

SUBJECT:	ALLIANCE PARTNERSHIP STRATEGY WITH INDIA, 2016-2021
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Section A: Overview

1. Executive Summary

- 1.1 At its December 2014 meeting, the Board requested the Secretariat to develop a comprehensive strategy for Alliance engagement with India, given the country's forthcoming transition out of Gavi support. This report presents the strategy guided by principles endorsed by the Programme and Policy Committee (PPC) (Annex B), and recommendations by the PPC at its October 2015 meeting, for decisions by the Board.
- 1.2 With almost 27 million children born each year, India is the most populous Gavi-eligible country. Although India still accounts for one-fifth of child deaths worldwide and more than a quarter of all under-immunised children in Gavi-eligible countries, it has made tremendous progress in reducing child mortality and has more than halved child deaths since 1990. India was certified polio-free in 2014, and maternal and neonatal tetanus was eliminated in 2015.
- 1.3 India remains eligible for Gavi support based on its GNI level. Yet, given the large birth cohort of the country, Gavi has limited its support to catalytic funding to India. Until 2011, there was a cap placed on Gavi support to India, which was removed with the condition that the Board continues to review any new support case by case. Because of this approach, Gavi commitments to India have been considerably lower, in proportion to the country's size, compared to Gavi support for other eligible countries. This is notable as compared to other large countries like Pakistan and Nigeria, which have similar or higher levels of gross national income. India is much lower in terms of absolute level of overall investments by Gavi, despite its much larger birth cohort. In terms of Gavi investment per child, India ranks as 72nd out of the Gavi73 countries given commitments to date.



- India has now been increasingly focusing its efforts on hard to reach 1.4 populations through evidence-based strategies. 'Mission Indradhanush' is one of the latest initiatives to intensify routine immunisation in 200 low coverage districts of the country. India has also struggled with strong antivaccine lobbies which have attempted to block introduction of new lifesaving vaccines in their public health programme, the Universal Immunisation Programme (UIP). As a result, India was the second-to-last country in Gavi's portfolio to introduce pentavalent vaccine. There is now a positive political environment for immunisation seeking to address inequities in access to immunisation as well as introduce new vaccines, including rotavirus, pneumococcal, rubella and human papillomavirus (HPV) vaccines. As the long-term financial implications of introduction of all the new vaccines have not been planned for in its current planning cycle¹, these introductions will likely be delayed without catalytic external support. India is now projected to cross Gavi's income eligibility threshold in 2017 and will transition out of Gavi support by 2021. Now is an opportune time for Gavi to build on this momentum and support India to maximise health impact through catalytic funding.
- 1.5 The Secretariat has had extensive discussions with the Government of India and partners to set joint priorities and align on areas of strategic partnership, based on the government's long-term vision for immunisation and Gavi's added value. The Secretariat proposes a strategic partnership to maximise the benefits for both India and Gavi: 1) Increase immunisation coverage and equity in India through targeted support to strengthen the routine immunisation system; 2) maximise health impact by accelerating adoption of new vaccines in India; 3) maximise procurement savings and vaccine supply security by sharing information, coordinating tactics and building a long-term strategy that strengthens local public and private sector manufacturers; and 4) ensure that vaccine programmes in India will be sustainable beyond 2021 by supporting the government to plan for the transition and advocating for increased domestic financing of immunisation.
- 1.6 This strategy presents aligned areas of partnership between Gavi and India, and a recommendation from the PPC of up to US\$ 500 million of investment, after deliberations on a range of financial and impact scenarios (Annex D). The Audit and Finance Committee has subsequently confirmed that sufficient funding is available. With this amount, Gavi has the potential to avert 440-860 thousand future deaths, about half of which would fall within 2016-2020, thereby increasing Gavi's impact goal of 5-6 million deaths averted in the strategy period by 5-8%. Collaborating with India on procurement and supply of vaccines has the potential to save Gavi and countries US\$ 100 million to US\$ 300 million and the government US\$ 100 million over the 2016-2020 time frame. The PPC emphasised the catalytic nature of support for four vaccines in India to maximise public health impact and the value of a strategic partnership. They also recommended next steps to articulate the commitments of both Gavi and the Government of India.

¹ Government's current five-year plan is from 2013-2017.



1.7 The PPC recommendations have been discussed with the Government of India. The Health Minister has responded with a letter welcoming the strategic partnership and future catalytic support from Gavi, but requested the Gavi Board to consider a higher allocation and additional years of support (Annex E). The Minister also indicated that the government would sustain and continue scale-up of the programmes once Gavi support ends.

2. Recommendations

- 2.1 The Programme and Policy Committee recommends to the Board that it:
 - (a) <u>Approve</u> the Gavi strategic partnership with India (the "India Partnership Strategy ") on a time-limited and catalytic basis as set out in Section 5 of Doc 08², including an indicative allocation of vaccines and cash support in Option 2 of Table 1 of Annex D to Doc 08³ for a total estimated amount of up to US\$ 500 million, using available resources from the Gavi 2016-2020 strategy period.
 - (b) <u>**Request**</u> the Secretariat to enter into a memorandum of intent or an appropriate equivalent with the Government of India ("Gol") to implement the India Partnership Strategy setting out:
 - i. a final allocation of vaccines and cash support;
 - key principles of Gavi support (to the extent these differ from the Partnership Framework Agreement) including milestones for the India Partnership Strategy, focus on equity and a framework for the Gol to provide regular updates;
 - iii. the process governing the application and approval process for vaccine and cash support for the Gol;
 - iv. commitments from the GoI to fund the balance of the costs of the relevant campaign(s) and/or introduction(s) and to sustain the programme(s) following the introduction(s).
 - (c) Recognising the importance of manufacturers based in India and the critically important role of the Government of India ("Gol") in the procurement of vaccines for India's children, successful collaboration around vaccine supply and procurement between Gavi and the Gol should contribute to enhance supply security and a sustainable supply base to maximise procurement outcomes for Gavi and the Gol: **request** that the Gavi Secretariat and partners invite Gol to explore together how to share information and plan supply and procurement for vaccines in the Gol and Gavi portfolios and explore potential coordination to maximise the sustainability and affordability of vaccines with an initial report back to the PPC in October 2016 and to the Board in December 2016.

² Section 5 of this paper to the Board reflects Section 5 of Doc 09 to the PPC (available for consultation on myGavi) and takes into account discussion at the PPC meeting on 7-8 October ³ This range of investment options was presented in Table 1 of Doc 09 to the PPC (used as a basis in the PPC recommendation)



(d) <u>**Request**</u> the Secretariat to provide regular updates and a formal update in 2018 on the progress of the India Partnership Strategy to be considered by the PPC and the Board, as appropriate.

Section B: Content

3. Immunisation in India and Gavi's critical role in accelerating greater achievements of health impact

- 3.1 With a birth cohort of 27 million children born each year, India accounts for one third of children born in Gavi-eligible countries. While India has made substantial progress in reducing the number of under-5 deaths, it is still the highest in the world (1.3 million in 2013, 20% of the global total). The gravity of the problem varies significantly among states and areas of residence⁴.
- 3.2 Vaccine-preventable diseases are a key cause of mortality and morbidity. India has ~20% of pneumococcal, rotavirus and measles deaths worldwide, 25% of cervical cancer deaths, and 38% of the global congenital rubella syndrome (CRS) burden in terms of cases⁵.
- 3.3 Under India's Universal Immunisation Programme, vaccination is currently provided to prevent DTP (diphtheria, pertussis, tetanus), polio, measles, severe forms of childhood tuberculosis, hepatitis B (HepB), haemophilus influenzae type B (Hib) infections, and Japanese encephalitis (in selected districts).
- 3.4 Gavi provided catalytic support to accelerate the introduction of HepB, pentavalent and inactivated polio (IPV) vaccines, as well as safe injection devices (INS) and on HSS⁶. Under an exemption to the Alliance's co-financing policy, Gavi provides time-bound support and the government pays for introduction costs and related immunisation commodities, taking on full self-financing for vaccines or devices after Gavi support ends (Fig. 1).

⁴ Annex C of the partnership strategy paper to the PPC (7-8 October 2015) contains further information from the MDG India country report 2014 with selected child mortality indicators.

⁵ Source: WHO for pneumococcal and rotavirus deaths. WHO Weekly Epidemiologic Record, 2014, 89, 509-516 for measles deaths. CDC modelling for CRS cases. See Annex C for further information on disease burden.

⁶ Pentavalent: DTP-HepB and Hib combination vaccine. IPV funding through the Global Polio Eradication Initiative. Annex F of the PPC paper contains further information on Gavi's support to India to date.



Fig 1. Gavi support to India to date, with programmes sustained/to be sustained by the Government of India (US\$ millions)



* Projected based on current price assumptions; subject to change with future procurement conditions

3.5 Though the UIP has been operating for more than 30 years, only 65% of children receive all vaccines during vear. 7 their first While WHO/UNICEF coverage estimates for India were revised upward this vear (from 72% to 83% DTP3 coverage),⁸ India is still the country with the largest number of un- or under-vaccinated children in the world, at 4.1 million in 2014 (Figure 2). Vaccination coverage varies significantly among geographies (Figure 3). Some of India's states



are among the largest and poorest in Gavi's portfolio. Uttar Pradesh, for example, is larger than every Gavi-eligible country except Nigeria, has gross national income per capita of only US \$422, and has a DTP3 coverage of only ~60%. Coverage also varies depending on gender, area of residence, wealth and caste ⁹. Operational challenges in demand generation, cold chain and logistics management, and other areas hinder progress (see Section 5.3).

^{7 &}quot;Fully immunised children" are defined in India as children aged between 12-23 months who have received BCG, three doses of DTP, three doses of OPV, and two doses of measles vaccines.

⁸ WUENIC dataset was retrospectively revised for all vaccines based on extrapolation from data reported by the national government.

⁹ cMYP 2013-2017. Reference to Joseph L Mathew (2012): "Inequity in Childhood Immunization in India: A Systematic Review," Indian Pediatrics, Volume 69, March 16, 2012. Annex E of the PPC paper contains further information on coverage and equity performance.





Figure 3. Percent of Fully Immunized Children (FIC)⁶ in large Indian states¹⁰

- 3.6 The recent years have marked a turning point for the UIP. India's polio-free certification in 2014 and its elimination of maternal and neonatal tetanus in 2015 are landmark achievements. The political environment for immunisation is also particularly strong now. The prime minister's public announcement in July 2014 of the introduction of four new vaccines (IPV, rotavirus, rubella and Japanese encephalitis)¹¹ demonstrated renewed commitment. In August 2015, the National Technical Advisory Group on Immunisation (NTAGI) recommended the introduction of pneumococcal vaccine. This is an exciting moment as India has only introduced two new vaccines nationwide since the 1980s (HepB/pentavalent vaccines).
- 3.7 In December 2014, the government launched the world's largest immunisation drive, "Mission Indradhanush", aimed at increasing immunisation coverage to more than 90% by 2020 by targeting districts that have the most unvaccinated or partially vaccinated children. Initial results are encouraging: 2 million children were fully immunised in the first four rounds of the mission.¹²
- 3.8 Mission Indradhanush builds on new approaches that are implemented through Gavi's catalytic HSS grant. The US\$ 107 million grant focuses on 12 underperforming states.¹³ An innovative pilot electronic information system to manage vaccine logistics is being scaled up in three states.¹⁴

¹⁰ 2011 India Census Survey, Indian Annual Health Survey 2012-2013, Indian District Level Household Survey 2012-2013.

¹¹ Japanese encephalitis vaccine has been provided to children in endemic districts, but was newly introduced to target adults in selected districts.

¹² Annex E of the PPC paper contains further information on the Government's efforts to advance immunisation coverage and equity.

¹³ A subset of the 18 National Health Mission priority states with low immunisation coverage.

¹⁴ Involves a mobile- and web-based technology that allows real-time management of stock and enables health workers to better manage their supply chains. Preliminary data from pilot districts of the new technology showed a <1% stockout rate at the primary health care level in less than 14 months, and a



Regular supportive supervision of cold chain points has been initiated at primary care level, and state-level communication plans have been created. The experience and expertise gained in the vast polio infrastructure is being applied to routine immunisation, contributing to India's goal of universal coverage.

- 3.9 The government has also increased resources over the years and demonstrated a good track record of sustaining and scaling up catalytic support from external resources.
 - (a) Building on Gavi support for HepB and safe injection devices, the government has not only sustained but also scaled up and universalised their use across the country.
 - (b) The government has taken on the full cost of all laboratory support for acute flaccid paralysis (AFP) and measles surveillance from WHO since 2012, expanding the network and enhancing laboratory capacity.
 - (c) Gavi HSS funds have been used by the government in collaboration with UNICEF to establish the national cold chain vaccine management resource centre (NCCVMRC), which is fast becoming the national hub for cold chain training, innovation and data systems. While HSS funds supported the one-time equipment cost, the recurring operational costs including human resources are fully financed by the government, contributing to about 70% of total expenditure.
 - (d) While the catalytic HSS grant supported state and district level train-thetrainer sessions in selected low-performing states, the government has borne all costs of sub-district level trainings of front-line workers. The government has also replicated and scaled up behavioural change interventions pioneered through the HSS support across all targeted districts in the country for its Mission Indradhanush initiative.
 - (e) Transition planning for the Gavi-supported pentavalent and IPV vaccine programmes are under way. The government held a first-of-its-kind meeting with manufacturers to discuss long-term forecasts for all vaccines. Product specification for pentavalent and IPV vaccines have been sent to the government's procurement division to initiate nationwide procurement after Gavi support ends in 2016.

A critical time to act

3.10 According to the revised transition policy recently approved by the Board, India is projected to cross the Gavi eligibility threshold in 2017, at the same time all current support for pentavalent vaccine, IPV and health system strengthening is expected to end.

reduction in response time to address stockouts by 62%. Symposium on Computing for Development (ACM DEV) 2014: <u>https://app.box.com/s/97o422cw1i503096moa4m3hqbhojf16a</u>



3.11 While India remains a Gavi-eligible country, future support needs to be approved by the Board since India has always been treated as an exception because of its size. The Board capped funding to India until 2011 and continues to review any new support case by case. Because of this approach, Gavi commitments to India have been considerably lower, in proportion to the country's size, than support for other eligible countries (Figure 4). This is notable especially as compared to other large countries like Pakistan and Nigeria, which have similar or higher levels of gross national income.

Figure 4. Gavi commitments since inception by country population (in births per year)



3.12 With the significant momentum in UIP and strong political environment in India, the time is now ripe for Gavi to build on its strategic partnership with India to achieve and sustain greater health impact. Otherwise, without Alliance support, the progress on universal coverage and new vaccine introductions could be delayed, resulting in missed opportunities for immunisation.

4. The importance of India as a manufacturing base

- 4.1 Vaccine manufacturers in India are a key source of supply for Gavi. In 2014 they provided nearly 60% of vaccine volume, representing just over 30% of the total value of procurement. A single Indian manufacturer supplied 100% of measles-rubella (MR) and meningococcal A (MenA) conjugate vaccines and 80% of measles vaccine, while four manufacturers supplied over 80% of pentavalent vaccine.
- 4.2 Vaccine demand in India could reach nearly 30% of total demand in the 73 Gavi countries. The resulting significant increase in market volumes presents both risk and opportunity. It could disrupt supply of important



vaccines if coordination is insufficient. If the increase is managed well, however, it will allow optimisation of production costs and procurement savings.

- 4.3 Indian manufacturers' contribution to Gavi will grow as vaccines now in the pipeline are prequalified. For the five vaccines with the highest total cost for Gavi, nearly all long-term competition will include Indian suppliers. In addition, publically held manufacturers (Public Sector Undertakings or PSUs) will contribute to the supply of vaccines for use domestically and could eventually enter export markets. It is important that the Alliance engage effectively with all manufacturers to strategically increase the supply base and enhance supply security for India, Gavi and other low income countries.
- 4.4 India has struggled with access to high-quality cold chain equipment (CCE) so it could benefit from Alliance support and a stronger domestic supply base. There is a nascent manufacturing base of optimal CCE to meet the needs of the expanded UIP. At least one manufacturer will be producing equipment that qualifies for procurement through Gavi's CCE optimisation platform. The potential for additional manufacturers to supply both local and global markets with optimal CCE should be explored.

5. Strategies and objectives

- 5.1 A strengthened partnership in the coming years offers considerable benefits for both India and Gavi. Our vision is that between 2016 and 2021, Gavi's targeted support will accelerate India's efforts to introduce new vaccines and achieve universal immunisation coverage. Millions more children will be immunised by several vaccines in Gavi's portfolio, increasing the number of future deaths averted with Gavi support by at least half a million¹⁵. India will reach a position where it can sustain a self-financed, multi-faceted and equitable immunisation programme. Gavi and India will both benefit by capitalising on procurement savings and enhancing vaccine supply security, while forging a collaborative, learning-based relationship.
- 5.2 To realise this vision, we propose a comprehensive, multi-pronged strategic Alliance partnership with India. The strategy builds on the principles endorsed by the PPC at its May 2015 meeting (Annex B), it takes India's priorities and Gavi's added value into consideration, and envisages timebound, catalytic support:

1) Increase immunisation coverage and equity in India through targeted support to strengthen the routine immunisation system.

2) Maximise health impact by accelerating adoption of new vaccines in India.

¹⁵ Magnitude of impact will be driven by funding to be approved by the Gavi board.



3) Maximise procurement savings and vaccine supply security by sharing information, coordinating tactics and building a long-term strategy that strengthens local public and private sector manufacturers.

4) Ensure that vaccine programmes in India will be sustainable beyond 2021 by supporting the government to plan for the transition and advocating for increased domestic spending on immunisation.

5.3 **The coverage and equity opportunity**

- (a) India has already made significant progress in defining a coverage and equity agenda and investing significant resources in launching Mission Indradhanush. Nevertheless, there remains scope to capitalize on the strong commitment by identifying specific areas where increased support could improve effectiveness of coverage and equity interventions. India also presents the opportunity for generating and leveraging new, innovative approaches to coverage and equity with potential relevance domestically and further abroad. Maintaining momentum, fostering innovation, and ensuring sustainable and equitable coverage will be the focus of our future efforts, which will further be refined and elaborated in the coming 6-12 months.
- (b) Based on discussions with the government and Alliance partners to date, a number of key obstacles in the routine immunisation system have been identified:
 - i. Generating demand can be difficult. Routine house-to-house monitoring indicates that on average, 60% of the children missed for immunisation are missed because their families lack awareness of the benefits of immunisation or fear adverse events following immunisation (AEFI).
 - ii. Cold chain and logistics management requires urgent attention. In an Effective Vaccine Management (EVM) assessment in 2013, twothirds of indicator scores were below 60%^{16.} Cold chain capacity assessment in 2014 showed a significant gap in equipment and human resources capacity. Of particular significance is the insufficient number of cold chain points, which limits access to immunisation in remote places.
 - iii. Microplanning, monitoring, data management and disease surveillance are all important aspects of the health system. While capacity building in these areas has been undertaken, it needs to be expedited as several vaccine introductions are due to take place soon.

¹⁶ EVM scores across all levels were below 80%, a level WHO deems as satisfactory performance.



- (c) The current HSS support is already targeting some of the above areas, but the implementation period of this grant is only three years. Further support in the transition period, informed by the forthcoming mid-term and end-of-grant reviews, will be required while domestic resources are being secured to scale up the new approaches. In the absence of such support, the aims of strengthening the health system could be left unrealised, just as India is stepping up efforts to introduce new vaccines.
- (d) While the precise nature of support will be detailed once the Board has approved a funding allocation, these are some potential new areas within which Gavi can look to invest, based on preliminary discussions with the country¹⁷:
 - i. Cold chain and logistics management: The cold chain equipment (CCE) optimisation platform recently approved by the Gavi board offers an exciting, synergistic opportunity. To meet CCE capacity requirements of all the new vaccines, India currently faces a significant gap with a need to replace equipment and rationalise distribution across geographies (totalling over US\$ 450 million in the next five years)¹⁸. The government also wants to pursue a "Make in India" initiative to bridge the technology gap. By providing access to the new CCE platform, Gavi will enable India to access better technologies at competitive prices. Gavi can catalyse development of a strong domestic supply base, accelerate innovation and secure procurements savings over the long term. Cold chain and vaccine logistics management information systems integration presents another opportunity. Future areas of support will be guided by the newly finalised National Cold Chain and Vaccine Logistics Action Plan.
 - ii. Demand generation: Future efforts can include capacity building on media management and sensitisation of frontline workers on AEFI management and communication guidelines, and use of innovations for real-time monitoring and analysis. Civil society organisation (CSO) engagement¹⁹ should also be strengthened to leverage the polio mobiliser network to focus on routine immunisation.
 - iii. Vaccine preventable diseases (VPD) surveillance: The availability of quality surveillance data for VPDs is currently limited in India. With WHO support, India would like to increase VPD surveillance activities in a phased manner through 2020 by expanding field and sentinel sites surveillance and the laboratory network.

 ¹⁷ Annex G of the PPC paper contains further analyses supporting routine immunisation strengthening.
¹⁸ Source: UNICEF India Country Office

¹⁹ Under an umbrella grant to the Gavi CSO constituency, Gavi supported the launch in December 2013 of the Alliance for Immunisation of India (Aii), which has grown to include about 180 CSOs, with state chapters in Bihar, Jharkhand, Rajasthan and Uttar Pradesh. Aii is now also represented in the Immunisation Action Group, India's equivalent to the immunisation coordination committees in other countries.



(e) Areas of focus for future partnership will be informed by a mid-term review of Gavi's HSS grant and India's new comprehensive multi-year plan for immunisation (cMYP) for 2018-2022 (both of which are expected to be available in the first quarter of 2016), and further discussions to advance the coverage and equity agenda. With the US\$ 500 million recommended allocation by the PPC, future cash support will make up ~US\$ 100 million for the five-year transition period. Once the Board approves a resource allocation, Alliance partners will work with the Government of India to develop a detailed proposal with targets and indicators and ensure that future Gavi support further addresses coverage inequity issues in the country.

5.4 The new vaccines opportunity

- (a) With the positive political environment, India has an ambition to eliminate measles, introduce rubella (as part of MR vaccine), rotavirus, and pneumococcal vaccines in 2016-2017, and potentially HPV vaccine at a later time during the transition period. Rollouts of these vaccines are at different stages of planning given the status of recommendations from the National Technical Advisory Group on Immunisation (NTAGI) and political approvals for each vaccine²⁰.
- (b) Financial resource availability, however, is a constraint for UIP. Domestic budgets for UIP have not been secured for 2017 and beyond. Full rollout of these vaccines at the national scale could cost at least an additional US\$ 600 million annually (15 times the cost of traditional vaccines currently borne by the government)²¹. Without external support, India would very likely slow down the scale-up of these vaccines until further domestic resources are secured or potential new entries into the suppliers market bring down the price of some of the vaccines. Gavi support will play an important role in accelerating roll-out of new vaccines, which would be critical to argue for allocation of more domestic resources in the next national 5-year Plan and cMYP (2018 2022).
- (c) As part of the discussions on this strategy, the government requested commodity support from Gavi on four vaccines: rotavirus, pneumococcal, MR and HPV vaccines. The PPC was presented a range of investment options (Annex D). After deliberations, the PPC recommended providing funding to catalyse rollout of all four vaccines, given the public health impact potential (Table 1) and unique opportunities in engaging in each of the vaccines:

²⁰ In India, recommendations from the NTAGI for new vaccine introduction have to be approved by Ministry of Health and Family Welfare first, followed by the Mission Steering Group (MSG) of the National Health Mission before implementation. Currently, MR and rotavirus vaccine introductions have been approved by the MSG. PCV received NTAGI recommendation in August 2015. HPV has not been through the NTAGI process, and planning and introduction is subject to the approval through the institutional process and clearance of a litigation case surrounding a study.

²¹ Estimates using current vaccine price assumptions



	Estimated mortality/cases	% of total global burden		
Rotavirus disease	~100,000 deaths	~22%		
Pneumococcal disease	~140,000 deaths	~19%		
Measles	~28,000 deaths	~19%		
Congenital Rubella Syndrome	~36,000 cases	~38%		
Cervical cancer	~70,000 deaths	~25%		

Table 1. Disease burden in India and share of global burden²²

- i. **Rotavirus vaccine**: To date, India has only budgeted a small pilot introduction in <10% of the birth cohort in 2016. Scale-up can be accelerated with Gavi support in 2017, without which the government may delay rollout for at least two to three years until further resources are secured in the next planning cycle. From a market shaping perspective, an expanded market in India could help to increase and stabilise global supply by bringing manufacturers into the market.
- ii. **Pneumococcal vaccine**: Gavi support can accelerate vaccine introduction to as early as 2017. Without Gavi support, the government may delay introduction for the foreseeable future (until after 2020). From a market shaping perspective, the increased demand from India could help to optimise manufacturers' production costs and generate procurement cost savings for Gavi.
- iii. MR vaccine: With Gavi support, rubella vaccine will be introduced as part of a large-scale MR campaign targeting 390 million children, contributing to reduction in measles, rubella and CRS burden. Although the primary objective of Gavi's engagement in measles and rubella is disease control, this investment will also help India advance towards its commitment to the South East Asia Region's mandate of control of rubella and CRS and elimination of measles by 2020.
- iv. **HPV vaccine**: HPV vaccine is not included in India's current 2013-2017 plan but may be considered in the next planning period, subject to NTAGI recommendation and political approval. As the anti-vaccine movements against HPV vaccine are particularly active in country, Gavi support on advocacy in the near-term to ensure evidence-based dialogue would be particularly important to pave the way for vaccine introduction.
- (d) With the US\$ 500 million recommended investments by the PPC, vaccine support will make up ~US\$ 400 million, with indicative allocations as shown in Table 2.

²² See Annex C with further disease burden information



Table 2. Indicative vaccine allocations as discussed with the Government of India, given the PPC-recommended amount for the period 2016-2021*

	Scope of support**	Est. number of children immunised (mil)	Vaccine cost (\$ mil)
Rotavirus			
(routine)	~20% cohort for 3 years	15	~\$80
Pneumococcal			
(PCV) (routine)	~20% cohort for 3 years	15	~\$180
MR (campaign)	2 out of 4 phases	170	~\$110
HPV (routine)***	~15% cohort for 1 year	2	~\$30

* Financial and vaccine rollout (target population and duration) projections are approximates and are subject to change on the basis of technical expert group recommendations on phased rollout by state, vaccine prices and wastage assumptions. Flexibility to be built into operationalising these allocations upon Board approval. ** Rotavirus and PCV: Target birth cohort (26m); MR: Target 9 months to 15 years for a 4-phase campaign over 3 years (390m); HPV: Target single-age cohort (~12m), equivalent to 3% of 9-13 year-old girls (74m) indicated in the PPC paper.

*** Tentative assumptions for HPV given that the vaccine introduction has not been recommended by NTAGI.

- (e) The Government of India is committing to cover all other costs of the programmes at the time of introduction (i.e. forgoing ~US\$ 130 million of combined vaccine introduction grants, campaign operational support and injection devices support that a Gavi-eligible country would have received), and to sustain and continue scale-up of these programmes after Gavi support ends (which may cost over US\$ 600 million annually at national scale)²³. The remaining phases of MR campaign would require domestic funding of an estimated >US\$ 140 million, if Gavi supports half of the campaign as indicated in Table 2.
- (f) With the PPC-recommended US\$ 500 million support, Gavi has the potential to avert an additional 440-860 thousand future deaths, about half of which would fall within 2016-2020, thereby increasing Gavi's impact goal of 5-6 million deaths averted in the strategy period by 5-8%. Gavi support will not be limited to commodity cost support, but will also involve Alliance partners to provide technical assistance on new vaccine introductions. Meticulous planning and implementation is key to success in phasing the rollout of new vaccines, taking into account many factors including disease mortality, systems strength including safety surveillance capacities, and programmatic readiness by state.

²³ \$130m estimated combined vaccine introduction grants, campaign operational support and device support based on current policy and scale of support with the PPC-recommended \$500m; \$600m/year estimated cost of the four vaccine programmes at national scale based on current vaccine price assumptions.



(g) Support for advocacy efforts to counter anti-vaccine movements in India also needs to be heightened, as media reactions in India can hamper progress not only locally but also globally. Advocates against Hib, polio and more recently HPV and rotavirus vaccines have gained media and political attention (and in some cases involve public interest litigations), and are a persistent risk. With our convening power in mobilising international experts and access to global scientific evidence, Gavi can help India ensure an evidence-based dialogue on new vaccines.

5.5 **The market-shaping opportunity**

- (a) The strategic partnership between Gavi and the Government of India offers opportunities to optimise both short- and long-term vaccine supply security, to capture procurement cost savings based on the increased demand, and to share information and best practices on managing vaccine markets effectively. Each vaccine market will require a specific approach. The markets with the greatest opportunities today for procurement savings are pentavalent and pneumococcal. While other markets, such as IPV, MR and rotavirus, have limited scope for procurement cost savings, these markets will require close coordination with regard to supply. Building a strong local base of private and public vaccines and cold chain equipment that complements the global availability will be beneficial across the whole portfolio. Benefits of a wellexecuted partnership will extend beyond Gavi and India to include low income countries that are dependent on a reliable supply of low cost and high quality vaccines and cold-chain equipment.
- (b) Implementing a combination of strategies could generate procurement savings of US\$ 100 million to US\$ 300 million for Gavi and countries from 2016 to 2020, and could allow India to realise savings of up to US\$ 100 million over current plans. The order of magnitude of these potential savings therefore deserves attention, but the actual level of savings depends on several factors, including the ability to commence coordination immediately given the procurement timelines for the vaccines in scope. The value of these opportunities to Gavi should be considered as an important benefit that could reduce the total financial burden of increased investment in India.



- (c) The Secretariat will facilitate discussions between Alliance partners and India on actions aimed at achieving procurement savings while meeting the needs of manufacturers. Several mechanisms, including volume guarantees and financial incentives, can be deployed to maximise vaccine procurement savings, based on specific market circumstances. For all potential procurement opportunities, considerations such as the equitable prioritisation of supply in case of shortages, pricing, delivery terms and choice of procurement agencies will all need to be addressed. Since India and Gavi will procure from an overlapping set of manufacturers, these opportunities could be implemented directly with manufacturers. Because of the commercially sensitive nature of the actions required to achieve these outcomes, full details will not be outlined in this paper.²⁴
- (d) Alliance partners have gained significant knowledge and experience in effectively managing large, complex vaccine markets. The availability of lower cost vaccines for lower income countries has been increased using tools such as demand forecasting, bespoke procurement methods, manufacturer relationships and a deep understanding of global vaccine markets, including pipeline vaccines. Our market-shaping successes have been secured by improving communication and transparency between stakeholders, including industry, procurers and countries. Gavi should establish a more consistent dialogue with India to share information and methodologies in these areas, with the aim of allowing manufacturers to more readily meet the needs of all low income countries.
- (e) Vaccine supply security depends on a diverse base of manufacturers capable of producing sufficient volumes of quality vaccines. The magnitude of potential demand from introductions in India could itself destabilise global supply of some vaccines, thus introductions done under partnership carry a reduced risk of short-term supply disruptions. Gavi and India should work together to manage the impact of a rapid increase in demand on the supply base, to ensure sufficient supply in situations where vaccines are sourced from a small number of common manufacturers. Gavi and Alliance partners could also partner with India on initiatives to help local vaccine manufacturers increase vaccine security domestically, support local research and development across public and private companies, facilitate technology transfer and access and support the government's efforts to prioritise domestic industry development.

²⁴ Annex H of the PPC paper contains further details and analyses by vaccine.



(f) The initiation of the Cold Chain Equipment (CCE) Platform has begun Gavi's role in CCE market shaping. While the manufacturing industry for optimal CCE in India is nascent, the potential for it to support not only local but also export markets is important. With the incentives provided in the platform, India should explore not only improvements in its cold chain capacity but also the role of local industry in supplying optimal equipment locally as well as globally.

5.6 Ensuring sustainable programming

- (a) India has a successful track record in continuing the HepB and INS programmes with its domestic resources after Gavi support ended. The government has also indicated in writing to the Gavi Secretariat its commitment to sustain and further scale up rotavirus, pneumococcal and HPV programmes and self-finance MR routine immunisation after future catalytic support ends. However, given the magnitude of increase in resources expected with the launch of new vaccines (two to ten-fold increase by 2021 from the current ~US\$ 40 million per year on vaccine costs only ²⁵), Gavi engagement with India to ensure successful transitioning is critical.
- (b) Alliance advocacy for political commitment to increase health spending, including immunisation, is paramount. A Political Forum on Child Health & Survival which includes selected Members of Parliament was recently formed in 2012. This new structure serves as a forum for political and public discourse around the need for high-quality, cost-effective public health interventions, including vaccines. As fiscal devolution continues in India, state level advocacy will become even more important. Gavi engagement in the form of senior leadership advocacy and support via communication and advocacy agencies will help drive evidence-based policy discussions at both the national and state levels to achieve a higher prioritisation for health issues.
- (c) Intensified efforts to ensure financial and also programmatic sustainability would be key in the coming years. Gavi will initiate broader engagement with the government and convene relevant partners to support transition preparedness. A clear plan for each vaccine including start and end of Gavi support, budget incorporation into the government's new five-year plan, and timing of the procurement process will be laid out. Bottleneck analysis will be conducted as part of the new cMYP and HSS grant development, to ensure that the key capabilities are built for long-term programmatic sustainability. An Alliance advocacy plan to sustain political advocacy for immunisation should be developed. Evolving approaches and tools developed at the global level as part of Gavi's strategic focus area on sustainability will be leveraged in the India context.

²⁵ Current vaccine cost is sourced from the Annual Progress Report 2014. Magnitude of increase is dependent on the scale of rollout of each new vaccine in 2016-2021, and the projected prices.



Section C: Financial implications, and risk implication and mitigation

6. Financial implications

- 6.1 The PPC deliberated on a range of financial options ranging from \$300 million to US\$1 billion with a mix of vaccines and scope of support and the associated health impact (Annex D), and recommended a total estimated amount of up to US\$ 500 million for the period 2016-2021, using available resources from the Gavi 2016-2020 strategy period. As rotavirus, pneumococcal and MR vaccine introductions and any future HSS grant could all start as early as 2016/2017, funding is expected to be front-loaded and covered in the 2016–2020 period. Timing of support for HPV vaccine is most tentative and associated funding of <US\$ 30 million may fall into the next strategy period.
- 6.2 The US\$ 500 million is inclusive of the US\$ 220 million of vaccine funding that is already budgeted for India; therefore, incremental investment beyond the current forecast is US\$ 280 million. By 2018, we recommend an update to the PPC on resource commitments within the approved allocation, based on submitted applications to Gavi, vaccine rollout plans, vaccine presentation choice and associated projected prices and wastage assumptions. Also, India's next five year national plan and cMYP (2018–2022) will be available by then with a firm commitment for resources to sustain immunisation.
- 6.3 Procurement savings potential: Implementing a combination of strategies could generate savings ranging from US\$ 100 million to US\$ 300 million for Gavi from 2016 to 2020 and could allow the government to realise savings of up to US\$ 100 million over current plans. Actual savings will depend on several factors, including the need for immediate coordination.

7. Risk implication and mitigation

- 7.1 If no additional Gavi resources are made available to support the immunisation programme in India, nationwide rollouts of rotavirus, pneumococcal, rubella and HPV vaccines could be delayed for a few years or potentially substantially longer until domestic resources are secured. This would result in a missed opportunity to avert 30 thousand rotavirus deaths, 10-60 thousand pneumococcal deaths, 6-8 thousand rubella deaths, and 110-180 thousand cervical cancer deaths per year of delay²⁶. Currently supported HSS efforts could be left unfinished or new interventions to address coverage and equity challenges may not be implemented. This would also damage the Gavi-India partnership, jeopardising collaboration on market shaping.
- 7.2 The strong anti-vaccine lobbies in India have the potential to delay introduction of new life-saving vaccines. Gavi's convening power in mobilising international experts, access to global scientific evidence and

²⁶ Range of estimates used for impact metrics: ~1, 1-3, ~0.3, and 10-15 deaths per 1000 vaccinated for rotavirus, pneumococcal, rubella and HPV vaccines respectively. See Annex I.



increased support on advocacy to ensure an evidence-based dialogue on new vaccines would help counter these anti-vaccine movements.

- 7.3 Previous experience with HepB and pentavalent vaccines has shown risks of delayed implementation of new vaccines in India, even with Gavi support. To mitigate these risks, clear milestones will be developed as part of the new vaccines and HSS proposal development process. Implementing partners and the Gavi Secretariat will focus efforts on planning and monitoring, and ensure that the implementation plans are conducted in a timely manner.
- 7.4 Failure to coordinate and share information on procurement strategies and vaccine supply security could jeopardise savings opportunities and increase the chances of global supply disruptions. The Gavi Secretariat will coordinate greater communication and coordination with India on managing the supply and procurement of vaccines and cold chain equipment.
- 7.5 Failure by India to continue rollout of the new vaccines after Gavi support ends is a risk to successful transition. The strategy on ensuring sustainable programming highlights the importance of continued advocacy for increased health expenditure from all development partners at the highest levels. As India develops its next five-year plan, Gavi needs to ensure that it reflects ambitious but realistic plans and required resources for UIP expansion. Implementing partners also need to ensure that Gavi HSS efforts are part of the overall strengthening plan and that the activities are reflected in the annual Project Implementation Plans (PIPs) for the relevant states for sustainability.
 - (a) Specifically for rubella vaccine, WHO recommends achieving and sustaining 80% of coverage through routine immunisation and/or campaigns once the vaccine is introduced, to mitigate the potential of a paradoxical effect of increased Congenital Rubella Syndrome (CRS). For measles, a higher vaccine coverage is needed to prevent outbreaks, and periodic follow-up campaigns are needed. Once MR vaccine is introduced, SAGE recommends that follow-up campaigns are also conducted using the MR vaccine. In this regard, consistent with the new measles rubella strategy that was reviewed by the PPC in October 2015, we recommend that India includes the necessary follow-up campaigns and ensure availability of budget in its long-term planning, and raise routine immunisation coverage in districts and states where coverage is <80% (however, these would not be funded by Gavi).</p>

Section D: Implications

8. Impact on countries

8.1 Gavi's catalytic support will help India achieve greater and more equitable coverage, and accelerate rollout of new vaccines. With the PPC-recommended US\$ 500 million support, Gavi has the potential to avert an additional 440-860 thousand future deaths, about half of which would fall



within 2016-2020, thereby increasing Gavi's impact goal of 5-6 million deaths averted in the strategy period by 5-8%.

- 8.2 Opportunities also exist to share learning from India (e.g. piloted interventions to advance coverage and equity agenda, vaccine study results), to enhance effectiveness of implementation or policy decision-making in other countries.
- 8.3 Partnering with the Government of India on managing supply and taking advantage of collective demand to seek procurement cost savings could benefit low income countries, including Gavi countries, by increasing supply security and by lowering costs.

9. Impact on Gavi stakeholders

- 9.1 Alliance partnership is key to success in implementing this strategy. At the country level, a core group of partners in immunisation including the Immunisation Technical Support Unit, WHO, UNICEF, UNDP, the Bill and Melinda Gates Foundation, and CSOs play complementary roles in supporting decision-making, planning and implementation. USAID contributes to wider maternal, newborn, child and adolescent health efforts, including immunisation. DFID supports broader HSS efforts. The expansion of immunisation services in the coming years would demand tighter collaboration among all partners. Regional and global alliance partners will also have a vital role in providing technical assistance to implement the strategy once approved. Resources from Gavi partners, specifically the Bill and Melinda Gates Foundation, will be required to successfully implement the recommended market-shaping activities. These resources will be used to carry out the partnership activities described.
- 9.2 Continued advocacy by senior leadership at partner organisations will be critical to ensure political commitment to immunisation.

10. Impact on Secretariat

- 10.1 On approval of the Alliance partnership strategy, the Secretariat will work with the Government of India and partners to lay out a joint plan of action and operationalise the strategy. Efforts will continue to manage grant implementation and negotiate any flexibilities on policy implementation as required given the size and complexity of the country.
- 10.2 Resources above those budgeted for 2016 and beyond from the marketshaping team will be required to successfully implement the recommended activities. The resources will be used to carry out the partnership activities as described above that are currently not in scope or resourced through the market shaping team.

11. Legal and governance implications

11.1 Subject to Board approval:



- (a) in respect of the coverage and equity opportunity and the new vaccines opportunity, appropriate legal and grant arrangements will be made with partner organisations, the Government of India and, if applicable, CSOs to implement the strategic partnership;
- (b) for the implementation of the market-shaping opportunity, appropriate legal arrangements will be put in place; and
- (c) in 2018, the Secretariat will provide an update on the progress of the strategic partnership to be considered by the PPC and the Board, as appropriate.

12. Consultation

12.1 This report results from extensive collaboration and consultation with the Government of India and in-country partners, to ensure alignment on the details of future collaboration. A global group of advisors with representation from Alliance partner agencies was also consulted to guide the strategy development process and content (Annex A).

13. Gender implications

13.1 India's current cMYP and previous coverage evaluation surveys noted inequities in vaccination coverage according to gender and other social determinants. Gavi funding will be directed towards interventions that address specific gender, socio-economic and other inequities in vaccination. Support for HPV vaccine in particular will help address cervical cancer, which is the leading cause of cancer among women in India.

Section E: Annexes

- Annex A: Acknowledgements and consultation
- Annex B: Programme and Policy Committee (PPC) endorsed principles for the partnership strategy with India
- Annex C: Disease burden in India relative to other countries
- Annex D: Range of financial and impact options presented to the PPC
- Annex E: Letter from the Minister of Health to Gavi CEO, in response to communication around the PPC recommendations



Annex A: Acknowledgements and consultation

The authors thank the Ministry of Health and Family Affairs of India (including Immunisation Technical Support Unit) as well as Alliance partner organisations (WHO, UNICEF, UNDP, BMGF, USAID, DFID, CSOs) for discussions and written inputs on future areas of partnership to inform the development of this strategy.

We also thank the global advisory group for guiding the development of this strategy:

- WHO: Thomas Cherian
- UNICEF: Satish Gupta
- World Bank: Robert Oelrichs
- Bill and Melinda Gates Foundation: Violaine Mitchell
- DFID: Jason Lane
- USAID: Susan McKinney
- Civil Society Organisation constituency: Naveen Thacker



Annex B: Programme and Policy Committee (PPC) endorsed principles for the partnership strategy with India

At its May 2015 meeting, PPC endorsed the following principles that underlie the Alliance engagement with India:

- Gavi support should be based on a comprehensive strategy, including efforts to improve coverage and equity, new vaccine support and market shaping.
- The support should continue to be catalytic with clear plans for India to transition to full financing by final graduation.
- The strategy should balance addressing India's current priorities with ensuring Gavi support adds value. It should focus on "win-win" opportunities including areas where India and the Alliance may have common objectives.
- Gavi's engagement should be holistic, combining financial support with political engagement, technical support and public advocacy to secure improved immunisation outcomes, and not merely a financial package.
- Gavi should not define a fixed envelope of potential support for India before better understanding the Government's priorities, reviewing potential options and impact.
- In order to maximise potential impact, Gavi should remain flexible on the timing of this support as long as it is part of the strategy approved by the Board and fully expended prior to India's graduation date.



Annex C: Disease burden in India relative to other countries

Based on 2012 WHO estimates, neonatal causes account for 52% of under-five mortality in India, followed by pneumonia (15%), diarrhoeal disease (11%), measles (3%) and others. The public health burden of rubella, including subsequent deafness and blindness, is only starting to be realized, with an estimated >36,000 cases of congenital rubella syndrome (CRS) occurred annually in India²⁷. Cervical cancer, mainly caused by Human Papillomavirus (HPV) infection, is a leading cause of cancer among women in India, taking the lives of 70,000 women each year²⁸.

Rotavirus disease Number and percent of global total child rotavirus deaths by country (2008): global total=453,000



Pneumococcal disease: Number and percent of global total child pneumococcal deaths by country (2000): global total=753,000



²⁷ 2008 estimate, US Centers for Disease Control and Prevention

²⁸ GLOBOCAN estimates 2012





Measles: Number and percent of global total child measles deaths (2013):

Congenital Rubella Syndrome, CRS: Estimated incidence worldwide (2010)





Cervical cancer: Estimated mortality worldwide (2012)



Annex D: Range of financial and impact options presented to the PPC

At its October 2015 meeting, the PPC was presented and deliberated on a range of financial investment options with illustrated resource requirements based on different scopes of support for rotavirus, pneumococcal, MR and HPV vaccines. The high-end scenario represents the government's request for vaccine commodity and HSS support. The low-end scenario illustrates potential scope of support given the \$220 million of vaccine funding that is already budgeted for India.

Option	(1) <\$300m*	(2) ~\$500m	(3) ~\$650m	(4) ~\$800m	(5) \$1,000m (Country Request)**
No. of vaccines supported	two	four	four	four	four
Rotavirus (routine)	20% cohort for	20% cohort for 3 years	25% cohort for 3 years	25% cohort for 3 years	25% cohort for 5 years
Pneumococc al (PCV) (routine)	3 years for rota, <u>or</u> 2 years for PCV	20% cohort for 3 years	25% cohort for 3 years	25% cohort for 3 years	25% cohort for 5 years
MR (campaign)	2 out of 4 phases	2 out of 4 phases	2 out of 4 phases	All 4 phases	All 4 phases
HPV (routine)		15% cohort for 1 year***	30% cohort for 1 year***	30% cohort for 1 year***	30% cohort for 1 year***
Cash support	<\$100m	~\$100m	~\$100m	~\$100m	~\$150-200m

Table 1: Financial investment options with indicative vaccine and cash allocations

* Defined as a minimum scope of support for rotavirus, pneumococcal and MR vaccines in order for Gavi support to be at a sufficient scale to demonstrate impact and assure predictability of funding, and incentivise the government to continue scale-up.

** \$1-1.1 billion given the range in cash support.

*** Very tentative assumptions for HPV given that the vaccine introduction has not been recommended by NTAGI. 15/30% of a single-age cohort (~12m) is equivalent to the <5% of 9-13 year-old girls (74m) originally indicated in the PPC paper.

To inform PPC deliberations, impact and cost-effectiveness analyses were conducted with different combinations of vaccines in the investment options.

- Gavi's impact numbers include direct financing (i.e. Gavi's contribution to country impact where Gavi provides direct financial support for a vaccine) and catalytic support (Gavi's contribution to country impact where Gavi does not provide direct support, but where it still has a catalytic effect.)
- The forecasted impact numbers rely on the latest available estimates of population size, disease burden, forecasted introduction dates, and assumptions of scale-up in coverage. All of these data points have levels of uncertainty associated with them, which in turn leads to high levels of uncertainty around the projected estimates of Gavi impact.





Health impact considerations by investment option²⁹

	(1) <\$300m		(2) ~\$500m	(3) ~\$650m	(4) ~\$800m	(5) ~\$1,000m
	(MR/rota)	(MR/PCV)				
Future deaths averted ('000s)*	510 300	<u>250</u>	860 440			- 1270 - 650

While there are some limitations to the analysis, with wide uncertainty ranges around country-specific estimates, the analyses showed that directionally, higher investments would yield higher impact. Given the ranges around the impact figures, cost effectiveness measures also have associated uncertainty ranges, which overlap across the scenarios.

²⁹ Annex I of the PPC paper contains further information on the impact and cost effectiveness analyses



Annex E: Letter from the Minister of Health to Gavi CEO, in response to communication around the PPC recommendations



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The Ministry also welcomes the decision of Gavi PPC on endorsing future collaboration plans for vaccine security, mutually discussed between Gavi officials and the Government of India. However, an enhanced support against our request for approxs. US \$ 1 billion may kindly be taken up in the upcoming meeting of the Gavi Board.

With regards,

Yours sincerely,

199602

(Jagat Prakash Nadda)

Mr. Seth Berkley M.D. Chief Executive Officer Gavi – The Vaccine Alliance 1202 Geneva Switzerland