FOR DECISION

The Board requested that a prioritisation mechanism be developed during 2010 to help inform future funding decisions on New Vaccine Support (NVS) and cash-based programme country proposals recommended by Independent Review Committee (IRC). The Programme and Policy Committee (PPC) took responsibility for developing this mechanism and appointed a time-limited task team to guide the analytical work, which was carried out by the Secretariat. The PPC reached consensus on all aspects of the mechanism including the principles, objectives, and criteria/indicators that should govern, direct and define the pilot phase of the mechanism, as well as several rules and procedures necessary to implement the pilot.

Concurrent with this, the PPC recommends that the Alliance continue preparatory activities for the four 'new' vaccines (HPV, JE, rubella and typhoid) and only open new applications windows following the pilot period of the proposed prioritisation mechanism and the definition of the 2011-2015 GAVI Strategy, and subject to funding availability.

Therefore the Programme and Policy Committee requests the Board to:

- Approve the GAVI Alliance Pilot Prioritisation Mechanism (Annex 1).

Also note that the PPC recommended that GAVI should fund the centrally administered Yellow Fever emergency stockpile in the amount of approximately US$22 million for the period 2011-2013, given its potential impact. This will be referred to the Audit and Finance Committee for financial review and the Executive Committee for approval in July.

GAVI Alliance Pilot Prioritisation Mechanism

Background

Current demand and resource forecasts suggest that GAVI faces a large fiscal deficit in coming years if it intends to fully fund its ambition. Since GAVI may not be able to fund all technically sound proposals for all vaccines in the current portfolio and/or cash-based programmes at its November 2009 meeting the Board agreed that criteria should be developed under the oversight of the Programme and Policy Committee and submitted to the Board (or Executive Committee) for approval.[1] The Board directed that a ranking of vaccines to guide decisions about the portfolio and rules for deciding which country proposals recommended for funding by the IRC should be funded in a particular application round when resources are constrained.

A major objective of the new prioritisation mechanism is to inform decisions on the twenty IRC-recommended proposals awaiting the Board's consideration since October 2009.

[1] Section 14 of the 17-18 November 2009 Minutes

FOR DECISION

The PPC at its February 2010 meeting endorsed a general plan for creating a prioritisation mechanism and the establishment of a time-limited task team.[2] Subsequently, at its May 2010 meeting the PPC endorsed a pilot prioritisation mechanism. This paper describes that mechanism for consideration.[3]

A Pilot and a Prioritisation Mechanism for the Longer-term

Looking ahead, the funding challenge means that IRC recommendations will not by themselves be sufficient to guarantee funding approval from the Board. Introducing a prioritisation mechanism to inform which of the technically sufficient proposals should be funded will significantly change GAVI's operations and will require a pilot to signal and test these changes. For this and other reasons, the PPC recommends that GAVI should 'pilot, assess and plan to improve' the prioritisation mechanism developed. Further, the PPC recommends that the pilot phase last at least two application rounds (e.g. the October 2009 round, and the subsequent round, whenever this is held) in order to test it.

Whilst the majority of the recommendations relate to the pilot mechanism, the general principles and objectives are intended to apply beyond the pilot, and some recommendations for longer-term improvements are included as part of the section outlining "next steps".

Principles for a Prioritisation Mechanism

The PPC identified a series of principles that should guide the prioritisation mechanism recognising that these would need to be consistent with GAVI's operating principles. The principle of country choice, or "supporting nationally-defined priorities", is at the heart of the mechanism. The Committee also identified three additional principles to govern the mechanism: objectivity, transparency, and feasibility.

- Objectivity implies reliance on evidence. Although expert judgment can play a role, it must be informed by evidence and subject to clear guidelines.

- Transparency includes reliance on broadly available data and argues for simplicity and might also make the outcome of prioritisation decisions more predictable.

- Feasibility comes into play in at least three ways. The required data must be available and comparable across countries; the entities charged with collecting, presenting, and assessing evidence must be ready and willing to do so; and the necessary procedures must be in place. Clearly, there are significant differences between long- and short-term feasibility.

Whilst these principles seem uncontroversial, they have important implications for prioritisation criteria and mechanisms for applying them.

[2] Terms of Reference available upon request

[3] The prioritisation mechanism and associated references and should be considered parallel to the Secretariat's recommendations with regard to GAVI's resource envelope.

FOR DECISION

Proposed Objectives for Proposal Prioritisation

A proposal prioritisation system could be designed to promote one or more of several objectives. The PPC recommends to the Board that the mechanism seek to achieve the following:

- Maximise overall health impact (i.e. reduction of disease burden)
- Maximise value for money (i.e. cost-effectiveness)
- Reinforce the financial sustainability of immunisation programmes
- Focus GAVI's support on countries with the greatest need/least ability to pay
- Ensure country readiness for use of GAVI-supported vaccines
- Distribute GAVI's resources more equitably among countries (in terms of the number of vaccine proposals per country that can be funded per round)

Like the governing principles, these objectives are expected to hold for both a short-term pilot and any longer-term mechanism that follows it. These objectives are broadly consistent with the new GAVI Strategy being proposed.

However, given that these objectives might be in tension with each other, the PPC has assigned weights to indicate the relative importance of each. Whilst all the objectives are important, the PPC assigns the highest priority to:

- Maximise overall health impact (i.e. reduction of disease burden)
- Maximise value for money (i.e. cost-effectiveness)

"Reinforce the financial sustainability" was the third most important objective with need, readiness, and equitable distribution of GAVI resources given relatively less weight.

Health impact and value for money are considered the most important objectives for prioritisation because the PPC felt that GAVI should focus its limited resources on those programmes that are likely to save the most lives and avert the most disease in the most economical way. This reflects GAVI's mission to save lives and improve health and is consistent with the board's approach to GAVI's new vaccine investment strategy portfolio in 2008. The emphasis on financial sustainability reflects GAVI's focus on this at the strategic level.

Proposed Criteria and Indicators for Proposal Prioritisation

In the short run, given the lack of certain kinds of data and the constraints imposed by the GAVI's existing proposal guidelines and proposal assessment process (which cannot be changed before a pilot prioritisation mechanism must be implemented), the number of indicators that meet these standards is relatively small. After considering a broader set of possible indicators, the PPC arrived at the list detailed in Table 1, below, for the pilot period for NVS proposals.

One of the most important choices made by the PPC is that the health impact and cost-effectiveness of new vaccine proposals be assessed at the country level, in a way that takes into account country-specific disease burden and the likely impact of

particular vaccines in particular settings. This approach would enable GAVI to combine proposal and vaccine prioritisation, at least in part (see section below on vaccine ranking). Among other factors, assessing the health impact and value of a proposed programme requires understanding country-specific disease burden, vaccine efficacy, immunisation coverage, and vaccine cost. No single, readily available indicator incorporates all of these dimensions. The PPC however, endorsed the task team's proposal to use simple formulae built from available data in order to serve as good, if imperfect, indicators of the relative impact and cost-effectiveness of new vaccine proposals.

These simple formulae do not incorporate all the considerations that influence the actual impact of introducing a new vaccine. But they should capture the key factors that largely determine the relative impact of one proposal over another. Several quite sophisticated models have been or are being developed to estimate more precisely the health impact and cost-effectiveness of new vaccines in particular settings. An example is the TriVac model, derived from the ProVacc initiative model developed by PAHO. It is not clear, however, that this model, which was developed for a quite different purpose, could be adapted and the necessary data found in time for it to be used to rank the paused 2009 proposals before the June board meeting. Moreover, while a model would give more precise estimates of health impact and cost-effectiveness, it would make the process of proposal prioritisation far less transparent, since most countries and other stakeholders would not be familiar with the model and would have trouble assessing its implications for particular proposals. Finally, rankings produced using the simple formulae were quite similar[4] to those produced by the TriVac model, thus validating the proposed indicators. For this reason, the PPC endorsed a simpler approach, at least for the pilot phase.

These indicators of health impact and cost-effectiveness can be applied immediately to proposals for pneumo, rota, and Hib-containing vaccines, and thus to the NVS proposals in the 2009 round. Extending them to other vaccines, including some (measles 2nd dose, yellow fever, and potentially Men A) for which countries might submit proposals in a 2010 round, will require some additional consultation with GAVI's technical partners.

For financial sustainability, the PPC proposes using the share of government health spending in total government spending as the indicator. Although national health accounts data are not perfect, consultation with an expert from the World Bank consulted by the study team further suggests that these data are sufficiently robust and comparable across countries. While the data in some cases included funding from external sources (e.g. foreign aid assistance) as well as governments' own resources, this is consistent with the definition of financial sustainability approved by the GAVI Board. Beginning after the pilot phase, co-financing performance would be used as a second indicator of financial sustainability: proposals from countries that have paid more than the required co-financing amount would be given higher priority,

4 Comparing the cost-effectiveness ranking of hypothetical penta proposals from all GAVI countries using the approach simple formulae proposed here, 7 out of the 10 proposals ranked highest by the TriVac model also scored in the top 10 using the simple formula; 9 out of 10 proposals were also among the lowest ranking on both lists.

while those that had been in default within the previous two years would receive lower scores.

GNI per capita would serve as the indicator of need. This is consistent with the choice of this indicator to define eligibility, although in this case it would be used (together with the other indicators) to rank proposals from GAVI-eligible countries.

No criteria of readiness would be applied in the pilot, but the IRC should rank country readiness to introduce requested vaccines on a simple scale, which could then be used in proposal prioritisation. This scale could draw on tools such as the Vaccine Management Assessment (VMA) and the Efficient Vaccine Management (EVM), but might also consider broader aspects of health system readiness to deliver new vaccines. Adopting this indicator would require changes to guidelines for both country proposals and IRC proposal assessment.

On the final objective, equity in distribution of GAVI's resources, the PPC recommends the application of a simple rule: only one NVS proposal per country should be considered in each proposal round.

Table 1: Overview of proposed objectives, criteria indicators and weighting for the pilot mechanism for NVS proposals

Objectives	Criteria	Potential indicator	Data source	Weight
Health impact	• Deaths averted per 1000	• Country- and disease-specific death rate x immunisation coverage x vaccine efficacy	• WHO (disease burden) • WHO/UNICEF (coverage) • Weekly Epi Record, no.23(84); WHO and technical consensus (efficacy)	• 30%
Value for money (cost effectiveness)	• Cost per death averted	• Vaccine price x doses/deaths averted (calculated as in health impact formula)	• GAVI secretariat (projected prices) • Health impact indicator	• 30%
Financial sustainability	• Government commitment to health	• Share of government health expenditure in total government expenditure	• National Health Accounts (published by WHO)	• 25%
Need (equity among countries)	• Country income	• GNI per capita (Atlas method)	• World Bank	• 15%
Equitable distribution of GAVI resources	• Number of proposals that can be funded per application round	• This objective would be embodied in a rule that only one NVS proposal from each country would be considered in each proposal round. See discussion of 'Additional rules' in 'Proposal prioritisation mechanics' section below		

FOR DECISION

Budget Caps

In keeping with the principle of supporting nationally defined priorities, it was noted that given a particular funding limit in a proposal round, (large) countries might wish to:

- Split up their applications, for example, focusing initially on the high burden or the high performing provinces first, and then following up with applications to cover the remaining population in later rounds. This would allow large countries to have more competitive applications and be able to phase in a vaccine gradually.
- Cover costs of vaccines for provinces not covered by GAVI support by offering to co-finance at reasonably high levels from the outset.
- At a later date, self finance vaccine introduction in provinces not covered by GAVI support.

While these choices may be acceptable for some countries, others, when presented with such difficult political decisions, will opt out. Similarly, approaches 2 and 3 may be financially prohibitive for some countries, whereas they may be possible for others. Indeed, there are precedents of countries applying for partial introductions and/or covering costs to reach the remaining population through co-financing or self-financing partial introduction at a later date (e.g. India for HepB and pentavalent vaccines; Kenya and Niger for Yellow Fever routine vaccination; and China when it was GAVI-eligible for HepB vaccines).

Considering this, the PPC proposes GAVI announce budget caps for NVS proposals ahead of each future application round to encourage countries to explore nationally defined priorities given a budget constraint, and then to submit proposals consistent with the caps. The exact amount of the caps could be determined based on projected available resources and the issue is explored in GAVI's Resource Envelope paper.[5] Further, future country applications and subsequent monitoring could look more closely at planned partial introduction and phased roll-out where introduction plans are constrained by budget caps.

Treatment of Cash-based Windows

As mentioned above, the Board requested that the scope of this work include provisions for prioritising across vaccine as well as cash-based country proposals. The PPC recommends that GAVI define relative shares of funding shares for (i) the NVS window and (ii) cash-based programmes windows. This allows prioritisation criteria to be tailored to the specific objectives of the different funding windows. The magnitude of these shares is discussed in GAVI's Resource Envelope document.

5 However, the budget caps would be prospective and for new NVS proposals rather than countries (i.e. they would not look retrospectively and count what GAVI may have already committed to countries); they would be application round-specific (i.e. the cap could change depending on availability of funding); and finally the budget cap will apply for future application rounds that occur after the pilot mechanism is effective (i.e. they will not apply to the October 2009 round of proposals since these were submitted before a cap could be announced).

FOR DECISION

Criteria to Rank Proposals for Cash-based Programmes

Since GAVI could receive cash-based proposals whose combined value is greater than the funding GAVI allots for those windows, there need be a system for ranking such proposals. The PPC recommends that only need and commitment to financial sustainability be considered in ranking IRC-recommended proposals for cash-based support. Proposals from countries with higher under-five mortality, higher health share of government expenditure, and lower DTP3 coverage* would receive higher priority. As with NVS proposals, cash-based programmes would be ranked using an index that combines these indicators, as described in Table 2 below.

*NB: Given the role of cash-based programmes in strengthening health systems in general as well as specifically for the delivery of immunisation services, the PPC acknowledged that unlike NVS proposals where higher performing countries (with higher DTP3) would be given preference, for cash-based programmes, lower performing countries (with lower DTP3) should be given preference.

HSS Proposals Funded Through the Health Systems Funding Platform

In the future, HSS funding is likely to come from a separate funding platform and the applications are likely to come through a new applications process (the Health Systems Funding Platform – HSFP). The approach to ranking cash-based programmes is intended to apply to HSS proposals submitted to GAVI under the current HSS window rules (e.g. from the October 2009 round) and to any future HSS proposals GAVI might elicit outside of the HSFP, not to proposals funded through the HSFP.

Table 2: Overview of proposed objectives, criteria indicators and weighting for cash-based proposals

Objectives	Criteria	Potential indicator	Data source	Weight
Need	• System weakness	• DTP3 coverage	• WHO/UNICEF	• 50%
	• Overall health burden	• U5MR	• Inter-agency Group for Child Mortality Estimation	• 25%
Financial sustainability	• Government commitment to health	• Share of government health expenditure in total government expenditure	• National Health Accounts (published by WHO)	• 25%

FOR DECISION

Proposal Prioritisation Mechanics

For a prioritisation system to produce a complete ranking of proposals recommended by the IRC in a given proposal round (including the October 2009 round) and inform funding decisions, it must include more than a set of indicators. Some way is needed to aggregate the scores from the separate indicators with one another, as is a set of supplementary rules. The PPC recommends that an index be used to aggregate indicator scores. A detailed explanation of the index is given in Annex 2.

To ensure that GAVI can rank all proposals and allocate resources across proposal rounds, a series of additional rules are needed:

Ties

It is possible that some proposals will have the same score. As such, it is recommended that the health impact indicator should be used to break ties for NVS, and DTP3 should be used to break ties for cash-based programmes. In the case of the latter, the lower DTP3 coverage estimate would receive priority.

Multiple NVS proposals from the same country

The PPC recommends that in times of resource constraint, no more than one NVS proposal per round should be approved from a particular country. When a country has more than one IRC-approved proposal (as is the case in the 2009 round), countries should be allowed to choose which proposal they would like to see funded. The other proposal would not be considered until the next application round.

Proposals that straddle the funding limit

No matter where the funding limit is set for each proposal round, there will always be a proposal that cannot be funded in full without going over the spending limit. This issue is a key operational consideration of GAVI's Resource Envelope and is therefore dealt with in that document.

Fate of unfunded proposals

The PPC recommends that for the pilot prioritisation mechanism, proposals that are not funded in a particular round would automatically go into the pool of new applications for the next application round. However, they noted that if in the next round, these proposals are not funded, then countries would be asked to reapply.

Vaccine Prioritisation

At its November 2009 meeting, the Board agreed that GAVI should explore prioritisation of vaccines and proposals, using the framework developed for the vaccine investment strategy (VIS) as well as market-shaping considerations. The Board further indicated that vaccine prioritisation could entail limiting the menu of vaccines available to countries or delaying introduction of new vaccines. However, given GAVI's commitment to supporting nationally defined agendas, the PPC was not

comfortable enforcing vaccine prioritisation from a 'global' perspective. And, given that the proposal prioritisation mechanism described above considers vaccine health impact and cost-effectiveness at the country rather than at the global level, it allows GAVI to get a better return on its investments by taking country-specific disease burden and vaccine efficacy into account. Moreover, the PPC agreed that a sufficiently rigorous ranking based on quantitative dimensions alone or on a combination of quantitative and qualitative dimensions could not be developed in the time to guide the Board in 2010.

Importance of Existing GAVI Commitments

Although the PPC decided against a formal ranking of all vaccines in GAVI's portfolio, in part based on one of GAVI's operating principles as well as on technical grounds, the PPC acknowledged that GAVI's vaccines could be divided into groups based on a more practical consideration:

Group 1: Already introduced vaccines with funding commitments

- HepB and Hib-containing vaccines, especially pentavalent
- Pneumococcal conjugate
- Rotavirus
- Yellow fever
- Measles second dose

Group 2: Pending investment cases: partial funding commitment

- Meningitis A
- Yellow fever stockpile

Group 3: Board-recommended VIS vaccines: no funding commitment

- HPV
- Typhoid
- Japanese encephalitis
- Rubella

These groupings reflect the type and degree of commitments to countries, suppliers, and Alliance partners. For these reasons, the PPC acknowledged that GAVI should respect the groupings in the absence of compelling evidence to do otherwise. The PPC's recommendations on prioritisation among GAVI's vaccine portfolio follow these grouping as explained below.

Already Introduced Vaccines (Group 1)

GAVI should continue to accept proposals for these vaccines. Differences in health impact and cost-effectiveness among the vaccines in this group should be assessed at the country level as a critical element of proposal prioritisation (see above). Thus for this group of vaccines, the PPC recommends that vaccine ranking be handled by the proposal prioritisation mechanism.

FOR DECISION

Investment Cases (Group 2)

The yellow fever and Meningitis A (Men A) investment cases represent a challenge vis-à-vis prioritisation. On one hand, the investment cases have been accepted by the Board and some funding has already been committed. Moreover, the two investment cases have been represented by their developers and proponents as all-or-nothing propositions, not subject to GAVI's standard country proposal approval processes. Both vaccines are against epidemic diseases, an argument for funding all countries in the worst affected regions at once. On the other hand, funding the two investment cases (totalling around $465 million) in their entirety would absorb much of the uncommitted resources GAVI expects to have over the next six years. This would leave little or nothing for new proposals for other vaccines, including those from the October 2009 round and including potentially higher impact vaccines like pneumococcal vaccines. Therefore, the PPC recommends that the investment cases be restructured and partially funded.

The Men A investment case currently requests funding for extensive catch-up campaigns for all 25 countries in the African Meningitis belt (as well as other operational and M&E costs), and would cost some $285 million.[6] The PPC recommends a change to a country-driven approach, in which countries would apply for support to introduce Men A and proposals would be assessed through GAVI's standard NVS application processes, including the proposed proposal prioritisation mechanism. Proposals could include a request for GAVI support for the catch-up campaigns, whilst countries would be expected to pay a substantial share of routine immunisation costs, since the vaccine price, is expected to be at $0.40-0.50 per dose and anticipated to be affordable by countries. The share of this cost that countries would pay could be determined by the co-financing policy revision.

The yellow fever investment case includes funding for an emergency stockpile of vaccine (to be held centrally) and preventative campaigns in high-burden countries. In order to maintain the stockpile, it is estimated that 6 million doses of vaccine per year would be required, at an annual cost of $6-7 million per year. Funding was originally requested in the investment case for preventive campaigns in two further countries (Ghana and Nigeria) over the period 2011-2014, for which projected demand totals some 136 million doses. Together, the stockpile and campaigns and their administration are estimated to require around $180 million.

The PPC recommends that the emergency stockpile be funded, but for the preventative campaigns, countries would have to request funding through the standard proposal process.

[6] The Board has already approved funding for some elements of the investment case, including a stockpile of polysaccharide vaccine for control of outbreaks and conjugate vaccines for catch-up campaigns in three countries (Burkina Faso, Mali and Niger) which are expected to begin later this year once the vaccine is prequalified

FOR DECISION

If these recommendations are accepted, four issues would need to be addressed:

- Epidemiological implications of disaggregating the investment cases: Ideally, preventative campaigns for epidemic diseases such as yellow fever and Meningitis A are tightly sequenced across strongly affected regions. The Secretariat should consult with the investment case preparers on this issue, as it may be possible to find a way to minimize any negative consequences from disaggregation, perhaps through coordinating country proposals in some way. It should be stressed that the alternative to the disaggregated approach proposed here would almost certainly be no funding at all for these campaigns.

- Amending GAVI's NVS country application and IRC processes: GAVI's current country application processes are designed to review the technical sufficiency of routine immunisation proposals; new guidelines would have to be developed for Men A catch-up and routine immunisation proposals and for yellow fever preventative campaign proposals.

- Determining how operational costs are funded: In addition to the costs of vaccines, the investment cases include funding for operational costs that would be borne largely by WHO and UNICEF Program Division. Across the two investment cases, these operational costs total almost $170 million (~37% of the total required). If the recommended approach is endorsed, GAVI would need to decide how to handle these associated costs.[7]

- Consistent measurement of health impact: The proposal prioritisation mechanism would have to be extended to enable assessment of health impact and cost-effectiveness of country proposals requesting yellow fever preventive campaign support and Men A campaign and routine immunisation support. The health impact formula described above would need to be adapted to account for the epidemic cycles associated with these diseases. The extension would have to balance tailoring the approach for epidemic diseases with a need to preserve comparability with other vaccines. CDC and WHO indicated their willingness to undertake these activities on GAVI's behalf with assistance from the Secretariat and in collaboration with the AVI and other academic/technical experts.

VIS vaccines (Group 3)

Given that GAVI will have great difficulty funding existing demand for vaccine programmes that have begun implementation (Groups 1 and 2 above); and given the significant preparatory activities (e.g. new country application processes) that need to be conducted for some of these vaccines, the PPC recommends that the Alliance continue preparatory activities for the four 'new' vaccines (HPV, JE, rubella and typhoid) and only open new applications windows following the pilot period of the proposed prioritisation mechanism and the definition of the 2011-2015 GAVI Strategy and subject to funding availability.

[7] Payments to countries and partners could be made when specific proposals are approved, in same proportion as total operational costs to total vaccine costs in current investment case (or on a per dose unit cost basis). Alternatively, partner costs could be channelled as part of the Workplan activities that GAVI funds for multilateral partners.

FOR DECISION

Implications of the Proposed Prioritisation Mechanism

Implications for countries

The weight placed on health impact and cost-effectiveness in the proposal prioritisation mechanism virtually assures that if funding is substantially constrained, only proposals from countries with relatively high disease burdens will be funded. Moreover, the less poor GAVI-eligible countries, and graduating countries in particular, will have difficulty obtaining funding. This is not primarily because country income is itself a criterion, but because disease burden is highly correlated with income: with some exceptions, the countries with the highest disease burden tend to be among the poorest. As a result, it is unlikely that graduating countries will be able to introduce new vaccines with GAVI funding. Short of exempting proposals from these countries from prioritisation, it is difficult to see how this outcome can be avoided in a way that is consistent with the basic objectives selected for the mechanism.

Similar to the situation for graduating countries, depending on the amount of funding that is made available for each proposal round and the rules applied for proposals that straddle the funding line, it is likely that large countries would struggle to be funded. However, as highlighted above, this challenge can, to some extent, be mitigated by announcing explicit budget caps for each application round. Large countries would still then have to determine whether they could pull together a targeted proposal that was within the budget envelope announced.

Implications for vaccines

Although the PPC has endorsed an approach in which GAVI will not take any of the vaccines in its current active portfolio 'off the table', the proposal prioritisation system proposed here will favour some vaccines over others, on the basis of their health impact and cost-effectiveness in particular settings. The task team's preliminary analysis suggests that in most settings pneumococcal vaccines will likely receive the highest ratings, while rotavirus vaccines will in general fare worse than either pneumo or penta proposals. However, the rankings of particular proposals will depend on the country: rota proposals from high-burden countries will fare better than pneumo proposals from low-burden countries.

Monitoring and Evaluation Plan

GAVI will have to put in place a coherent and well-defined monitoring and evaluation plan for the pilot prioritisation mechanism. The exact nature of this plan will be determined by the mechanism that the GAVI Board approves. However, it will likely involve the following aspects.

- Data issues: GAVI will need to assess whether the criteria and indicators that are selected prove to have the necessary characteristics identified by the time-limited task team (e.g. objectivity, transparency, easily understood, based on data that is available and comparable and regularly updated for all GAVI eligible countries).

- Ranking trends: GAVI will need to monitor the rankings from round to round to assess whether particular classes of country and/or vaccines are systematically ranked lower or higher than another – and if so, why this might be happening, whether it is appropriate, and, if not, how the system might need to be changed.
- Communication effectiveness: In addition, the Alliance will need to monitor communication of prioritisation decisions. Do country representatives understand the system and the notion that an IRC recommendation no longer equates to automatic funding approval? Do they feel that the scoring system is fair, sufficiently transparent and allows for an explicit ranking of proposals?
- Country feedback: GAVI will need to assess how countries perceive the pilot mechanism. Do they understand the approach and understand how the funding decisions have come about? Do they feel like that applying is a waste of time?
- Effects on supply and demand: GAVI will need to monitor the effects of the proposed prioritisation mechanism on demand and its ability to shape markets. In addition, close attention will need to be paid to predictability and supplier responses to GAVI's new way of working
- Effects of budget caps: Given that the PPC is recommending NVS proposal budget caps be considered, if introduced, the effects of these should be monitored particularly to avoid long-term inequities resulting within countries.

Next Steps

Several next steps have been identified that must get underway as soon as the GAVI Board have decided whether to approve the PPC's proposed prioritisation mechanism. Some of these next steps are necessary for implementation of the pilot mechanism while others are required to lay the groundwork for strengthening of the mechanism for future iterations of the mechanism.

Implementing the Mechanism

If approved by the Board, the GAVI Secretariat will lead implementation activities of the mechanism. This will encompass everything from publishing hypothetical scores for all countries and all permutations of proposals on the GAVI website, composing the ranking for each proposal round, informing countries about the IRC recommendation and subsequent prioritisation scoring.

Communicating the Changes

The most important feature of a pilot prioritisation mechanism will be to de-link, for the first, IRC recommendation from proposal funding. This will represent an important change for GAVI and for countries. As such, the key to the success of the pilot will be to communicate this basic change to eligible countries and GAVI Alliance partners, ensuring sufficiently clear and robust communication on how countries and partners should engage with and interpret the pilot mechanism while at the same time soliciting suggestions on how the mechanism could be improved.

Secondly, since the pilot mechanism is based on published data, GAVI will strive to ensure transparency by publishing on its website the country-by-country (and vaccine-specific) indicators as well as the likely proposal scores sufficiently far in advance of each future application round. This information can help countries decide on whether to submit an application, and/or to assess the likelihood of ranking on the higher or lower side – thereby setting expectations around the potential funding decisions.

Analytical Work

Extension of the health impact and cost-effectiveness indicators to other vaccines. As mentioned above in the discussion around the investment cases, GAVI will need to extend the approach such that it is capable of assessing country proposals for measles 2nd dose, yellow fever routine and preventive campaign vaccination, as well as meningitis A catch-up and routine vaccination in addition to pentavalent, pneumococcal and rotavirus proposals. Beyond the pilot period, further extensions to the approach will be required to add in HPV, JE, rubella, and typhoid vaccines.[8] It is proposed that the extension of the approach to measure health impact and cost-effectiveness be undertaken by the Secretariat in collaboration with WHO and CDC and subject matter experts; e.g. from the AVI.

Policy Revision and Process Development

Revision to GAVI's application processes and other policies: If the proposed approach to disaggregate the meningitis A and yellow fever investment cases is approved and countries are required to apply for these vaccines using the same process as for other vaccines, supplementary guidance for countries and the IRC would need to be developed and other policies and country guidelines would need to be updated. The AVI will be charged with extending GAVI's processes here in addition to their work to prepare for future vaccines (i.e. HPV, JE, rubella and typhoid).

Finally, if the Board approves the recommendation to define budget caps for NVS proposals, then the AVI's Large Country Sub-team will need to tailor its strategies and tactics towards the largest GAVI-eligible countries given the funding limitations.

Process Development – Necessary for Next Iteration of Mechanism

Extension of the EVM tool: The Effective Vaccine Management (EVM) tool looks at the performance of the system for the past 12 months and indicates how the immunisation supply chain was performing given the necessary throughput of the existing immunisation programme – This is something that is currently optional and may be required in future GAVI NVS applications. An additional module will now need to be designed to assess infrastructure capacity adequacy to accommodate more vaccines at the same time as the EVM is conducted with the overarching aim to enable GAVI to assess country readiness to introduce the new vaccine (in a quantitative manner). This would ideally be executed through the WHO Optimize team who are working on the roll out and refinement of the EVM.

[8] The approach is already capable of assessing pentavalent, pneumococcal, and rotavirus routine vaccination proposals and since there are only these three vaccines among the IRC-approved October 2009 proposals, it can be used as is for these paused applications now.

FOR DECISION

IRC Assessment of Readiness and Proposal Strength/Quality: The optimum approach for assessing country readiness as well as ranking proposals in terms of quality would require that the IRC provide some kind of assessment of these proposal characteristics. Given that this will only be possible once the results of the current IRC evaluation and response are clear, it will be explored in a later iteration of the prioritisation mechanism. If the evaluation leads to changes in the IRC process, it is possible that these changes could incorporate the exploration of the IRC playing a greater role to assess relative country readiness and proposal strength and quality.

ANNEX 1

GAVI Alliance Pilot Prioritisation Mechanism Summary

Draft

1. Goals

1.1. This pilot mechanism aims to inform GAVI's funding decisions in a resource constrained environment by enabling the ranking of country proposals recommended by the Independent Review Committee (IRC) for New Vaccine Support (NVS) and cash-based programmes and also informs the prioritisation of vaccines within GAVI's portfolio.

2. Scope

2.1. During the pilot phase, funding decisions for the following vaccines will be subject to the NVS proposal prioritisation mechanism described here: HepB and Hib- containing vaccines; Yellow fever routine vaccines; Measles 2nd dose; Pneumococcal conjugate vaccines from GAVI-eligible countries; Rotavirus vaccines; and Meningitis A routine + catch-up and Yellow fever preventive campaigns.

2.2. NVS application windows for JE, HPV, rubella, typhoid vaccines will not be opened at this time (see "Timeline for implementation and updates" section below).

2.3. During the pilot phase, funding decisions for existing cash-based programmes will be subject to the NVS proposal prioritisation mechanism described here however Health System Strengthening (HSS) proposals submitted through a new applications process – the Health Systems Funding Platform (HSFP) will not be subject to this mechanism.

3. Principles and Objectives

3.1. The pilot prioritisation mechanism is designed to (a) Support nationally defined priorities; and also to be (b) Objective; (c) Transparent; and (d) Feasible

3.2. The pilot prioritisation mechanism is directed by objectives to (i) Maximise health impact and value for money; (ii) Reinforce financial sustainability of immunisation programmes; (iii) Support countries with the greatest need; (iv) Promote equitable distribution of GAVI's resources among countries (as accorded by a maximum of one NVS proposal per round).

ANNEX 1

4. Criteria

4.1. The following criteria will be applied in a weighted index to rank IRC-recommended NVS proposals:

- Deaths averted per 1,000 vaccinated (as a proxy for "health impact").
- Cost per death averted (as a proxy for "value for money").
- Health share of government expenditure (as a proxy for "financial sustainability").
- Gross national income per capita (as a proxy for "need").
- A maximum of one NVS proposal per country can be approved per application round (as a proxy for "equity among countries" applied as a rule rather than an input to the index).

4.2. The following criteria will be applied in a weighted index to rank IRC-recommended cash-based proposals:

- Under-five mortality ("overall health burden") and DTP3 coverage ("system weakness") which together serve as a proxy for "need."
- Health share of government expenditure (as a proxy for "financial sustainability").

5. Operational design

5.1. Weighting of objectives for NVS proposals: Health impact-30%; Value for money-30%; Financial sustainability-25%; Need-15%

5.2. Weighting of objectives for cash-based programme proposals: System weakness-50%; Overall health burden-25%; Financial sustainability-25%

5.3. Ties: The health impact indicator should be used to break ties for NVS, and DTP3 should be used to break ties for cash-based programmes. In the case of the latter, the lower DTP3 coverage would receive priority.

5.4. Fate of unfunded proposal: Proposals that are not funded in a particular round would automatically go into the pool of new applications for the next application round. If in the next round, these proposals are still not funded, then countries would be asked to reapply.

6. Data sources

6.1. GNI per capita (Atlas method) from the World Bank

6.2. DTP3 coverage from WHO/UNICEF estimates

6.3. Disease burden for vaccine preventable strains of Hib influenza, pneumococcal disease and Rotavirus from WHO

6.4. Vaccine efficacy from the Weekly Epi Record, no.23(84) for rota; and WHO and technical consensus for Hib and pneumo

6.5. Average price per course over the period (2010-2015) from GAVI average weighted price projections

6.6. Share of government health expenditure as a proportion of total government expenditure from WHO National Health Accounts data

6.7. Under five mortality from Inter-agency Group for Child Mortality Estimation

ANNEX 1

7. Timeline for implementation and updates

7.1. The pilot prioritisation mechanism will be in effect for two application rounds including the prioritisation of IRC-recommended proposals from Oct 2009.

7.2. Applications windows should be prepared for Meningitis A routine + catch-up and Yellow fever preventive campaigns so these proposals can be requested, accepted and prioritised within the pilot prioritisation mechanism

7.3. While the prioritisation mechanism is being piloted, GAVI should continue preparatory activities for JE, HPV, rubella, typhoid vaccines, and only open windows for these vaccines after the pilot, subject to funding availability and the finalisation of the GAVI strategy 2011-2015

7.4. The subsequent iteration of this mechanism will be introduced once the pilot has been evaluated and possibly strengthened e.g. with the addition of a measure of Country Readiness added to the index to prioritise NVS applications and additional means of measuring Financial Sustainability.

ANNEX 2

Prioritisation Mechanism Indices

As mentioned above, in order for a prioritisation system to produce a complete ranking of proposals recommended by the IRC in a given proposal round and inform funding decisions, it must include more than a set of indicators. Some way to integrate the scores from the separate indicators is necessary. As such, the PPC recommends that an index be used to aggregate indicator scores. The full spectrum of possible values for all GAVI countries for each indicator was broken down into five equally sized categories (i.e. quintiles) and a score assigned to each category. The ranges of scores for each indicator are proportional to the weights assigned to the corresponding objectives (see Table 1 for weights). The final index is simply the sum of the scores for each indicator. Table A2.1 delineates the criteria, categories and scores for NVS applications while Table A2.2 does the same for cash-based programme applications.

By way of example, assuming a country applied for a particular vaccine, (referring to table 3 below): If the country had a disease burden and hence potential impact by using a particular vaccine of 1.5 deaths averted per 1,000 vaccinated, it would receive a score of 30 points for that criterion. If this translated into $2500 in vaccine costs per death averted, the country proposal would get a further 18 points. If the country also happened to spend 6% of its total government expenditure on health expenditure, it would receive a further 10 points and if that same country's per capita income was just $300, it would receive a further 15 points. In total, the country proposal would thus receive a total score of 73.

Table A2.1: Categories and scores by criterion for NVS proposals

Objective	Criteria	Categories	Proposal Score
Health Impact	Deaths averted per 1000	0 - .33	6
		.33 - .57	12
		.57 - .83	18
		.8 – 1.38	24
		> 1.38	30
Value for Money	Vaccine cost (US$)/ death averted	0-1295	30
		1295-2271	24
		2271-3717	18
		3717-6177	12
		> 6177	6
Financial Sustainability	Share of government health expenditure in total government expenditure	0-4.85%	5
		4.85-7.73	10
		7.73-9.72	15
		9.72-13.4	20
		> 13.4	25
Need	GNI per capita (US$)	0-$375	15
		375-600	12
		600-960	9
		960-1470	6

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		>1470	3

Table A2.2: Categories and scores by criterion for cash-based programme proposals

Objective	Criteria	Categories	Proposal Score
Disease burden	U5MR	0 - 49	1
		49-75	2
		75-115	3
		115-154	4
		> 154	5
System weakness	DTP3 coverage	0 – 66%	10
		66 - 80	8
		80 - 86	6
		86 - 93	4
		> 93	2
Financial Sustainability	Share of government health expenditure in total government expenditure	0-4.85%	1
		4.85-7.73	2
		7.73-9.72	3
		9.72-13.4	4
		> 13.4	5