



Report to the GAVI Alliance Board

12-13 June 2012

Subject:	Vaccine introduction grants and operational support for campaigns
Report of:	Nina Schwalbe, Managing Director, Policy & Performance
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Agenda item:	13
Category:	For Decision
Strategic goal:	SG1 - Underused and new vaccines

Section A: Overview

1. Purpose of the report

- 1.1 This report presents the recommended revisions to GAVI's vaccine introduction grant policy and GAVI's operational support for campaigns, including proposed levels of support and their financial implications. The Programme and Policy Committee (PPC) endorsed the policy to the Board in its meeting on 23-24 April 2012.

2. Recommendations

- 2.1 The PPC recommends that the GAVI Alliance Board:

- **Approve** the GAVI vaccine introduction grant and operational support for campaigns policy (the "**Policy**"), as described in Annex 1 of Doc 13;
- **Request** the Secretariat to make the necessary arrangements to ensure that vaccine introductions and campaigns occurring on or after 1 September 2012 benefit from the Policy regardless of when the country proposal was approved.

3. Executive summary

- 3.1 Consultations concluded that vaccine introduction grants have been appreciated by countries and, when disbursed in a timely manner, are seen as critical to successful vaccine introduction. Likewise, GAVI's operational support to campaigns has facilitated implementation of campaigns and contributed to increased planning certainty for countries. However, feedback from countries and partners indicate that the current policies in place for these two types of cash support have some major weaknesses, which the current revision attempts to address.

- (a) Introduction grants cover less than half of total estimated introduction costs for the larger countries receiving US\$ 0.30 per child. While some countries have managed to mobilise additional funds quickly to cover the gaps, others have not and have solely relied on the GAVI grants and have planned the introduction activities accordingly. In these cases, insufficient availability of funding before introduction has led to critical introduction activities being missed or undertaken at sub-optimal scale. Since introduction-related activities are estimated to cost more for vaccines such as rotavirus, pneumococcal and HPV vaccines, the potential negative consequences of lack of timely funding are likely to be exacerbated in the future.
 - (b) Actual cost of vaccination campaigns is higher than the amount assumed under the existing policy, and the share covered by GAVI has been insufficient. As a consequence, many countries experience difficulties in mobilising their contribution to campaigns. Inadequate funding can result in suboptimal execution and/or delays.
- 3.2 In light of these findings, the PPC endorsed the recommendation to the Board to increase GAVI's funding support for one-off introduction grants from the current level of \$0.30 to \$0.80 per child in the birth cohort, and an increase in funding for operational costs of campaigns from \$0.30 to \$0.65 per targeted individual. Given the special features of programmes to deliver HPV vaccines to adolescent girls, the PPC recommends funding a higher amount of \$2.40 per targeted girl. These amounts correspond to roughly 80% of the estimated average introduction costs for new vaccines and campaign delivery, respectively. Countries and partners are expected to mobilise the remainder of their funding needs. In addition, countries are expected to fully self-finance the incremental systems costs for delivery of the routine vaccines that incur on a recurrent basis after introduction.
- 3.3 The total incremental cost of the new policy amounts to \$418 million from 2012 to 2020 for 249 vaccine introduction grants and 100 grants for campaigns. This includes: For proposals that have already been approved or endorsed by the Board and for which introduction is expected after the September 2012 effective date of the new policy, the total incremental cost of the recommended policy amounts to \$24 million for vaccine introduction grants and to \$36 million for operational support for campaigns.¹ The total cost estimates for expected new proposals are based on strategic demand forecast (SDFv5) and amount to \$142 million for vaccine introduction grants through to 2020 (compared to \$55 million under the current policy) and to \$470 million for operational support for campaigns through to 2020 (compared to \$217 million under the current policy). Grants for product switches are difficult to estimate but expected not to exceed \$2 million per year.

¹ These incremental costs reflect current best estimates of the timing of vaccine introductions and campaigns. Furthermore, at the time of writing of this paper, due to issues of supply constraints and country readiness, it was likely that four countries' introductions would likely be postponed until fall 2012. This would represent an additional expenditure to GAVI of \$3.8m.

- 3.4 While critical for countries, these types of support taken together would continue to represent a relatively modest outlay for GAVI, accounting for 5.4% of total projected expenditures over the nine year period (compared to 2.4% under the current policy).

4. Context

Background

- 4.1 Under the current policy, GAVI provides vaccine introduction grants based on US\$ 0.30 per child in the birth cohort of the year of vaccine introduction or US\$ 100,000 as a lump sum, whichever is largest. GAVI funds a share of the operational costs of campaigns by providing US\$ 0.30 per person in the target population.
- 4.2 From 2001 to March 2012, GAVI has disbursed nearly 150 vaccine introduction grants to countries, totaling \$28.6 million. This amount is equivalent to about 1% of new vaccine support and 4% of GAVI cash support disbursements over this period.
- 4.3 When GAVI's vaccine introduction grant policy was last reviewed and adjusted in 2007, a policy review was anticipated for 2010 or later to take into account potential additional costs for rotavirus and pneumococcal vaccine introductions. In addition, the grant levels need to be established for the two vaccines recently added to GAVI's portfolio: HPV vaccines for routine delivery and Measles-Rubella vaccines for campaigns and subsequently routine delivery. The Secretariat has therefore reviewed both GAVI's policies towards vaccine introduction grants and operational support for campaigns.

Policy review process

- 4.4 The policy review examined how the grants have been used to date and whether the objectives, scope, amount, and implementation arrangements are still adequate, particularly in light of the changing landscape of vaccines now supported and to be supported in the coming years.
- 4.5 Consultations were carried out with 15 countries and independent experts in different areas (such as cold chain and logistics, HPV, measles, rubella).
- 4.6 In the development of this policy, the Secretariat worked closely with WHO and UNICEF, under the guidance of the GAVI Immunisation Financing and Sustainability (IF&S) Task Team², and conducted country and expert consultations. The policy review was supported by the Results for Development Institute.
- 4.7 The Secretariat drew on different sources to estimate introduction costs. WHO and UNICEF provided a comprehensive analysis of non-vaccine routine and

² The Task Team includes representatives from WHO, UNICEF, PAHO, World Bank, Bill & Melinda Gates Foundation, Sabin Institute and independent consultants.

campaign costs in GAVI eligible countries.³ The Clinton Health Access Initiative (CHAI) reviewed and shared information on the actual costs, cost drivers, and financing sources for pneumococcal vaccine introductions in Ethiopia, Kenya, and Malawi.⁴ A team from WHO and PATH estimated introduction costs for national HPV vaccination.⁵ A summary of the cost estimate analyses and the review prepared by WHO/UNICEF are available on the myGAVI site. Of note, data availability on actual introduction costs is limited for all vaccines, but particularly for HPV vaccines as it has only been introduced nationwide in a few GAVI eligible countries.

- 4.8 Following PPC mandate in 2011,⁶ the Committee discussed a first report on the topic during its teleconference on March 19, 2012.⁷ Based on feedback received from the PPC, recommendations for changing the current policies have been developed and were presented to the PPC for endorsement at its meeting on April 23-24 April.⁸

Objectives, scope and operating guidelines

- 4.9 The proposed objectives, scope and operating guidelines for the new policy are detailed in Annex 1.

Recommended approach for vaccine introduction grants

- 4.10 Based on cost analyses,⁹ the PPC endorsed the following approach:
- (a) Create two different support levels for routine vaccine introductions: (1) a fixed amount per child in the birth cohort for vaccines delivered to infants, and (2) a fixed amount per target girl for HPV vaccines.
 - (b) Maintain a minimum lump sum amount of \$100,000 for small countries for both categories of vaccines. Countries would either get the lump sum or the amount according to the funding formula, whichever is higher.
- 4.11 Several other approaches to setting the size of new vaccine introduction grants were also considered, but ultimately rejected in favour of the recommended approach (see April 2012 report to PPC).

³ Lydon P, Gandhi G. Introduction of New Vaccines: analysis of non-vaccine routine and campaign costs. April 2012 update.

⁴ Clinton Health Access Initiative, "PCV Introduction Costs and Funding Sources in Kenya, Ethiopia and Malawi: Preliminary CHAI analysis", January 2012 (unpublished).

⁵ Raymond Hutubessy, Ann Levin, Carol Levin, Vivien Tsu, and Susan Wang, "Financial Costs of HPV Vaccine Delivery", work-in-progress (confidential), February, 2012.

⁶ Review of the Vaccine Introduction Grant. Report to the Programme and Policy Committee for Guidance. PPC-2011-Mtg-1-Doc07, GAVI Alliance PPC meeting 3-4 March 2011.

⁷ Vaccine introduction grants. Report to the Programme and Policy Committee for Guidance/Discussion. GAVI Alliance PPC teleconference 19 March 2012.

⁸ Vaccine introduction grant and operational support for campaigns. Report to the Programme and Policy Committee for Decision. GAVI Alliance PPC meeting, 23-24 April 2012

⁹ Please refer to the March PPC report for a summary of the cost estimate analyses and the review prepared by WHO/UNICEF (Lydon P./Gandhi G.). Both documents are available on the myGAVI site.

- 4.12 The current grant policy of \$0.30 per child or \$100,000, whichever is larger, was mainly designed to cover part of the one-time introduction costs associated with replacing existing DTP-containing vaccines with pentavalent vaccines. The amounts were not based on an analysis of estimates of the full introduction costs and the appropriate share that GAVI should finance.
- 4.13 The PPC recommends that GAVI support for introductions of routine vaccines be set at \$0.80 per child in the birth cohort for infant vaccines and at \$2.40 per girl for HPV vaccines. On balance, these recommendations reflect the view that GAVI should provide a relatively high share (80%) of the estimated total costs. A number of considerations were assessed and balanced in order to determine the share of the total cost that GAVI should cover. These included: (1) the potential negative consequences of insufficient funding: critical introduction activities (such as social mobilisation and training) may not take place or at insufficient scale, jeopardising the successful roll out of the new vaccine; (2) Funding 80% of the overall average needs still leaves a role for countries and partners to contribute to the cost of these activities;¹⁰ (3) These types of cash disbursements continue to represent a relatively small outlay for GAVI. The grants have the advantage of providing flexible cash support with a very direct link to immunisation activities.
- 4.14 The total cost to GAVI for 249 vaccine introduction grants (for infant and HPV vaccines) for the period 2012-2020 is estimated at \$187 million, an incremental \$111 million over the baseline of the current policy. Of this, \$24.5 million is provided as additional to already approved or endorsed proposals for which introductions are expected to happen after the September 2012 effective date of the new policy.

Recommended approach for product switches after first introduction

- 4.15 Some countries may introduce a certain product and switch to a different one after some time (e.g. from a lyophilised pentavalent vaccine to a liquid or from single to multidose presentations). Such a switch may be requested by the country or requested by GAVI or a procurement partner in order to respond to the evolving supply situation or market shaping considerations. As part of the vaccine introduction grant review, the Secretariat considered the country request for providing an additional grant for cases when such a switch results in additional costs at country level (for example for refresher trainings to health workers, logisticians, lab workers, surveillance staff, small upgrades in cold chain, setting up of additional or complementary surveillance systems).
- 4.16 The needs will necessarily vary across countries depending not only on the type of switch, but also on the general strength of the immunisation system, the ability of health staff to deal with different vaccine presentations and the status of the cold chain system. The PPC endorsed the recommendation that countries can apply¹¹ for an additional grant to facilitate transition to a new

¹⁰ Countries would be expected, on average, to contribute a higher absolute amount for HPV vaccine introductions (\$0.60/girl) compared to introduction of infant vaccines (\$0.20/child).

¹¹ Through the Annual Progress Report or if urgent on an ad-hoc basis through a letter to GAVI and the procurement partner.

product for an existing antigen if they can show that certain criteria are met (see Annex 1). The feasibility of accommodating such a switch will be assessed and approved through GAVI's IRC process in the first instance or through the Secretariat in the case of a switch requiring a more rapid response (such as a switch to accommodate a supply shortage).

- 4.17 In case of a change in a WHO recommendation on the use of a vaccine or its dose regimen, the Secretariat would review the need for an additional grant and submit the case for decision to the Executive Committee as this would likely affect more than one country.
- 4.18 The frequency and magnitude of such switches is very difficult to estimate as the former is often driven by external factors (such as the supply situation). One-third of a full grant is estimated to defray costs mostly related to training for instance on a new presentation, small cold chain modifications and changes to the surveillance system. It is estimated that this type of grant will not exceed \$2 million per year. This annual amount is built into the financial impact numbers presented in section 9.

Recommended approach and grant size for operational support for vaccine campaigns

- 4.19 Under the current policy, GAVI funds a share of the operational costs of campaigns by providing \$0.30 per person in the target population. This was calculated to be half of average total operational campaign costs (\$0.60 per person in the target population) at the time when the measles, yellow fever and serogroup A meningococcal vaccine investment cases were submitted to GAVI.¹² Countries and partners are expected to contribute the remainder of the funding. Going forward, this policy will also cover measles-rubella (MR) campaigns and any new vaccine supported by GAVI.
- 4.20 Latest estimates of total average operational costs for delivering campaigns are \$0.80 per individual in the target population.¹³ In recalibrating GAVI's support to campaigns, an additional concern is that countries are experiencing difficulties in mobilising additional funding necessary to run the campaigns effectively and in a timely manner. According to the WHO/UNICEF study, countries are often not managing to contribute anything close to half of the expected funding from their highly constrained budgets. This has led in some instances to delays in the execution of campaigns.¹⁴ Since catch up campaigns (e.g. for Yellow Fever and MenA) target a large population of a country, budgetary needs can be significant. The analysis found that at the time of application, countries face great uncertainty with respect to financing

¹² Measles Investment Case II – submitted to the Global Alliance for Vaccines and Immunization by the Measles Partnership (June 2005), p. 54, 55; Yellow Fever Stockpile Investment case - submitted by Yellow Fever Task Force to GAVI Alliance (December 2005), p.84; Eliminating serogroup A meningococcal meningitis epidemics as a public health problem in Africa: An investment case for the GAVI Alliance (May 2008), p. 85/86

¹³ Lydon/Gandhi (April 2012 update)

¹⁴ Initial experience indicates that the MenA campaigns, at least in hyper-endemic countries, may not have the same difficulties in raising national contributions given the strong political and community demand for the vaccine. However, there are still concerns as to whether these funds are being pulled from other high priority programmes.

for the operational costs of the campaigns.¹⁵ Country governments were found to actually finance less than 10% of total operational costs.

- 4.21 There are several factors that argue for GAVI assuming a larger share of campaign costs. The GAVI supported campaigns target a large share of a country's total population, often in one single year.¹⁶ For example, the expected government/partner contribution to the delivery of MR campaigns is equivalent to more than twice the country's co-financing contributions in the campaign year for over 70% of the countries. Countries may be unable to find this level of funding in already highly constrained budgets or would do so only by pulling funding from other high priority programmes.
- 4.22 The potential negative consequences of a lack of sufficient funding are considerable ranging from an increased risk of outbreaks if campaigns get delayed to sub-optimal coverage levels if social mobilisation efforts and outreach activities are cut back.¹⁷ However, if GAVI takes on the full costs it may detract from country ownership. The Secretariat therefore recommends that GAVI increase its contribution towards the operational costs of campaigns by providing \$0.65 per individual in the target population, corresponding to 80% of the updated average operational cost of \$0.80 observed across different vaccines and countries.
- 4.23 The total cost to GAVI for 100 operational support for campaign grants over the period 2012-2020 is estimated at \$537 million, an incremental \$289 million over the baseline of the current policy. Of this, \$36 million is provided as additional to already approved or endorsed campaigns that are expected to happen after the September 2012 effective date of the new policy.

Other elements of the proposed policy

- 4.24 **Phased vaccine introductions or campaign:** Countries that are approved for phased vaccine introductions or campaigns should receive grants corresponding to the size of the target population approved in that proposal. Subsequently approved proposals for further roll out of the vaccine or campaign would be eligible for an additional grant, the size of which would again correspond to the incremental target population.
- 4.25 **Application, reporting, monitoring and evaluation:** Countries would apply for new vaccine introduction grants and operational support for campaigns as part of their normal application to GAVI for vaccine support. Countries would be asked to report on the use of the grants in their annual progress reports to GAVI.
- 4.26 **Review of policy:** The grant funding levels as well as the financial management requirements will be reviewed every two years by the GAVI

¹⁵ Lydon P, Gandhi G. (April 2012 update)

¹⁶ MenA mass campaigns target 1-29 year olds, Yellow Fever preventive campaigns target entire population >9 months; and Measles-Rubella catch up campaigns target 9 months to 14 year olds.

¹⁷ High coverage is particularly important for campaigns with rubella containing vaccines in order to effectively reduce circulation of the rubella virus.

Secretariat in consultation with partners to take into account new evidence of actual costs of introductions and campaigns and to include vaccines that may be added to GAVI's portfolio in the future. A full review and update of the policy should take place in 2017.

- 4.27 **Enhanced support:** GAVI Alliance partners are encouraged to continue and enhance, where needed, financial and technical support to countries to complement funding from GAVI and countries. Efforts to improve the knowledge base on the actual full costs and financing of introductions and campaigns, using prospective and retrospective assessments are encouraged.¹⁸ One further possible method would be to include an introduction cost component in a sample of Post Introduction Evaluations.¹⁹

5. Next steps

- 5.1 The Secretariat will implement any recommendations in change in policy. For already approved or endorsed proposals, the Secretariat will make the necessary adjustments to the grant amounts and inform countries and partners accordingly.

6. Conclusions

- 6.1 Vaccine introduction grants and operational funds for campaigns, while entailing relatively modest amounts of money, are important instruments of GAVI support to countries. The recommended increase in grant levels from GAVI and other recommended policy changes will help to address weaknesses in the current policy. The new policy can be expected to facilitate the timely and effective roll out of new vaccines and delivery of campaigns.

Section B: Implications

7. Impact on countries

- 7.1 The increased amounts recommended are expected to enhance the support to countries introducing vaccines and carrying out campaigns, resulting in improved vaccination programmes.
- 7.2 While the vaccine introduction grant can fund some cold chain expansion, it will not be sufficient, nor released early enough, to finance large cold chain upgrades or expansions that may be necessary to accommodate the new vaccines in some countries. Under current procedures, countries are requested to assess these needs carefully ahead of the NVS application, to

¹⁸ For example: WHO is leading a study that will provide information on the cost of HPV, rotavirus and pneumococcal vaccine introductions in Rwanda. The Bill & Melinda Gates Foundation plans to fund several country studies on the costs and financing of routine immunisation programs in countries that have recently introduced new vaccines.

¹⁹ This was done in Ethiopia in 2007. Results are summarized in Ulla Griffiths, Viola Korczak, Dereje Ayalew, Asnakew Yigzaw, "Incremental system costs of introducing combined DTwP-hepatitis B-Hib vaccine into national immunization services in Ethiopia", *Vaccine* 27 (2009): 1426-1432.

mobilise funds from other sources, and to show the planned or ongoing upgrade as part of the NVS application.

8. Impact on GAVI Stakeholders

- 8.1 Governments and partners continue to be expected to contribute additional funding in order to facilitate effective vaccine introductions and the delivery of campaigns.

9. Impact on the Business Plan / Budget / Programme Financing

- 9.1 The total projected financial cost to GAVI of the proposed vaccine introduction grant and operational support for campaigns policy is provided in Tables 1 and 2 of Annex 2. The total incremental cost amounts to \$418 million from 2012 to 2020 for 249 vaccine introduction grants and 100 grants for campaigns. These costs can be divided into the following components: For proposals that have already been approved or endorsed by the Board and for which introduction is expected after the September 2012 effective date of the new policy, the total incremental cost amounts to \$24 million for vaccine introduction grants and to \$36 million for operational support for campaigns.²⁰ The total cost estimates for expected future demand are based on SDFv5 and amount to \$142 million for vaccine introduction grants through to 2020 and to \$470 million for operational support for campaigns through to 2020. An estimated maximal annual amount of \$2 million for grants related to product switches is built into the total cost projections summarised in Annex 2.
- 9.2 While critical for countries, these types of support would continue to represent a relatively modest outlay for GAVI, accounting for 5.4% of total projected expenditures over the nine year period.
- 9.3 The incremental cost of the new policy is identified separately in the financial forecast shared with the Board at the June meeting (see document 04).
- 9.4 The vaccine introduction grants and the operational support for campaigns are two types of cash support to countries. As such, these amounts will be counted towards the Board provision to provide between 15% and 25% of GAVI's overall expected expenditures for cash support. The increased support resulting from the new policy falls within the envelope already approved for cash programmes and is therefore not truly an incremental outlay.

10. Risk implications and mitigations

- 10.1 There is a risk that some countries experience much higher start-up costs for introducing a new vaccine than average. New proposal reviews by the Independent Review Committee (IRC) should assess the feasibility of sufficient

²⁰ These incremental costs reflect current best estimates of the timing of vaccine introductions and campaigns. Furthermore, at the time of writing of this paper, due to issues of supply constraints and country readiness, it was likely that four countries' introductions would be postponed until fall 2012. This would represent an additional expenditure to GAVI of \$3.8m.

funding being available to recommend approval of applications. The Effective Vaccine Management (EVM) tool and the country's improvement plan derived from the EVM that are submitted together with a NVS application are expected to provide important information related to cold chain to guide the IRC review.

- 10.2 Insufficient funding from countries or partners could lead to sub-optimal coverage. Early and regular communication on the need for country funding will be required by the Secretariat and partners.
- 10.3 The higher GAVI contributions for these two types of support may raise concerns of country ownership and sustainability. However, country ownership of the new vaccines is assured through GAVI's co-financing policy and through the fact that countries are expected to fully self-finance the incremental recurrent systems cost for vaccine delivery after introduction.
- 10.4 The cash grants will be subject to GAVI's fiduciary oversight measures as per GAVI's TAP policy. In addition, introduction grants and operational support for vaccine campaigns of \$250,000 or more require mandatory audits when these funds are directly disbursed to countries.²¹ One quarter (25%) of the grants below \$250,000 will be selected at random for audit, which means that all countries will need to maintain adequate books and records for these amounts.
- 10.5 During the consultations, countries were clear that the absolute amounts of the introduction grants were not sufficient to influence vaccine choice of HPV over vaccines delivered to infants. The higher absolute amount expected to be contributed by countries and partners for the HPV vaccine also helps to reflect relative introduction costs at country level.

11. Legal or governance implications

- 11.1 Requirements on countries set out in the policy will be reflected in the grant arrangements between GAVI and countries.

12. Consultation

- 12.1 Fifteen countries were consulted. The consultations aimed at gathering feedback from key stakeholders (EPI managers and other senior Ministry of Health and Finance staff) about their experiences with the vaccine introduction grants and what adjustments might be desirable. A summary of the country consultations was provided in the March PPC paper.
- 12.2 Consultations with experts from WHO, PAHO, UNICEF, PATH, BMGF and independent experts (in cold chain and logistics, HPV, measles, rubella) informed the policy review.
- 12.3 The analyses, findings and recommendations provided by WHO/UNICEF and others, were presented and reviewed by the IF&S Task Team.

²¹ The financial management requirements will be adjusted if funds are disbursed through an intermediary.

13. Gender implications / issues

- 13.1 The revised policy provides for a higher allocation in support of introduction of HPV vaccines. This is because it will be administered to 9-13 year old girls, a population that has not previously been routinely served by immunisation services. Clear and sensitive information, education and communication (IEC) activities need to be developed and implemented to ensure high uptake and coverage levels for a new target group.

14. Implications for the Secretariat

- 14.1 The Secretariat will implement any recommendations in change in policy. Given the feedback that introduction grant disbursement has not always been executed in a timely way, the Secretariat will adjust internal procedures to aim to disburse introduction grants six months before vaccine introduction and clearly communicate when funds will be disbursed.
- 14.2 The Secretariat will also put in place a monitoring and evaluation framework to assess the effectiveness of the new policy in reaching its objectives.

Annex 1: GAVI Vaccine Introduction Grant and Operational Support for Campaigns Policy

DOCUMENT ADMINISTRATION

VERSION NUMBER	APPROVAL PROCESS	DATE
1.0	Prepared by: Nina Schwalbe, Policy and Performance	
	Reviewed by: GAVI Programme and Policy Committee	23 April 2012
	Approved by: GAVI Alliance Board	[Date of approval]
		Effective from: 1 September 2012
		Review: Every two years for grant funding levels and financial management requirements. Full review and update in 2017.

GAVI Vaccine Introduction Grant and Operational Support for Campaigns Policy

1. Objectives

- 1.1. **GAVI Vaccine Introduction Grant:** The aim of GAVI's vaccine introduction grant is to facilitate the timely and effective implementation of critical activities in the national vaccine introduction plan in advance of a new vaccine introduction.
- 1.2. **GAVI Operational Support for Campaigns:** The aim of GAVI's operational support for campaigns is to facilitate the timely and effective delivery of vaccines to the target population.
- 1.3. Both types of grants are one-time investments expected to cover a share of the pre-introduction activities and campaign operational costs, respectively, with the remainder being funded by the government and partners, if necessary. The government contribution aims to ensure country ownership of the new vaccine introduction and the campaign.

2. Scope

- 2.1. The introduction grant policy applies to first introductions of all vaccines supported by GAVI, including vaccines introduced on a routine basis following campaigns.²²
- 2.2. Pre-introduction activities that may be funded through the GAVI vaccine introduction grant may include but are not limited to health worker training, information, education and communication (IEC) and social mobilisation, microplanning, expansion or rehabilitation of some cold chain equipment and additional vehicles if needed, printing and purchase of materials (such as immunisation cards), technical assistance, and modifications to the surveillance systems. The government is encouraged to work with civil society organisations and other in-country partners to determine how these activities are best carried out.
- 2.3. In addition, for GAVI operational support for campaigns, the following types of expenses may also be included: volunteer incentives for vaccine delivery or monitoring, health workers and supervisor per diems, cold boxes and ice packs, transport, monitoring and evaluation and civil society organisation and/or volunteer incentives for social mobilisation.
- 2.4. The introduction costs covered by the GAVI grant are start-up investment costs, distinct from incremental recurrent costs resulting from the addition of a new vaccine to the immunisation schedule that would occur year after year. This grant is not intended to cover such recurring delivery costs.

3. Operating guidelines

- 3.1. Application of the policy should be guided by GAVI's operating principle to support national priorities, integrated delivery, budget processes and decision-making, as well as by the following guidelines:

²² Vaccines currently included in GAVI's portfolio include: DTP-HepB-Hib containing, pneumococcal, rotavirus, yellow fever, measles (2nd dose), meningococcal A, rubella (MR vaccine), and HPV vaccines. Japanese encephalitis and typhoid conjugate vaccines may be included once appropriate WHO pre-qualified vaccines become available.

- Vaccine introduction grants and support for operational costs of campaigns can be used in a flexible manner by countries to cover the types of expenses mentioned above.
- The grants are intended to help cover initial start-up investment costs of introducing a new vaccine and for conducting the campaigns, but not as the sole source of funding for these costs.
- The grants should be made in a timely way ahead of first introductions and campaigns;
- The procedures and requirements related to these grants should be simple to understand and implement by countries;
- The grants are separate from other forms of cash support.
- The grants cannot be used to fund co-financing obligations or vaccines.

4. Funding Levels

- 4.1. Vaccine introduction grant for all GAVI supported vaccines delivered to infants on a routine basis²³: GAVI provides US\$0.80 per child in the birth cohort (based on 80% of estimated average per child introduction costs) for the year of introduction or a lump sum amount of \$100,000 whichever is higher.
- 4.2. Vaccine introduction grant for GAVI supported HPV vaccines delivered to adolescent girls on a routine basis²⁴: GAVI provides \$2.40 per girl in the country's target population (based on 80% of estimated average per girl introduction costs) for the year of introduction or a lump sum amount of \$100,000 whichever is higher.
- 4.3. Operational support for all GAVI supported vaccine campaigns²⁵: GAVI provides \$0.65 per individual in the country's target population (based on 80% of estimated average campaign operational costs) for the year of the campaign.

5. Phased vaccine introductions or campaigns

- 5.1. Countries that are approved for phased vaccine introductions or campaigns will receive grants corresponding to the size of the target population approved in that proposal. Subsequently approved proposals for further roll out of the vaccine or campaign would be eligible for an additional grant, the size of which would again correspond to the incremental target population.

6. Product switches

- 6.1. Countries can apply for an additional grant to facilitate transition to a new product for an existing antigen if it can show that at least two of the following criteria are met:
 - The switch to a different product is requested by GAVI or its procurement partners
 - The new product requires larger cold chain capacity and requires an expansion at country level.

²³ This currently includes routine introductions of DTP-HepB-Hib containing vaccines, pneumococcal, rotavirus, yellow fever, measles (2nd dose), meningococcal A, and rubella (MR vaccine).

²⁴ This currently includes routine introductions of the human papillomavirus vaccine (HPV)

²⁵ This currently includes campaigns with meningococcal, yellow fever and measles-rubella vaccines.

- The new product represents a change in terms of administration and handling for health workers or other staff involved in the vaccine management and requires additional training because the product features are new to the country.
- 6.2. The size of the grant for product switches will correspond to one third of a full vaccine introduction grant (rounded to \$0.25 per child for infant vaccines and \$0.8 per girl for HPV vaccines).

7. Application, reporting and oversight

- 7.1. Countries apply for new vaccine introduction grants and operational support for campaigns as part of their normal application for vaccine support to GAVI.
- 7.2. Countries are requested to report on the use of the grants in their annual progress reports to GAVI.
- 7.3. The cash grants will be subject to fiduciary oversight measures: Introduction grants and operational support for vaccine campaigns of \$250,000 or more require mandatory audits when these funds are directly disbursed to countries²⁶. One quarter (25%) of the grants below \$250,000 will be selected at random for audit, which means that, countries are expected to maintain adequate books and records for these amounts.

8. Effective date and review of policy

- 8.1. This policy comes into effect as of 01 September 2012 and will apply to all new vaccine introductions and campaigns taking place after this date.
- 8.2. The grant funding levels as well as the financial management requirements will be reviewed every two years by the GAVI Secretariat in consultation with partners to take into account new evidence of actual costs of introductions and campaigns and to include vaccines that may be added to GAVI's portfolio in the future. The new levels and vaccines will be reflected in an updated policy.
- 8.3. A full review and update of the policy should take place in 2017.

²⁶ The financial management requirements will be adjusted if funds are disbursed through an intermediary.

Annex 2: Projected financial costs

Table 1: Projected financial cost vaccine introduction grants (US\$ million)

	2012	2013-2017	2012-2020
Approved & endorsed proposals			
Baseline (current policy)	11	9	20
New policy	22	22	45
Forecasted demand as per SDFv5.0			
Baseline (current policy)	-	43	55
New policy	-	109	142
Product switches: Estimated maximum amount under new policy	-	10	16
Total cost VIG & product switches			
Baseline (current policy)	11	52	75
New policy	22	141	203

Table 2: Projected financial cost operational support for campaigns (US\$ million)

	2012	2013-2017	2012-2020
Approved & endorsed proposals			
Baseline (current policy)	24	6	30
New policy	53	14	66
Forecasted demand as per SDFv5.0			
Baseline (current policy)	-	187	217
New policy	-	406	470
Total Operational Support			
Baseline (current policy)	24	194	248
New policy	53	419	537