Annual Progress Report 2007

Submitted by

The Government of

The Republic of India

Date of submission: 25th June 2008

Please note only relevant sections to the situation in India have been included in this report. Sections that do not apply to India and have been removed include: Immunization Services Support (ISS) 1.1.1-1.1.2; vaccine co-financing, Immunization Financing and Financial Sustainability table 2.2 and 2.3; and section 4 on Health System Strengthening (HSS). Relevant sections from 1.1.2 (Major activities and EPI studies) and section 1.1.4 have been moved to section 1.2.

(To be accompanied with Excel sheet as prescribed)

Please return a signed copy of the document to:
GAVI Alliance Secretariat; c/o UNICEF, Palais des Nations, 1211 Geneva 10, Switzerland.

Enquiries to: Dr Raj Kumar, rajkumar@gavialliance.org or representatives of a GAVI partner agency. **All documents and attachments must be in English or French, preferably in electronic form. These can be shared with GAVI partners, collaborators and general public.**

This report reports on activities in 2007 and specifies requests for January – December 2009

Signatures Page for ISS, INS and NVS

For the Government of **India**.....

Ministry of Health:

Title: Assistant Commissioner

Signature: .....

Date: 25/06/08

Ministry of Finance:

Title: Not required

Signature: .....

Date: .....

We, the undersigned members of the Inter-Agency Co-ordinating Committee endorse this report, including the attached excel sheet. Signature of endorsement of this document does not imply any financial (or legal) commitment on the part of the partner agencies or individuals.

Financial accountability forms an integral part of GAVI Alliance monitoring of reporting of country performance. It is based on the regular government audit requirements as detailed in the Banking form.

The ICC Members confirm that the funds received from the GAVI Funding Entity have been audited and accounted for according to standard government or partner requirements.

Name/Title	Agency/Organisation	Signature	Date
Mr. Naresh Dayal	Secretary, Ministry of Health & Family Welfare, Government of India		24.6.08
Mr. Billy Stewart	Senior Health Advisor, DFID		10.6.08
Ms. Anjali Nayar	Country Director, PATH		6.6.08
Ms. Ann Hasselbalch	Officer in Charge, UNICEF		6/6-08
Mr. Robert Clay	Director PHN,USAID	for	6-6-08
Dr. Salim Habayeb	WHO Representative to India		5.6.2008
Dr. G. N. V. Ramana	Lead Public Health Specialist, WORLD BANK		9-6-2008

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Text boxes supplied in this report are meant only to be used as guides. Please feel free to add text beyond the space provided.

1.2 GAVI Alliance New & Under-used Vaccines Support (NVS)

1.2.1 ICC meetings

How many times did the ICC meet in 2007?
Are any Civil Society Organizations members of the ICC and if yes, which ones?

The ICC in India has not been meeting regularly. However, there are several existing forums of partner coordination. These include: the National Technical Advisory Group on Immunization (NTAGI) and its subcommittees, the Norway-India Partner Initiative (NIPI), Development Partners' Meetings, and the Joint Review Mission (JRM) of the National Rural Health Mission (NRHM).

The NTAGI is a national technical working group that meets to provide technical recommendations related to immunization programs to the Government of India (GoI). The partner organizations represented on NTAGI include: UNICEF, WHO, Indian Council of Medical Research (ICMR), Immunization Basics, Path, WHO-NPSP, India Academy of Paediatrics (IAP), Indian Medical Association (IMA) & various government technical institutions, state governments and GoI. The terms of reference for the NTAGI are included in Annex 1. Apart from NTAGI, there are NTAGI sub-committees that provide recommendations on immunization issues related to specific vaccines. They report directly to the GoI. An example of the minutes from a Hepatitis B partners meeting and the last NTAGI meeting are attached in Annex 2.

The ICC reconvened in May 2008. The partners expressed the importance of regular meetings of ICC and their commitment to having an ICC in India. They urged the GoI to plan for future meetings. The recommendations from the May meeting include: the GoI should host three meetings in a year; the terms of reference should be reviewed and approved; and ICC members should be provided the opportunity to participate in various other working groups within the GoI and NRHM structure. The membership and the ICC draft terms of reference are attached in Annex 3.

1.2.2 Please report on major activities conducted to strengthen immunization, as well as problems encountered in relation to implementing your multi-year plan

The Government of India (GoI) launched the National Rural Health Mission (NRHM) in 2005. To date, it has already shown an impact on the immunization program and significant impact on the strengthening of health services. One of the goals of the NRHM is to strengthen the infrastructure and also increase the spending on health from 0.9% of the GDP in 1999 to 2-3% of the GDP by 2008-09. The strategy aims to improve resources, management capacity, accountability and state autonomy through decentralization of funds to the states. In India, the state program and operational needs are very diverse. States are required to develop project implementation plans (PIPs) and funds are released to the states based on these plans. The PIPs cover areas for strengthening the service delivery component of routine immunization. These include:

- Alternate vaccine delivery to ensure reach of immunization services into every village
- Alternate vaccinators to ensure that vaccination sessions are held on a regular basis
- Social mobilization to ensure demand within community
- Strengthening supportive supervision
- Support for POL to assist active supervision
- States and districts meet twice every year to ensure monitoring.

In 2005, under the NRHM, two significant immunization safety policy decisions were rapidly and successfully implemented by the GoI. The first decision was to introduce the use of Auto Disable (AD) syringes for all immunization programs across the country. Secondly, the GoI decided to downsize the BCG vaccine vials from a 20 dose to a 10 dose vial, respectively, in order to reduce the wastage of doses. The GoI has also made a decision to introduce vaccine vial monitors (VVMs) on all vials in the Universal Immunization Program.

The Norway-India Partnership Initiative (NIPI) is also supporting the efficient implementation of selected components of the NRHM, including immunization, in five priority states. One of the outcomes of NIPI is to sustain routine immunization coverage at 80% or above from 2007 onwards. NIPI supports strengthening immunization programme support, capacity building of vaccine logistics and cold chain systems, and VPD surveillance and outbreak response.

The GoI has also been involved in undertaking policy decisions that will have a major impact on the

immunization program in India. A DPT + Hepatitis B tetravalent vaccine combination is currently under the active consideration of the GoI. However, in April 2008, a subcommittee of the National Technical Advisory Group on Immunization (NTAGI), made an alternative recommendation for the introduction of a DPT + Hepatitis B + Hib pentavalent vaccine. The NTAGI will review the pentavalent vaccine proposal and provide official recommendations to the GoI. A decision is expected by July 2008.

More specific activities relating to strengthening infrastructure, capacity building and training, data management, injection safety and waste management are provided in Annex 4.

Please report on studies conducted regarding EPI issues during 2007 (for example, coverage surveys).

The National Family Health Survey (NFHS) and the Coverage Evaluation Survey (CES) are two large surveys that had results available in 2007. Though the results from both surveys are not comparable due to the differing methodologies, the independent results of each survey suggests an increase in immunization coverage rates in India.

The NFHS-III reported immunization coverage rates for all living children born five years preceding the survey. Thus children born in 2000 onwards were included in the states that were surveyed in 2005, and children born in 2001 onwards were included in states that were surveyed in 2006. The coverage rate for all basic immunizations completed at 12-23 months of age (BCG, DPT, measles, and Polio (excluding birth dose)) is 44%. The NFHS-III reported an increase in coverage rates from 42% the NFHS-II (98-99) and 35% in the NFHS-I (92-93). Furthermore, the percentage of children not receiving any vaccinations has decreased from 30% in NFHS-I to 14% in the NFHS-II to 5 % in the NFHS-III. Please refer to the NFHS-III report for more details*. A NFHS-III Fact Sheet is included in Annex 5.

The CES, conducted by UNICEF, was done in 2006 (with results available in 2007). The CES reported an increase in coverage rates from 55% (reported in the 2005) to 62% in 2007, for fully immunized children aged 12-23 months. India is a very large and diverse country that has varying health systems within the states. Though overall coverage rates remain low, there is a large variation in coverage rates between states. India has been successful in reporting greater than 80% coverage rates for children 12-23 months of age in fifteen states/territories reporting in the CES. Table 1 shows the distribution of states/territories' coverage rates. India is taking steps to improve coverage rates in low coverage areas through the strengthening of service delivery, information management and human resources under the NRHM.

Table 1: Distribution of coverage rates by states/territories for fully immunized children aged 12-23 months

>90%	80-89.9%	50-79.9%	<50%
5	10	11	9

For more details, please see the CES (2005) and CES (2006) in Annex 5.

*** The NFHS-III can be found at www.nfhsindia.org**

1.2.3 *Background on Hepatitis B program in India:*

With the support of GAVI Alliance, the Government of India (GoI) launched a Hepatitis B pilot project in 15 cities and 33 districts in 2003. The recommended schedule was a three dose Hepatitis B program provided at 6, 10, and 14 weeks. An optional schedule also included a three dose Hepatitis B program with a birth dose, followed by a dose at 6 and 14 weeks*.. (* Note a birth dose was provided at the time of institutional delivery, accounting for 30 % of deliveries in India in 2005.)

The objective of the pilot project was to assess the feasibility of introducing a new vaccine into the UIP. In 2007, the coverage data demonstrates a satisfactory implementation of the pilot project. The overall coverage rate for the 14 cities was approximately 60% (Note: Patna (the 15th city) did not implement the pilot phase). The coverage rates in the districts were higher at approximately 80% (See table 1.2 and 1.3 for more detail on coverage of the pilot phase by district and city).

In 2005, a proposal for Phase II was initiated, to expand the four dose monovalent Hepatitis B program to 11 states with overall high coverage rates. The 11 states to be included in phase II were Jammu & Kashmir, Himachal Pradesh, Madhya Pradesh, Chhattisgarh, Punjab, West Bengal, Andhra Pradesh, Karnataka, Tamil Nadu, Kerala and Maharashtra. Phase II was scheduled to begin in 2007. Due to various delays and consideration of implementing a combination vaccine, the approval process for Phase II to implement a four

dose monovalent Hepatitis B program in the 11 states was completed in the last week of November 2007. Some of these 11 states launched the program in December 2007 /January 2008. As of May 2008, eight states have launched Phase II. The three states that are still pending introduction of Phase II include: West Bengal, Maharashtra and Chattisgarh. These three states are ready to start Phase II, but are held up due to some state specific operational issues that are being resolved.
In 2007, the pilot project in the 15 cities and 33 districts continued. Therefore, the coverage results and activities reported in this annual report refer mainly to the pilot project and do not reflect the implementation of Phase II.
The 11 states to be covered in Phase II, do not cover 11 districts and 6 cities that were included in the pilot project. The GoI has taken the appropriate steps to continue to support the Hepatitis B program in these 11 districts and 6 cities.
Currently, a policy decision is being sought by the GoI to replace the monovalent Hepatitis B program with a combination vaccine. A DPT + Hepatitis B tetravalent vaccine combination is under active consideration by the GoI. However, in April 2008, a subcommittee of the National Technical Advisory Group on Immunization (NTAGI) made an alternative recommendation for the introduction of a DPT +Hepatitis B + Hib pentavalent vaccine. The NTAGI will review the proposal and provide official recommendations regarding the introduction of the pentavalent vaccine to the GoI. A decision will be made by July 2008. Once a decision is made, the GoI will request support from GAVI under the New Vaccine Support initiative.

1.2.4 Major activities

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

The major activities to strengthen immunization programs in India, including strengthening of services have been mentioned above in section 1.2.

More Specific activities related to the introduction of Hepatitis B vaccine include:
Approval was obtained for the implementation of Phase II in which Hepatitis B vaccine program will be expanded and implemented in all districts of 11 states.

The Government of India (GoI) is in the process of making a major policy decision regarding the implementation of a Hepatitis B tetravalent or pentavalent vaccine. In 2007, the GoI conducted a thorough review of Hepatitis B data and developed a proposal for approval to expand the Hepatitis B program through the implementation of a DPT + Hepatitis B tetravalent vaccine. The proposal includes a monovalent Hepatitis B dose at birth and three doses of the tetravalent vaccine at 6, 10, and 14 weeks. This proposal is under active consideration for approval. If approved, the estimated implementation date is last quarter of 2008. However, in April 2008, a subcommittee of NTAGI recommended the implementation of a DPT + Hepatitis B + Hib pentavalent vaccine. The NTAGI will review the pentavalent vaccine proposal and provide recommendations to the GoI. Currently a policy deliberation is being sought. A decision for a Hepatitis B tetravalent or pentavalent vaccine is expected by July 2008.

Other specific activities related to the implementation of the Hepatitis B pilot project in 2007 include:

- Operational Guidelines for the monovalent Hepatitis B program have been drafted.
- Monitoring visits were made to 3 States (Kerala, Chandigarh and Chennai) and 3 districts (Indore, Jaipur & Puduchcheri).
- The GoI has made provision in internal budget to absorb the costs for AD syringe supplies from 2007 onwards.
- The GoI has made arrangements for Hepatitis B vaccine procurement to continue in 11 districts and 6 cities included in the pilot project but not included in Phase II.

Problems encountered:
Delay in implementation in Phase II:
Implementation of phase II in 11 states with > 80% DPT 3 coverage was planned to begin in 2007. But due to various levels of approvals within GoI and the consideration to introduce a DPT + Hepatitis B tetravalent vaccine, implementation was delayed by several months. Monovalent Hepatitis B vaccine was distributed to these 11 states in first quarter of 2007, but could not be included into the program without the final approval from GoI.

Approval for Phase II was obtained in the last quarter of 2007. Implementation began in December 2007 and January 2008. The letter of approval for Phase II is attached in Annex 6.

Other more specific problems encountered include:

- Inadequate human resources at the national level to support the program and monitor the implementation of new vaccines.
- Variable program implementation capacities in different states.
- There has been variable training capacity in the 11 states prior to implementation of Phase II.

1.2.5 Receipt of new and under-used vaccines during 2007

When was the new and under-used vaccine introduced? Please include change in doses per vial and change in presentation, (e.g. DTP + HepB mono to DTP-HepB) and dates shipment were received in 2006.

Table 1: Hepatitis B vaccine supply for the year 2007 (Source: UNICEF *)

Hepatitis B vaccine	Vial size	Quantity in Doses / Boxes	Date of introduction	Date of shipment received (2007)
Pilot Project details (Phase – I) (NVS)**				
Hep B	(10 dose vials)	575,000 500,000 100,000 450,000	Introduced under Phase – I in 2003 in 33 districts and 15 cities. After introduction of Phase – II in 11 States, this pilot is now running in 17 districts/cities also.	29/01/2007 31/01/2007 31/01/2007 09/03/2007
Total Hepatitis B vaccine for Phase I		**1,625,000**		
11 States Project (Phase – II)				
Hep B	(10 dose vials)	2,768,000 5,610,400 978,000 4,432,000 5,063,000 10,728,000 2,670,280 2,192,720 2,522,500	December 2007	03/11/2006 13/12/2006 19/12/2006 20/12/2006 13,14,20 & 22/02/2007 03/03/2007 12/03/2007 22/03/2007 28/03/2007
Total Hepatitis B vaccine for Phase II		**36,964,900**		

*Source – UNICEF: Shipment of Vaccines on behalf of GAVI. (for more detail s, please see Annex – 7)
**New Vaccine Supply (NVS)

Table 1.2 Reported Hep-B Coverage in 33 districts for pilot phase, 2007**

Reported Hepatitis B Coverage of 33 Districts under GAVI Pilot *** (Data as of 31/12/2007)							
S No	**State**	**Districts**	**Target Birth Cohort**	**Hep - I**	**Hep - II**	**Hep - III**	**% Hep III**
1	Andaman & Nicobar	Andaman & Nicobar	1675	1657	1721	1748	104.36*
2	Andhra Pradesh	Vizianagaram	46897	37233	34602	35574	75.86
3	Andhra Pradesh	Chittoor	83326	74207	73223	72447	86.94
4	Assam	Jorhat	17010	12349	10791	10879	63.96
5	Assam	Sibsagar	18993	5764	5276	4981	26.22
6	Goa	Goa	23821	26478	21811	22731	95.42
7	Gujarat	Surat	66700	41498	42027	42094	63.11
8	Harayana	Panchkula	11651	10498	10186	10260	88.06
9	Harayana	Ambala	17429	15029	14456	15473	88.78
10	Himachal Pradesh	Solan	2608	2140	2277	2447	93.84
11	Himachal Pradesh	Hamirpur	8208	6096	6325	6761	82.37
12	Jammu & Kashmir	Udhampur	6340	6968	6751	6483	102.26*
13	Jammu & Kashmir	Rajouri	17739	5011	4595	4936	27.83
14	Karnataka	Mysore	44299	42849	41699	42120	95.08
15	Karnataka	Shimoga	30955	26745	27058	29195	94.32
16	Karnataka	Kodagu	8261	5811	5890	6471	78.33
17	Kerala	Ernakulam	48250	46775	46173	46787	96.97
18	Kerala	Alappuzha	17843	15463	14110	13883	77.81
19	Kerala	Pathanamthitta	1808	1349	1138	1093	60.45
20	Lakshadeep	Lakshadweep	309	242	254	262	84.79
21	Madhya Pradesh	Balaghat	34737	31354	33853	34089	98.13
22	Maharastra	Satara	46318	30128	29375	28188	60.86
23	Maharastra	Ratnagiri	14366	0	0	9194	64.00
24	Maharastra	Chandrapur	19102	0	0	18670	97.74
25	Orissa	Sundergarh	35932	9460	6927	5958	16.58
26	Pondicherry	Pondicherry	18629	13573	13346	13567	72.83
27	Punjab	Rupnagar	11268	12808	12726	12882	114.32*
28	Punjab	Hoshiarpur	27240	23882	22597	23380	85.83
29	Tamil Nadu	Ramnathapuram	0	0	0	0	
30	Tamil Nadu	Virudhu Nagar	29691	24770	25105	25038	84.33
31	Tamil Nadu	Nilgiri	10639	10825	10456	10868	102.15*
32	Tamil Nadu	Madurai	54450	44288	43559	43948	80.71
33	Uttranchal	Nainital	14052	19871	19424	19511	138.85*
		Total	**790543**	**605121**	**587731**	**621918**	**78.67**

***Source: MOHFW, GOI* (Coverage Report attached in Annex-8). Complete report not received.

******* Note: As mentioned earlier in this report, approval for Hepatitis B Phase II was provided in November 2007. Some of the 11 states launched the program in December 2007 and January 2008. Therefore coverage reports for Phase II in 2007 are not available. The pilot project continued in 2007. The coverage rates in the tables above are for the 15 cities and 33 districts.

**** Likely a result of an error in the calculation of the denominator***

Table 1.3 Reported Hepatitis B coverage for 14* cities in pilot phase, 2007**

Reported Hepatitis B Coverage of 14 Cities *under GAVI Pilot *** (Data as of 31/12/2007)**							
Sno	**State**	**Cities***	**Target Birth Cohort**	**Hep - I**	**Hep - II**	**Hep - III**	**%Hep - III**
1	Andhra Pradesh	Hyderabad	26095	25046	24930	32449	124.35*
2	Delhi	Delhi	260000	258478	199769	186165	71.60
3	Gujarat	Vadodara	30000	31091	29666	29037	96.79
4	Gujarat	Ahmedabad	43850	30061	28503	27651	63.06
5	Karnataka	Bangalore	45553	35149	30477	32182	70.65
6	Madhya Pradesh	Indore	0	0	0	0	
7	Madhya Pradesh	Bhopal	56528	45900	45936	43524	77.00
8	Maharashtra	Pune	28723	0	0	32423	112.88*
9	Maharashtra	Mumbai	223433	109865	90649	128561	57.54
10	Rajasthan	Jaipur	67132	46246	30311	27189	40.50
11	Tamil Nadu	Chennai	66000	73594	51761	52935	80.20
12	Uttar Pradesh	Lucknow	59984	21098	20201	19721	32.88
13	Uttar Pradesh	Kanpur	124425	40915	35193	31140	25.03
14	West Bengal	Kolkata	37833	20284	25806	26064	68.89
		Total	**1,069,556**	**737,727**	**613,202**	**669,041**	**62.55**

**Patna (the 15th city) did not implement the Hepatitis B pilot.*

***Source: MOHFW, GOI (see annex8 for more details). Complete report not received.*

******* Note: As mentioned earlier in this report, approval for Hepatitis B Phase II was provided in November 2007. Some of the 11 states launched the program in December 2007 and January 2008. Therefore coverage reports for Phase II in 2007 are not available. The pilot project continued in 2007. The coverage rates in the tables above are for the 15 cities and 33 districts.

**** Likely a result of an error in the calculation of the denominator***

1.2.6 Use of GAVI funding entity support for the introduction of the new vaccine

These funds were received in: _April, 2008_____

Please report on the proportion of introduction grant used, activities undertaken, and problems encountered such as delay in availability of funds for programme use.

Funds of $ 1.1 million USD were received by WHO for use by Government of India. The implementation plan is attached in Annex 9.

1.2.7 Effective Vaccine Store Management/Vaccine Management Assessment

The last Effective Vaccine Store Management (EVSM)/Vaccine Management Assessment (VMA) was conducted in __October 8-16, 2007 _____

Please summarize the major recommendations from the EVSM/VMA

The first Effective Vaccine Store Management (EVSM) in India was conducted in Karnal from the 8th to 16th October 2007, by UNICEF, in collaboration, with the Ministry of Health and Family Welfare. The lessons learned from this initial EVSM will be used to expand and conduct a larger scale EVSM in India. A standardized tool that is applicable in the Indian context will be developed.

Using the WHO-UNICEF EVSM initiative, an assessment of the Government Medical Store Depot (GMSD) Karnal was conducted. The goal was to evaluate the current status of GMSD Karnal and identify gaps that need to be addressed.

In India, four of the seven GMSDs are equipped with cold chain facilities to store and manage EPI vaccines. GMSD Karnal is responsible for receiving and distributing all routine vaccines required by 10 states; receiving and distributing all JE vaccine for India; and distributing campaign OPV.

Recommendations from the EVSM include:
1) Re-examining the role of GMSD Karnal in light of the entire planning of vaccine procurement and distribution by the MOHFW for all 4 GMSDs.
2) In order to prevent stocks from reaching nil doses, a safety stock factor is required in the planning phase.
3) A centralized online and computerized system should be set up for timely update of information.
4) The temperature sensors of the cold rooms need to be calibrated in order to protect the vaccines from unsafe temperatures.
5) All walk in freezers(WIF) and walk in coolers (WIC) require continuous monitoring and an alarm system
6) Another correctly sized walk in freezer space to support the OPV loads for campaigns is required.
7) Human resources require strengthening to support efficient and effective functioning of the GMSD.
8) The building structure needs refurbishing in order to effectively support the need for space.

A Vaccine Management Assessment (VMA) was carried out in the state of Orissa from 6-22 December 2007. It was conducted at the state, 7 regional and 12 district level cold chain stores using Standard WHO/UNICEF Format and criteria's. This was also used as an opportunity to conduct capacity building exercises for the cold chain handlers working within various capacities in the vaccine stores. Issues were identified and recommendations were made in the following categories: infrastructure, equipment and staff; practices to be introduced and maintained; capacity building; and sustaining quality. The implementation of each recommendation within each of the above categories was then prioritized based on specific timelines. The timelines ranged from immediate implementation, implementation within 3 months, 6 months, 1 year and within 2-3 years. Details of the recommendations can be found in Annex 10.

A copy of the Karnal and Orissa reports can be found in annex 10.

Was an action plan prepared following the EVSM/VMA: Yes
If so, please summarize main activities under the EVSM plan and the activities to address the recommendations.

The following actions have been initiated for improving vaccine, cold chain and logistics management:

1. A national cold chain assessment has been initiated. This includes a review of collected information, field visits to selected stores and data analysis. The report will estimate the current cold chain capacity; the major gaps in vaccine management and key recommendations.
2. A web based Management Information System (MIS) is being developed to link national, state and regional vaccine stores. The goal is to improve vaccine and logistics forecasting, tracking of vaccine flow and cold chain equipment. Eventually the plan includes interlinking MIS systems with the district level systems.

Enhancing the capacity of state immunization and cold chain officers by organizing vaccine management courses. There are two courses planned for the3rd and 4th quarter of 2008. Practical sessions on VMA tools will be incorporated.

The next EVSM/VMA will be conducted in: September 2008 in Bihar, Rajasthan and Jharkhand* *All countries will need to conduct an EVSM/VMA in the second year of new vaccine support approved under GAVI Phase 2.

1.3 Injection Safety

1.3.1 Receipt of injection safety support

One of the most effective interventions by the Government of India (GoI) has been the successful scale-up of injection safety supplies. In 2007, the GoI is providing 100% of financial support for the procurement and distribution of injection safety supplies (including AD syringes).

India received in kind AD syringes from GAVI in 2006. In 2007, India obtained in kind supplies of AD syringes to support the Hepatitis B program, under the GAVI NVS & INS which is mentioned in the table below.

Please report on receipt of injection safety support provided by the GAVI Alliance during 2007 (add rows as applicable).

*Table 1.4: Receipt of injection safety support by the GAVI Alliance, 2007**

Hepatitis B vaccine	Quantity in Doses / Boxes	Date of introduction	Date of shipment received (2007)
Pilot Project details (Phase – I) (NVS)*			
AD Syringes (0.5 ml)	523,200 475,200 400,800 98,400	Ongoing since 2003	01/01/2007
Total AD Syringes (pilot phase): 1,497,600			
11 States Project (Phase – II)			
AD Syringes (0.5 ml)	712,800 674,400 672,000 182,400 16,598,400 15,223,200 15,518,400 10,027,200	December 2007	29/03/2007 29/03/2007 07/04/2007 07/04/2007 20-27/04/07 / 12/05/2007 20-27/04/2007 / 12/05/2007 20-27/04/2007 / 12/05/2007 20-27/04/2007 / 12/05/2007
Total AD syringes for Phase II: 59,608,800			

**Source: UNICEF*

Please report on any problems encountered.

There were no problems encountered in the receipt of injection safety support from GAVI.

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

If support has ended, please report how injection safety supplies are funded.

AD syringes were introduced in India in 2005. As of 2007, the Government of India (GOI) has been providing 100% financial support for procurement and distribution of injection safety supplies. The GOI has introduced AD syringes in all existing routine immunization programs and committed to support AD syringes for all new vaccines that will be introduced into the routine immunization program. Monitoring data from Uttar Pradesh and Bihar, two of the states with the lowest coverage rates and highest populations, have shown significant increases in AD syringe use since 2006. In Uttar Pradesh, AD syringe use has increased from 91% in 2006 to 97% in 2007. In Bihar, AD syringe use has increased from 88% in 2006 to 97% in 2007.

Please report how sharps waste is being disposed of.

Since 2006, a second supply of Hub cutters has been provided for the districts by the MOHFW. Funds for waste disposal pits have been allocated by the GoI to the states for construction of waste disposal pits in

PHCs/last vaccine storage points. In 2005, India introduced waste disposal guidelines, developed by the Central Pollution Control Board.(A copy of CPCB guideline are attached in Annex 11).

Please report problems encountered during the implementation of the transitional plan for safe injection and sharps waste.

One area that requires strengthening is the inadequacies in monitoring safe disposal of sharp waste. A focal person is required at the national level to manage monitoring, evaluation and follow-up of safe injection and sharps waste plan needs to be developed, approved and implemented in order to strengthen safe injection and sharp waste. A monitoring system is planned to be fully implemented in UP and Bihar by the last quarter in 2008. The system will monitor service delivery of routine immunization sessions, including: logistics, vaccine supply, injection safety practices, and presence of ASHA, Anganwadi workers and ANMs. The existing Central Pollution Control Board (CPCB) guidelines for waste disposal are being reviewed for viability and applicability in the immunization context.

1.3.3. Statement on use of GAVI Alliance injection safety support in 2007 (if received in the form of a cash contribution)

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

GAVI alliance injection safety support received in kind.

2. Vaccine Co-financing, Immunization Financing and Financial Sustainability

Table 2.1: Overall Expenditures and Financing for Immunization

The purpose of Table 2.1 is to help GAVI understand broad trends in immunization programme expenditures and financing flows. In place of Table 2.1 an updated cMYP, updated for the reporting year would be sufficient.

Table 2.1: Overall Expenditures and Financing of Immunization

	2007	**2007**	**2008** ŧ	**2009§**
All costs are in INR	Actual*	Planned*	Planned*	Planned
Expenditures by Category				N/A
Vaccines**	1,508,600,000	1,605,000,000	1,380,000,000	N/A
Injection supplies	833,700,000	795,000,000	900,000,000	N/A
Cold Chain equipment	38,300,000	200,000,000	500,000,000	N/A
Operational costs	1,267,900,000	1,250,000,000	1,500,000,000	N/A
Other (please specify) Hepatitis B	201, 900,000	300,000,000	3,350,000,000	N/A
Other: Research	3,700,000	7,000,000	20,000,000	N/A
Financing by Source				N/A
Government (incl. WB loans)ŦŦ	3,652,200,000	3,857,000,000	4,300,000,000	N/A
GAVI Fund ŧ	201,900,000	300,000,000	3,350,000,000	N/A
UNICEF***				N/A
WHO***				N/A
Other (please specify) Norway-India Partner Initiative (NIPI)***				N/A
				N/A
Total Expenditure	**3,854,100,000**	**4,157,000,000**	**7,650,000,000**	N/A
Total Financing	**3,854,100,000**	**4,157,000,000**	**7,650,000,000**	N/A
Total Funding Gaps				N/A

* all costs are in INR. The costs are based on GoI financial year April to March

** This cost includes the cost of the birth dose of Hepatitis B vaccine (funded by the GoI). These costs do not include Polio vaccine.

*** Unicef, WHO and NIPI provide funding for cold chain implementation; training; and/or operational costs. These funding sources have not been included here.

ŦŦ The GoI funds the birth dose of Hepatitis B

Ŧ In 2008, the GoI is actively considering the implementation of a tetravalent vaccine (Hepatitis B + DPT). The cost estimates reflect the monovalent Hepatitis B vaccine program and the cost of the tetravalent vaccine (if implementation is recommended by the GoI).

§ the 2009 cost estimates are not available

Please describe trends in immunization expenditures and financing for the reporting year, such as differences between planned versus actual expenditures, financing and gaps. Give details on the reasons for the reported trends and describe the financial sustainability prospects for the immunization program over the coming three years; whether the funding gaps are manageable, a challenge, or alarming. If either of the latter two, explain what strategies are being pursued to address the gaps and what are the sources of the gaps growing expenditures in certain budget lines, loss of sources of funding, a combination.

To date, the GoI have purchased all the vaccines under the UIP. GAVI has provided 100% financial support for the introduction of Hepatitis B in the Pilot Phase I and Phase II.

NOTE: The application to GAVI to which this annual progress report pertains was not made under the co financing mechanism, hence Tables 2.2 and 2.3 are not applicable.

Table 2.2: Country Co-Financing (in US$)

Table 2.2 is designed to help understand country level co-financing of GAVI awarded vaccines. If your country has been awarded more than one new vaccine please complete a separate table for each new vaccine being co-financed.

For 1st GAVI awarded vaccine. Please specify which vaccine (ex: DTP-Hep B)	**2007**	**2007**	**2008**	**2009**
	Actual	Planned	Planned	Planned
Co-financing amount (in US$ per dose)				
Government				
Other sources (please specify)				
Total Co-Financing (US$ per dose)				

Please describe and explain the past and future trends in co-financing levels for the 1st GAVI awarded vaccine.

For 2nd GAVI awarded vaccine. Please specify which vaccine (ex: DTP-HepB)	**2007**	**2007**	**2008**	**2009**
	Actual	Planned	Planned	Planned
Co-financing amount (in US$ per dose)				
Government				
Other sources (please specify)				
Total Co-Financing (US$ per dose)				

Please describe and explain the past and future trends in co-financing levels for the 2nd GAVI awarded vaccine.

Not Applicable

Table 2.3: Country Co-Financing (in US$)

The purpose of Table 2.3 is to understand the country-level processes related to integration of co-financing requirements into national planning and budgeting.

Q. 1: What mechanisms are currently used by the Ministry of Health in your country for procuring EPI vaccines?			
	Tick for Yes	List Relevant Vaccines	Sources of Funds
Government Procurement- International Competitive Bidding			
Government Procurement- Other			
UNICEF			
PAHO Revolving Fund			
Donations			
Other (specify)			

Q. 2: How have the proposed payment schedules and actual schedules differed in the reporting year?		
Schedule of Co-Financing Payments	Proposed Payment Schedule	Date of Actual Payments Made in 2007
	(month/year)	(day/month)
1st Awarded Vaccine (specify)		
2nd Awarded Vaccine (specify)		
3rd Awarded Vaccine (specify)		

Q. 3: Have the co-financing requirements been incorporated into the following national planning and budgeting systems?	
	Enter Yes or N/A if not applicable
Budget line item for vaccine purchasing	
National health sector plan	
National health budget	
Medium-term expenditure framework	
SWAp	
cMYP Cost & Financing Analysis	
Annual immunization plan	
Other	

Q. 4: What factors have slowed and/or hindered mobilization of resources for vaccine co-financing?
1.
2.
3.
4.
5.

3. Request for new and under-used vaccines for year 2009

*Section 3 is related to the request for new and under-used vaccines and injection safety for **2009**.*

3.1. Up-dated immunization targets

Confirm/update basic data approved with country application: figures are expected to be consistent with those reported in the WHO/UNICEF Joint Reporting Forms. Any changes and/or discrepancies **MUST** be justified in the space provided. Targets for future years **MUST** be provided.

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

At this time, India seeks vaccine support for Phase II Hepatitis B program which covers 11 states in the country. A policy decision is currently under review to expand the Hepatitis B program by replacing the monovalent Hepatitis B program with a combination vaccine. A DPT + Hepatitis B tetravalent vaccine combination is under active consideration by the GoI. However, in April 2008, a subcommittee of the National Technical Advisory Group on Immunization (NTAGI) recommended the introduction of a DPT + Hepatitis B + Hib pentavalent vaccine. The NTAGI will review the proposal and provide official recommendations to the GoI. A decision will be made by July 2008. Once a decision is made, the GoI will request support from GAVI under the New Vaccine Support initiative.

Table 5: Update of immunization achievements and annual targets. Provide figures as reported in the JRF in 2007 and projections from 2008 onwards.

Number of	Achievements and targets									
	2006 (source-JRF2006)	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
DENOMINATORS										
Births	25.98	27.36	27.84	28.32	28.81	29.32	29.83	30.35	30.88	31.42
Infants' deaths		1.59	1.62	1.65	1.68	1.71	1.74	0.03	1.80	1.84
Surviving infants		25.77	26.21	26.67	27.13	27.32	28.08	30.32	29.07	29.58
Infants vaccinated till 2007 (JRF) / to be vaccinated in 2008 and beyond with **1st dose** of DTP (DTP1)*	NA	JRF 2007 is under finalization.#Assumption of Calculations	26.21	26.67	27.13	27.32	28.08	30.32	29.07	29.58
Infants vaccinated till 2007 (JRF) / to be vaccinated in 2008 and beyond with 3rd **dose** of DTP (DTP3)*	24.29	25.77	26.21	26.67	27.13	27.32	28.08	30.32	29.07	29.58
NEW VACCINES **										
Infants vaccinated till 2007 (JRF) / to be vaccinated in 2008 and beyond with **1st dose** of * Hep B			11.04	11.22	11.54					
Infants vaccinated till 2007 (JRF) / to be vaccinated in 2008 and beyond with 3rd **dose** of *Hep B*			11.04	11.22	11.54					
Wastage rate till 2007 and plan for 2008 beyond*** *(new vaccine)*	25	20	20	20	20					
INJECTION SAFETY****										
Pregnant women vaccinated / to be vaccinated with TT	30.02	30.10	30.18	30.26	30.34	30.42	30.50	30.58	30.66	30.74
Infants vaccinated / to be vaccinated with BCG	27.02	27.09	27.16	27.23	27.31	27.38	27.45	27.52	27.60	27.67
Infants vaccinated / to be vaccinated with Measles (1st dose)	27.02	27.09	27.16	27.23	27.31	27.38	27.45	27.52	27.60	27.67

* Indicate actual number of children vaccinated in past years and updated targets (with either DTP alone or combined)
** Use 3 rows (as indicated under the heading **NEW VACCINES**) for every new vaccine introduced
*** Indicate actual wastage rate obtained in past years
**** Insert any row as necessary

 # Assumptions for Calculation:

ESTIMATED BENEFICIERS FOR IMMUNIZATION AND CHILD HEALTH PROGRAMME 2007-08

Source : E&I data

Infants : Based on estimated population projections adjusted with Census 2001 and calculated
Population = Population 2007(1+NGR/100)^ n; where n=(current year- 2007)
*Live Births= Population*CBR/1000*
*Infants = Live Birth-(Live Births*IMR)/1000*

3.2 Confirmed/Revised request for new vaccine *(to be shared with UNICEF Supply Division)* for 2009

In case you are changing the presentation of the vaccine, or increasing your request; please indicate below if UNICEF Supply Division has assured the availability of the new quantity/presentation of supply.

Hep B requirement for 11 States for 2009

27.3 million of Monovalent Hep B vaccine (6 months requirement) were received from UNICEF for Hepatitis B vaccination Programme in 11 States.

Out of the total supply of Hepatitis B vaccine received 19.5 million doses were released to the States and 7.8 million are in balance with Government Medical Store Depots (GMSDs). Taking into consideration average monthly consumption in these States it is likely that the available stock would last up to July 2008. We seek 6 months requirement of Monovalent Hep B vaccine which is about 27.3 million doses for continuation of vaccination.

The requirement as mentioned above may change, as a policy decision is being sought by the GoI to replace the monovalent Hepatitis B program with a combination vaccine. A DPT + Hepatitis B tetravalent vaccine combination is under active consideration by the GoI. However, in April 2008, a subcommittee of the National Technical Advisory Group on Immunization (NTAGI) recommended the introduction of a DPT + Hepatitis B + Hib pentavalent vaccine. The NTAGI will review the proposal and provide official recommendations to the GoI. A decision will be made by July 2008. Once a decision is made, the GoI will request support from GAVI under the New Vaccine Support initiative.

Monovalent Hep B Vaccine requirement for 11 States (PHASE II), 2009 and 2010**

		Formula	2009**	2010**
A	Target children for Hep B Vaccination for *11 states (see table below)*	#	11.22	11.54
B	Number of doses per child	3	3	3
C	Number of ….doses	A x B	34	35
D	AD syringes (+10% wastage)	C x 1.11	This requirement will be born by GOI.	
E	AD syringes buffer stock (*2*)	D x 0.25		
F	Total AD syringes	D + E		
G	Number of doses per vial	#	10	10
H	Vaccine wastage factor (*3*)	Either 2 or 1.6	1.33	1.33
I	Number of reconstitution syringes (+10% wastage) (4)	C x H X 1.11/G		
J	Number of safety boxes (+10% of extra need)	(F + I) x 1.11/100		

1 Contribute to a maximum of 2 doses for Pregnant Women (estimated as total births)

2 The buffer stock for vaccines and AD syringes is set at 25%. This is added to the first stock of doses required to introduce the vaccination in any given geographic area.

3 Standard wastage factor will be used for calculation of reconstitution syringes. It will be 2 for BCG, 1.6 for measles and YF

4 Only for lyophilized vaccines. Write zero for other vaccines.

** Note: These projections are based on the assumption that the GoI is only providing a three dose monovalent Hepatitis B vaccine. A DPT + Hepatitis B tetravalent vaccine combination is under active consideration by the GoI. Alternatively, in April 2008, a subcommittee of the National Technical Advisory Group on Immunization (NTAGI) recommended the introduction of a DPT + Hepatitis B + Hib pentavalent vaccine. The NTAGI will review the proposal and provide official recommendations to the GoI. A decision will be made by July 2008. Once a decision is made, the GoI will request support from GAVI under the New Vaccine Support initiative.

Note:

- Assumption of calculations (#) is the same as provided in table above.
- Vaccine requirement based on the figures provided above including wastage factor of 1.33 and 25 % buffer stock for the first year.

Vaccine Requirements for 2009 and 2010 in India**

Year	Doses in million
2009**	133.55*
2010**	108.90

**Note: Considering that introduction of Pentavalent vaccine is being proposed throughout the country, the number of doses of Pentavalent Vaccine required for 2009 is 133.55 million* and for the year 2010 is 108.90 million.
*Note: This includes 25% buffer

.

Remarks

- **Phasing:** Please adjust estimates of target number of children to receive new vaccines, if a phased introduction is intended. If targets for hep B3 and Hib3 differ from DTP3, explanation of the difference should be provided
- **Wastage of vaccines:** Countries are expected to plan for a maximum of 50% wastage rate for a lyophilized vaccine in 10 or 20-dose vial; 25% for a liquid vaccine in a10 or 20-dose vial; 10% for any vaccine (either liquid or lyophilized) in a 2-dose vial, 5% for any vaccine in 1 dose vial liquid.
- **Buffer stock:** The buffer stock is recalculated every year as 25% the current vaccine requirement
- **Anticipated vaccines in stock at start of year 2009:** It is calculated by counting the current balance of vaccines in stock, including the balance of buffer stock. Write zero if all vaccines supplied for the current year (including the buffer stock) are expected to be consumed before the start of next year. Countries with very low or no vaccines in stock must provide an explanation of the use of the vaccines.
- **AD syringes:** A wastage factor of 1.11 is applied to the total number of vaccine doses requested from the Fund, excluding the wastage of vaccines.
- **Reconstitution syringes:** it applies only for lyophilized vaccines. Write zero for other vaccines.
- **Safety boxes:** A multiplying factor of 1.11 is applied to safety boxes to cater for areas where one box will be used for less than 100 syringes.

Table 7: Wastage rates and factors

Vaccine wastage rate	5%	10%	15%	20%	25%	30%	35%	40%	45%	50%	55%	60%
Equivalent wastage factor	1.05	1.11	1.18	1.25	1.33	1.43	1.54	1.67	1.82	2.00	2.22	2.50

3 Confirmed/revised request for injection safety support for the year 2009

Not Applicable: No support is sought under injection safety support for year 2009.

Table 8: Estimated supplies for safety of vaccination for the next two years with …… *(Use one table for each vaccine BCG, DTP, measles and TT, and number them from 8a, 8b, 8c, etc. Please use same targets as in Table 5)*

		Formula	2009	2010
A	Target if children for ….. Vaccination (for TT: target of pregnant women) *(1)*	#		
B	Number of doses per child (for TT: target of pregnant women)	#		
C	Number of ….doses	A x B		
D	AD syringes (+10% wastage)	C x 1.11		
E	AD syringes buffer stock *(2)*	D x 0.25		
F	Total AD syringes	D + E		
G	Number of doses per vial	#		
H	Vaccine wastage factor *(3)*	Either 2 or 1.6		
I	Number of reconstitution syringes (+10% wastage) (4)	C x H X 1.11/G		
J	Number of safety boxes (+10% of extra need)	(F + I) x 1.11/100		

1 Contribute to a maximum of 2 doses for Pregnant Women (estimated as total births)

2 The buffer stock for vaccines and AD syringes is set at 25%. This is added to the first stock of doses required to introduce the vaccination in any given geographic area.

3 Standard wastage factor will be used for calculation of reconstitution syringes. It will be 2 for BCG, 1.6 for measles and YF

4 Only for lyophilized vaccines. Write zero for other vaccines.

If quantity of current request differs from the GAVI letter of approval, please present the justification for that difference.

5. Checklist

Checklist of completed form:

Form Requirement:	Completed	Comments
Date of submission		
Reporting Period (consistent with previous calendar year)	January to December 2007	
Government signatures	X	Please see page 2
ICC endorsed	X	Please see page 2
ISS reported on	Not applicable	
DQA reported on	Not applicable	
Reported on use of Vaccine introduction grant	Not applicable	
Injection Safety Reported on	X	Please see section 1.3
Immunisation Financing & Sustainability Reported on (progress against country IF&S indicators)	Not applicable	
New Vaccine Request including co-financing completed and Excel sheet attached	X	Please see section 2 and 3
Revised request for injection safety completed (where applicable)	Not applicable	
HSS reported on	Not applicable	
ICC minutes attached to the report	X	Attached in Annex 3
HSCC minutes, audit report of account for HSS funds and annual health sector evaluation report attached to report	Not applicable	

6. Comments

ICC/HSCC comments:

One ICC members' summarized the progress of the NRHM (in relation to routine immunization in India) and provided anecdotal evidence to support areas that require improvement.
NRHM has provided various inputs in the program however it is time to do an assessment of these inputs vis a vis their impact on coverage. Some examples from field observations are:

1) Alternate vaccine delivery (AVD) to ensure delivery of vaccine to session site and collect the reports and unused vaccine/injection waste on the same day:
    a. It is not implemented in the same concept as it was conceptualized.
    b. It has become an extra source of income to a health worker in most states
    c. At many places is not functioning optimally due to untimely/irregular fund flow , it is only followed during Immunization Weeks in some states
    d. No-funds/unclear guidelines at few places
    e. Difficult to find porters/vehicles at present cost
    f. Still vaccines & reports returned on next day
2) Alternate Vaccinators to ensure sessions are held:
    a. States have not been able to identify and employ these alternate vaccinators.
    b. They don't have plans for missed sessions.
    c. Record for organized missed sessions not available.
3) Social Mobilization to ensure demand creation in community:
    a. Canvassing pressure led to wrong selection of ASHAs' at few places.
    b. No guidelines to remove non performing ASHA.
    c. At few places ASHA are not working due to non payment.
    d. Guidelines not clear about many payments to ASHA.
    e. Monetary Commission being asked to utilize untied funds
4) Strengthening Supportive supervision: Although funds have been provided to State & District level officers for Supervision however this is probably the weakest link in the entire system.
    a. There is gross understaffing of managers/supervisors
    b. The Program managers (PM) are not aware about supportive supervision.
    c. There is a delay in sending the guidelines for supervision from the center

    d. No records are available with the Program managers regarding their supervisory visits.
5) National level review of the immunization program with states: This is very important and needs to be on regular basis at least bi-annually. However at present this is not at the desired frequency.
6) Support for POL to assist active supervision:
    a. Some Program Managers have expressed that the funds provided are not sufficient. This needs to be reviewed
7) Auto Disable syringes to ensure injection safety: AD syringes are available in the field however we need to understand that providing only the syringes do not solve the issue of injection safety. There are various issues which need to be addressed like
    a. Supply of mixing syringes grossly inadequate
    b. Disposal guidelines not clear/difficult to follow
    c. Hypochlorite sol. not being used for disinfection
    d. Hub cutters have got non functional
    e. Pits not constructed or got filled/blocked
    f. Officials have not received disposal guidelines
8) Vaccine management: The central Government needs to address this issue urgently by putting in place a system and personnel's for forecasting, procurement, monitoring of vaccine and logistic supplies. Today many parts of the country are facing shortages or stock outs of vaccines (especially TT etc). There are other issues like
    a. Vaccine vans not used to distribute vaccine to block
    b. Supply to district/block is 'on-push' basis
    c. Officials not aware of buffer stock at district/block
    d. Actual estimation of requirement not followed
    e. Varying degree of stock piles & stock outs at blocks
9) Cold Chain: The Government needs to upgrade/replace the existing cold chain equipment. In view of introduction of new vaccines (DPT-HepB or Pentavalent) the cold chain requirement will increase and issues such as given below need to be addressed urgently
    a. There is no designated person for maintaining cold chain at many places; this is being handled by class IV employees, LHV/ANM who are not trained to handle the cold chain resulting in wastage of vaccines at many places.
    b. No record of inventory or repairs
    c. No Assistant to Immunization officer (Cold chain handler) for support during RI days
    d. Maintenance fund inadequate/irrationally distributed. POL Generator funds not made available for routine immunization
10) Improve data management: The use of RIMS as envisaged still not there. It was meant to get regular, timely information & provide feedback to States/districts however, more than half of the districts are not using the software to even upload the data. Hardly any PM is using the software to provide feedback to subordinates.

Last but not the least there are no plans at any level to address the issue of 11.5 Million un-immunized/partially immunized children in the country. This becomes more relevant when we are moving towards introducing newer and more expensive vaccines into the system. ICC should address this issue and as given above all partners including Government should develop joint plans to address this issue at the earliest.

~ End ~