increasing hospital delivery and maximizing TBD in hospitals, critical to the high TBD achievements. Some of the technical issues identified seem to be a result of misunderstanding of new guidelines, and were addressed with better communication and supervision. On the other hand, financial issues around provincial co-funding or lower level operational funds were harder to address. The PO and OAG had no authority to mandate funding allocations, and project savings provided a potential source of temporary support to underperforming areas. Although the OAG supported such efforts, they were not undertaken for various reasons. Ultimately, these financial constraints are only relieved by other GOC policies.

Making use of project savings proved to be extremely challenging. Although the PO and the OAG seemed able to come to agreement on reasonable re-programming of the savings money, several planned activities did not take place. Although there had been discussions of what to do with the

savings since 2004, the first significant activities took place in 2008, and 70 percent of the expenditures did not take place until 2010, as shown in Table 12.

Table 12: Use of Project Savings (USD)

	2006	2007	2008	2009	2010	Total	Percent of Total
Sero-Survey	556,849	0	0	0	0	556,849	2%
IEC	0	0	198,600	0	1,004,431	1,203,031	5%
Training and Supervision	0	0	1,593,114	0	0	1,593,114	6%
Activities for Catch-up Campaigns	0	0	4,013,726	0	4,830,133	8,843,859	34%
Birth dose pilot projects	0	0	1,439,127	0	3,485,968	4,925,095	19%
Final Evaluation	0	0	0	0	546,529	546,529	2%
End of Project Activities	0	0	0	0	706,056	706,056	3%
Information System	0	0	0	0	7,909,897	7,909,897	30%
Total	556,849	0	7,244,567	0	18,483,013	26,284,430	
Percent of Total	2%	0%	28%	0%	70%		

Source: Cui Fuqiang Doctoral Thesis.

By the 2006-2007 period, when making use of the project savings became a higher priority, the GOC began to make substantial increases in health spending. Some of the planned expenditures were not undertaken because the GOC separately funded them.

For the large part, project management did respond effectively to project challenges and to the changing health environment. The PO used its direct relationship to the MOH to work to address co-funding issues, but was only able to exert limited influence. It provided inputs to new government policies related to hospital delivery and in support of primary health care (PHC) to ensure alignment with Hepatitis B priorities.

4.3.4 Roles of Partners and Other Groups in Planning, Monitoring and Implementation

Many other partners played important roles both directly involved in project management and oversight, and/or in support of localized projects related to Hepatitis B control and injection safety. WHO, UNICEF, and PATH in particular were active participants in the OAG. US CDC played a critical role by funding staff in the position of the project Co-manager throughout the life of the project. Table 13 provides an overview of some of the key partner inputs over the project life.

Table 13: Overview of Partner Inputs

Partner/s	Inputs/Activities
WHO	- Overall support to EPI including preparing FSP (2004/05) - Support of EPI through policy discussions with GOC - Various trainings on Hepatitis B control and EPI more generally - Review communication strategic plan for Hepatitis B in Heilongjiang (2004) - Strategies for improving TBD in Qinghai, Ningxia and Gansu (2006-2009)
UNICEF	- EPI training in Ningxia and Chongqing (2002/3) - Evaluation of introduction of AD syringes into immunization services in Anhui (2004) - Various injection safety pilot programs (2001-2005) - Various projects to improve TBD, including hospital delivery pilots - Ongoing work supporting immunization for migrant children
US CDC	- Funding international Project Co-managers (2002-2010)
Luxembourg	- Training in Qinghai on injection safety (2002/3)
PATH	- Evaluation of Uniject device outside the cold chain to improve TBD in Hunan (2003)
Others – China Fdtn for Hepatitis Control and Prevention, Rotary Intl, Asian Liver Center at Stanford, ZeShan Foundation	- Demonstration projects to provide training and vaccination on Hepatitis B virus in Qinghai (2006-8) - Support catch-up campaign work

As important as each of their individual activities, more important was the high level of collaboration through the OAG in support of the project objectives and Hepatitis B control more broadly. Both the GOC and international partners expressed satisfaction with the functioning of the OAG and noted the level of constructive discussion. Many credit the good management of the PO to ensure effective OAG meetings.

The role of WHO and its contributions to health policy discussions were extremely important, even though their work was not directly related to this project. As discussed in Section 3.6, WHO engagement in options for improving public health post-SARS influenced financing policies that had important impact on the sustainability of Hepatitis B and all childhood immunization in China. WHO was very visible in China during and immediately post-SARS, and its influence was noted by both international and Chinese informants.

Lastly, while US CDC is seldom recognized as a partner in this project, it played a critical role by funding staff in the position of International Co-manager. These staff played key roles in design and implementation of the project. Many informants credit their technical expertise, their influence within the MOH, as well as their working relationships within CCDC as critical factors to project success.

4.3.5 Summary of Findings on Implementation and Efficiency

Evaluation Question	Findings	Robustness Ranking*
To what extent was the project implementation plan relevant and	The PO played a critical role in effective implementation. Co-management by a CCDC staff and an international advisor	(A) Findings are substantiated through documentary evidence, key informant data,

appropriate?	ensured access both to external technical experience and knowledge, as well as to knowledge, authority and access from within Chinese health system to ensure timely progress. Vaccine prices were lower than originally anticipated and well below international prices, allowing for efficient use of GAVI funds and providing savings that were used for additional activities. Disbursement of co-funding from the central government seemed to be timely, but delayed disbursement or lack of funding at province level and below in some areas may have affected project implementation, including use of AD syringes for other EPI vaccines, and effective training.	and historical prices.
To what extent were the activities implemented as planned and in a timely manner?	Despite some delay due to SARS, implementation occurred as planned, with credit due to the structure of the Chinese health system, which ensured smooth implementation of cascaded training, supervision, and social mobilization. The project had high level commitment that was critical to ensuring support of actors outside of disease control, including MCH, education, etc.	(B) Findings based on well-substantiated key informant data, but there is no implementation plan with timelines against which to objectively measure timeliness.
To what extent was management appropriately adaptive in response to implementation challenges and evolving circumstances?	The PO and OAG responded effectively to problems identified. However, one problem it was not able to resolve was insufficient co-funding at provincial level and below for AD syringes and to conduct project activities such as training and supervision.	(A) Findings are substantiated through documentary evidence and key informant data.
To what extent were partners and relevant groups involved in the program planning, monitoring and implementation?	Key partners including WHO, UNICEF, and PATH worked closelytogether in support of project implementation through the PO. US CDC also was critical in funding staff in the position of project Co-manager.	(A) Findings are substantiated through documentary evidence and key informant data.

* See Section 2.4 for definition of robustness rankings.

4.4 Effectiveness

Evaluation Questions:
6) To what extent were the planned results achieved by the end of GAVI's support?
7) What factors, including country factors and characteristics of GAVI's support to China, contributed to the overall effectiveness of the project?

The evaluation team reviewed coverage data, as well as data from earlier evaluation studies for evidence of results, while examining the factors contributing to effectiveness by analyzing data from key informants and other information on the Chinese health system. An overview of data sources and data quality precedes discussion of the evaluation questions.

4.4.1 Sources of Coverage Data and Data Quality

The administrative data compiled by CCDC is the most complete source of coverage data over the project period. Coverage rates for HepB3 are available by province and county from 2000, and for HepB TBD from 2004. Regular reporting on TBD was only required beginning in 2004, so TBD coverage rates prior to 2004 were only available through periodic surveys, and were only reliable at national level.

Two coverage surveys and one sero-survey were conducted during the project period. Although survey data is generally considered more reliable, two surveys are only representative at the national level, while one can be disaggregated to the province level. This level of detail is insufficient to evaluate the effectiveness of the project. Table 14 provides a summary of the available sources of data.

Table 14: Overview of Sources of Coverage Data

Data Source	HepB3	TBD	Comments and Limitations
CCDC Administrative data	• Complete from 2000 • Available by province and county	• Complete from 2004 • Available by province and county	• Evaluation team found discrepancies between data from CCDC and provincial CCDC for one county
1992 serosurvey	• No data	• No data	• Unclear whether sampling was representative at province level
2004 coverage survey	• Available by province • No county level data	• Available by province • No county level data	•
2006 serosurvey	• National level coverage data from 1992-2005 • No province or county level data	• National level coverage data from 1992-2005 • No province or county level data	• Unclear whether sampling was representative by province (total n=40129, sample size per birth year 1992-2001 approximately 2500 per year)
2010 coverage survey	• Available by region for 2002-2009	• Available by region for 2002-2009	•

Although administrative data tends to overestimate coverage, the evaluation team chose to use this as the primary source, because it is the most complete over time, and the only source of data by county. A comparison of reported and survey coverage by region provides an indication of the magnitude of the discrepancies, as well as the improvement over time. Table 15 compares reported HepB3 coverage rates with survey-based coverage rates at regional level.

Table 15: Comparison of Reported and Survey Hepatitis B3 Coverage Rates

	2002	2003	2004	2005	2006	2007	2008	2009
Reported Coverage								
Eastern	98.54	99.11	98.86	98.92	98.64	98.92	99.00	99.19
Central	96.08	97.47	98.91	99.24	99.26	99.27	99.34	99.40
Western	91.06	93.24	96.79	97.16	97.12	97.69	98.32	98.66
Overall	95.61	96.68	98.23	98.89	98.47	98.77	98.95	99.13
2010 Survey Results								
Eastern	88.80	85.51	87.59	92.19	95.80	91.72	88.69	92.09
Central	65.51	81.27	85.85	90.02	87.96	92.03	93.21	96.27
Western	46.89	67.39	76.45	80.96	84.81	86.19	88.75	90.21
Overall	71.73	84.01	86.75	90.18	91.36	91.39	91.35	93.19

Source: Cui Doctoral Thesis.

The gap between reported and surveyed coverage narrows over time, primarily because survey results find increasing coverage rates. In 2002, national HepB3 coverage was reported to be 95.61 percent, while surveyed coverage was 71.73 percent, a difference of approximately 24 percentage points. This discrepancy narrows over time, and in 2009, the difference between reported and surveyed coverage is only six percentage points. This magnitude of improvement is greater for western region, with a discrepancy of 44 percentage points in 2002 declining to eight percentage points in 2009.

Administrative data allows analysis at regional and provincial level not available with survey data. Comparison of discrepancies between these survey and administrative data show that over-estimation with reported data has declined over time.

4.4.2 Achievement of Planned Results

The planned results based on the objectives in the revised MOU were:

- HepB3 coverage will reach 90 percent at the county level (original MOU targets 85%)
- >75 percent of newborns at the county level will receive the first dose of hepatitis B within 24 hours of birth
- All immunization injections will be with AD syringes.

Although APRs reported on progress at national level, we also review progress in project areas only to assess project effectiveness. The evaluation team reviewed the coverage results in two ways:

- Across project supported areas
- At county level for project and non-project areas nation-wide

The coverage rates reported are based on administrative data from the CCDC. The CCDC had also used two alternative coverage indicators during the project period – HepB3/DTP3 and HepB TBD/DTP1. These alternative indicators were created as a check against potentially unreliable population targets. As a rule, we did not rely on this indicator because it largely tracked the more

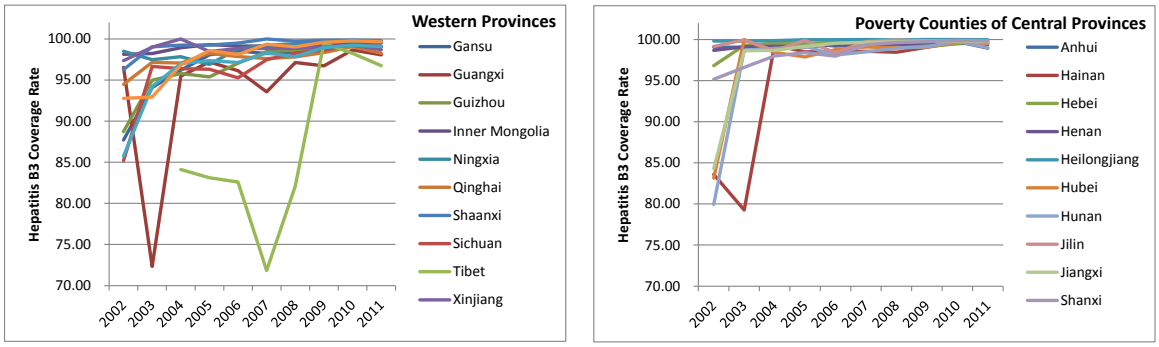
basic HepB3 and HepB TBD coverage rates. These alternative indicators are presented in one section, however, as other historical data was only available in that format.

Achievements related to injection safety and use of AD syringes are discussed separately, as data on this indicator are less robust, and there are more complex outstanding issues in this area.

Coverage in Project Supported Areas

All project areas achieved the target of 90 percent HepB3 coverage by the end of 2009, the end of the extended project period. Figure 3 shows the HepB3 coverage rate from 2002 to present for western provinces (left panel) and poverty counties of central provinces (right panel.)

Figure 3: Hepatitis B3 Coverage Rates in Project Supported Areas

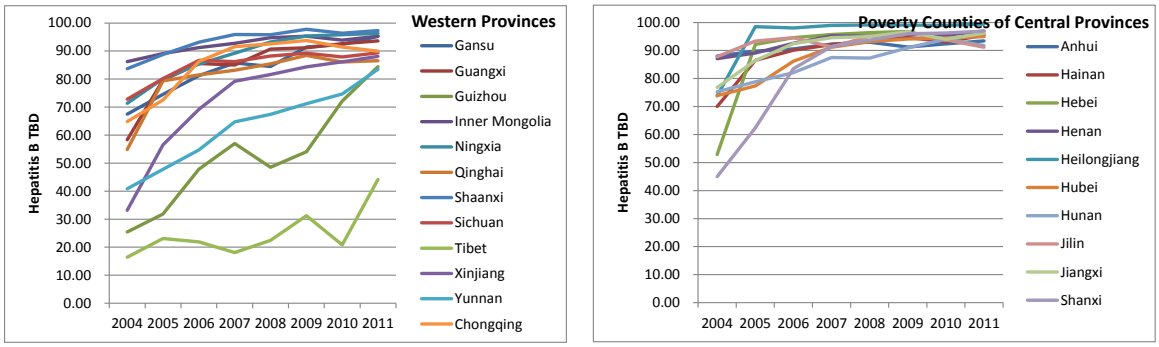


Source: Administrative data.

There was much variability in coverage rates at the start of the project, with HepB3 coverage rates in some areas of 80 percent. By 2009, all provinces achieved HepB3 coverage rates over 95 percent, and this rate has been maintained in the subsequent two years. This goal had been attained by 2004 (with the exception of Tibet, which caught up later,) well before the end of the project period.

TBD rates were not reported as part of routine coverage data until 2004. In that year, the coverage rate across all western provinces was 57 percent, and as low as 16 percent in one province, as shown in Figure 4.

Figure 4: Hepatitis B TBD Coverage Rates in Project Supported Areas

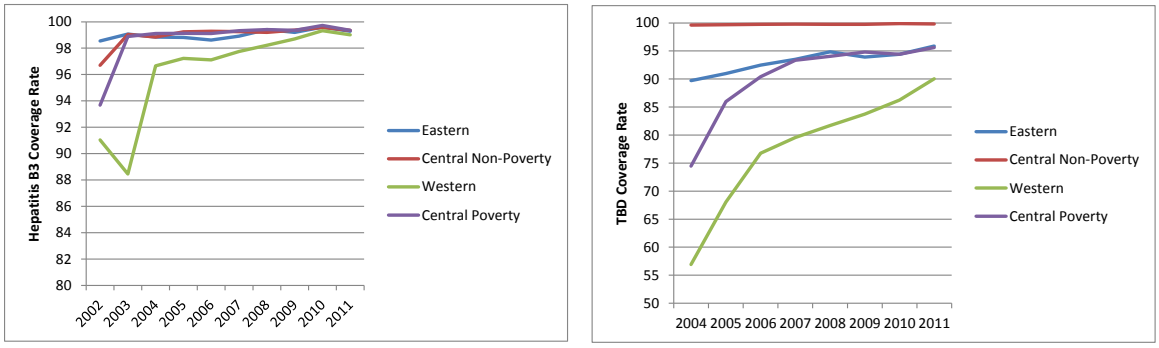


Source: Administrative data.

This TBD target was more challenging, with three provinces (Guizhou, Yunnan, and Tibet) unable to achieve the goal of 75 percent TBD by 2009. Nonetheless the improvements in TBD coverage were even greater than in HepB3 coverage in some respects, with 84 percent coverage across all western provinces in 2009, a 27 percentage point increase from 2004. Further progress has been made and by 2011 coverage in western provinces was 90 percent, with only one province unable to reach this goal at the provincial level.

Although not a stated objective in the MOU, targeting support to western provinces and poverty counties in central provinces aimed to close the coverage gap between western and other lower income areas and wealthier areas. To examine progress in this area, the evaluation team compared coverage rates in western provinces and poverty counties of central provinces (project-supported areas) to coverage rates in eastern provinces and non-poverty counties (non-supported areas) to see whether differences seen at project inception have been narrowed. As shown in Figure 5, a difference in HepB3 coverage rate (left panel) of approximately eight percentage points in 2002 has been completely eliminated, with almost no difference in coverage rates between supported and non-supported areas in 2009-2011.

Figure 5: Change in Hepatitis B Coverage Rates for Project and Non-project Areas



Source: Administrative data.

For the HepB TBD coverage rate, the difference between the western provinces and the highest performing group, the non-poverty counties of central provinces, was 43 percentage points in 2004. By 2009, the gap had been narrowed to a difference of 16 percentage points. Although in 2011, the TBD coverage rate in western provinces is still 10 percentage points below the highest performing group, narrowing of the gap by 33 percentage points in seven years represents a major achievement.

Coverage at County Level

The evaluation team did not analyze trend data at the county level, instead relying on data reported in APRs, and an earlier evaluation. There are approximately 3,000 counties in China, and compilation of these data over 10 years would have been a significant burden on the CCDC. Further, the evaluation team did request county level coverage data for the three provinces visited and found data issues in one province, with data at central level not matching data at province level for one county.

Based on data reported in the APRs, we see that by 2006, 78 percent of all counties had reached 85 percent HepB3/DTP3, while 58 percent of all counties had attained 75 percent HepB TBD/DTP1

coverage, as shown in Table 16. This indicator is not provided in later APRs. Data for 2009 and 2011 show significant improvements in county level achievement of these targets, with only a handful of counties in 2011 yet to reach these targets. Although the data is not entirely comparable over time, the final result is that nearly all of China's 3,000 counties have achieved the project objectives.

Table 16: Percent of Counties Reaching Coverage Targets

	2005	2006	2009*	2011*
Percent of counties with HepB3/DTP3 coverage rate over 85%	70%	78%	98%	99%
Percent of counties with HepB TBD/DTP1 coverage rate over 75%	49%	58%	80%	98%

Source: APRs for 2005 and 2006, Cui Fuqiang Doctoral Thesis, CCDC.

* 2009 and 2011 data is for GAVI-supported counties only, and uses the reported population as the denominator, not DTP3 or DTP1.

Injection Safety

Injection safety was a significant component of the project, with more than half the project funding allocated for injection safety equipment in initial budgets. The primary strategy for strengthening injection safety was to transition to AD syringes for all EPI vaccines, including Hepatitis B. The stated goal in the MOU was that all immunization injections would use AD syringes. Despite this goal, there was little data collected during the project period to monitor actual practices. Instead, APRs always reported 100% achievement, despite making note of serious constraints:

- *…national action plan on safe injections has still not been finalized…training for introduction of AD syringes was inadequate… and another round nationwide is needed* (May 2004)
- *It is needed to explore the day-to-day management tool to assess the implementation of introducing AD syringes rather than the reporting approach* (June 2005)
- *Accurate evaluation of implementation of introducing AD syringes will require better supervision assessment tools and special studies rather than just using the reporting approach* (June 2006)

In both 2005 and 2006, there was recognition that monitoring of the use of AD syringes was inadequate, but little action was taken to introduce new management or supervision tools or to undertake special studies as recommended.

There is no routine monitoring information with which to assess effectiveness in this area. Baseline information is not very robust and relies on small scale project assessments and an EPI review conducted in 1999. The 1999 EPI review described a dire situation, with shortages of injection and sterilization equipment. At that time both sterilizable and disposable injection equipment was in use, and problems were found with safety in the use of both types of equipment. A 2002 report of a World Bank loan found that none of the project areas used AD syringes. The best evidence of current use of AD syringes comes from a study conducted in 2010 by CCDC.

Significant progress had been made, particularly in project areas. In contrast to the 2002 situation, the 2010 study found that 78 percent of facilities in western provinces, 73 percent of facilities in central provinces, and 25 percent of facilities in eastern provinces used AD syringes for immunization.

Further, the study found that use of sterilizable equipment had been eliminated, all injections were given with disposable equipment, and there was nearly no re-use of disposable equipment. It should be noted that this study was done two years after the central government began providing full funding for AD syringes for immunization. Nonetheless, based on these data, project areas are performing better than non-project areas. Although the project did not achieve its original objective of exclusive use of AD syringes for all immunizations, these data show that significant progress has been made.

4.4.3 Factors Driving Project Effectiveness

This project resulted in huge achievements in Hepatitis B vaccine coverage and significant achievements in injection safety. The basic premise of the project – to increase use of Hepatitis B vaccine and AD syringes by removing financial barriers – clearly proved effective. This section focuses on how specific elements of GAVI support, implementation, and country context contributed to effectiveness. The unique project design (project office, local procurement, 50% co-funding) discussed in the previous section was tailored for the China context, and proved appropriate. Of these design features, the PO was critical in ensuring achievement of the project objectives. Four factors, including the inputs of the PO, were particularly important for attaining the project outcomes:

- Management inputs from the PO
- Structure of the health system, and infrastructure and capacity at lower levels
- High level political commitment
- Government health policies, particularly in support of hospital delivery

Two strategies of the PO were particularly useful in ensuring the effectiveness of this project – providing very detailed implementation guidance to provinces that created a sense of discipline around project activities, and guidance in pursuing health education activities at all levels of the health system. The project implementation plan issued to provinces provided clear goals, instructions on training and social mobilization, lower level responsibilities, injection safety requirements, and supervision requirements for all levels. This roadmap was the definitive guidance for project implementation.

Many informants mentioned that social mobilization and public education played a critical role in the project outcomes. In fact, informants in field sites were split on the relative importance of free vaccines vs. improved education in producing the project outcomes. It was unclear whether public education was so important because there had not been education specific to Hepatitis B, or whether general education on the importance of immunization had not previously been conducted. The implementation guidance specified that health departments should mobilize all sectors of society, and organize multiple forms of health activities through multiple channels to raise public awareness of the importance of disease prevention. In the initial introduction reports for the evaluation team provided by field site staff, all mentioned the importance of various public education activities that they had conducted. Many informants also stressed the particular importance of public education with respect to increasing TBD coverage rates.

Despite strong support and guidance from the PO, this management model that relied on implementation of national level guidelines flowing down four administrative levels, could not have been successful in most GAVI countries. Central level Chinese officials, when questioned about consultations with lower levels prior to project implementation, generally responded that it was not necessary. Yet based on most reports, and the evaluation team's field visit findings, for the large part,

activities were conducted as required. Not only were lower level staff ready to carry out work as instructed despite limited finances, but all of the supporting infrastructure was in place. Cold chain facilities and logistics infrastructure at provincial level were adequate, as were appropriate organizational relationships at all levels of the health system. The strong authority of the central government, the health system infrastructure, as well as the level of capacity and resourcefulness of health staff at all levels, were critical to project success.

There was tremendous political support for this project at central and lower levels of government. Health staff mentioned that everyone wanted to meet the targets because their local leaders stressed their importance in public education efforts. This leadership was not only instrumental in motivating EPI staff, but also ensuring collaboration with other key contributors to the effort.

With the inception of this project, the GOC also issued new guidelines requiring that whoever assists with delivery gives the first dose of Hepatitis B vaccine. Implementing these guidelines required enormous effort to train maternal health workers in providing vaccines safely and to realign responsibilities of primary health workers. This effort required tremendous political support from upper as well as lower levels of government and is widely considered to be a key factor in increasing TBD.

The second critical strategy for increasing TBD was increasing the rate of hospital deliveries. Originally initiated through UNICEF's Safe Motherhood project in western provinces, the central government in 2007 began reimbursement of hospital delivery through the New Rural Cooperative Medical Scheme on a national scale. As discussed in the previous section, TBD coverage rates have continued to increase in recent years, likely as a result of this policy. Nonetheless, informants report that TBD remains a challenge in some counties, particularly among minority groups or migrant populations, despite concerted efforts.

4.4.4 Summary of Findings on Effectiveness

Evaluation Question	Findings	Robustness Ranking*
To what extent were the planned results achieved by the end of GAVI's support?	The project achieved and has since surpassed its stated objectives of increasing HepB3 coverage to over 85% and TBD coverage to over 75%, at both the national and provincial level, except for one province. As of 2011, there are only a handful of counties that have not met these targets. Although the project MOU specified use of AD syringes for all immunizations, government guidance did not mandate use of AD syringes. Current use of AD syringes for immunization is 78%, 73% and 25% in western, central, and eastern provinces.	(A) Finding is supported by a variety of qualitative and quantitative data.
What factors, including country factors and characteristics of GAVI's support to China,	Four critical factors to success include: • Management from the PO, especially in issuing detailed guidelines and emphasizing the	(B) Finding is based on qualitative analysis of widely corroborated key informant data.

Evaluation Question	Findings	Robustness Ranking*
contributed to the overall effectiveness of the project?	importance of social mobilization. • Structure of the health system, and infrastructure and capacity at lower levels • High level political commitment • Government health policies, particularly those in support of hospital delivery	

* See Section 2.4 for definition of robustness rankings.

4.5 Impact and Value-Added

Evaluation Questions:
8) What is the evidence of project impact?
9) What was the extent of the value-added from the GAVI Alliance's support to China, over and above what would have been accomplished without the Alliance?
10) What unintended consequences occurred as a result of GAVI support, both negative and positive?

These questions aim to examine the extent to which this project contributed to increases in Hepatitis B immunization. The evaluation team examines project impact using existing studies of death and disease averted, estimates of global disease related to Hepatitis B infection, and data from key informants regarding likely developments in the absence of GAVI. These analyses do not precisely attribute impact to GAVI, but provide an estimate of the impact from this project, and the value-added of GAVI.

4.5.1 Evidence of Project Impact

Statistical analysis of differences between project and non-project areas was planned, however, further understanding of the context of project inception rendered such a comparison non-meaningful. Although the project supported vaccines and syringes for only a portion of the country, Hepatitis B vaccine was provided for free nationwide (like other childhood vaccines, small provider service fees still applied) through a national policy coinciding with the inception of this project. The lack of a reasonable counterfactual for quantitative analysis made it difficult to quantify project impact. Instead the evaluation team used key informant data to describe potential counterfactuals in the absence of GAVI and this project. Thus, this section relies on other studies for estimates of quantitative project impact, and qualitatively evaluates GAVI's contributions against what might have happened otherwise.

There were two studies conducted to estimate impact of Hepatitis B vaccination in China since 1992, and to estimate impact from this project. The first study, published in 2009 based on findings from a sero-survey conducted in 2006, found that HBsAg prevalence was 1.0 percent for children <5 years,

compared with prevalence of 9.7 percent in 1992.[4] The prevalence of HBsAg among immunized persons was 2.1 percent, compared with 9.4 percent among un-immunized persons, providing strong evidence of the benefits of immunization.

As shown in Table 17, this study also found prevalence to be lower among children <5 years (coinciding with the project inception and national policy for free Hepatitis B vaccine) compared with children aged 5-14 (coinciding with the initial availability of the vaccine at full cost.) Additionally, the proportional difference between immunized and unimmunized populations in all groups is highest among children <5 years (coinciding with project emphasis on TBD.) GAVI and this project contributed to this decrease by securing commitment to integrate Hepatitis B vaccine into the EPI for children nationwide (thus eliminating the vaccine charge although small service charges still applied,) emphasizing the importance of TBD, and supporting social mobilization and public education to increase immunization coverage in project areas.

Table 17: HBsAg Prevalance by Age Group (2006 sero-survey)

Age Group	HBsAg Prevalence (%)
1-4	1.0
5-9	1.4
10-14	3.2

Using a widely accepted model to project future disease,[5] this same study found that for children aged 1-14 years, the reduction in prevalence found between sero-surveys conducted in 1992 and 2006 would translate into a reduction of 16-20 million chronic infections and 2.8-3.5 million future Hepatitis B related deaths nationally across China. These estimates of health impact span 14 years and the whole of China – there are no serological data from the inception of this project or specifically for project areas that could serve as a good baseline to estimate the impact specifically from this project.

Another study that is forthcoming estimates the impact of this project specifically by modeling vaccine coverage rates for the project period based on pre-project trends (1992-2002,) and comparing that with actual coverage rates during the project. This analysis finds that actual coverage rates substantially exceeded predicted coverage rates in project areas. There are two limitations to this approach: 1) the predicted coverage is unable to take into account what the GOC might have done in the absence of GAVI, including possibly providing free Hepatitis B vaccine; and, 2) it cannot capture the impact from changes in government health financing and other health programs, including policies like central government funding for vaccines or reimbursement for hospital delivery that occur post-2002. These new policies would have impacted actual coverage rates during the project period.

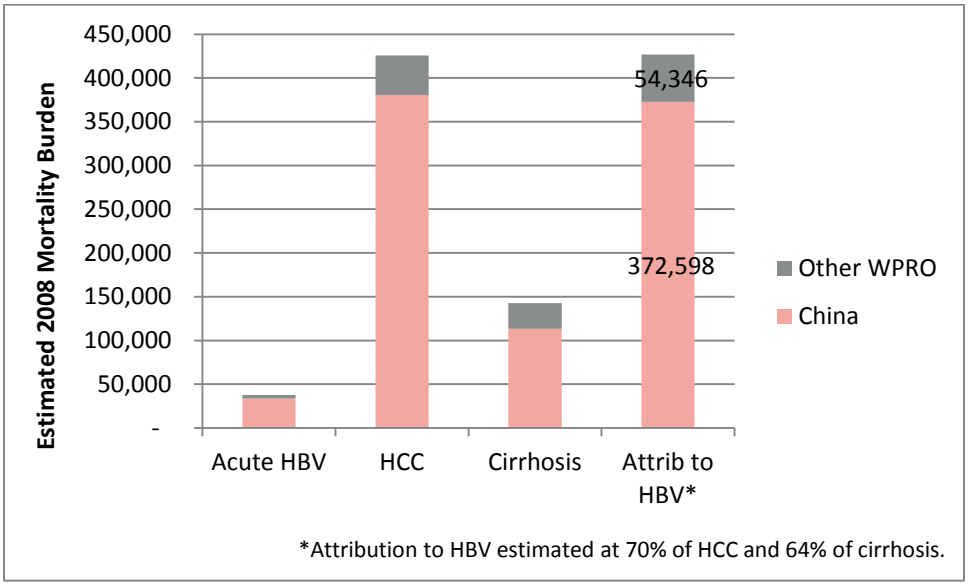
[4] Liang X, Bi S, Yang W, et al. Epidemiological serosurvey of hepatitis B in China--declining HBV prevalence due to hepatitis B vaccination. *Vaccine.* 2009 Nov 5;27(47):6550-7. Epub 2009 Sep 1.

[5] Goldstein ST, Zhou F, Hadler SC, et al. A mathematical model to estimate global hepatitis B disease burden and vaccination impact. *Int J Epidemiol.* 2005 Dec;34(6):1329-39. Epub 2005 Oct 25.

This study also applied the three-dose and TBD coverage rates to total births in project areas of 39.7 million from 2003-2009 to estimate that a total 3.82 million carriers and 685,000 future deaths were prevented in project areas during the project period. Although this estimate is limited to project areas and the project period, it is not adjusted for immunization coverage that would have occurred in the absence of the project, and thus overestimates total impact.

Another gauge of the project's contribution is to examine the portion of Hepatitis B related disease within the Western Pacific region found in China. Figure 6 shows 2008 mortality data from three Hepatitis B related diseases – fulminant hepatitis (acute Hepatitis B Virus (HBV) infection,) cirrhosis, and hepatocellular carcinoma (HCC). Also shown is an estimate of total mortality from these three diseases that is attributable to Hepatitis B infection. China accounts for 87 percent of all Hepatitis B related mortality in the region, with 372,598 deaths annually.[6] Prevention of Hepatitis B infection in China will have substantial impact on Hepatitis B related diseases in the region.

Figure 6: Hepatitis B Related Mortality in China and Western Pacific Region, 2008



Source: WHO.

The global burden of disease project (GBD) combines estimates of the burden of disease on both morbidity and mortality using the disability-adjusted life-years (DALYs) metric.[7] The initial GBD estimates were based on data from 1990, and were partially repeated and enhanced in 2000, 2004 and 2008. The newest data from the 2010 project, to be released in December 2012, will estimate liver cirrhosis and HCC burden due to HBV as well as acute fulminant hepatitis, and thus give a more accurate estimate of reduction in burden than was previously available. Further analysis as additional data become available is necessary to validate and refine estimates of the impact on disease from immunization.

[6] Based on attribution to HBV assumptions of 70% of HCC and 64% of cirrhosis, from Goldstein etc al, 2005.

[7] Murray CJL and Lopez AD. Mortality by cause for eight regions of the world: Global Burden of Disease Study. *Lancet* 1997; 349: 1269 – 1276.

Based on discussions with key informants, the GOC mostly likely would have fully integrated Hepatitis B vaccine into the EPI program even without GAVI support – but the question of when cannot be definitively answered. A reasonable outer boundary of this timing estimate would be 2008, when central government takes over funding for all childhood vaccines. Since the GOC was already considering full integration of Hepatitis B vaccine with potentially some central government funding, likely there would have been progress before 2008. Provincial governments may also have made additional contributions before 2008, particularly in central region. In one of the provinces visited, provincial health budget was used to provide subsidies for provider service fees in the early years of the project. A reasonable counterfactual is that the GOC would have integrated Hepatitis B vaccine into the EPI at some point between 2003 and 2008. Thus, it is safe to say that GAVI through this project accelerated the GOC's commitment to provide free Hepatitis B vaccine for infants by at least one and up to five years.

GAVI contributed to improved injection safety by raising visibility of the issue, and supporting injection safety equipment and training in the project areas. The EPI Multi-year Plan for 2001-2005 identified ensuring injection safety as one of four goals, with the specific objective that "100% of immunization injection are given with AD syringes" in urban areas by 2003, and in rural areas by 2005. Despite this goal, there did not appear to be specific policies or strategies to ensure progress outside the project areas.

We are unable to measure the scale of impact precisely, but current data on use of AD syringes provide evidence that project-supported areas are outperforming non-project areas. Based on a 2010 study, use of AD syringes is highest in western provinces (78 percent) supported through the project and lowest in eastern provinces (25 percent) that received no support, with use in central provinces (73 percent) that received partial support falling in the middle. Given that central government began providing funding to provinces for syringes in 2008, removing any financial barriers preventing AD syringe use by the time of this study, the higher use in western provinces of 53 percentage points can be reasonably considered a result of this project.

4.5.2 Value Added of GAVI Support

At the time of project design, the GOC placed a high priority on Hepatitis B control. Nonetheless, no action had been taken to promote access to Hepatitis B vaccine for all infants. Although central government funding for Hepatitis B vaccine had been proposed before Congress in 1999-2000, there was no firm commitment. Several key informants credit the GAVI project with securing commitment from the MOF to co-fund the project, and from the MOH to mandate government funding for vaccines nationally.

The value of GAVI support derived not from the amount of funding provided – the contribution of USD 38 million was relatively small in relation to GOC or MOH resources, even in 2001/2002. Instead, GAVI's added value was that it catalyzed central government commitment (at a time when it was not yet ready to act), and coalesced provincial and lower level government inputs to support free access to Hepatitis B vaccine.

At the end of 2001, the MOH and MOF jointly issued a notice to provincial, autonomous region, and municipal governments informing them that Hepatitis B vaccine should be integrated into EPI, and instructing these governments to fund and procure Hepatitis B vaccine for all children. GAVI support not only ensured vaccines in the project areas, but ensured access to vaccines nationally. Admittedly,

HepB 3 coverage rates were quite high in non-project areas even before 2002 despite the fees associated with the vaccine. Nonetheless, this official integration of Hepatitis B vaccine into EPI signaled increased responsibility from all level governments.

Also a result of the project was a new emphasis on the importance of the TBD. While the official guidance on dosing of Hepatitis B vaccine had included the first dose within 24 hours of birth, knowledge and adherence was limited. Reporting of TBD was not even required until 2004. The project elevated the importance of achieving TBD targets, and introduced a variety of effective strategies to support this goal.

Further, this project provided support for, and encouraged, social mobilization and public education related to Hepatitis B vaccination. Even if the government provided free vaccines, it is not certain that widespread public education activities would have been carried out without GAVI support. Many informants at lower levels reported that these efforts were at least as important as free vaccines in increasing coverage rates.

It would be a stretch to conclude that this project was the primary factor driving current GOC policies around free childhood immunization. Most informants agree that all of the changes in central government policies to improve primary health services were an outgrowth of strong economic growth and reaction to SARS, factors unrelated to GAVI. In fact, most agree that the current situation of central government support for immunization would likely have come even without GAVI support. However, GAVI at a minimum accelerated the access to free Hepatitis B vaccine by several years, and focused attention on TBD and public education, which had not been a high priority. It also demonstrated what could be achieved with high government commitment, and improved guidance and management, and paved the way for further funding commitments.

4.5.3 Positive and Negative Unintended Consequences

The evaluation team assessed the issue of unintended consequences in three ways – potentially negative effects on lower level CCDCs from loss of revenues from vaccines, effects on the immunization program overall, and effects on overall research and interest in Hepatitis B and Hepatitis B vaccination.

Prior to the inception of this project, Hepatitis B vaccine was distributed from province to prefecture to county levels and below at full cost, with each level adding an additional charge to cover cost of distribution. With the inception of this project, fees were no longer charged, and so revenue from the distribution of Hepatitis B vaccine was eliminated at all levels. At the same time that this revenue source was interrupted, more activities were required at all levels to conduct additional training, supervision, and social mobilization. During discussions with key informants in the Inception Phase, there were reports that this situation was demotivating for CCDC staff and affected CCDC functions at all levels.

During provincial visits, all sites visited in all three provinces were asked about any negative impact from lost revenue. No informant reported this to be a major problem. All reported that the fees from Hepatitis B sales were only a small portion of CCDC revenues. The few that agreed that free vaccine distribution did affect revenues reported that the impact was small. Most said they were able to make up for the revenue shortage through increasing fees in other areas. There was not sufficient time for more thorough investigation of which types of fees were increased and what impact that might have had. Whether previous reports overestimated the potential impact, or whether informants no longer

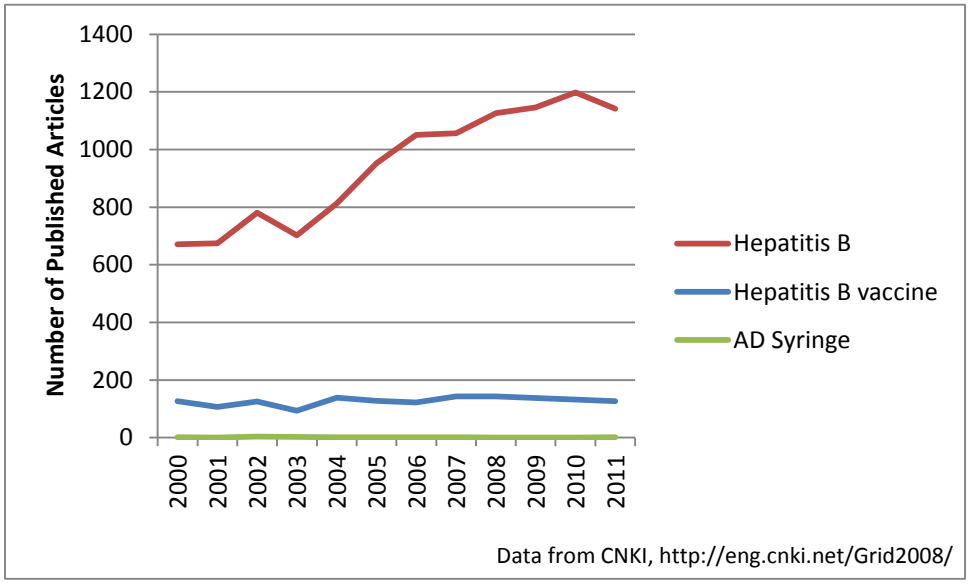
recall the initial severity of the impact is unclear, but the evaluation team did not find significant negative impact from lost revenues on Hepatitis B distribution.

The evaluation team also explored the impact of this project on the immunization program overall, primarily probing about potential positive impact from improved management practices. Many informants both at central and lower levels reported that this project helped to improve management of the immunization program. This project instilled structured planning for supervision and training, and greater emphasis on social mobilization and public education. More structured supervision and project review helped to resolve problems and improve performance.

Several informants at central level also reported improvements in data reporting, monitoring, and analysis. Review of reported and survey coverage rates shows that the discrepancy between surveyed and reported coverage decreased substantially during the project period, and particularly in western provinces. Table 15 in Section 3.4.1 shows a decrease in the surveyed and reported coverage rate for HepB 3 from 44 percentage points to eight percentage points. Though the project did not conduct activities targeting data quality, there appears to have been improvements over the project period, which may have resulted from improved management and supervision more generally.

Lastly, the evaluation team examined whether there was any effect on research in Hepatitis B vaccination over the project period. We conducted a search in CNKI (http://eng.cnki.net/Grid2008/) which is the highest impact Chinese research database, for three words: Hepatitis B (*yi gan*,) Hepatitis B vaccine (*yi gan yi miao*,) and AD syringe (*zi hui shi zhu she qi*) in the title, key words, or content. As shown in Figure 7, the results are inconclusive, with significantly higher number of publication related to Hepatitis B, but little increase in Hepatitis B vaccine or AD syringe. Some informants also believe that the technical collaboration with international experts that served as project co-managers increased research quality.

Figure 7: Published Research related to Hepatitis B and AD Syringe



4.5.4 Summary of Findings on Impact and Value-Added

Evaluation Question	Findings	Robustness Ranking*
What is the evidence of project impact?	A forthcoming study finds that 3.82 million chronic infections and 685,000 future Hepatitis B related deaths were prevented in project areas during the project period, although this includes immunization that would have occurred in the absence of the project. A sero-survey conducted in 2006 shows significant decline in HBsAg prevalence in children <5 to 1.0 percent, compared with 9.7 percent in 1992. GAVI and this project contributed to this decrease by securing commitment to free Hepatitis B vaccine for children nationwide, emphasizing the importance of TBD, and supporting social mobilization and public education to increase immunization coverage in project areas. Use of AD syringes is 53 percentage points higher in project provinces than non-project provinces.	(B) There is qualitative and quantitative evidence of impact, but not all results can be exclusively attributed to GAVI.
What was the extent of the value-added from the GAVI Alliance's support to China, over and above what would have been accomplished without the Alliance?	GAVI catalyzed central government commitment and coalesced provincial and lower level government inputs to support free access to Hepatitis B vaccine. While the GOC may have been able to achieve the current results on its own, GAVI support at a minimum sped up the process, reducing disease for several cohorts of newborns.	(B) Evidence is corroborated across many key informants.
What unintended consequences occurred as a result of GAVI support, both negative and positive?	This project led to structured planning for supervision and training, greater emphasis on social mobilization and public education, and improvements in data reporting, monitoring, and analysis.	(B) Evidence is corroborated across many key informants.

* See Section 2.4 for definition of robustness rankings.

4.6 Sustainability and Factors Contributing to Sustainability

Evaluation Questions:

11) To what extent are the achievements of the project sustainable from a financial and programmatic point of view?
12) What factors have contributed to the sustainability of the results achieved?

Central GOC commitment to fund all childhood vaccines and syringes, including payments to health workers delivering the vaccines, effectively resolved sustainability issues related to Hepatitis B and other immunization. The evaluation team examined the extent to which the project contributed to this decision, whether policies are fully implemented, and whether outstanding issues remain.

4.6.1 Financial and Programmatic Sustainability

All the evidence at hand lead us to conclude that the achievements during the project period will be sustained, and improvements in Hepatitis B immunization, as well as other childhood immunizations will continue. Both financing for immunization and programmatic management of immunization have become stronger since the beginning of the project.

Over the last ten years, fundamental GOC policies regarding how childhood immunization should be financed have changed dramatically. At the time of project inception, users paid a substantial share of the cost of immunization, and nearly all government funding was from provincial and sub-provincial governments. A study of immunization financing conducted in 2004 found that only 27 percent of the cost of immunization was provided by government funds, and only 0.7 percent from central government funds. Since then, the central government has provided an increasingly larger share of the cost, from providing funding for vaccines and syringes to funding subsidies to providers to increasing the number of vaccines covered. Table 18 summarizes the key changes in policies over the project period.

Table 18: Evolution of Hepatitis B Vaccination and EPI Financing in China

Year	Vaccines in EPI	Financing for Vaccines	User Fees
From 1992	BCG, DTP, Polio, Measles, Hepatitis B (self-payment)	Provincial and municipal governments pay for all vaccines, except for Hepatitis B, which must be purchased by users/parents.	Users pay administration fee to provider of RMB 1-3 and up, plus cost of syringe for 6 EPI vaccines. Users pay full cost of Hepatitis B vaccine.
2002 (GAVI Inception)	BCG, DTP, Polio, Measles, Hepatitis B	Provincial and municipal governments pay for all vaccines. GAVI and GOC pay for Hepatitis B vaccines in GAVI project areas.	Administration fee to providers limited to RMB 1-3 in western and central provinces. No limit on user fees in eastern provinces.
2005	No change	No change	Providers may no longer collect user fees for immunization. Central government provides subsidies of RMB 1-2 in central and western provinces.
2008	Other vaccines added (beginning in 2007)	Central government takes over funding for all EPI vaccines and syringes, instructing provinces to allocate funding previously used for vaccines to operational costs of EPI.	Central government also allocates funding to providers for vaccination.
Current	BCG, DTP, Polio, Measles, Mumps, Rubella, Hepatitis B,	No change.	National guidance issued for peripheral levels to provide subsidies to providers of RMB 5

	Hepatitis A, Japanese Encephalitis, Meningococcal Meningitis A and C		per dose, and to allocate RMB 1 per capita for EPI operational costs, funded from central government funds for PHC.

With GAVI support, the GOC was able to mandate full inclusion of Hepatitis B within EPI, through a mix of GAVI, central government, and provincial government funding. From GAVI's side, China was the first country to provide substantial co-funding from the onset, increasing the probability of project sustainability. Actual progress made in terms of GOC responsibility for financial sustainability exceeds either side's expectations at inception – with the central government funding not only Hepatitis B vaccine, but also other traditional EPI vaccines, newer vaccines, as well as subsidies to providers, and some portion of operational costs.

Programmatically, management and implementation improvements that were introduced under the project have largely been maintained and integrated into the immunization program. The project instilled more attention to planning and management, particularly in the areas of supervision, training, and education and health education activities. Informants at all levels reported that the project created more planning and structure around these activities by providing clear guidelines. Informants reported conducting supervision periodically prior to the project, but not necessarily developing and adhering to a plan as they did during the project, and currently. Education and public promotion activities were also scaled up under the project and are currently maintained.

The evaluation team investigated other topics related to sustainability during their field visits – user fees, vaccine stock-outs, and funding for operational costs. All informants reported that user fees are no longer being charged, with some differences as to when they were eliminated (between 2003 to 2006) due to differences in local subsidies that were provided and possibly delayed implementation of the national policy. There were no reports of stock-outs of Hepatitis B or any other childhood vaccines in any of the sites visited, although a few reported brief shortages of other adult vaccines. Transition of procurement responsibility from central to provincial governments occurred without any disruption to supplies. All sites visited reported that vaccines and syringes were delivered regularly.

Funding for operational costs, particularly at prefecture, county, and township levels had been documented as a challenge facing many areas during the project period. This issue was also raised throughout our site visits, although always with the caveat that the required activities (training, supervision, etc.) were always conducted as planned using either CCDC self-generated revenues or by leveraging off another activity. Over time, the challenge became less acute as local CCDCs received additional funding for different programs from which to draw upon. More recently, additional funding for PHC directed toward township hospitals and lower level facilities further alleviates this problem. Nonetheless, funding for immunization activities at county and prefecture levels continues to be limited. While these CCDCs are well-accustomed to the funding constraints and there is unlikely to be any serious impact, access to discretionary funding particularly in lower performing areas may generate innovations that lead to additional coverage improvements.

The evaluation team had proposed analysis of government budgets for immunization at national and subnational levels, but learned during the inception phase that at subnational levels, the budgets within CCDCs are co-mingled with other activities and cannot be easily disaggregated. Although national level budgets were reported to be available, the team ultimately was not able to get data of

any detail. Table 19 presents the information that was made available through key informant interviews.

Table 19: Estimated Central Government Expenditures on Immunization 2004-2012

Year(s)	Expenditures per Year (RMB)		Total USD (millions)
	Vaccines	Other	
2004-2007	120-200 million		15-25
2008	2.0 billion	0	290
2009	2.0 billion	2.9 billion*	721
2010-2012	2.0 billion	0	294-323**

* These expenditures were for cold chain improvements.

** Variance due to exchange rate fluctuations.

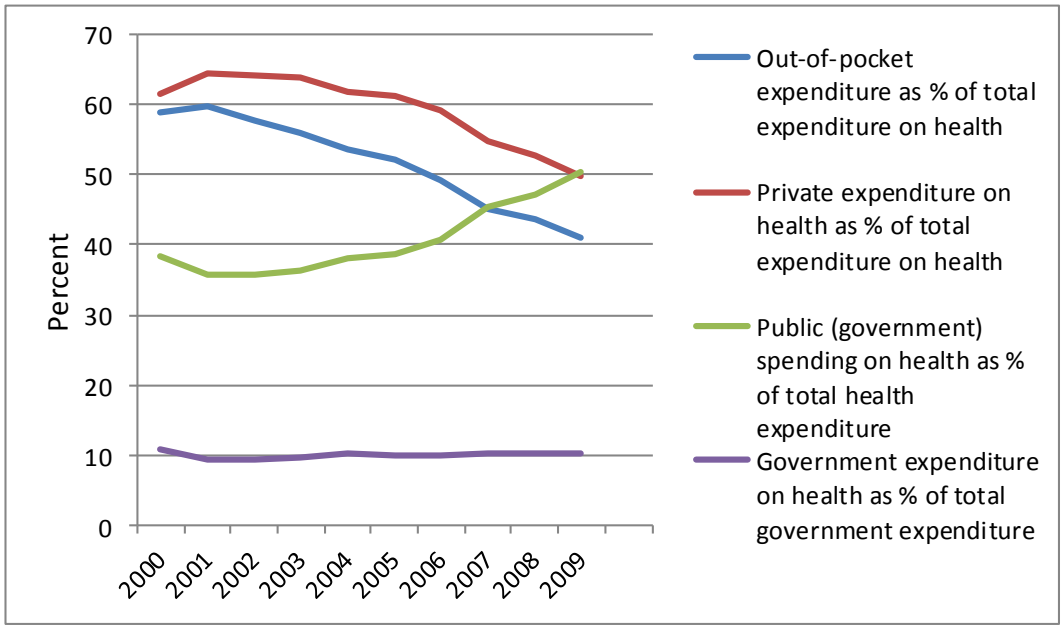
Based on this data, the central government expenditures on immunization have increased over tenfold. There are no indications that this level of expenditure allocation would not continue.

4.6.2 Factors Contributing to Sustainability

The inception of the project coincided with the SARS epidemic (January to June 2003,) which initially delayed implementation, but ultimately proved to be of significant benefit to public health and childhood immunization in China. By all accounts, SARS was instrumental in putting health on the political and development agenda in China, spurring significant increases in public funding for health. Three factors were critical in helping to take advantage of the opportunity presented by SARS: 1) double digit economic growth during this period; 2) engagement of GAVI partners in discussions related to government responsibility for public health; and, 3) project experience of central government contributions for vaccines.

As a result of the rapid pace of economic growth, government expenditures on health increased approximately five-fold from 2000 to 2009, while remaining approximately 10 percent of government expenditures, as shown in Figure 8. Also shown is the increasing share of health expenditures contributed by government, from less than 40 percent in 2000 to approximately 50 percent in 2009. Directly correlated is the decrease in private expenditures for health. Additionally, Out-of-Pocket Expenditures for health decline from approximately 60 percent of Total Health Expenditures (THE) to 40 percent of THE, a sharp decline in such a short period. The sustainability of this project, and immunization more generally, is largely derived from the increased government funding.

Figure 8: Health Expenditure Trends in China, 2000-2009



Source: WHO

GAVI partners played an important part in advocating for appropriate health policies post-SARS. The joint international review of the EPI program in 2004 provided recommendations on financing for immunizations, and explicitly challenged the user fees for immunization. These recommendations were incorporated into the 2005 policy that prohibited user fees. WHO prepared an analysis of recommendations post-SARS to ensure better disease surveillance and public health, with specific recommendations for immunization and immunization financing.

While the experience with this project may not have been the critical factor leading to central government financing of all childhood vaccines, it certainly planted a seed and provided proof of results. It demonstrated the potential for improvement given high level support, improved guidance and management, and elimination of financial barriers. This combination of increased health funding, policy support, and proven results all lead to increased commitment to immunization and a sustainable and strong immunization program.

4.6.3 Summary of Findings on Sustainability and Factors Contributing to Sustainability

Evaluation Question	Findings	Robustness Ranking*
To what extent are the achievements of the project sustainable from a financial and programmatic point of view?	Prospects for future sustainability are excellent since the largest cost components for Hepatitis B and other childhood immunizations (vaccines, syringes, provider fees) are now provided for by the central government. Effective supervision, social mobilization, and training activities are well-integrated into routine immunization work.	(A) Data are strong across all sources. Funding for immunization has increased over tenfold. Government funding for health continues to grow in the last five years, with increasing allocations toward primary health. Key informant data, as well as policy

	Recent central government decisions to direct funding to primary health care facilities help to alleviate constraints in funding operational costs, but funding at county and prefecture levels remains limited.	decisions, point to continued constraints at county and prefecture levels.
What factors have contributed to the sustainability of the results achieved?	Project sustainability can be attributed to increased government commitment to public health, largely driven by high economic growth, reaction to SARS, influence of GAVI partners in the public health dialogue, as well as the positive outcomes of the project.	(B) The true drivers of increased government commitment are not known, but conclusions are based on perceptions collaborated by many key informants.

* See Section 2.4 for definition of robustness rankings.

4.7 Lessons Learned

Evaluation Questions:

13) How could the various components of the project, including design, implementation and sustainability have been improved?
14) What lessons can be drawn in relation to equitable introduction of new vaccines by China in the future, in particular for Haemophilus influenza type B, pneumococcal and rotavirus vaccines?
15) What lessons can be drawn from the design and management of the project to help inform GAVI's future support to other countries, including those graduating from GAVI support?

The evaluation team used findings along each of the evaluation criteria to draw implications and lessons learned that are applicable to future GAVI project design and vaccine introduction in China.

4.7.1 Potential Project Design or Implementation Improvements

For the most part, project design and implementation were very effective. Nonetheless, there are three potential components of project design that may have allowed for improved outcomes:

- Greater recognition of differences between project areas and allowing for flexibility in implementation
- Advance communication of co-funding requirements, both at provincial level for AD syringes and at lower levels for operational costs, with mechanisms to assist areas with severe constraints
- Better monitoring of injection safety, both to document use of AD syringes and potential risks of disposable syringes

As a rule, the detailed implementation guidelines and the specific requirements of all actors worked in favor of strong implementation – it is what is expected at lower levels – and the model has proven effective overall. However, there are differences between western provinces, and between rural counties in western provinces. The MOH and CCDC tend to favor adoption of uniform strategies, partly because China is so big that it is difficult to support implementation of a variety of strategies or to keep track of many exceptions to the rules. Nonetheless, there may be areas that might have

performed better if allowed a greater degree of innovation and flexibility. Staff in one field site suggested providing grant funds for local CCDCs to pilot innovative approaches. A portion of the project savings was used to fund pilot birth dose projects, but overall the project management did not encourage innovation or flexibility.

Detailed co-funding requirements were not spelled out at each level until the training/launch meeting for the project. In most cases, the local CCDCs could not plan for the additional funding needed. The funding challenges in the early years may have affected the quality of implementation (training, supervision). While any quality issues were addressed in subsequent trainings, more oversight and guidance in financial planning may have avoided these problems. Just as there are geographical differences between project areas that may necessitate different technical strategies, economic differences between project areas might call for different funding strategies. While GOC policies ultimately alleviated financing challenges, earlier action to assist areas with severe financing constraints (through project or other sources) may have sped up improvements in coverage.

Lastly, project management could have made more concerted efforts to ensure use of AD syringes. The first step would have been to develop a reliable monitoring system. Although national level procurements funded by the project specified AD syringes, there were no reports at national level of the type of syringes procured for EPI by provinces, or routine supervision of practices at field sites. Had the GOC been presented with data that it was not meeting the stated objective in the MOU, it might have coordinated more effective responses. In reality, there was little information to track progress in use of AD syringes, or actual practices with disposable syringes that demonstrate their increased risk.

4.7.2 Lessons for Introduction of New Vaccines in China

The experience with this project demonstrates the importance of country commitment. Once GOC commitment was solidified, all remaining challenges seemed minor. Once the project MOU was signed, full implementation nationwide occurred within approximately one year. Once the MOH was committed to free childhood immunization, it took responsibility for full national funding within three years. Once committed to the priority role of vaccines in controlling disease, vaccines for mumps, rubella, Hepatitis A, Japanese Encephalitis, Meningococcal Meningitis A and C, and others were added to EPI.

By contrast, there was no senior level commitment or influential champions of AD syringes for injection safety. The GOC was committed to injection safety – through use of disposable syringes – and sterilizable syringes have since been eliminated. Further, data on injection safety show that re-use of disposable syringes had virtually been eliminated. However, no new efforts were made to monitor the use of AD syringes, or enact policies to ensure exclusive use. Even today, safe waste disposal is seen as a higher concern for injection safety that exclusive use of AD syringes.

Both these experiences demonstrate the critical importance of high level commitment. The central GOC has the authority and resources to make enormous changes in health and health policy (and has) if it is convinced of the benefits. Applying this lesson to new vaccine introduction in China means ensuring evidence of disease burden and vaccine effectiveness, international advocacy, and identifying strong champions in order to achieve large scale impact. New vaccine introduction should also consider the this project's implementation experiences, including considering use of dedicated staff, focus on training and supervision, and ensuring adequate operational funding at lower levels.

Several informants reported that the GOC would not have undertaken this project had it been required to use imported WHO pre-qualified vaccines. The GOC has a history of supporting domestic research, production, and market development for high priority pharmaceuticals. There are currently four suppliers for Hepatitis B and four suppliers for AD syringes in China, ensuring reliable supply and competitive pricing. Ensuring viable vaccine markets through effective procurement strategies is an important element of new vaccine introduction, and the GOC recognizes its role in ensuring stable markets. In addition to strong champions, efforts to develop and ensure a viable domestic market are critical to decisions to add new vaccines to the EPI.

4.7.3 Lessons for Design and Management of GAVI Support to Other Countries

The dedicated PO played a critical role in ensuring smooth implementation. GAVI tended to impose few requirements on countries, particularly in those early years, but recognized that implementation in such a large country would benefit from project-specific staff and other resources. The structure of the PO was ideal, incorporating all the benefits of a stand-alone project (dedicated staff, project-specific budgets) as well as the benefits of working within the government structure (MOH support, CCDC resources at all administrative levels.) While "project-izing" GAVI support is not necessarily the solution, many countries would benefit from hands-on management assistance and expert technical input. The evaluation of ISS funding found that technical capacity and the level of partners' technical inputs affected performance of GAVI funds. Nonetheless, the way these inputs are structured must be carefully adapted to the country context. GAVI could play a more active role by supporting technical input or coordinating partner inputs to maximize the effectiveness of all its investments.

GAVI's experience in China is also an example of how a more tailored approach to support might be more effective in leveraging in-country strengths and building ownership. Had the standard approach for new vaccine support been applied to China, GAVI would not have been able to reach as many children as it did by leveraging 50 percent co-financing and procuring lower priced vaccines. While most GAVI countries would not have such advantages, assessing each country's capacity individually, rather than applying a formulaic approach to support may be more effective. The experience in China also highlights the benefit of a functioning health system that (despite the financing constraints found) could support such an implementation process.

GAVI played a small role in influencing the improvements in health financing that create the current environment where the central government funds 11 childhood vaccines and many associated costs, so it is difficult to identify how best to design a project that generates such results. More important influences were overall economic growth, SARS, and advocacy of other GAVI partners. Requiring substantial co-financing from the onset provides a way to both ensure country ownership and to ease future transition to national funding. However, requirements for co-financing at the level of 50 percent could only be met in the highest income GAVI-supported countries.

Lastly, vaccine cost is an important cost driver for immunization programs, particularly given the inclusion of newer more expensive vaccines. For GAVI-supported countries that are graduating, and for GAVI generally, access to low-priced, high-quality vaccines, regardless of source, can have substantial impact on affordability and sustainability.

4.7.4 Summary of Lessons Learned

Evaluation Question	Findings	Robustness Ranking*
How could the various components of the project, including design, implementation and sustainability have been improved?	Allowing for some degree of flexibility in implementation, advance communication of co-funding requirements and assistance to most constrained areas, and better monitoring of injection safety may have improved project outcomes.	(A) Suggestions on injection safety are derived from documentary data, and confirmed by many key informants. (C) Other suggestions are based on data from informants, but with little proof of potential effectiveness.
What lessons can be drawn in relation to equitable introduction of new vaccines by China in the future, in particular for Haemophilus influenza type B, pneumococcal and rotavirus vaccines?	High level commitment is a critical element for success. Providing robust evidence and identifying strong champions is needed to build high level commitment.	(B) Based on assessment of qualitative data from many key informants.
What lessons can be drawn from the design and management of the project to help inform GAVI's future support to other countries, including those graduating from GAVI support?	Many countries would benefit from hands-on management and expert technical input, but the way this is structured must be adapted to the country context. Assessing each country's capacity individually, rather than applying a formulaic approach, may be more effective. Substantial co-financing ensures country ownership and eases the transition to national financing, but is only feasible in higher-income GAVI countries.	(B) Based on assessment of qualitative data from many key informants.

* See Section 2.4 for definition of robustness rankings.

5. Conclusions

The GAVI-GOC Hepatitis B project has achieved and surpassed its original objectives of increasing HepB3 to over 85 percent and HepB TBD to over 75 percent at the national level. These targets were also attained at the province level, with the exception of one province's TBD coverage rate. Based on 2011 data, of the approximately 3,000 counties in China, all but 11 have reached the HepB3 target, and all but 26 have reached the TBD target. The breadth of improvements at the county level not only reflects the great public health achievement of this project, but is a true testament to improvements in the equity of immunization.

Although the project supported only lower income and lower performance areas, it was a catalyst for the GOC to commit to government financing for Hepatitis B vaccine nation-wide, provider service fees notwithstanding. While HepB3 coverage rates were already high in wealthier areas, the inception of this project focused attention to TBD that was previously lacking even in areas with high three dose coverage.

The dedicated PO was critical to implementation over such a large geography so quickly, providing support and oversight to provinces, as well as detailed implementation guidance. The teaming of an international advisor (funded by US CDC) with a CCDC manager, ensured access to best practices globally, as well as appropriate integration within the Chinese health system. The PO strengthened supervision, training, and monitoring, as well as introduced new strategies to improve health education and increase TBD.

The Chinese health system, led by the MOH and CCDC, and the dedicated workers at provincial, prefecture, county/district, township, and village levels also deserve much credit for the success of this project. The health infrastructure already in place (including cold chain, logistics, and management) was critical to smooth implementation of this project. Staff at all levels were ready to carry out work as instructed despite the challenges faced, and all of the supporting infrastructure was in place. The strong authority of the central government, the health infrastructure, as well as the level of capacity and resourcefulness of health staff throughout the system, were critical to project implementation.

For all the achievements of the project, the future would not look so optimistic if not for new GOC policies to increase government financing for health and to improve public health services. Overall government expenditures for health have increased fivefold in the last decade, and central government expenditures for immunization have increased over tenfold. The central government now funds 11 vaccines for childhood immunization, including all syringes and provider service fees. Compared with the situation at the beginning of this project, when only six vaccines were funded by government, and parents paid providers for administering the injection and for syringes (if disposable syringes were used), huge progress has been made. Complementing the immunization policies are policies for reimbursement of hospital delivery costs, impacting not only immunization rates but also maternal and child health more broadly. The SARS outbreak was a key driver of increased attention to public health, and led to significant increases in government health funding – active engagement of GAVI partners, especially WHO, in discussions related to government responsibility for public health post-SARS helped to maximize the opportunity presented by SARS.

There was tremendous political support for this project at central and lower levels of government. This leadership was not only instrumental in motivating EPI staff, but also ensuring collaboration from other key contributors to the effort.

Although use of AD syringes is significantly higher in project provinces than non-project provinces (53 percentage points,) the project did not meet its original objective of exclusive use of AD syringes. While the GOC was very committed to Hepatitis B vaccination as a key strategy for controlling Hepatitis B infection, its strategy for safe injection did not rely exclusively on AD syringes. Although the project MOU specified use of AD syringes for safe injection, the general government guidance focused on disposable syringes, which may or may not have been auto-disable. There has been significant progress from the beginning of the project, when AD syringes were seldom seen and sterilizable syringes were widely used – all injections use disposable syringes and there is nearly no evidence of re-use.

Unlike for Hepatitis B vaccine, there did not appear to be true champions of AD syringes, not within the MOH, CCDC, or even among international partners. Many informants did not seem to appreciate the additional benefits of AD syringes over other disposable syringes. Further research to assess potential risks of non-AD type disposable syringes in practice, review of these findings to inform high level policy, and development of a reliable system to monitor all aspects of injection safety is needed for further progress.

As a result of higher immunization rates, there have been significant declines in Hepatitis B infection in China. Based on a sero-survey conducted in 2006, HBsAg prevalence was 1.0 percent for children <5 years, compared with prevalence of 9.7 percent in 1992, with significantly lower prevalence in immunized persons compared with un-immunized persons, providing strong evidence of the benefits of immunization. A forthcoming study finds that 3.82 million chronic infections and 685,000 future Hepatitis B related deaths were prevented in project areas during the project period, although this includes immunization that would have occurred in the absence of the project. In the area of injection safety, use of AD syringes in project areas is 78 percent, compared with 25 percent in non-project areas. GAVI and this project contributed to significant reductions in Hepatitis B infection by securing integration of Hepatitis B vaccine into the EPI program nationwide, emphasizing the importance of TBD, raising visibility of injection safety, and supporting social mobilization and public education to increase immunization in project areas.

That the apportioned share of success to be credited to GAVI, CCDC, MOH policies, or other factors cannot be quantified should not diminish the reality of the positive results. GAVI was the spark that solidified GOC commitment to integrate Hepatitis B vaccine into the EPI program nation-wide, and this project set the trend for central GOC financing for vaccines. GAVI should continue to monitor disease burden data to develop better estimates of reduction in disease from Hepatitis B vaccine, even if it cannot be exclusively credited to GAVI.

The success of this project in China is a validation of the originally-conceived model for GAVI support – time-bound support for country-led programs that generate country commitment, while expanding vaccine markets to bring down prices to levels affordable within national budgets. Although it took a unique country to provide the proof of concept, GAVI should take advantage of other opportunities to provide individualized support for high priority, country-led initiatives.

6. Recommendations

Based on the findings from this evaluation, the team offers the following recommendations related to future design of GAVI country support:

1. GAVI should review project objectives carefully to ensure they are aligned with the areas of project support. An external review process to ensure data is collected to monitor progress accurately may be useful.

2. GAVI should consider taking a more tailored approach to design of country support. Closer collaboration with in-country implementers during the design phase would help to develop projects that take advantage of in-country strengths to maximize outcomes.

3. GAVI should play a more active role in supporting and coordinating technical assistance and management to support in-country implementation. Although not appropriate in all situations, GAVI should consider project offices with dedicated staff (local or international as appropriate) to provide more attention and prompt problem resolution under special circumstances or for very large projects.

4. Support to countries with stronger health systems better leverages GAVI's investments. GAVI should re-consider broader health system strengthening support to ensure effective implementation of immunization and other health programs.

5. GAVI should consider providing support to higher income countries. While higher income countries may seem to have less need, many have not integrated the newer vaccines into their NIPs. For GAVI, the prospects of time-limited support and transition to long term sustainability may be better in higher income countries,

6. GAVI partners can play an important role in advocating for appropriate country level health financing policies. GAVI could be more active in coordinating clear advocacy messages related to national budget financing for vaccines and immunization.

7. For countries with the budget means, substantial co-funding from project inception can ease the transition to self-sustainability.

8. For countries with domestic production capabilities and sufficient market size, GAVI may have an important role to play in facilitating technology transfer or other mechanisms that allow local production of new vaccines. Creation of a viable local market helps to generate interest in new vaccines, and promotes long term sustainability.

9. Since vaccine price is an important cost driver for GAVI programs, efforts to encourage global sourcing from Chinese and other low-priced, high-quality producers can have positive impact on efficient use of GAVI funding.

Annex A: Excerpt of GAVI RFP

4.0 BACKGROUND AND CONTEXT FOR THIS EVALUATION

4.1 GAVI Support to China

The China–GAVI Hepatitis B (HepB) Vaccination Project was established in June 2002 as a collaboration between the GAVI Alliance and China Ministry of Health to expand Hepatitis B vaccination and to purchase autodisable (AD) syringes for infants in 12 Western Provinces and selected poor counties in 10 central provinces. This 5-year $76 million project was equally co-funded by the Government of China and the GAVI Alliance, with the project funds used mainly for purchase of HepB vaccine and AD syringes for all infants born in project counties. The Government of China's funding included nationally allocated funds, as well as provincial co-funding to support purchase of AD syringes and operational costs. The GAVI Vaccine Fund also provided funds to establish a GAVI Project Office at the China Centre for Disease Control. The project Memorandum of Understanding (MOU), dated June 1, 2002, describes conditions for this project in detail.

Project funding was first made available in late 2002 by both the GAVI Fund and the Government of China. Project activities began in late 2002 but full implementation in all provinces was delayed until summer 2003 due to the SARS outbreak. The duration of the project was five years, as specified in the original MOU, with project funds initially expected to be used by the end of 2007.

During the initial four years of the project, substantial funds provided by the GAVI Fund remained unspent for several reasons. An amendment to the MOU for China-GAVI HepB Vaccination Project was established in June 2007 defining the basic conditions related to extending the duration of the China-GAVI HepB Vaccination Project beyond 2007, and utilisation of unspent funds provided by the GAVI Alliance for the China-GAVI Hepatitis B Vaccination Project. Two sequential no cost extensions of support were provided to China until December 2010.

Several modalities of supporting China were unusual compared to GAVI's typical ways of supporting countries. Most notably, China was one of the three countries in phase 1 of GAVI support (2000-2005) where a financial ceiling of $40 million was proposed, the other countries being India and Indonesia. In addition, a detailed MOU was signed with China to establish the basic conditions under which the GAVI Alliance would provide support to the Chinese Government. This MOU led to the targeting of specific poor provinces for the HepB project as well as a significant change to national legislation that resulted in the removal of user-fees for HepB vaccination.

Other specific characteristics of the support provided to China included:

- China's co-financing of 50% of the project from inception
- The GAVI project office established in China
- WHO's provision of dedicated technical assistance by appointing an international co-manager to the HepB project based in China
- GAVI's provision of funding for China to purchase locally produced injection safety equipment
- China's independent procurement of the locally produced HepB vaccine using GAVI funds

The project ended in December 2010 and the MOU stipulated a commitment to conduct an in-depth review of the project following China's graduation from GAVI support.

The following documents will be available to firms submitting letters of intent to participate:

- MOU/ amendment to the MOU
- Annual progress reports
- Published literature on GAVI's support to China, including a study that examined changes in seroprevalence of HepB surface antigen before and after implementation of the HepB project

5.0 SCOPE OF THE EVALUATION

The scope of this evaluation will cover the full range of support from GAVI to China, from the earliest discussions between GAVI and China to the end of GAVI's support to China. The evaluation will assess the project's relevance, implementation/efficiency, effectiveness, impact/value added and sustainability and highlight relevant lessons learned that could be used by GAVI to inform its support to other countries in the future.

6.0 QUESTIONS TO BE COVERED BY THE EVALUATION

The main evaluation questions to be addressed are:

- **Relevance**
  - To what extent were the design and objectives of GAVI's support to China relevant to:
    - China's needs and priorities?
    - GAVI's strategic priorities?
- **Implementation/efficiency**
  - To what extent was the project implementation plan relevant and appropriate?
  - To what extent were the activities implemented as planned and in a timely manner?

  - To what extent was management appropriately adaptive in response to implementation challenges and evolving circumstances?
  - To what extent were partners and relevant groups (Ministries, United Nations technical agencies, professional associations, civil society, etc) involved in the programme planning, monitoring and implementation?
- **Effectiveness**
  - To what extent were the planned results achieved by the end of GAVI's support?
  - What factors, including country factors and characteristics of GAVI's support to China, contributed to the overall effectiveness of the project?
- **Impact and value-added**
  - What is the evidence of project impact?
  - What was the extent of the value-added from the GAVI Alliance's support to China, over and above what would have been accomplished without the Alliance?
  - What unintended consequences occurred as a result of GAVI support, both negative and positive?
- **Sustainability**
  - To what extent are the achievements of the project sustainable from a financial and programmatic point of view?
  - What factors have contributed to the sustainability of the results achieved?
- **Lessons learned**
  - How could the various components of the project, including design, implementation and sustainability, have been improved?
  - What lessons can be drawn in relation to equitable introduction of new vaccines by China in the future, particularly for Haemophilus Influenza type B, Pneumococcal and Rotavirus vaccines?
  - What lessons can be drawn from the design and management of the project to help inform GAVI's future support to other countries, including those that are graduating from GAVI support?

In order to encourage innovation in the approaches and methods used, only high level evaluation questions are provided here. Bidders may propose changes to these questions, with justification. Proposed changes and their justification will be assessed through the adjudication process as part of the overall assessment of the strength of proposals.

7.0 METHODOLOGY

Proposed methodologies should be described in detail in bidders' proposals. The appropriateness, feasibility and innovativeness of proposed methodologies will be assessed as part of the overall strength of proposals during the adjudication process.

It is anticipated that the evaluation will include, but not be limited to, the following approaches:

- A desk review
- Interviews with relevant stakeholders
- A visit to China to collect information at national and, as needed, provincial and district levels. This visit should not exceed 15 working days.

It is essential that bidders capitalise on relevant studies, particularly regarding the effectiveness and impact of HepB vaccination, that have already been conducted in China. Evaluators should provide a thorough assessment of the rigour of these studies and use their results wherever applicable. Any evidence gaps pertaining to the effectiveness and the impact of the HepB project should be identified and associated recommendations for future studies made. It is not foreseen that any new epidemiological surveys will be required as part of this study.

The evaluation should be conducted in accordance with the principles described in GAVI's Evaluation Policy.[8]

8.0 DELIVERABLES & TIMELINES

8.1 Expected deliverables

- Inception report
  - ✓ Satisfactory inception report required to issue a second contract to complete the evaluation
- Monthly reports
  - ✓ During implementation, the evaluation team will provide monthly progress reports
- Draft report
  - ✓ Describing framework, methods, findings, and evaluators' assessment of strength of evidence
- Final report
  - ✓ Describing framework, methods, findings, and evaluators' assessment of strength of evidence
- Executive summary (standalone document)
  - ✓ A standalone document that describes the methods, questions and main findings of the evaluation; length to be less than 10% of the length of the final report
- Recommendations
  - ✓ A standalone document that contains the evaluators' recommendations
- Presentations to Chinese stakeholders and GAVI Secretariat
  - ✓ Including slides summarising the methods and findings

[8] http://www.gavialliance.org/about/governance/corporate-policies/evaluation/

8.2. Timelines

Deliverable	Date
Submission of inception report	23 July
Submission of draft report	Week 15 October
Presentation/consultation on draft report (China TBC)	TBD
Submission of final report	Week 12 November
Submission of recommendations document	Week 12 November

Annex B: Discussion Guide for Inception Phase Interviews

Project Design

- Who were the critical decision makers during the project design phase, and what were their goals for the project?
- Why was it decided to open a GAVI project office?
- Were the agreements over pricing for different provinces agreed with provincial governments?
- Did partners' goals change over the course of eight years? How did that affect the project?

Implementation

- What were specific responsibilities of the GAVI China office? Were they involved in provincial level implementation or oversight? Was the GAVI China office involved in procurement or logistics?
- Can you describe the process for commodities procurement (who was responsible, were suppliers WHO prequalified, size of procurements, length of contract, etc)? Is there data on pricing by contract or by year?
- Did the central provinces provide co-funding as originally designed?
- What were the most challenging implementation issues?
- What were critical factors that supported and hindered project success?
- What were the critical decisions made during implementation period that affected outcomes?

Project Impact

- Is central government providing support to the project provinces and counties since the end of the project?
- Were there specific agreements between China CDC and provincial governments related to phase out of central support?
- How have the western provinces and poor counties performed since the end of this project? What is the trend in HepB coverage rates? Who does procurement for these provinces? Has use of AD syringes continued?
- Is sub-province immunization data (data by prefecture and county) available at the NIP office? Would it be available at the provincial offices?
- Has this project affected government and public attitudes toward vaccination and vaccine subsidies? Might the central government consider this approach for increasing coverage of other vaccines in poorer regions?

General Guidance

- Can you provide suggestions of critical persons to interview for our assessment?
- Do you have any guidance on selection of sites for provincial and sub-provincial visits?
- What are the issues that you think this evaluation should examine closely?

Annex C: Chinese Language Literature Review

National and Cross-Province

Title	Journal	Data/Method	Results
1999 年全国儿童计划免疫与乙型肝炎疫苗接种率及影响因素调查分析 National EPI Vaccination and Hepatitis B Vaccine Coverage Rate and the Related Factors: Results from the 1999 Nationwide Survey	China Planned Immunization,2000,6(4)	A nationwide survey was conducted in 1999 in 31 provinces of China. The survey used cluster sampling method to select children aged 18-34 months(n=25878); village immunization providers(n=3656) were recruited	HepB3 coverage rate was 70.17%, 63.5% of children had received 3 doses under 12 months of age. Eighty-five percent of immunization sites provided HepB vaccine. Factors associated with not receiving hepB: (1) hepB vaccine not provided at the immunization site; (2) parents were not aware that hepB was recommended; (3) the vaccine charge is too expensive. EPI services need to be improved in poor areas, minority populations, and mountainous areas in China.
中国10个省乙型肝炎疫苗接种率及其影响因素 The Hepatitis B (HB) Vaccine Coverage Rate in 10 Chinese Provinces and Its Influence Factors	China Planned Immunization, 1998,4(4)	Date: EPI baseline study of World Bank Project VII in 10 Chinese provinces. 8389 children born from 1st July of 1994 to 30th June of 1995 were analyzed.	(1) The average coverage rate of three injections was 44.73% , varying from 21.88% to 79.67% depending on provinces. The coverage rate of three injections on the required 0,1,6 months after birth was much lower, being 16.83% with range of 8.08% to 27.82%. (2)The economic condition, geography, EPI insurance contract and the EPI know ledge of the caretakers appear to be the influence factors. The coverage rate was 82.9% in urban area, 44.3% in first level rural area(high income rural area), 32.9% in second level rural area(middle income rural area) and 18.4% in third level rural area(lower income rural area).The coverage rate was 18.1% in mountain area, 36.3% in hilly area and 65. 5% in plain area.The coverag e rate was 63.3% in children having EPI insurance contract and 31. 5% without EPI insurance contract

中国不同省份1992-2006年乙型肝炎疫苗预防接种进展及乙型肝炎病毒表面抗原携带率变化分析 Vaccination Progress of Hepatitis B Vaccine and Epidemiology Changes of Carrying Rate of Hepatitis B Surface Antigen by Province in China, 1992-2006	Chinese Journal of Vaccines and Immunization, 2012,18(1)	Provincial data of vaccination coverage rate and HBsAg prevalence	（1）There was a 44.62% point increasing of HepB3 in average, the highest increased provinces are Hainan（82.86）, Tibet（76.91）, Guangdong（75.42）, Chongqing（70.78）and Xinjiang（70.22）, lowest increased provinces are Qinghai（25.00）, Shanghai（17.65）,Beijing（10.00）, Jiangsu（7.98） and Ningxia（6.19）. There was a 50.90 increasing of TBD in average, the highest increased provinces are Chongqing（88.65）, Sichuan（83.96）, Tibet（82.89）, Yunnan（81.41）, Guangdong（80.00） and Guizhou（71.95）; lowest increased provinces are Anhui（2.02）, Ningxia（4.65）, Guangxi（7.81）,Beijing（12.05）and Shanghai（17.92）.（2）The provinces with high coverage of HepB3, especially with the high coverage of TBD the lower the HBsAg prevalence decreased obviously in China, there was an negative correlation between TBD increasing and HBsAg carrying rate.
我国六个区域2006 年1-59岁人群乙型肝炎病毒感染现状及疫苗接种情况分析 The Seroepidemiological Study and Vaccination Status Analysis on Viral Hepatitis B among Population Aged 1-59 Years in Six Areas of China in 2006	Chinese Journal of Vaccines and Immunization, 2012,18(1)	The seroepidemiological survey data in China in 2006	Among the 1-59 years-old population, the coverage of HepB vaccination was 50.81％,53.78％, 50.02％, 47.93％, 31.21％ and 47.60％ respectively, and the prevalence of HBsAg was 3.73％, 5.37％, 7,72％, 8.84％, 8.05％ and 4.73％ respectively， and the prevalence of anti-HBs was 41.98％, 45.69％, 48.58％, 57.49％, 50.84％, and 46.57％ respectively in the North, Northeast, Eastern, Southwestern, Central, south and Northwest of China

中国东中西部地区1-14岁儿童乙型病毒性肝炎流行现状及乙型肝炎疫苗接种情况 The Hepatitis B Prevalence and the Vaccination Statutes of the 1-14 Years-old Children in Eastern, Central and Western Areas of China	Chinese Journal of Vaccines and Immunization, 2012,18(1)	The sero-epidemiological survey data in China in 2006	The HBsAg prevalence of 1-14 years-old children in eastern, central and western China was 2.31%,1.91% and 2.53% respectively, and the Anti-HBs prevalence was 61.23%, 63.91% and 55.78% respectively. The HepB vaccination coverage was 87.69%, 87.04% and 69.82% in the children of 1-14 years-old in eastern, central and western areas of China respectively.
中国3岁以上人群乙型肝炎血清流行病学研究 A study on the seroepidemiological survey of hepatitis B in Chinese population aged over 3-years old	Chinese Journal of Epidemiology, 2005,26(9)	Samples were collected by CCDC nutrition survey project. HBsAg, anti-HBs and anti-HBc in blood samples were tested using ELISA.	The prevalence rates of HBsAg, anti-HBs and HBV infection were 9.09%, 37.48% and 50.04% among population older than 3 yrs, while for children between 3-12 yrs they were 5.03%, 45.33% and 29.10% respectively.
中国 2005～2010 年报告乙型病毒性肝炎发病分析 Epidemiology Analysis on Reported Hepatitis B in China, 2005-2010	Chinese Journal of Vaccines and Immunization, 2011,17(6)	The data of hepatitis B from China information system for disease control and prevention	There was a increasing trend of hepatitis B morbidity during 2005 and 2009, and slight decreased in 2010 for the first time. Among reported hepatitis B cases, only 8% was acute. The morbidity of acute hepatitis B was decreased from 7.5/100,000 in 2005 to 5.6/100,000 in 2010, the proportion of hepatitis B under 15 years old among reported decreased from 5.56% to 1.92% in same period, morbidity for population under 15 years old was decreased from 1.23/100,000 in 2005 to 0.46/100,000 in 2010.

中国新生儿乙肝疫苗免疫效果评估 Assessment for immune effectiveness of hepatitis B vaccination among infant population in China	Chinese Journal of Public Health, 2009, 25(4)	Data: newborn number-national demographic report.HepB3 coverage rate-CCDC.-Method: on the basis of available data, the health economic evaluation and decision tree model were determined to analyze systematically the strategy of infant hepatitis B vaccination for 14 years in China.	A total of 65 229 476 cases (24 423 516 cases in urban area, 408 05 960 cases in rural area) hepatitis B virus infection, including 13 045 894 acute patients, 652 294 chronic patients, 60 076 cases cirrhosis and 6 007 hepatoma were prevented because of the hepatitis B vaccination among the infants during 1992 through 2005 in China. The BCR was 51 101:1(49 159:1 in urban area, 51 191:1 in rural area)
中国8个省18个县(区)乙型病毒性肝炎监测病例分析 Analysis on Reported Hepatitis B Cases on Pilot Surveillance in 18 Counties of 8 Provinces of China	China Planned Immunization, 2007, 13(4)	Epidemiological study in 18 pilot surveillance counties of 8 provinces (Beijing, Jilin, Zhejiang, Shandong, Henan, Guangdong, Sichuan, Gansu) by CCDC in 2006.	Among 2858 cases of hepatitis B reported in 2006, 1968 cases were male and 890 cases were female, the gender ratio was 2.21:1. The average age was 36. Oral treatment, family contacting, shaving face and beard in hair salons, treatment with hurt in beauty salons etc. , were the major risk factors of the reported acute hepatitis B. According to the confirmed cases by laboratory, the incident rate of acute and chronic hepatitis B were 6.15 and 15.69 per 100 thousands population respectively.
中国不同地区产妇住院分娩率与新生儿乙型肝炎疫苗接种率分析 Analysis on New Born Hepatitis B Immunization Coverage and Pregnant Women Hospital Delivery Rate in Different Regions	Chinese Journal of Vaccine and Immunization,2007,13(1）	Comparing the hospital delivery rate from national health service survey in 2003 and the reported immunization coverage from routine immunization database in 2005.	Result: Hepatitis B vaccine coverage is high in urban areas with high hospital delivery rates than rural areas with low hospital delivery rates, in rural areas, the higher the hospital delivery rate, the higher immunization coverage of timely birth dose. Conclusion: In order to accelerate the control for hepatitis B, improving the coverage for hepatitis B vaccine, hospital delivery rate should be improved, and to ensure all the infants can get immunization of hepatitis B vaccine after birth; For those infants born at home, specific strategies should be developed to ensure them to get immunization in

			time with birth dose of hepatitis B vaccine.
乙型肝炎病毒高流行区儿童接种乙型肝炎疫苗5～16年免疫效果评价 Evaluation on Immue Effect of Hepatitis B Vaccine Immunization among Children Aged 5-16 Years in High Epidemic Areas of Hepatitis B Virus	Chinese Journal of Vaccine and Immunization,2011,17(4）	5001 children aged 5-16 years who had received the 3 doses of HepB immunization in infancy and no boosters were selected from HBV highly epidemic areas, while 2665 children were selected from HBV intermediate epidemic areas （The prevalent rate of HBsAg in population were between 2% and 7%）as control group. Blood plasma specimens were detected for HBsAg, antibody to HBsAg （anti-HBs）and antibody to HBV core antigen（anti-HBc）by chemiluminescence. Positive rates and geometric mean concentration（GMC）were compared between HBV high epidemic areas and intermediate epidemic areas.	The rates of HBsAg positive, anti-HBc positive, HBV infection, anti-HBs positive in HBV high endemic areas were 1.50％, 4.52％, 4.66％, and 47.33％ respectively and GMC is 77.68 mIU/ml［95％confidence interval（CI）:73.00-82.65mIU/ml］; while those in HBV intermediate endemic areas were 0.15％, 3.56％, 3.60％, 38.09％ respectively and GMC is 73.72mIU/ml（95％CI:66.92-81.22mIU/ml）. There were statistical significance for the rates of HBsAg positive, anti-HBc positive and HBV infection between HBV high epidemic areas and HBV intermediate epidemic areas（χ 2=4.724-60.262, P＜0.05）
中国儿童乙型肝炎疫苗预防接种效果分析 Seroepidemiological Study on Hepatitis B in Chinese Children	Chinese Journal of Vaccine and Immunization,2006,12(2）	HBsAg , anti-HBs and anti-HBc in blood samples were tested using ELISA reagents and revised by SPRIA and Abbott ELISA reagents.	Among the children aged 3 - 12 year-old , the prevalence rate of HBsAg is 5.03 % , the rate of HBV infection is 29.10 %. For the vaccinated children , the rates are 3.63 % and 26.88% respectively. For the unvaccinated children , the rates are 11.19 % and 47.03 % respectively. Among the children , the rate of HBsAg is 2.07 %

			in urban areas and 8.17 % in rural areas. For the vaccinated children , the rate of HBsAg is 1.96 % in urban areas and 6.65 % in rural areas. For the unvaccinated children , the rate of HBsAg is 2.39 % in urban areas and 10.84 % in rural areas.
中国人群乙型病毒性肝炎血清流行病学调查——乙型肝炎疫苗接种降低乙型肝炎病毒感染率 Seroepidemiological study on HepB in Chinese population: HepB vaccine reduce HepB infection rate	Chinese Journal of Vaccine and Immunization,2010,16(4）	A brief report of the results of 2006 national HepB seroepidemiological survey.	Among 1-59 yr-old population, the prevalence reate of HBsAg, Anti-HBs, and Ant-HBc were 7.2%, 50.1% and 34.1% respectively. Among less than 5 yr-old children, HBsAg prevalence rate was only 1.0%. HepB has been included into national child immunization plan after 1992, which contributed to this improvement.
中国乙型肝炎疫苗纳入儿童免疫规划实施情况调查分析 Analysis on Hepatitis B Vaccine Integration Into National Immunization Programme for Children in China	Chinese Journal of Vaccine and Immunization,2006,12(4）	Review the financial support, implementation of Hepatitis B vaccination, safe injection, performance of vaccination ,management of vaccine in 10 provinces selected from 22 GAVI project provinces in China.	Most Provinces have provided co-funding for purchase of AD syringes and operational funds for Hepatitis B integration into national immunization programme. The reported coverage has reached the goal (85 %) of GAVI project by Province ,but the estimated and investigated coverage of time birth dose was lower and has not met the project goal (75 %).
中国西部地区不同出生地点新生儿乙型肝炎疫苗首针及时接种情况分析 Analysis on Timely Birth Dose Coverage Among Infant Born in Different Places in Western Provinces of China	Chinese Journal of Vaccine and Immunization,2007,13(4）	Among 11 investigated provinces in western areas, 1 provincial ,2 prefecture level, 2 county level and 4 township hospitals were selected respectively in each province. Immunization information was compiled by t he trained staffs, timely birth dose coverage was analyzed for infants born in hospitals and compared with infants born at home.	The timely birth dose coverage was high among infants born at hospitals (above 90%), while 50% for infants born at home.

中国中西部地区新生儿乙型肝炎疫苗首针及时接种状况调查 Study on Hepatitis B Birth Dose Coverage in the Western and Midlevel Provinces of China	Chinese Journal of Vaccine and Immunization,2006,12(2）	A questionnaire and local survey for the coverage of Hepatitis B birth dose was implemented in 22 GAVI project provinces in 2004.	The coverage rates of HepB birth dose was 74.01 % among the children born in 2003 , and 81.55 % among the children born in 2004. The coverage of HepB birth dose in the children born at hospitals (81.55 %) was higher than those born at home (19 %) . The coverage of HepB birth dose in the children born in hospitals at county levels (88.27 %) was higher than those born at township hospitals.
中国乙型肝炎疫苗免疫策略及新生儿以外人群接种乙型肝炎疫苗的可行性分析 Chinese Hepatitis B Immunization Strategies and Feasibility of Expanding the Vaccination to Children and High Risk Population among Adult	Chinese Journal of Vaccine and Immunization,2008,14(6）	This is a commentary.	China is a country with endemic HepB virus, the chronic carriage rate of heB surface antigen(HBsAg) has declined after universal vaccination of hepB vaccine, huge success obtained among children born after 1992. However, in order to reduce the prevalence of HBV infection, China needs more efforts to expanded the immunization to children and high risk population among adults except for universal infant vaccination.

GAVI Evaluations

Title	Journal	Data/Method	Results
中华人民共和国卫生部/全球疫苗和免疫联盟合作项目地区乙型肝炎疫苗纳入免疫规划效果评估 Evaluation on Impact of Hepatitis B Vaccine Integrated into Routine Immunization in the Areas of Ministry of Health/GAVI cooperation Project P.R.China	China Vaccine and Immunization, 2009,15(4)	Children born between 2002 and 2005 were selected from 68 GAVI project counties by multi-stage random sampling method. Demographic information and hepatitis B vaccination history were collected by questionnaire and review of vaccination records, and 2-4ml serum sample was taken for testing of HBsAg, Anti-HBc and Anti-HBs by ELISA method.	Coverage of HepB3 and HepB TBD was 80.02% and 60.06% respectively, the younger, the higher. HepB coverage among children born in urban was higher than children born in rural, born in hospital was higher than born at home. The prevalence of HBsAg for children born between 2002~2005 was decreased to <2%.
四川省实施卫生部/ 全球疫苗免疫联盟提高边远少数民族地区新生儿乙型肝炎疫苗首剂及时接种率项目评价 Analysis of the Project Effect on MOH/GAVI Increasing the Coverage Rate of Timely-birth Dose Hepatitis B Vaccine in the Remote Minority Areas in Sichuan Province	Chinese Journal of Vaccine and Immunization,2011,17(6）	Aba and Liangshan two autonomous prefectures with the low HepB TBD coverage rate were selected as study sites. 360 villages in 180 townships were selected. Parents with children born between Jan. 1 2007 to Mar.1 2010 in those villages were recruited. Health service providers were also investigated. Intervention: build up the relationship between provincial CDC, MCH stations and hospitals; standardize the HepB1 immunization service in hospitals; improve the HepB1 rate among babies born in home; disseminate; provide vaccines and AD syringes; monitoring and	(1) Afer the interventions, HepB TBD coverage rates increased from 49.19％ to 67.83％;the hepatitis B prevention and control knowledge knowing rate of the parents increased from 15.41％ to 31.57％; the hepatitis B prevention and control knowledge knowing rate of the doctors raised from 47.39％ to 82.54％. (2)the baseline survey also shows the reasons why children cannot get HepB TBD: home delivery, parents do not have HepB information, and long distance between home and the health facilities contribute to low HepB TBD coverage rate.

		supervision. Survey: baseline-Oct. 2008; post intervention: May 2010.	
云南大理州2002-2009年GAVI 项目乙肝疫苗免疫效果 Effect of hepatitis B vaccine immunization of GAVI program in Dali Prefecture, Yunnan province in 2002-2009	China Tropical Medicine, 2011,11(12)	Data resources: county routine immunization reports （including county -level cities）， progress reports of GAVI programs， and end-project reports	Since Dali prefecture became GAVI project area in 2003， HepB3 and the estimated vaccination rate （HepB3/DPT3）have been increased from 65.16% and 60.21% (2002) to 96.51% and 96.68% (2009); The timely vaccination rate of HepB1， the timely vaccination rate of newborns delivered in hospitals and the estimated timely vaccination rate （HepB1/DPT1）were increased by 152.97 %， 110.85% ， and 169.43% (2002: 35.66%,45.70% and 33.50%; 2009:90.21%,96.36% and 90.26%). However， the timely vaccination rate in the newborns delivered at home was only 28.91%. According to the survey of 2006， the HBsAg positive rate of children in ages goup of of 1 to 3 years was 1.67%， a drop of 42.85% in comparison with that of 2003； anti-HBs positive rate was 66.67%， as drop of 82.61%， compared with that of 2003.

中国西部12个省（自治区、直辖市）乙型肝炎疫苗接种情况分析 Analysis on Hepatitis B Immunization Coverage in 12 Western Provinces in China	China Planned Immunization,2006,12(2)	Data: regular immunization report 2001-2004 from 12 western provinces. Method: comparing the DTP targeted and HBV administrated in the same cohort and period, and observing the differences between reported and estimated immunization coverage. Estimated HepB3 coverage=HBV administered population/DTP targeted population*100%	The reported HepB3 from 12 Western Provinces were relative high, with the average coverage of 86.95%,91.02%, 92.49%, and 96.67%, from 2001 to 2004 respectively. The estimated coverage were much low, with the average coverage of 48.2%, 52.53%,61.96%, 80.83%. The same period, the coverage of estimated birth dose of HBV in 2004 was only 58.38%.The gaps of reported and estimated coverage showed that there are challenges for the GAVI project, and that most of the provinces did not meet the national goals of 85% for three doses of coverage, and 75% for birth dose coverage. It is also suggested that the hepB immunization in western provinces should be enhanced
中国中西部地区新生儿乙型肝炎疫苗首针及时接种状况调查 Study on Hepatitis B Birth Dose Coverage in the Western and Mid2level Provinces of China	China Planned Immunization, 2006, 12(2)	a questionnaire and local survey for the coverage of Hepatitis B birth dose was carried out in the areas selected from the GAVI project provinces in 2004 and 2005.	The coverage rate of HepB TBD was 74.01% in the children born in 2003, and for 2004,the rate was 81.55%. The coverage of HepB TBD in the children born in the hospitals (81.55%) was higher than those born in home (19%). The coverage of HepB TBD in the children born in hospitals at county levels (88.27%) is better than those born in township hospitals (71.74%).
湖北省GAVI合作项目单位自毁型注射器使用情况调查 The use of AD syringes in GAVI project health facilities in Hubei province	Journal of Public Health and Preventive Medicine, 2007,18(1)	Sampling: 9 project counties in 3 cities were selected randomly. All the city level and county level health facilities were investigated. 1-2 township health clinics with low hospital delivery rate were also investigated. Method: observation, interview and group discussion with health service providers.	The rate of correct use of AD syringes is low: overall-45.83%. The rate of correct recycle process of AD syringes is 72.92%.

四川省实施卫生部/全球疫苗免疫联盟乙型肝炎疫苗合作项目评价 Assessment on Hepatitis B Vaccine Integration Into National Immunization Program for Children in Sichuan province	Chinese Journal of Vaccine and Immunization,2007,13(3）	Serological test of 324 blood samples collected from children < 3 years in 20 counties and 40 townships in Sichuan.	HepB3 coverage and HepB TBD coverage have been increased since GAVI project initiated in 2003 in Sichuan. The HBsAg carrier rate for children less than 3 years old was 0.63 %, which has been reduced by 79.74 % comparing with 2002. The HepB TBD for children born in both county and township hospitals was above 95%. EPI staffs and children's parents have been educated basic knowledge about hepatitis B. Safe injection have been promoted.
湖北省实施卫生部全球疫苗免疫联盟合作项目结果分析 The result of MOH/GAVI HepB Immunization project in Hubei province	Chinese Journal of Public Health Management, 2011, 27(5)	This is a summary report of provincial level end-project supervision.	HepB3 coverage was 99.31% (2009) and HepB TBD coverage was 94.97(2009). AD syringes have been used for HepB and all vaccines after 2006. The HepB incidence among children has been decreased.
贵州省《卫生部与全球疫苗免疫联盟理事会/儿童疫苗基金合作项目》实施情况调查分析 Survey and Analysis on the Situation of Implementation of Global Alliance for Vaccine and Immunization Project in Guizhou Province	Chinese Journal of Vaccine and Immunization,2006,12(2）	Provincial level supervision in 9 prefecture, 18 counties, 36 townships and 36 villages in 2005.	The HepB vaccines management still have problems. The amounts of vaccine received and delivered were inconsistent in some facilities. Data reporting was incomplete. The Hepatitis B coverage rate was relatively low. The Hepatitis B1 rate was 81.2% for new born infant from Jan 1, 2003 to Oct 31, 2004. The HepB TBD was 21.6%. The HepB3 was 38.8%.
甘肃省乙型肝炎疫苗纳入儿童免疫规划后血清学效果评价 Seroepidemiological study on the GAVI HepB project in Gansu province	Chinese Journal of Vaccine and Immunization,2008,14(3）	Serological test among 396 one-year children who have been vaccinated HepB3 in 5 prefectures of Gansu.	HBsAg positive rate 1.3%; Anti-HBs positive rate 88.9%. HepB TBD and HepB3 coverage rates are all 100%.

Injection Safety

Title	Journal	Data/Method	Results
乙型肝炎疫苗纳入免疫规划及安全注射培训评估 Evaluation of the Training on HepB Vaccine Immunization and Safe Injection	Chinese Journal of Vaccines and Immunization, 2007, 13(1)	China CDC conducted an evaluation on GAVI training activities in 16 project counties of 8 provinces (Hebei, Xinjiang, Guangxi, Sichuan, Jilin, Hubei, Ningxia, Gansu) in 2003. Both qualitative and quantitative methods including questionnaire, observation, focus group/informal discussion have been used in this evaluation. EPI staff from 678 villages, 204 towns and 16 counties have been recruited in this study. The total sample size was 1204.	Training for village level had been completed in most provinces, coverage rate was more than 80%. Most staff felt satisfied for training materials, but unsatisfied with the teachers and training condition. County staff and village doctors were tested about HepB transmission methods, vaccine storage condition and safe injection methods, contraindication, and the importance and methods to improve HepB TBD rate, etc. 80% questions can be answered correctly by county level staff, but less than half village doctors can answered correctly 50% questions. Conclusion: the training on HepB vaccine and safe injection has not achieved the expected goal. The reasons include: lack of training fund and materials, lack of necessary equipment for training.

我国农村不安全注射的研究现状 Current status of unsafe injection in rural China	Disease Control, 2002, 8(3)	This is a lit review. It summarize: the incidence of unsafe injection in China, health providers' knowledge about unsafe injection, and the preventive measures to unsafe injection.	Only 38.6% of the immunization stations used disposable syringes (2001 national data). Some local health workers do not know the proper procedure after use the disposable syringes. A survey in 2000 shows that 65% of the health workers know the correct procedure, while 25.83% just abandon the syringes directly. The local health staff also have little knowledge about safe injection. Unsafe injection behaviors are very common among the local immunization staff in rural China. The percentages of safe injection are low in several provinces.

加强我国预防接种中安全注射管理问题的探讨 To improve immunization injection safety in China	Chinese Primary Healthcare, 2008, 22(1)	This is a commentary.	Injection safety is a major public health problem in the developing countries, while unsafe immunization injection has been a greater concern as it might do harm to healthy children. In some regions of China, especially in the rural areas, unsafe injection practices in EPI have been common. Only a comprehensive approach addressing policies, technologies, behaviors can ensure injection safety. It is suggested that immediate and long-term measures, such as increasing input, intensive health education and training, introduction of AD syringe, enhanced supervision of immunization providers and management of syringe market, be undertaken to improve immunization injection safety.
儿基会40个强化项目县村卫生室安全注射现状分析（摘要） UNICEF Project Briefing: safe injection in village clinics in 40 counties of China	Chinese Rural Medicine, 2001, 8(2)	This is UNICEF project baseline survey in 2001. Village doctors and mothers with children less than 3 yrs in 40 counties in Ningxia, Gansu, Guizhou, Qinghai and Xinjiang have been recruited. Most villages locate in poor area.	Among the 441 village clinics, 71.6% do not have disposable syringe needles, and 61.8% do not have syringe tubes.

甘肃省乙肝疫苗纳入计划免疫和安全注射基层强化培训效果评估 Effectiveness evaluation of strengthening training on incorporating the hepatitis B vaccination into EPI and safe injection in Gansu Province	Chinese Health Education, 2007, 23(3)	This is a provincial report of Gansu for the 2003 national survey on training. Questionnaires, focus group discussion and quiz were used to evaluate the training effectiveness among the trained EPI staff in different counties and towns or villages.	The training covered 488 persons. 60 persons agreed that the participatory training methods was effective and the training contents could meet the need. The facility managers did not realize the importance of the training and the training was lack of the financial support. The textbooks and instruments and enough qualified teachers etc. were the major factors influencing the training effectiveness.
甘肃省2006年预防接种安全注射现状调查分析 Survey on safe injection of immunization in Gansu province in 2006	Chinese Rural Health Management, 2008, 28 (12)	Gansu CDC led a provincial level safe injection survey in the immunization stations 2006. In 14 prefectures, 20% (3527) of all the injection stations were selected for this survey.	68. 47% of the stat ions mainly adopted AD syringes and disposable syringes, yet some stations in rural areas still used glass syringes which are 3.23% o f the total. In all of the immunization stations “one syringe and one needle for each injection” could be achieved. Safe handling rate for used syringes reached above 95%, but in about 1% to 3% stations there are still unsafe injection and procedures existing.

Annex D: Interview Guide for International Key Informants

Project Design

1. How did this project fit into the GOC's health strategy in 2001/2002?
2. Before discussions with GAVI, had there been any discussions regarding how to address the disparity of HepB coverage rates between provinces? Was central government funding for HepB or any other vaccines considered in order to increase coverage considered?
3. Did the MOH have regulations for safe injection at the time of project design? What were included in the regulations?
4. What was the evidence regarding the importance of AD syringes and unsafe practices related to disposable syringes?
5. Why was it decided to open a MOH/GAVI project office? How was staffing and location of the office decided?
6. Was it difficult to get agreement from GAVI for local procurement of locally produced vaccine and syringes? Would the GOC have proceeded with the project if it were required to use UNICEF-procured supplies?
7. Was it difficult to obtain GOC agreement to co-fund the project? Who were the key supporters of this approach?
8. Were provincial governments involved in project design? Did they understand the project implications in terms of co-funding, operational costs, and lost revenue from sales of HepB vaccine?
9. How would you describe the change in the Chinese government's commitment to public health between 2001/2002 and today? What factors were most critical to that change?

Implementation – Core Project Period

10. What were specific responsibilities of the MOH/GAVI project office? Were they involved in provincial level implementation or oversight?
11. Can you describe the process for commodities procurement (who was responsible, qualification of suppliers, size of procurements, length of contract, etc)? Was it the same for vaccines and syringes? How did provincial governments provide co-funding for syringes?
12. Can you pls describe how the cascade training was implemented? Besides TOT at provincial level, how did the GAVI office support the cascade training? Besides the funding challenges in some provinces, were there any issues related to quality of the training?
13. For the provinces that initially faced challenges providing co-funding for injection equipment or operational costs, how did they identify the additional funds?
14. Were there any additional government funds (besides the $38 million committed to the project) used to support project activities? What types of activities were funded?
15. Were the ICC and OAG effective mechanisms to oversee project implementation?
16. What were activities undertaken by your organization that directly or indirectly supported this project?
17. Who were the key decision-makers in the decision for central government to fund all vaccines and syringes for immunization? What were the key reasons for this new policy?

18. How did SARS affect project implementation? Were there any other disease outbreaks or other health emergencies that affected implementation?
19. What were the most challenging implementation issues?
20. What were critical factors that contributed to project success?
21. What were the critical decisions made during implementation period that affected outcomes?

Implementation – Extension Period

22. Who was involved in decisions regarding how to use project savings? What criteria were considered in decision-making? Was there any disagreement on what activities to undertake?
23. Pls describe the investments in the health information system.
24. Were you involved in conducting the demonstration and research projects that were funded with project savings in recent years? Were there useful outcomes of these projects?
25. What are the key outcomes of the catch-up campaign, the TBD projects, and the HIS investments funded by project savings? Has there been a formal evaluation of these activities?

Project Impact

26. What are the respective responsibilities of the central and subnational governments in providing support for Hepatitis B and other immunizations since the end of the project? Do they differ for Eastern, Central and Western provinces, and for poverty counties?
27. How does the NIP currently support provincial and local governments that face challenges such as achieving coverage targets or raising sufficient funds? Do those provinces receive extra funding support? Do external partners provide project support?
28. How is procurement for vaccines and syringes done currently?
29. Are there currently strong advocates for use of AD syringes? Why do you think the GOC never fully committed to AD syringes? Do you think there was more this project could have done to ensure use of AD syringes nationally?
30. Has anything changed within the NIP since the end of this project? How is the program performing generally? Do they have sufficient funding to conduct needed training, monitoring, supervision activities?
31. How did the government policy to encourage hospital delivery affect the outcomes of this project, in particular TBD? What more can be done to increase TBD?
32. What are other external developments that had an important impact to the outcomes of this project?
33. How important was the experience with Hepatitis B project in the central government decision to finance all immunizations?
34. Has this project affected government, public, and provider attitudes toward vaccination and vaccine subsidies?
35. Could the GOC have accomplished the results of this project without GAVI support? Why do you think so?
36. What do you consider the most important lessons from this project that could be applied to other countries?

Annex E: Quantitative Data Requests and Data Availability

Data Request	Rationale/Proposed Analysis	Availability
Immunization Coverage Rates		
HepB infection rates by **PROVINCE** 2002 and prior	• Examine relevance of project design	• Data provided from sero-surveys conducted in 1979, 1992, 2006. Data from 1979 is not available by province.
Annual **HepB3** coverage rates by **PROVINCE** 1992-2002	• Examine relevance of project design	• Data before 2002 is incomplete.
Annual **HepB TBD** coverage rates by **PROVINCE** 1992-2002	• Examine relevance of project design	• TBD data is only available from 2004, as it was not previously reported.
Annual **HepB3** and **HepB TBD** coverage rates by **COUNTY** for field-visit counties 2002-2011	• Use 2010 data to select provinces/counties to visit • Comparison of GAVI and non-GAVI counties in central provinces	• HepB3 data provided • TBD data is available **from 2004** only as it was not previously reported
Annual **DTP3** and **Measles** coverage rates by **COUNTY** 2002-2011	• Examine positive or negative impact on other antigens • Comparison of GAVI counties and non-GAVI counties	• Not provided.
Commodities Prices		
Annual Prices for HepB vaccine by supplier 2002-2011	• Efficiency of domestic procurement, comparison with international benchmarks (UNICEF)	• Data provided from 2002-2007. Procurement was decentralized thereafter.
Annual Prices for AD syringes by supplier 2002-2011	• Efficiency of domestic procurement, comparison with international benchmarks (UNICEF)	• Data provided from 2002-2008. Procurement was decentralized thereafter.
Immunization Budgets		
Annual NIP budgets, with breakout for HepB vaccines 2002-2011	• Examine changes in government support to NIP	• Accurate data was not available, although rough estimates were provided.
PROVINCIAL Health Department or CDC budgets 2002-2011	• Examine changes in government support to NIP • Examine whether funding for HepB was additional, or diverted from other health programs	• Accurate data is not available, although approximations were made in field-visit sites.
COUNTY Health Department or CDC budgets 2002-2011 for counties in West and Central provinces	• Examine changes in government support to NIP • Examine whether funding for HepB was additional, or from other health programs	• Accurate data is not available, although approximations were made in field-visit sites.

Annex F: Interview Guide for MOH and CCDC Officials

Chinese Government Officials (tailored to informant) 中国政府官员 (根据不同访谈者做具体调整)

Project Design 项目设计

1. How did this project fit into the GOC's health strategy in 2001/2002?
    a. 在2001、2002年，这个项目是如何顺应中国政府的卫生战略?
2. Before discussions with GAVI, had there been any internal discussions regarding how to address the disparity of HepB coverage rates between provinces? Was central government funding for HepB or any other vaccines considered in order to increase coverage considered?
    a. 在同GAVI讨论前，对于如何解决乙肝疫苗接种率在各省之间有差异的问题是否进行过内部的讨论？中央政府有没有考虑过因为覆盖率的问题对乙肝疫苗或其他疫苗增加资金投入？
3. Did the MOH have regulations for safe injection at the time of project design? What were included in the regulations?
    a. 在项目设计时，卫生部是否有安全注射的规定？规定的具体内容有哪些？
4. What was the evidence regarding the importance of AD syringes and unsafe practices related to disposable syringes?
    a. 有何证据可以证明自毁型或一次性注射器非安全使用的重要性？
5. Why was it decided to open a MOH/GAVI project office? How was staffing and location of the office decided?
    a. 为什么要决定成立卫生部/GAVI项目办公室? 项目办的成员和工作地点是如何决定的？
6. Was it difficult to get agreement from GAVI for local procurement of locally produced vaccine and syringes? Would the GOC have proceeded with the project if it were required to use UNICEF-procured supplies?
    a. 让GAVI同意通过地方的采购体系使用当地生产的疫苗和注射器，有没有难度？如果需要采用儿基会采购的供应商，中国政府是否还愿意继续该项目？
7. Was it difficult to obtain GOC agreement to co-fund the project? Who were the key supporters of this approach?
    a. 获得中国政府同意为项目提供配套资金，是不是很困难？关键的支持者有哪些人？
8. Were provincial governments involved in project design? Did they understand the project implications in terms of co-funding, operational costs, and lost revenue from sales of HepB vaccine?

a. 省级政府参与到项目设计了么？他们知道项目的影响意义吗，在提供配套经费、产生执行成本和在销售乙肝疫苗上的收益损失等方面？

9. How would you describe the change in the Chinese government's commitment to public health between 2001/2002 and today? What factors were most critical to that change?

a. 同2001/2002年相比，您认为中国政府现在对公共卫生的承诺有何转变？转变的主要因素有哪些？

Implementation – Project Core Phase 实施 –项目核心阶段

10. What were specific responsibilities of the MOH/GAVI project office? Were they involved in provincial level implementation or oversight?

a. 卫生部/GAVI项目办的具体职责有哪些？他们是否参与到省级项目的实施或者监督？

11. Can you describe the process for commodities procurement (who was responsible, qualification of suppliers, size of procurements, length of contract, etc)? Was it the same for vaccines and syringes? How did provincial governments provide co-funding for syringes?

a. 您能描述一下商品采购的流程吗（谁负责、供货商的资格、采购规模、合同时长等）？疫苗和注射器也一样吗？省级政府是如何为注射器提供配套资金的？

12. Can you pls describe how the cascade training was implemented? Besides TOT at provincial level, how did the GAVI office support the cascade training? Besides the funding challenges in some provinces, were there any issues related to quality of the training?

a. 您能介绍一下如何进行逐级往下的培训的？除了在省一级对培训师进行培训，GAVI办公室还能如何支持逐级往下的培训？除了一些省份有资金紧张的问题，还有哪些问题会影响到培训的质量?

13. For the provinces that initially faced challenges providing co-funding for injection equipment or operational costs, how did they identify the additional funds?

a. 对于那些一开始就存在提供注射器或执行成本配套资金困难的省份，他们如何获得额外的资金？

14. Were there any additional government funds (besides the $38 million committed to the project) used to support project activities? What types of activities were funded?

a. 政府是否有其他的资金用于支持项目活动（除了承诺提供的3800万美元）？支持了哪些活动？

15. Were the ICC and OAG effective mechanisms to oversee project implementation?

a. 免疫协调委员会（ICC）和执行咨询小组（OAG）会议是不是一种有效机制来监督项目的实施?

16. What did external partners (WHO, UNICEF, PATH) bring to this project?

a. 外部的合作伙伴(WHO, UNICEF, PATH)对项目有何贡献?

17. Which department drafted the State Council regulation "Vaccine Circulation and Vaccination Management" issued in 2005? Why did these regulations not require use of AD syringes?

   a. 2005年，哪个部门起草了国务院发布的《*疫苗*流通和预防接种*管理*条例》？该《条例》为何没有规定要求使用自毁型注射器？

18. Who were the key decision-makers in the decision for central government to fund all vaccines and syringes for immunization? What were the key reasons for this new policy?
   a. 中央政府中决定为疫苗和免疫用注射器提供资金的主要决策者是谁？推行这一新政策的关键原因有哪些？
19. How did SARS affect project implementation? Were there any other disease outbreaks or other health emergencies that affected implementation?
   a. SARS对项目实施有何影响？有没有其他的疾病暴发或其他的卫生突发事件影响到项目的实施？
20. What were the most challenging implementation issues?
   a. 项目实施时最大的挑战有哪些?
21. What were critical factors that contributed to project success?
   a. 决定项目成败的重要因素有哪些？
22. What were the critical decisions made during implementation period that affected outcomes?
   a. 在实施过程中，有哪些重要的决定会影响到结果？

Implementation – Extension Period 实施 – 项目延期阶段

1. Who was involved in decisions regarding how to use project savings? What criteria were considered in decision-making?
   a. 谁参与决策了项目节余经费的使用？决策过程中的标准是什么？
2. Pls describe the investments in the health information system.
   a. 请介绍一下对卫生信息系统的投入.
3. What are the key outcomes of the catch-up campaign, the TBD projects, and the HIS investments funded by project savings? Has there been a formal evaluation of these activities?
   a. 由节余经费支持的初始强化免疫、首针及时接种（TBD）项目和卫生信息系统建设的关键成果有哪些？对这些活动有没有正式的评估？

Project Impact - 项目的影响

4. What are the respective responsibilities of the central and subnational governments in providing support for Hepatitis B and other immunizations since the end of the project? Do they differ for Eastern, Central and Western provinces, and for poverty counties?
   a. 项目结束后，中央和地方政府在为乙肝疫苗和其他疫苗提供支持时，各自的责任有哪些？东、中、西部省份之间是否有区别？贫困县是否有区别？

5. How does the NIP currently support provincial and local governments that face challenges such as achieving coverage targets or raising sufficient funds? Do those provinces receive extra funding support?
    a. 目前国家项目办（NIP）如何帮助省级和地方政府解决他们面临的挑战，例如达到覆盖率的目标或筹集足够的资金？这些省有没有收到额外的资金支持？
6. How is procurement for vaccines and syringes done currently?
    a. 现在的疫苗和注射器采购是如何完成的？
7. Has use of AD syringes continued? Do you think there was more the Hepatitis B vaccination project could have done to ensure use of AD syringes nationally (particularly in Eastern provinces)?
    a. 自毁型注射器是否仍然在使用？您认为乙肝疫苗项目是否应该为保证自毁型注射器在全国（尤其是东部省份）的应用作出更多的贡献？
8. How did the government policy to encourage hospital delivery affect the outcomes of this project, in particular TBD? What more can be done to increase TBD?
    a. 政府的鼓励医院提供服务的政策是如何影响到项目的结果，尤其是首针及时接种？提高首针及时接种率还需要做什么？
9. What are other external developments that had an important impact to the outcomes of this project?
    a. 还有哪些外部进展对项目的结果有重要影响？
10. How important was the experience with Hepatitis B project in the central government decision to finance all immunizations?
    a. 在中央政府决定负担所有的免疫接种费用时，乙肝疫苗项目的经验有多重要的影响?
11. Has this project affected government, public, and provider attitudes toward vaccination and vaccine subsidies?
    a. 这一项目是否影响了政府、公众和疫苗供货商对预防接种和疫苗补贴的看法?
12. Could the GOC have accomplished the results of this project without GAVI support? Why do you think so?
    a. 没有GAVI的帮助，中国政府能否独自取得项目结果？为什么？
13. What do you consider the most important lessons from this project that could be applied to other countries?
    a. 您认为这一项目最值得推广到其他国家的经验有哪些？

Annex G: Contact List for Field Visits

Administrative Level	Name	Interviewees
Province	Hunan	Mr. Gao Lidong, Deputy Director, Hunan CDC
		Mr. Li Zhuzhang, Director, EPI office Hunan CDC
		Ms. Xia Wei, EPI Office (in charge of GAVI project)
		Mr. Tao Xueyong, Director, Dept. of Disease Control, Hunan Health Bureau
		Mr. Tong, Director, Dept. of Finance, Hunan Health Bureau
Prefecture	Yueyang	Mr. Huang, head of CDC, began in 2009
		Mr. Wu, Deputy director of CDC, there for a long time
		Mr. Ye, director of Dept. of EPI, Yueyang CDC
		Mr. Li, deputy director of Dept. of EPI, Yueyang CDC
		Mr. Cheng, Director of Dept. of Disease Control, Yueyang Health Bureau
		Mr. Zhong, Director of Dept. of Finance, Yueyang Health Bureau
County	Pingjiang (in Yuyang)	Ms Huang, Deputy Director, Pingjiang CDC
		Ms. Deng, Secretary, Pingjiang CDC Communist Party
		Dr. Huang, Preventive Healthcare Special Officer, Fushoushan Township Hospital
		Mr. Zhang, Director, Pingjiang CDC
		Mr. Fang, Pingjiang Health Bureau
		Ms. Li, County Mayor, Pingjiang County
		Mr. Wang, EPI Director, Pingjiang CDC
		Mr. Wu Haibo, Director, Yueyang CDC
Township hospital in Pingjiang	Fushoushan Township Hospital	Dr. Wang, middle manager
District*	Yunxi** (in Yuyang)	Mr. Wang, Dept. of Disease Control, Yunxi District Health Bureau
		Mr. Wang, Director, Yunxi District CDC
		Mr. Li, Director, NIP Office, Yunxi District Health Bureau
		Mr. Zhang, Director, Dept. of Finance, Yunxi District Health Bureau
		Mr. Zhou, Director, Yunxi District Health Bureau
Township hospital in Yunxi	Lukou Township Hospital	Two doctors from the hospital
Province	Gansu	Ms. Chen Yin, director, Dept of Diseases Control, Gansu Health Bureau
		Ms. Li Hui, deputy director, Gansu CDC
		Mr. Zhang and, director, EPI Office, Gansu CDC
		Ms. AN Jing, deputy director, EPI Office, Gansu CDC
Prefecture	Tianshui	Mr. Li Xilin, director, Tianshui CDC
		Mr. Wang, deputy director, Tianshui CDC
		Mr. Liu, director, EPI office, Gansu Province
		Mr. Fan Duozhi, director, Tianshui Health Bureau
		Mr. Liu, director, EPI office, Tianshui CDC
		Mr. Li, director, Financial Department, Tianshui Health Bureau
County	Qin'an (in Tianshui)	Mr. Zheng, director, Qin'an CDC
		Mr. Zhang, Qin'an County Health Bureau
		Mr. Li Guochang, director, EPI office, Qin'an CDC
		Mr. Fan Duozhi, director, Tianshui health bureau
		Mr. Li Xilin, director, Tianshui CDC
Township Hospital	Xinfeng Central Hopsital (in Qin'an)	Mr. Wang, Director, Xinfeng Central Hospital

		Mr. Zheng, deputy director, Xinfeng Central Hospital
		Mr. Gan, in charge of EPI, Xinfeng Central Hospital
		Mr. Gao, Secretary, Qin'an County Communist Party
		Mr. Zhang, Qin'an County Health Bureau
		Mr. Guo, County Mayor, Qin'an County
		Mr. Zheng, director, Qin'an CDC
		Mr. Li, director, Publicity Department, Qin'an county
Prefecture	Dingxi	Mr. Luo, director, Dept. of Disease Control, Dingxi Health Bureau
		Mr. He, director, Dept. of Financial Planning, Dingxi Health Bureau
		Mr. Yang, director, Dingxi CDC
		Mr. Chen, EPI director, Dingxi CDC
		Ms. Han, deputy EPI director, Dingxi CDC
County	Anding district (in Dingxi)	Mr. Sun, Secretary, Anding Health Bureau Communist Party (in charge of finance)
		Mr. He, director, Anding District CDC
		Mr. Wang, EPI director, Anding District CDC
Township Hospital	Xigong Township Hospital	Mr. Mao, director, Xigong Township hospital
		Mr. Li, in charge of EPI, Xigong Township Hospital
Province	Qinghai	Mr. Li Xianming, director, Qinghai Health Bureau
		Mr. Zhaohui, director, Financial Department, Qinghai Health Bureau
		Mr. Chen Xin, director, Dept. of Disease Control, Qinghai Health Bureau
		Mr. Deng Ershou, director, Qinghai CDC
		Mr. Zhang and Zhao, EPI director, Qinghai CDC
		Mr. Ba, director, EPI division, Qinghai CDC
		Mr. Chen, director, Financial Department, Qinghai CDC
Prefecture	Haidong	Mr. Ba, director, Haidong CDC
		Mr. Ma, director, Haidong Health Bureau
County	Xunhua (in Haidong)	Mr. Ma Chengcai, director, Xunhua County CDC
		Mr. Ma Zhishan, deputy director, Xunhua County CDC
		Mr. Ma Xiaofeng, EPI director, Xunhua County CDC
		Mr. Ba, director, Haidong CDC
		Mr. Ma, director, Haidong Health Bureau
Township Hospital in Xunhua	Jishi Township Hospital	Ms. Zhang, deputy director, Jishi Township Hospital
Village Doctor	Tuoba Village Clinic (in Xunhua)	Mr. Ma, village doctor
Prefecture	Xining	Ms. Zhao, deputy director, Xining CDC
		Ms. Li, EPI director, Xining CDC
County	Huangzhong (in Xining)	Mr. Xing, Huangzhong County Health Bureau
		Mr. Ma, Dept. of Disease Control, Huangzhong County Health Bureau
		Mr. Liu, director, Huangzhong CDC
		Mr. Li, deputy director, Huangzhong CDC
		Mr. Li, Financial Department, Huangzhong CDC
		Mr. Zhang, EPI director, Huangzhong CDC
Township Hospital in Huangzhong	Shangxinzhuang Central Hospital	Mr. Zhao Longfu, hospital director
		Mr. Tian Dongchun, director, Public Health Division

*District is at the same level as a county but is in an urban as opposed to a rural area
**Yunxi was a non-poverty and non-project county in Hunan Province

Annex H: Interview Guide for Field Visits

Provincial Level Officials 省级官员

Project Design 项目设计

1. Were you or other provincial-level officials involved in discussions about project design, such as:
    a. 您或其他的省级官员参与了项目设计的讨论吗？例如:
        i. Amount of provincial co-funding
            1. 省级配套资金的金额
        ii. Responsibilities for operational costs related to project implementation?
            1. 所负责的由项目实施产生的执行成本
        iii. Lost revenue from sales of HepB vaccine
            1. 销售乙肝疫苗的收益损失
        iv. Impact on providers from reduced patient user fees
            1. 由降低患者费用而产生的对供应商的影响
2. Over the course of project implementation, were there changes in the funding arrangements and expectations of provincial and local governments for operational costs?
    a. 项目实施的过程中，资金安排以及省级和地方政府对执行成本的预期是否有变化？

Project Implementation 项目实施

1. How did you learn of the project, and the project implementation plan?
    a. 您是如何获悉这一项目及项目的实施计划的？
2. How did you interact with the HepB Project office? Was there a channel for you to voice concerns and raise problems? Were your concerns/problems addressed?
    a. 您如何同乙肝疫苗项目办沟通？是否有传达您（对项目）的顾虑和提出问题的渠道？您的顾虑/问题是否得到了解决？
3. Were you involved in procuring HepB vaccines and syringes? Were there ever any problems with procurement?
    a. 您是否参与了乙肝疫苗和注射器的采购？采购过程中有没有出现什么问题？
4. Can you pls describe the training that was provided to lower levels related to HepB vaccination and injection safety? How did you conduct training to lower levels? Was the support/training you received from CCDC sufficient?
    a. 您能介绍一下对下级进行的有关乙肝疫苗和安全注射的培训？您是如何对下级进行培训的？您从中国CDC得到的支持/培训是否充足？
5. Related to provincial funding:

a. 关于省级配套资金:
    i. Did you have any problems providing co-funding for syringes as required by the project?
        1. 你们在根据项目要求提供注射器的配套资金时，有没有遇到问题？
    v. Did you provide provincial funding for other activities related to Hepatitis B vaccination?
        1. 你们是否为与乙肝疫苗接种相关的其他活动提供过资金?
b. Did you provide funding to support training or other activities at prefecture or county level? If so, how was that disbursed?
    i. 你们是否提供资金，支持地级或县级的培训或其他活动？如有，如何分配的资金？
c. Can you tell us the amounts each year allocated to these activities?
    i. 您能告诉我们，你们每年要为这些活动配置多少资金？
d. Was the amount of provincial funding required for this project more or less than what was previously allocated for immunization? Where did that budget come from?
    i. 根据项目要求配置的省级资金同之前在预防接种领域投入的资金相比，是多了还是少了？预算从何而来？
e. Was there always sufficient funding? If not, how did that affect project implementation?
    i. 资金一直都很充沛吗？如不是，这对项目实施有何影响？
f. [For central provinces] Did you provide similar funding for non-poverty counties?
    i. [对中部省份]你们是否为非贫困县提供了同样的资金？

2. Did provincial level authorities conduct supervision at lower levels? Was supervision conducted more frequently because of the HepB project, or did you include supervision on HepB as part of supervision on routine supervision? What were the results?
    b. 省级机构是否会对下级机构进行监管？监管会因为乙肝疫苗项目更加频繁吗？还是你们将乙肝项目作为常规监管的一部分？结果如何？

6. Was your province involved in the more recent activities such as the catch-up campaigns, the TBD projects, and the HIS improvements? What were the results of these activities?
    a. 你们省有没有参与最近的初始强化免疫、首针及时接种（TBD）项目和完善卫生信息系统项目？这些项目的结果如何？

7. How did SARS affect project implementation?
    a. SARS对项目实施有影响吗？

8. What were the most challenging implementation issues?
    a. 项目实施时最大的挑战是什么？

9. What were the critical factors that contributed to project success?
    a. 决定项目成功的关键因素有哪些？

10. [For central provinces] Over the course of the project, how has the provision of vaccination services differed in the poverty and non-poverty counties (procurement, training, type of syringe used, overall financial inputs)?
    a. [对中部省份]在项目过程中，预防接种服务的提供在贫困县和非贫困县之间有什么区别？（采购、培训、使用的注射器类型、总体资金投入）

Project Impact 项目影响

11. How well did the province meet the main project indicators?
    a. 你们省对项目主要指标的完成程度如何？
12. Were there big differences between counties in the province? What was the reason for the differences between counties?
    a. 省内各县之间是否有较大的差异？各县之间有差异的原因是什么？
13. Did the provincial government ever fund vaccines and syringes – was there a gap between the end of the GAVI-GOC project and central government funding?
    a. 省政府有没有为疫苗和注射器提供资金？从GAVI-中国政府项目结束后到中央政府提供资金前，是否存在资金断流?
14. Did the provision of free HepB vaccine negatively affect the revenues that were generated by sales of vaccines at provincial, prefecture, and county level? How did you replace these funds? Was there a negative impact on other services?
    a. 免费提供乙肝疫苗对在省、市、县三级水平上销售疫苗的收益是否有负面影响？你们是如何补偿收益的？对其他的服务是否有负面影响？
15. How are immunization services funded currently? Do you receive supplies from central government or funding? Does the provincial health department procure its own vaccines and supplies? Do you provide funding to prefecture or county levels for operational costs? Do you feel you have adequate resources and support to provide needed immunization services?
    a. 预防接种服务的资金现在从何而来？你们是否得到了中央政府的支持和经费？省卫生厅自己采购疫苗和设备吗？你们是否给地市级和县级单位提供资金，补贴其执行成本？您觉得你们是否有充足的资源提供必需的预防接种服务?
16. How does the current total provincial budget for immunization compare with 2007, and 2002?
    a. 同2002和2007年分别相比，省级财政现在给预防接种的预算有何变化？
17. Are there still challenges with funding for childhood immunization?
    a. 儿童的预防接种是否还有资金问题？
18. For immunization, what type of syringes do you currently procure and why?
    a. 你们现在为预防接种采购的是哪种注射器，为什么？
19. Are there still challenges with injection safety in your province?
    a. 你们省是否还有注射安全方面的挑战？

20. Has this project affected government and public attitudes toward vaccination and vaccine subsidies?
    a. 这个项目是否改变了政府和公众对于预防接种和疫苗补贴的看法？
21. What do you consider the most important outcomes, and lessons from this project?
    a. 你认为从这个项目中得到的最重要的结果和经验有哪些？
22. [For central provinces] How are the poverty counties that received support doing in comparison to the non-poverty counties related to HepB coverage rates, and use of AD syringes? What are the reasons for any differences?
    a. [对中部省份] 贫困县同非贫困县相比，获得政府扶持的同时在乙肝疫苗接种率和自毁型注射器的使用方面做得怎么样?有区别的原因是什么？
3. [For central provinces] What if any steps are you taking to address remaining disparities in outcomes among counties?
    b. [对中部省份]你们将采取什么样的步骤解决各县之间依然存在的结果不公平问题？

Prefecture and County Level Officials 地级和县级官员

Project Design 项目实施

1. How did you learn of the project, and how it was to be implemented?
    a. 你们是如何获悉这一项目的？是如何实施的？
2. How did you interact with the HepB Project office? Who would you turn to if you had concerns or challenges?
    a. 你们是如何同乙肝疫苗项目办交流的？如果你有顾虑或困难，你会向谁咨询？
3. Did you contribute to the Provincial Implementation Plans?
    a. 你们是否参与了省级实施计划的制定？
4. How were you involved in procuring HepB vaccines and syringes? Were there ever any problems with supplies/stockouts?
    a. 你们如何参与乙肝疫苗和注射器的采购？是否曾经出现过供应商方面的问题，或者断货问题？
5. Can you pls describe the training that was provided to you regarding HepB vaccination and injection safety? How did you conduct trainings for lower levels? What were some of the successes or challenges?
    a. 请你介绍一下你所接受的有关乙肝疫苗和注射安全的培训?你是如何对下级培训的？有哪些成功经验和挑战？
6. Were there concerns raised by health workers/vaccinators related to the new vaccine (contraindications, adverse events, AD syringes)?
    a. 防保人员/接种员是否提出了对新疫苗（禁忌症、不良反应、自毁型注射器）的疑问?
7. Did the prefecture/county provide funding for HepB vaccination or other immunization related activities? What types of activities or expenses were funded?
    a. 地市级/县级政府是否为乙肝疫苗接种或其他预防接种活动提供资金支持？资助了什么样的活动或开支？
        i. Can you tell us the amounts each year allocated to these activities?
            1. 你能告诉我们每年分配给这些活动的资金数额吗?
        ii. Was the amount of provincial funding required for this project more or less than what was previously allocated for immunization? Where did that budget come from?
            1. 根据项目要求配置的省级资金同之前在预防接种领域投入的资金相比，是多了还是少了？这部分预算从何而来？
        iii. Did you provide funding to support activities at lower levels?
            1. 你们是否为下级政府的活动提供资金?
        iv. Was there always sufficient funding? If not, how did that affect project implementation?
            1. 资金一直都很充沛吗？如不是，这对项目实施有何影响？

v. [For central provinces] Did you provide similar funding for non-poverty counties?
    1. [对中部省份]你们是否为非贫困县提供了同样的资金？

8. Did prefecture/county level authorities conduct supervision at lower levels? Was supervision conducted more frequently because of the HepB project, or did you include supervision on HepB as part of supervision on routine supervision? What were the results?
    a. 地市、县级机构是否会对下级机构进行监管？监管会因为乙肝疫苗项目更加频繁吗？还是你们将乙肝项目作为常规监管的一部分？结果如何？
9. Was your prefecture/county involved in the more recent activities such as the catch-up campaigns, the TBD projects, and the HIS improvements? What were the results of these activities?
    a. 你们市/县有没有参与最近的初始强化免疫、首针及时接种（TBD）项目和完善卫生信息系统项目？这些项目的结果如何？
10. What were the most challenging implementation issues?
    a. 项目实施时最大的问题与挑战是什么？
11. What were the critical factors that contributed to project success?
    a. 决定项目成功的关键因素有哪些？
12. [For central provinces] Over the course of the project, how has the provision of vaccination services differed in the poverty and non-poverty counties (procurement, training, type of syringe used, overall financial inputs)?
    a. [对中部省份]在项目过程中，预防接种服务的提供在贫困县和非贫困县之间是否有区别？（采购、培训、使用的注射器、总体资金投入）

Impact and Current Situation 影响与现况

1. How well did the prefecture/county meet the main project indicators?
    a. 你们市/县对项目主要指标的完成程度如何？
2. Did the provision of free HepB vaccine negatively affect the revenues that were generated by sales of vaccines at prefecture/county level? How did you replace these funds? Was there a negative impact on other services?
    a. 免费提供乙肝疫苗对在市/县级水平上销售疫苗的收益是否有负面影响？你们是如何补偿收益的？对其他的服务是否有负面影响？
3. Were there any challenges in the implementation of the central government policy to fund immunization services, such as delays in funding disbursement, procurement, etc?
    a. 在实施中央政府资助预防接种服务的政策中有哪些挑战，例如资金支付滞后、采购等？
4. How are immunization services funded currently? How do you obtain supplies? Are you responsible for disbursing incentives to health workers? Do you feel you have adequate resources and support to provide needed immunization services?

   a. 预防接种服务的资金现在从何而来？你们是如何获得疫苗供应的？你们是否对防保人员的奖金负责？您觉得你们是否有充足的资源提供必需的预防接种服务?

5. How does the current total prefecture/county budget for immunization compare with 2007, and 2002?
   a. 同2002和2007年分别相比，市/县级财政现在给预防接种的预算有何变化？
6. Are there still challenges with funding for childhood immunization?
   a. 儿童的预防接种是否还有资金问题？
7. Are there still challenges with injection safety in your province?
   a. 你们省是否还有注射安全方面的挑战？
8. Has this project affected government and public attitudes toward vaccination and vaccine subsidies?
   a. 这个项目是否改变了政府和公众对于预防接种和疫苗补贴的看法？
9. What do you consider the most important outcomes, and lessons from this project?
   a. 你认为从这个项目中得到的最重要的结果和经验有哪些？

Facility Staff 卫生机构的工作人员

1. Did you receive training related to HepB vaccine and injection safety? How many staff from this facility were trained? How long was the training? Did it cover all the questions about when to administer the vaccine, and potential adverse events? Did it affect your recommendation of the vaccine to your patients?
    a. 你是否接受过有关乙肝疫苗和安全注射的培训？你们机构内有多少人参加了培训？培训了多长时间？是否涵盖了有关疫苗注射和可能的不良反应的所有问题？这是否对你向患者推荐疫苗产生影响？
2. How do you get your vaccines and syringes for immunization? Are they free? Did you used to pay for them?
    a. 你是如何得到预防接种所用的疫苗和注射器的？免费的？你之前是否购买疫苗和注射器？
3. Do you use AD syringe or disposable syringe? Are they both provided to you for free?
    a. 你使用的是自毁型注射器还是一次性注射器？这两种注射器都是免费的吗？
4. During the last 10 years, did you ever experience stock outs of vaccines or AD syringe? Do you currently experience stock outs?
    a. 在过去10年中，你是否经历过疫苗或自毁型注射器断货？你们现在是否经常断货？
5. Do you currently charge any user fees to families for the Hepatitis B vaccine (for the vaccine, syringe, or administration)? How have these user fees changed over the last 10 years?
    a. 你们现在是否向接种乙肝疫苗的家庭收费（疫苗费、注射器费用、注射费）？过去10年中患者付费有何变化？
6. How did the elimination of the user fee affect acceptance of the vaccine?
    a. 取消患者付费会如何影响疫苗接种的接受程度？
7. Over the last 10 years, has your income changed because of changes in allowable user fees for immunization? Has the source of your income changed? Is your income reliable and adequate?
    a. 在过去的10年中，您的收入是否因为允许收取预防接种费用而发生改变？收入的来源是否改变？您的收入是否稳定和充足？
8. What has changed over the last 10 years to encourage higher vaccine coverage rates, particularly HepB TBD? (probe for MCH delivery of birth dose, initiative to encourage hospital delivery, etc)
    a. 过去10年中，鼓励提高接种率的方法有何改变，尤其是乙肝疫苗的首针及时接种？（提示：妇幼保健院出生婴儿注射疫苗，鼓励医院接种等）
9. Does this facility provide screening for pregnant mothers and HBIG? How much does this cost? How often are these services used?

a. 您所在的机构是否为孕妇提供筛查和乙肝免疫球蛋白？花费多少钱？使用这些服务的频率如何？

10. What challenges to high immunization coverage remain?

a. 保持高预防接种率的挑战有哪些？

Appendix I: Analysis Approach by Evaluation Question

Evaluation Question	Data Sources	Indicator (if applicable)	Analysis Methods
Relevance			
1. To what extent were the design and objectives of GAVI's support to China relevant to: • China's needs and priorities • GAVI's strategic priorities	• NIP strategy documents • MOU and Inception Report • Hepatitis B vaccine coverage and infection prevalence rates at national and subnational level • Key informant interviews with ICC members and GAVI officials	• Indications of common elements between national priorities and project objectives • Hepatitis B infection prevalence • Hepatitis B vaccine coverage rates, by province	• Triangulation of documentary evidence and key informant data on national priorities, mapped to GAVI project objectives • Trend analysis of Hepatitis B infection • Comparison of vaccine coverage rates in GAVI-supported geographic areas with other areas
Implementation/Efficiency			
2. To what extent was the project implementation plan relevant and appropriate?	• MOU and Inception Report • Annual Progress Reports • Key informant interviews • TOR and staffing for GAVI Project office • Vaccine prices over the project period	• Sufficient implementation plan in Inception Report • Effectiveness of Project office in addressing implementation problems • Engagement of subnational governments in implementation plans • Vaccine and AD syringe prices	• Triangulation of documentary evidence and key informant data to assess implementation plan, and project office effectiveness • Level of provincial government agreement to their agreed upon contributions and roles • Comparison of vaccine and AD syringe prices with international benchmarks
3. To what extent were the activities	• MOU and Inception Report	• Number of planned	• Chronology of initial timeline and all

Evaluation Question	Data Sources	Indicator (if applicable)	Analysis Methods
implemented as planned and in a timely manner?	• Annual Progress Reports	milestones met	subsequent changes, with documentation of factors affecting timeliness
4. To what extent was management appropriately adaptive in response to implementation challenges and evolving circumstances?	• ICC meeting minutes • Communications with GAVI • Key informant interviews	• Time lapsed between identification and resolution of implementation challenges	• Triangulation of documentary evidence and key informant data regarding management response to identified challenges
5. To what extent were partners and relevant groups involved in the program planning, monitoring and implementation?	• ICC and OAG meeting minutes • Key informant interviews	• Planned and expected partner contributions compared with actual contributions • Assessments of partners' strengths and weaknesses	• Triangulation of documentary evidence and key informant data to assess contributions by each of the NIP partners, compared with technical needs and documented agreements • Triangulation of key informant data regarding the effectiveness of ICC, OAG, GAVI Project Office
Effectiveness			
6. To what extent were the planned results achieved by the end of GAVI's support?	• MOU and Annual Progress Reports • HepB3 coverage rates	• Achievement of targets in amendment to MOU	• Comparison of documented outcomes with the targets in the original and revised MOU, with documentation of subnational results
7. What factors, including country factors and characteristics of GAVI's support to	• Key informant interviews • Documentation on structure of Chinese health	Not applicable	• Triangulation of documentary evidence and key informant data to identify key drivers of

Evaluation Question	Data Sources	Indicator (if applicable)	Analysis Methods
China, contributed to the overall effectiveness of the project?	system		success • Analysis of synergies between the structure of the Chinese health system and the design of GAVI support
Impact and Value-added			
8. What is the evidence of project impact?	• HepB3 coverage rates by province (and GAVI targeted counties if available) • Timely birth dose coverage rates • Data from published literature on Hepatitis B infection in China • National and provincial health budgets	• Differences in pre-post vaccine coverage rates for GAVI-supported and non-GAVI supported counties and provinces • National government budget for vaccines and immunization • Prevalence of Hepatitis B infection	• Difference-in-differences analysis of HepB3 coverage pre- and post-GAVI in western provinces and poor counties in central provinces compared with non-supported provinces and counties • Similar analysis of coverage of timely birth dose if data is available • Analysis of trends in national government budgets for vaccines and immunization • Critique of published literature and unpublished data on Hepatitis B infection rate to assess study validity and rigor, and the extent that existing studies provide strong evidence of GAVI impact
9. What was the extent of the value-added from the GAVI Alliance's support to	• Key informant interviews	• Indications of catalytic effect of GAVI Alliance • Evidence of impact of	• Triangulation of documentary evidence and key informant data to examine effect of

Evaluation Question	Data Sources	Indicator (if applicable)	Analysis Methods
China, over and above what would have been accomplished without the Alliance?		Hepatitis B project experience on decision to fund all childhood immunization	GAVI support on government and other partner commitments
10. What unintended consequences occurred as a result of GAVI support, both negative and positive?	• Key informant interviews • Coverage rates of other vaccines over the period of GAVI support • Vaccine coverage rates in non-poor counties in central provinces, if available • National health budget trends	• Changes in coverage rates of other antigens • Changes in coverage rates in non-GAVI support counties of central provinces • Changes in government funding for immunization	• Analysis of changes in coverage of other antigens, changes in coverage rates in counties not supported by GAVI, and changes in health budgets for other health programs • Triangulation of documentary evidence and key informant data to identify other unintended consequences
Sustainability			
11. To what extent are the achievements of the project sustainable from a financial and programmatic point of view?	• Key informant interviews • HepB vaccine coverage rates post-GAVI support • National health budgets	• Change in Hepatitis B vaccine coverage rates post GAVI • Change in national budgets for vaccines and AD syringes post GAVI • Change in user fee post GAVI • Change in vaccine availability post GAVI	• Analysis of trends since the end of GAVI support in: a) HepB3 and birth dose coverage rates b) government budgets for HepB vaccines and AD syringes c) user fees for HepB vaccines or AD syringes d) other changes such as vaccine availability, etc.
12. What factors have contributed to the sustainability of	• Key informant interviews • National and	Not applicable	• Triangulation of key informant data to assess the

Evaluation Question	Data Sources	Indicator (if applicable)	Analysis Methods
the results achieved?	provincial government budgets • Vaccine prices		importance of factors such as government budget availability, vaccine prices, effectiveness data, subnational commitment, etc.

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