



**REPORT OF THE NEW PROPOSAL
INDEPENDENT REVIEW COMMITTEE TO THE
GAVI ALLIANCE SECRETARIAT ON THE
REVIEW OF APPLICATIONS**

**Geneva
November 9th-20th 2015**

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List of Acronyms

AEFI	Adverse Effects Following Immunization
AFP	Acute Flaccid Paralysis (Polio Surveillance)
AHI	Adolescent Health Intervention
BCG	Bacillus Calmette–Guérin (vaccine against tuberculosis)
CC	Cold Chain
CCE	Cold Chair Equipment
CCL	Cold Chain Logistics
cIP	Country improvement plan (cold chain)
cMYP	Comprehensive multi-year plan for immunization
CSO	Civil society organization
cVDPV	Circulating Vaccine-Derived Polio Virus
DHS	Demographic and Health Survey
DTP3	Diphtheria-Tetanus-Pertussis, 3rd dose
DQSA	Data Quality Self-Assessment
EPI	Expanded Programme on Immunization
EVM	Effective Vaccine Management, an assessment tool
FCE	Full Country Evaluation
FMA	Financial Management Assessment
GPEI	Global Polio Eradication Initiative
HCW	Health Care Worker
Hep B	Hepatitis B vaccine
HPV	Human Papilloma Virus
HR	Human Resources
HSCC	Health Sector Coordination Committee
HSSP	Health Sector Strategic Plan
HSS	Health Systems Strengthening
ICC	Inter-Agency Co-ordination Committee (for immunization)
IDQA	Independent Data Quality Assessment

IDP	Internally Displaced Person
IDSR	Integrated Disease Surveillance and Response
IHP+	International Health Partnership +
IHR	International Health Regulations
IM	Intra Muscular
IPV	Inactivated Polio Vaccine
IRC	Independent Review Committee
ISCL	Immunization Supply Chain and Logistics
JE	Japanese Encephalitis
JRF	Joint Reporting Form (on Vaccine Preventable Diseases, WHO / UNICEF)
MCV	Measles Containing Vaccine
MDG	Millennium Development Goals
MDVP	Multi-Dose Vial Policy
MICS	Multiple Indicators Cluster Survey
MMR	Measles, Mumps and Rubella vaccine
MNCH	Maternal Neonatal and Child Health
MenA	Meningococcal A vaccine
MoH	Ministry of Health
MR	Measles-Rubella vaccine
MSD	Measles Second Dose
NCD	Non Communicable Diseases
NITAG	National Immunization Technical Advisory Group
NRA	National Regulatory Authority
NVS	New and underused Vaccine Support
OPV	Oral Polio Vaccine
PCV	Pneumococcal Conjugate Vaccine
PEF	Partners' Engagement Framework
PFSA	Pharmaceutical Fund and Supply Agency
PIE	Post Introduction Evaluation

PMU	Project Management Unit
PQS	Performance, Quality and Safety (of immunization equipment)
RBF	Result Based Financing
REC	Reaching Every Community
RED	Reaching Every District
RI	Routine Immunisation
RV	Rotavirus Vaccine
SAGE	Strategic Advisory Group of Experts (WHO)
SC	Sub Cutaneous (injection)
SCM	Senior Country Manager
SDD	Solar Direct Drive (vaccine refrigerators)
SIA	Supplementary Immunisation Activities
SWAp	Sector Wide Approach
TA	Technical Assistance
TT	Tetanus Toxoid
TWG	Technical Working Group
VDPV	Vaccine-Derived PolioVirus
VIG	Vaccine Introduction Grant
VPD	Vaccine Preventable Disease
VVM	Vaccine Vial Monitors
WUENIC	WHO and UNICEF

EXECUTIVE SUMMARY

The IRC met between November 9th and 20th 2015 in Geneva, Switzerland and reviewed 27 applications submitted by 22 Gavi eligible countries. Country applications included 7 HSS proposals and request for support for each of the following vaccines: MR campaign (2), Measles SIA (2), HPV Demo (3), Rotavirus (2), MenA (6), MenA campaign (2), HPV National rollout (2) and JE (1). Applications are summarised in Figure 1 below.

To achieve the review goal during this period, a 23-person independent review committee focused on the following specific tasks:

- Review funding requests and all other documentation attached to the requests that include Health Sector Plans, comprehensive Multi Year Plans and supporting documents as applicable to each country.
- Provide the GAVI Secretariat with final evaluation reports and recommendations of support for each country.

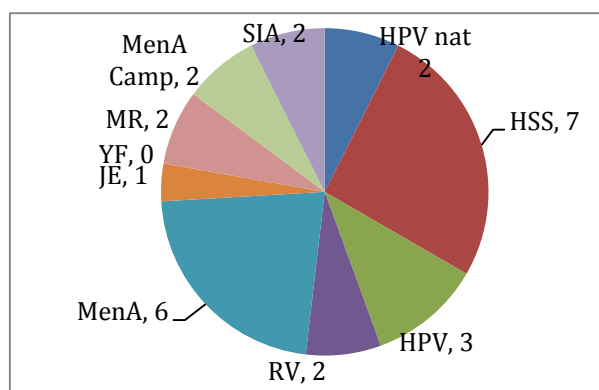


Figure 1: Summary of Country Applications by

- Provide the GAVI Secretariat with a consolidated report of the review, including recommendations for improving funding requests, including planning, budgeting, M&E, financial management, gender and equity considerations;
- Provide the Board and the Alliance partners with recommendations improving the processes relating to GAVI policies, governance, and structure.

Twenty three (23) reviewers from a range of disciplines took part in the review. (Refer to Page 38). The review team was made of reviewers with expertise in Health Systems strengthening, EPI, MNCH, RH program management, epidemiology, monitoring and evaluation, financial analysis, BCC and Gender. One (1) reviewer is also a crosscutting member of the Technical Review Panel of the Global Fund.

Main Findings

The main findings are summarized in Figure 2 below. 24 out of the 27 proposals were approved by the IRC (89% approval rate for all proposals). The high approval rate for vaccine support is driven mainly by campaigns responding to predicted outbreaks and catch-up campaigns associated with new vaccine introductions. HSS proposals reviewed had an approval rate of 86%. Three country applications were recommended as resubmissions. Country applications approved were requested to strongly consider additional comments and recommendations by the IRC to strengthen their interventions whilst at the same time requested to address/clarify critical concerns within thirty days of receipt of their decision letters.

The IRC recognises the continued improvement in the quality of proposals submitted by countries and commend the efforts of the Secretariat and Alliance partners for their technical support.

However, there are still gaps and weaknesses, which can result in the proposals needing to go back to the countries for further reviews through the resubmission process. The IRC particularly notes that resubmissions help to further strengthen the quality and feasibility, and enhance value for money of submitted proposals. The IRC strongly encourages countries and Secretariat to embrace this process from a positive perspective rather than see this process as failure for a country's application.

The IRC found that there was limited effort to involve CSO in the majority of the proposals, and even where this happened, it was unclear how this translated into corresponding allocation of funds. As the Gavi strategy 4.0 evolves, it is imperative that there are clear guidelines on how CSO participation and involvement will be more inclusive and robust.

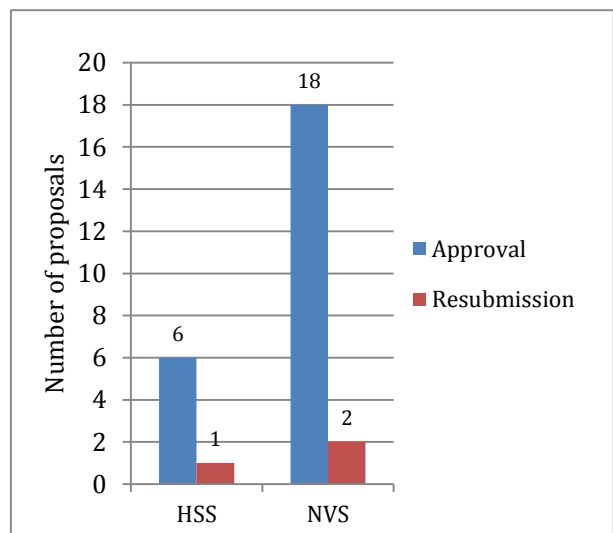


Figure 2: Main Review Findings

PURPOSE

This report outlines the recommendations of the independent review committee for the November 2015 review. It also summarizes the IRC process to review submitted applications, final recommendations, and lessons learned.

INTRODUCTION

The GAVI Secretariat convened the review of new vaccine and HSS applications, including resubmissions, from November 9th to 20th 2015 in Geneva, Switzerland. The review committee consisted of twenty three (23) experienced public health, immunization, health care financing, gender and health systems specialists as reviewers.

1.1 Terms of Reference of the November 2015 Review Committee

During this period, members of the committee reviewed all country submissions alongside relevant country documents. The review process included consideration and review of 27 country applications from 22 countries. The primary role of the IRC is to advise the Gavi Alliance Board on whether to fund country plans and programmes – both for new vaccine support and health systems strengthening support in line with the newly revised categories. The review committee was also requested by the Secretariat to recommend the proposals using the following criteria:

1. Approval; and where necessary, action points on minor issues flagged to the country to address within 30 days of receipt of the decision letter;

2. Re-submission; material conditions and/or major gaps are flagged and country will need to address within six months or rewrite a new proposal.

1.2 Methods

The IRC review meeting commenced with an initial 3-day training and background briefings across various topics provided by WHO, UNICEF, Gavi Secretariat (M& E, Finance, Policy & Performance and Senior Country Managers).

The proposal review process began with a demonstration review of a country application as part of the skills building process for reviewers. Subsequently, two plenary sessions were held concurrently each day and chaired by Bola Oyeledun and Sandra Mounier-Jack with Zeenat Patel and Linda Eckert as deputy chairs. Two reviewers were assigned to each country, and a country report was generated for each submitted proposal. Country specific presentations were made during the daily plenary sessions. Extensive discussions by all reviewers focussed on the applications as submitted by each country. Additional country specific information were provided by the Country Managers and their team members and WHO. Selected IRC members focused on the cross cutting issues of supply chain and logistics and gender and equity. Proposals were assessed against application requirements as outlined in Gavi application guidelines, as well as taking into account the degree to which proposals met the overall Gavi mission and strategic goals. Comments and decisions were agreed upon and one consolidated report finalised based on inputs from all the reviewers and comments from the plenary session. A revised process of work to create better efficiencies saw the consolidated reports being shared with the country managers and key Secretariat staff for inputs before review and finalization. The chairs reviewed all proposals submitted. In addition to the individual country reports and recommendations this global report was also developed focusing on the main themes arising from the review. The IRC commends the continued engagement by the Secretariat through the country management teams and the partners through WHO.

1.3 Focus of IRC Review

Key decision and recommendations were made by the IRC based on the extent to which proposals (a) meet mandatory requirements and (b) principles of support as specified in Gavi guidelines and (c) contribution to achieving Gavi mission and strategy.

1.4 Secretariat response to previous IRC recommendations

The IRC acknowledges work in progress by the Secretariat to further simplify processes especially with the introduction of the online portal, provide better guidance to country applications by working on improving guidelines for 2016 and technical assistance especially to PEF countries. Additional broad considerations especially relating to Policy to address HRH incentives and salary top-ups, PMU whilst realigning the transition process.

Key Findings and Recommendations

1.5 Data Quality, Immunization Coverage

The IRC devoted particular attention to how countries are addressing the critical challenge of reducing discrepancies between routine and survey estimates of immunization coverage. Annex 2 presents an analysis of the problem among 57 Gavi-supported countries and a case study of 3 countries with large and persistent discrepancies. This review highlights the following 3 issues:

Issue 01: Getting the denominator right

Issue 02: Getting the numerator right;

Issue 03: Getting the surveys right.

The IRC offers the following recommendations to address these issues:

1. Consider the range of factors which may contribute to discordant coverage estimates:
 - When analysing the reasons for the gap between routine and survey estimates, the national immunization program (NIP) and reviewers (including those on the Joint Appraisal) should, instead of simply attributing the problem to “data quality issues”, distinguish between problems with the numerator, problems with denominator estimation and possible problems with the most recent survey(s).
2. Increase efforts towards more reliable numerators:
 - An international technical consensus is required on best approaches for assessment of the routine information system. This should be based on a review of existing assessment methodologies and the evidence of their effectiveness. Components of routine data quality assessment include data verification (a.k.a. “data audit”)¹ root cause assessment (e.g. DQS, IDQA, DQA, PRISM²),³ and annual desk review. Of these, some form of data verification and some form of root cause assessment are most frequently now undertaken by countries. However, additional robust evidence of the reliability and usefulness of such assessment approaches is needed.

¹ Data verification involves surveying a sample of health facilities in order to compare registers with the reported data. Data verification, also known as a “data audit” is still required by the Global Fund and is typically included as part of the SARA survey which Gavi guidelines suggest as one activity to improve data quality.

² The PRISM Tool aims to characterize three dimensions of the routine information system: organizational (information culture, structure, resources, roles, and responsibilities of the health system at each level), behavioral (knowledge, skills, attitudes, values, and motivation of the people who collect and use data) and technical (data collection and data management forms and processes).

³ Various approaches have been developed and are now widely used to assess the root causes of poor routine data quality. These include: DQS (Data Quality Self Assessment), IDQA (Immunization Data Quality Self Assessment), HIS System Assessment (a module included with the SARA) and the Performance of Routine Information System Management tool (PRISM). David Boone’s web posting provides a brief overview of the most common approached now used.

<https://measurevaluation.wordpress.com/2014/07/09/call-for-integrated-data-quality-assurance-approach/>

- Gavi guidelines should further elaborate on what is meant by an “annual desk review”—now a Gavi requirement for all applications.⁴ Countries need to understand that this involves a systematic approach to review of the completeness/timeliness and internal consistency of routine data.⁵
- Joint Appraisals as well as applications to Gavi should estimate the completeness⁶ of routine data. Countries lacking a reliable system for assessing completeness should establish one. Joint Appraisals as well as applications to Gavi should also describe whether and how the routine district-level data have been reviewed for inconsistencies including extreme outliers, negative dropout rates and implausible year-to-year fluctuations.
- Gavi HSS guidance should encourage applicants to include activities to strengthen motivations for good record keeping and reporting by vaccinators. These might include more systematic feedback on data quality (something which can be automated using electronic systems such as DHIS); reinforcing facility-level analysis and use; linking performance bonuses to data quality; etc.
- Gavi should, along with other donors, support activities to strengthen data management systems.⁷ Electronic data management systems have definite advantages over paper-based reporting systems.⁸ At the same time, they are resource-intensive and can easily distract a Health Management Information System (HMIS) unit from the other activities required to promote better data quality. Gavi should encourage a balanced approach to strengthening of the health information system that supports economical and sustainable approaches to strengthening data management while paying due attention to the other organizational and behavioral constraints.
- Need for increased support to strengthen analytic capacity for robust performance reviews: Gavi HSS and NVS funds provide considerable funding for review meetings. The technical rigor of these meetings should be strengthened by investing in activities to build capacity for analysis of routine data (including data quality review) and triangulation using data from routine data, health facility assessments (e.g. SARA), household surveys and special studies.

⁴ The General Guidelines for Applications for All Types of Gavi Support specifies that “Gavi requires that countries applying for all types of Gavi support: 1) undertake routine monitoring of vaccination coverage data through an annual desk review; 2) conduct periodic (once every five years or more frequently where appropriate) in-depth assessments of routine administrative vaccination coverage data; and 3) conduct periodic (at least once every five years) nationally representative vaccination coverage surveys.”

⁵ WHO/IER have developed and are supporting the use of Data Quality Review (DQR) tools consisting of either an Excel workbook or DHIS applications. The approach has been carried out in a growing number of countries. Reports from repeated use of this approach Cambodia can be downloaded from a WHO website (http://www.who.int/healthinfo/publications_topic_data_quality/en/).

⁶ The annual completeness of monthly reports is equal to the number of monthly reports received from health facilities in a year divided by the 12 times the number of health facilities which deliver immunization services.

⁷ Here defined narrowly as the means of entering, transmitting, aggregating, storage and automated analysis of routine data

⁸ Some advantages of electronic data management include fewer transcription errors, more efficient transmission, automated data validation, access at every level to fully disaggregated data, automated tracking of completeness and timeliness, automated dashboards, automated screening for extreme outliers and other internal inconsistencies.

- Gavi should review its guidelines for all references to disaggregation of routine data by sex. The guidelines should delete all such references or make it clear that, like WHO, Gavi do not recommend disaggregation of routine data by sex. Such disaggregation of routine data doubles the record keeping and reporting burden and reduces data quality. Review of the experiences of countries that have disaggregated their routine immunization data by sex (Ghana, Tanzania, Zimbabwe) shows that the data are seldom analyzed by sex and when the disaggregated data are analyzed they are typically found to be too internally inconsistent to be reliable.
3. Focus on assisting countries achieve more reliable denominators:
- Gavi HSS guidance should encourage applicants to include activities to reach a technical consensus on national and sub-national estimates of the number of surviving infants. To assure that the revised estimates are mutually consistent, the consensus building process should take place at national level, be led by qualified national experts, and focus on systematic analysis of data derived from national censuses, nationwide immunization campaigns, aerial imagery and other robust sources.
 - Focus on alternatives to the present JRF-derived equity indicators. To track progress with geographic equity, Gavi's performance portal is designed to extract data from the country's Joint Report Form on the percentage of districts with various levels of coverage as estimated with routine data. Analysis of DHIS data from several countries shows that even when routine data are of reasonable quality, a large percentage of districts have coverage of greater than 100%.⁹ Clients do not always respect district boundaries when seeking health services. As a result, defining the "catchment area" of a district can become almost impossible. It is notable that the JRF does not ask countries to report on the percentage of districts estimated to have coverage greater than 100%. The JRF should be modified to include this as an indicator of the reliability of the district-level estimates. For most countries, survey-derived estimates of sub-national coverage remain the only robust indicators of geographic equity.
4. Ensure that reliable surveys are conducted at appropriate frequency and used fully for national decision making
- Investigate instances where survey findings appear unreliable or are disputed by national authorities. These instances are fortunately the exception. Findings from a high quality survey remain the closest thing available to a "gold standard". However, there is evidence that the reliability of surveys can be strengthened.¹⁰ There are also instances where national authorities prefer to estimate coverage in their own way. Such

⁹ For example, the routine estimates of 2014 DTP1 coverage were greater than 100% for 31% of districts in Tanzania and 39% of districts in Zimbabwe.

¹⁰ included in the WUENIC database had samples of fewer than 12 to 23 months of age; 4) Adequate documentation of the sampling methodology is not available for some immunization coverage surveys (e.g. some surveys selected households using a "random walk" approach that did not include mapping and listing or rigorous segmentation of the cluster), particularly the post-campaign surveys.

instances warrant careful assessment and an equally persistent, multi-partner response. Funding for a repeat coverage survey may be necessary.

- Assure that WHO's new guidelines on household surveys, to soon be released, are practical, acceptable to NIPs and used. It would be prudent to carefully evaluate initial use and NIP reaction to the guidelines.¹¹
- Support more frequent household surveys in countries where the gap between routine and survey estimates is 20% or greater. Gavi now require a high quality coverage survey each 3 to 5 years. For some countries, this could mean that coverage remains highly uncertain for 5 years or more (due to the delay in publication of survey results and the fact that surveys provide estimates for the prior year). This can severely compromise planning and review of immunization activities and limit progress towards Gavi's coverage and equity goals.

1.6 HPV Proposals

Issue 04: Gavi Guidance to Countries Conducting a Second HPV Demonstration Project

Kenya being the first country to apply to conduct a second demonstration project, the IRC noted issues during the review of this application that were the direct result of the absence of specific Gavi guidelines and parameters to countries planning to conduct a second demonstration project. The current Gavi HPV Demonstration Guidelines state *"Countries will be allowed to apply for a second demonstration programme if they wish to further explore the feasibility, acceptability, and cost of various strategies for HPV vaccination prior to national introduction"* (pg. 18). One issue encountered was whether a country is eligible for "bridge funding" to cover the missing cohort between two demonstration projects. There is precedence for Gavi providing "bridge funding" to countries between the completion of a demo project and a national rollout, however, there is no guidance on whether a country is eligible to "bridge" a cohort between two demonstration projects. A second issue that was encountered is whether countries are eligible for funding for AHI implementation activities that resulted from the AHI Desk Review in the 1st demo or for funding for activities related to the review of the Cervical Cancer Prevention and Control Strategy if this was not done/completed during the 1st demo.

Recommendation: Gavi should ensure that it provides countries with specific guidance on funding eligibility when conducting a second demonstration project including eligibility for bridge funding between two demonstration projects.

Issue 05: HPV Demonstration projects need to transition from "Learn by Doing" to "Learn in order to Scale-up"

Countries, eager to initiate HPV Demo projects and eager to maximize coverage and "success" have devised HPV vaccine delivery strategies that have been primarily school based campaign style and typically conducted in the highest performing districts. Rarely have HPV Demos utilized "routine

¹¹ According to an informed source, the new guidelines may call for abandonment of the "random walk" approach to sampling households and require mapping/listing/rigorous segmentation of each cluster. While such guidance is technically sound, it may not be easy to convince NIPs and their contractors to adopt them.

delivery” as one of the strategies to test. Also, rarely have HPV Demos taken the opportunity to test two different strategies in the two years of the Demo Project. In this IRC meeting, Malawi applied for a phased national rollout of HPV vaccine. Having realized that their school based campaign style for HPV delivery was too expensive for national scale up, Malawi proposed a national delivery strategy using routine delivery with outreach, a strategy that they had not tested in their Demo project.

Recommendation: Gavi guidelines need to more strongly encourage testing of HPV Demo strategy (ies) that will be scalable. To do this, Gavi should encourage countries in at least one location/year of the Demo Project to test “routine” delivery. Gavi should consider funding costing exercises for each of the delivery strategies tested, and may need to relax the timeline between Year 1 and Year 2 of the Demo project if countries need more time to analyze the cost/coverage information to alter strategies for the second year. If the country proposes a phased national rollout, as Malawi did, Gavi guidelines need to be more clear about how to calculate the target population (eg is it the size of the cohort in the first year of the rollout or is it the total cohort size once the project is national scale) as this has major implications for co-financing and introduction grant calculations.

Issue 06: Out-of-schoolgirls in HPV vaccine delivery

Most demonstration project protocols suggest “outreach” to reach such out-of-school (OOS) girls with strategies similar to those for in-schoolgirls. The reality is that these OOS girls may need profoundly different approaches. Their numbers and location may be largely unknown and the appropriate method and dissemination of health education messages for them or how to achieve high vaccine coverage with this population is also not known. These girls are among the most vulnerable and reaching these girls is an equity issue.

Recommendation: Gavi should consider supplying technical support to countries specifically to address these out of school girls, utilizing social science approaches and expertise.

Issue 07: Mass Psychological illness

A phenomenon not confined to vaccination is when an external event or environment triggers a negative reaction in a few individuals that can quickly escalate to involve many. This is called a Mass Psychological Illness (MPI). There are usually similar symptoms or behaviours that are repeated in many individuals in the group. It requires line of sight of the event or in some cases, media transmission of news of an event. Any place where vaccines are given to older children or adults who can see a vaccinee ahead of them in the queue experiencing symptoms or behaviour abnormalities (not just fainting) may follow suite. This can trigger an MPI. The advice to ALL programmes offering injectable vaccines to vaccinees other than small children is that they run the risk of triggering an MPI, and should administer each dose out of sight of the waiting queue e.g. behind a screen or in another room. This is not a trivial matter – entire national immunization programmes have been shut down because it was assumed the vaccine was contaminated. Such an event was documented recently in an Australian school administering HPV to girls.

Recommendation: Countries should be encouraged to state how they will deliver the HPV vaccine in a manner that will minimize risk of MPI

1.7 Other NVS proposals

Issue 08: Maximizing the “draw” of the Men A vaccine

This vaccine is coveted and has the ability to attract a large population as countries are very aware of Meningitis and the success of this vaccine. It has the potential to serve as a catalyst for delivery of other vaccines and services.

Recommendation: When countries are introducing Men A into routine, and/or when having their catch up campaign, Gavi guidelines should stress combining Men A with other less popular vaccines (such as measles) or other health interventions (such as Vitamin A or deworming).

Issue 09: Choice of Japanese Encephalitis vaccine

Vietnam introduced a locally produced inactivated, mouse brain-derived (MBD) JE vaccine in 1997. In 2006, WHO stated that, compared to the live, attenuated JE vaccine, MBD JE vaccine has a limited duration of vaccine-induced protection, requires multiple doses from infancy through adolescence, and, in most countries, is expensive.

Despite these limitations, in 2014, Vietnam expanded their existing MBD JE vaccination programme to a national programme whereby all 1- to 5-year-old children received three primary vaccine doses. At the same time, the Vietnam MOH announced plans to locally produce one of the newer generation JE vaccines in the future. Vietnam has a National Regulatory Authority that has been WHO certified so was able to approve the vaccine for use in Vietnam.

Vietnam has purchased the rights to a Japanese-developed Vero cell-derived inactivated JE vaccine that was licensed by the Japanese authorities in February 2009. Clinical trials have shown that the vaccine is safe and immunogenic, with sero-conversion rates exceeding 95%. In the meantime, the date of manufacture of the new Vietnamese vaccine is uncertain, and even less certain is the date the vaccine will be introduced for use. In this interval, the Vietnamese GAVI application proposes that the new vaccine introduction grant should support the use of a MBD vaccine that WHO feels is now out-dated. A live attenuated vaccine based on the SA 14-14-2 strain of the JE virus is widely used in China and in an increasing number of countries within the Asian region, including India, the Republic of Korea, Sri Lanka, and Thailand. This is the vaccine now supplied by UNICEF.

There are more recent vaccines that are attractive for use including the new live attenuated, JE–yellow fever chimeric vaccine recently licensed in Australia and Thailand. A single dose of this chimeric JE vaccine was found to be safe, highly immunogenic and capable of inducing long-lasting immunity in both preclinical and clinical trials. Vietnam has expressed a preference for using such a vaccine for their GAVI-funded SIA, although they know that they would have to pay for the difference if it were to cost more than the UNICEF-supplied live attenuated vaccine. The application suggests a willingness to use the UNICEF-supplied vaccine if necessary.

The issue for GAVI is whether to award a V.I.G. for a vaccine that a) has already been introduced nationwide; b) requires 5 or more doses to achieve lasting immunity; c) causes more local reactions; and d) is not WHO pre-qualified. The vaccine the Vietnamese will manufacture is for national consumption only, and will be approved by the Vietnamese National Regulatory Authority (which itself HAS been

approved by WHO). So although the vaccine has not been pre-qualified by WHO, it does fall within the correct WHO guidelines.

Recommendation: GAVI guidelines need to clarify whether “whether the VIG should be funded when a vaccine has already been introduced by the country, following up a GAVI funded catch up campaign”

1.8 Campaigns and Measles SIA

SIAs are intended to complement routine immunization rather than replace it. SIAs are typically used in countries with weak immunization delivery systems and where there is evidence or concern as to the ability of routine immunization programmes to reach all at-risk children. The aim of mass campaigns is to interrupt circulation of childhood diseases by immunizing every child regardless of immunization history, the idea being to vaccinate children who are either not immunized or only partially immunized. Despite the investments in SIA, there have been reports of poor quality measles SIAs and the IRC highlights some of the root causes as issues to be addressed below:

Issue 10: Poor quality SIA:

The literature suggests that regular measles SIAs combined with high coverage with one dose of measles vaccine given in the routine system will effectively control measles. However, certain countries (e.g. Chad and DRC) have been conducting SIAs for a number of years with apparently high coverage. But outbreaks of measles continue to occur annually throughout the countries.¹² Either the vaccine potency is compromised (e.g. from excess heat in transit or immediately after reconstitution), or the denominator is wrong and the campaign is not reaching the large numbers of non-immune children claimed. There are two solutions

- Improve the quality of the SIA to cover more children, reaching children not previously reached.
- Evaluate the cold chain with data loggers to establish if there has been vaccine exposure to excessive heat.

Either way, the root cause of why measles is not controlled by repeated campaigns must be undertaken before SIAs are funded again. It is imperative that Secretariat and Alliance partners work with countries to move away from doing the same thing over and over again and expecting a different result. Countries such as DRC, Chad and Sudan have hard-to-reach target groups for a number of differing reasons. There was unconvincing documentation from the applications that they were trying hard to reach these groups in the campaigns.

Equally important is the question of whether to invest in a country that focuses on repeat SIAs to control measles rather than raising both MCV1 and MCV2 coverage. While SIAs have specific roles and will probably continue to be relevant in many countries for some time to come, they are less sustainable as a strategy compared with achieving high routine coverage levels of MCV-1 and MCV-2 in all districts. More efforts and resources need to be deployed to strengthen routine coverage of MCV1.

Recommendations:

¹² Helleringer S, Frimpong J, Adelwahab J, Asuming P. (2012). Supplementary polio immunization activities and prior use.

- SiA's, when needed, should be designed to meet specific needs, must be carried out effectively and safely with very high coverage, and should be integrated with other public health interventions to make them more cost-effective. Little benefit is likely to be derived from a poorly executed SIA.
- Creative and innovative approaches to increasing MCV coverage are required. For example, new approaches to reach hard-to-reach groups more effectively, or testing the introduction of routine MCV2 in some highly intensive SIA countries..

Issue 11: Silo approach to SIA:

Little thought is given to planning an SIA in concert with other public health measures, including immunization campaigns for another antigen (ie. Measles SIA and mini-catch up for Men A)

Recommendation: There is a need to synchronize activities such as training, social mobilization, cold chain planning etc and ensure they are carried out synergistically just the once to include all the modalities. Conducting measles SIA combined with popular MenA can possibly contribute to increased coverage.

Issues 12: Polio staff

There is little evidence from the Chad and DRC applications that polio surveillance staff and polio programme resources are contributing to planning and execution of measles SIAs. In places where polio is now under control e.g. Nigeria, polio staff might be more receptive to helping with planning, surveillance and implementation of measles SIAs other in sub-Saharan Africa.

Recommendation: Maximise the window of opportunity to use polio staff and machinery to further support routine immunization.

Issue 13: Impact on routine immunization

There is strong evidence that SIAs may divert resources away from Primary Health Care services, especially in countries with weak health systems.¹³ In Chad, there was over a month between campaigns and training for health care staff, and it can be said with some certainty that those staff who were training and conducting the campaign were not conducting routine immunization during that time.

Recommendation: There is a need for country level partners and key stakeholders to ensure that there is a right and complementary balance between routine immunization and SIA. Availability of routines immunisation services during campaigns also need to be systematically and closely monitored.

1.9 Health System Strengthening

General Overview:

A total of seven (7) HSS applications were reviewed during this period. The applications comprised of three *new applications and four resubmissions. Two applications, from Ethiopia and Pakistan, were new proposals. Four, from Bangladesh, Bolivia, Lao PDR and Zambia, were resubmissions from the

¹³ Schreuder B, Kostermans C. (2001). Global health strategies versus local primary health care priorities--a case study of national immunization days in Southern Africa. *S African Med J*, 249-254.

March 2015 round. The *proposal from Afghanistan was an additional component (on data quality) of the HSS3 application recommended for funding in June 2015. Six out of seven proposals (86%) were recommended for funding, with variable range of minor “issues to be addressed” by the applicants and the Secretariat. A summary is provided in Table 1.

Table 1: Summary of HSS Applications

Country	Type of Application	IRC outcome	HSS approach	Targeting "missing %"	Implementation Arrangements	Budget Request (cash)	Budget granted	Budget Recipients			National HSSP period	Alignment (years)	JANS / HSSP Review / Mid-Term Review report	Response to JANS / Review	Proposal development and approval (ICC, HSCC,)
								Gov	CSO	Partner					
Afghanistan (Special review)	HSS complementary application	Re-submission	Supplement to HSS for DQI	na	MoH	2.3	2.3				2016-2020 in preparation	virtual 100%			
Bangladesh	HSS	Approved	Through WHO and UNICEF	na	Through WHO and UNICEF	34	34	1%	0%	99%	2011-2016	1 20%	World Bank mid-term review of HPN HSDP	No	Local Consultative Group (LGG) on health
Bolivia	HSS re-submission	Approved	Strengthening I & II level of care for EPI program	10 municipalities. 70% of Bolivian population	MoH	5.2	3.3	100%	0%	0%	2016-2017	2 100%	September 2014-September 2015	no in the documents attached	MOH, DG Health Services, PAHO, UNICEF
Ethiopia	HSS new application	Approval (4 years)	Pooled fund financing HSTP	Yes, under served regions (in HSTP)	Pooled fund financing HSTP	80.6	80.6	100%	0%	0%	2016-2020	4 100%	JANS (June 2015)	yes	MoH and DPs
Lao PDR	HSS re-submission	Approval (3 years)	Integration EPI with nutrition and MCH services.	YES. In 46 weak districts, integration with MCH and nutrition	MoH, SWG, existing institutional and coordination arrangements	7.56	7.56	na	na	Na	2016-2020 draft	100%	Joint Appraisal (EPI) June 2014, internal MTR	no info	Health systems strengthening task force. Approval by ICC on 7/1/2015
Pakistan	HSS new application	Approval	Pooled fund mechanism, part of multi donor trust fund	YES	MDTF	84.0	84.0	94%	6%	0%	2015-2020	5 100%	Annual Joint Appraisals		partners, NICC
Zambia	HSS re-submission	Approval	Logistics; HRH including RBF; communities and CSO involvement	No clear targets.	Min of CDMCH, existing arrangements	9.09	9.09	57%	28%	16%	2016-2020 in preparation	virtual 100%	JANS on HSSP 2011-2015	no info	MCDMCH (Gov), ICC, consultations

The IRC noted definite strengths and improvements in the overall quality of the proposals submitted especially in the following areas:

- Improving quality of applications, based on sound situation analysis and, in three countries, addressing the challenges identified by the HSS evaluation recently concluded (in Bangladesh, Ethiopia and Zambia)
- Better timelines alignment with the National Health Sector Plans (four out of seven fully aligned - Bolivia, Ethiopia, Lao and Pakistan – and two aligned - Afghanistan and Zambia where national plans are currently being prepared. A huge progress since March 2015, when eight out of ten proposals were not aligned). This is considered positive, although it is not sufficient to ensure consistency with national health sector plan and ensure integration.
- Focus on underserved areas and aim to reach the “missing %” in most proposals except Bangladesh and Afghanistan for which the purpose of the proposal was focus on a subset of technical objectives (cold chain, information system, surveillance)", with strategies to expand coverage in marginalized sections of the population.
- Slightly wider stakeholders’ involvement in the HSS proposal preparation and implementation.
- Stronger monitoring and evaluation frameworks.

However, the IRC identified some critical recurring challenges especially relating to the fact that most applications did not include a financial gap analysis nor a clear background of donor mapping. The weakness of these two critical parameters made it more challenging for the IRC to assess some proposals especially in the cases of pooled funding arrangements.

Most countries did not indicate, in their application package, the data verification method (admin data, WUENIC or surveys) that they would like to utilize for verifying their eligibility to receive the performance payment (PBF component); even after the WHO pre-review, provision of template and related solicitation. Therefore, this was requested by the IRC in the country reports.

The findings of the HSS evaluations could have been even better exploited in the design of the proposals, such as the recommended systemic approach to human resources (e.g. in Zambia) and integrated solutions to address operational challenges within the health sector.

The specific issues highlighted in the review of the seven HSS applications, and the related recommendations, are as follows:

Issue 14: Dealing with Country institutional changes / Health sector reforms and their impact on immunization

Countries that are undergoing institutional changes and reforms, in the health sector or in the wider public administration, present challenges related to governance and management, service delivery, political priority setting, that may affect immunization programmes and outcomes.

Recommendation: Where considered and correctly faced, these challenges could become profound opportunities. The IRC recommends that HSS grants be better used to mitigate

possible challenges and more especially to facilitate innovative ways to make these institutional changes benefit immunization. Opportunities provided by these changes need to be maximised at the advantage of immunization outcomes. Gavi Secretariat and Alliance partners are requested to ensure countries are well informed and encouraged to do so. Countries should endeavour to use these resources to catalyze their systems through design of innovative and sustainable solutions. Examples of these include the under listed:

- Health insurance schemes being designed in several countries in the framework of UHC and related financing: Gavi HSS grant can be used to ensure inclusion of EPI in the basic package, with the aim to make it fully funded by domestic resources and sustainable.
- Health sector reforms ongoing in Honduras, where the current HSS grant has the opportunity to strengthen the EPI in the framework of the reform and under the existing “Immunization Law”.
- Transition of immunization logistics functions from MoH to PFSA in Ethiopia, with efficiency improvement: the HSS supports this process.
- Decentralization process in Kenya and in Pakistan: potential contribution to sustained EPI functions across levels of administration.

Issue 15: Surveillance, IDSR and IHR

The issue is the current emphasis on Global Health Security, implying renewed efforts on disease surveillance – including IDSR – and adherence to International Health Regulation. Key global actors such as WHO and CDC are Gavi Alliance partners. Gavi grants are already being used in VPD surveillance in several countries.

This is a systemic issue where Gavi could strategically invest more, without big programmatic effort or changes, building on a number of elements, including: 1- it is instrumental to the surveillance of vaccine preventable diseases, 2- this field of knowledge and activity is in great need of strengthening and development (as demonstrated by the Ebola epidemic), 3- it is a matter of concern in the current emphasis on global health security (triggered by Ebola), 4- the key global actors supporting the countries in strengthening surveillance are Gavi partners, i.e. WHO, CDC, several governments.

Recommendation: explore relevance and opportunities for Gavi to invest / capitalize on investments on surveillance, IDSR, HIS. Also contribute to the definition of roles and responsibility between Gavi, WHO and country authorities / actors. Need to build on the polio eradication experience and structures.

Examples: Lao PDR, Pakistan and Bangladesh are investing Gavi funds on surveillance. RDC has active IDSR and measles surveillance appears to be critical, also to make the repeated campaigns more effective and support the transition to fully routine immunization.

Issue 16: Gavi’s catalytic role

Gavi’s role needs to be seen in the full context, by Gavi and by the country itself and its added value should be defined in the development of the proposal. Often times, this is the only external funding support dedicated to immunization and ensuring some years of predictable financing. It is then acts as the basis to catalyze other partners’ contributions and increasing domestic financing.

Recommendation: The Gavi HSS proposal should be considered in the country context by the applicant, the Secretariat and the IRC, with attention to their potential catalytic role.

Example: starting innovative PHC strengthening that is then picked up by other bigger partners in Afghanistan.

Issue 17: Sustainability

Sustainability is relevant for HSS grants, not only in terms of financial sustainability (addresses in the financing section) but also in terms of technical and programmatic sustainability. However, this is not often clearly illustrated in the proposals.

Recommendation: The HSS proposals can include a wide range of responses to system's needs. They have to be justified, the proposal should show how the system is being strengthened (durable changes) and how Gavi support will be phased out during the lifetime of the grant.

Examples: Honduras and Bolivia both have a "Vaccination Law" that allocates resources for EPI when the national budget is formulated and incrementally takes over from external funding.

Issue 18: Integration

Integration of immunization activities into the health sector needs to be emphasized again.

Recommendation: The HSS grant must be aligned to the national health sector strategic plan and serve to integrate immunization activities / assets / systems into the wider health systems. This approach is consistent with the general goal of Universal Health Coverage to which Gavi contributes.

Issue 19: Other elements related to the application and review process

- **The funding gap analysis** is requested in HSS applications but often not provided.

Recommendation: it should be a firm requirement, as it is essential for proper review of proposals, especially with pooled fund arrangements. The funding gap analysis can be instrumental to the point above, the catalytic role. Considering the limited reliability of such analysis and the rapidly changing donors' landscape especially in fragile settings, what can be reasonably requested and useful is a mapping of funds (domestic and external) against the national health plan. This is requested by other donors and is something the countries are able to provide, including firm commitments and pledges, in a living document. This critical information on funding gap should be provided to IRC in a more digest and use friendly document

- **Pooled funding arrangements.** For the applying country the requirements are now clear in the guidelines 2016. However, no guidance is provided to the IRC on how to assess these proposals.

Recommendation: the IRC needs clear indications about the assessment of proposals with pooled funding arrangement, particularly in terms of level of

details the applying country should provide on the Gavi portion of the pooled funding.

- **Measurement of HSS performance.** It is not well documented how this how this critical information is / can be collected nor to what extent the “intermediate indicators” are being provided and are sufficient for evaluation. Overall, intermediate indicators seem to have improved but still need to be more focused on tangible changes in service availability, accessibility and quality, efficiency and effectiveness of any HSS investments or measures implemented. Performance based funding strategies is a move in this direction. Baselines remain an issue, in countries like Bolivia, Lao PDR and Pakistan.

Recommendation: The new Performance Framework being introduced could be an additional instrument, it should include indicators to measure improvements in health system performance, aligned to the country M&E.

- **HSS Evaluation.** Three countries reviewed for HSS have recently undergone a HSS evaluation. Findings indicate that most of the challenges documented through these evaluations are addressed in broader terms in the newly submitted HSS proposals. However, this process could be even better exploited.

Recommendation: some points could be incorporated in the IRC reporting template to track the consistency or inconsistency between findings from evaluations and country HSS applications.

- **IRC Review Procedures:** The IRC needs clearer guidance on HSS resubmissions: There is a need to define to both IRC and country applicant very clearly on what has to be re-assessed in any given resubmission package. It is presently unclear in terms of either the whole proposal or only the changes made.

Recommendations: Where the country decides to re-write the resubmitted proposal, this should be clearly stated and in case of where changes are made to the existing proposal, these must be clearly tracked, highlighted and referenced if need be.

HSS approval for three years in case of draft national health sector plan. What is the subsequent procedure? Once the NHSP is final and formalized, is the grant extended by the HLRP?

- **New application guidelines.** As recommended in previous meeting, the development of new guidelines should include a step of consultation with the IRC (quick online consultation with 2 or 3 IRC members) and with “end users” in country (2 or 3 people from MoH / EPI in different countries and also 2 or 3 WHO / UNICEF officers who will assist in the development of the proposal).

1.10 Gender and Equity

During this review, the IRC found that even where countries had equity studies to draw on, the links between the studies and the proposals were weak. The activities and budgets did

not address equity challenges specific to their national situations (for example, fragility, nomads, linguistic/ethnic groups, lower coverage in boys). In terms of M&E frameworks, countries are expected to include two “mandatory” equity indicators with baselines and objectives. This was not always observed. Other critical issues as identified are also described below:

Issue 20: Many NVS proposals reviewed are quite “generic” from the gender and equity perspectives. The country may note that an equity study has been done but the implementation plan does not address specific equity challenges. Frequently the proposal will state that the use of RED or REZ or REC strategy will meet equity concerns. Proposal reviewers found it impossible to determine if a country’s RED approach had been validated or was well supported with adequate budget, training, supervision and community involvement. The shift to REC means a focus on high risk children, the children who are usually missed. But proposals were not explicit.

Furthermore, in several countries where there had been successful polio eliminations, the reviewers could not find evidence that lessons learned in reaching the hardest to reach were being transferred to MenA, rota, or Measles related activities.

Strategies for reaching out of school girls engaged in child labour, prostitution, or already married are absent or weak in most of the HPV proposals reviewed. This is important as they are exposed to early sex and therefore more in danger. Applications also did not include required information on adolescent health and cancer control strategies.

Recommendations

Under Gavi 4.0, there are better opportunities for dialogue with Alliance partners and countries through the Joint Appraisal process. Gavi should consider calling on G&E expertise to help prepare and participate in Joint Appraisals. More work needs to be done on the links between women’s empowerment and vaccination coverage.¹⁴

Gavi 4.0 includes a renewed focus on governance. Both Health Sector Coordination Committees (HSCCs) and ICCs could be reminded/urged to include national CSOs, researchers, voices of the marginalized including women (for example, one country has set up Task Group on “Equity, Gender and Voice” as part of its HSS planning).

1.11 Financing and Sustainability

1.11.1 Analysis of budgets in HSS applications

Budgets of five HSS applications were reviewed: Bangladesh, Bolivia, Laos, Pakistan and Zambia. Ethiopia’s HSS application is under a pooled funding scheme and did not include a budget. Total funding of the five applications amounted to US\$ 137 million, with 61% for the Pakistan application (US\$ 84 million) and 25% for the Bangladesh application (US\$ 33 million).

¹⁴ Thorpe S, VanderEnde K, Peters C, Bardin L, Yount KM. The Influence of Women’s Empowerment on Child Immunization Coverage in Low, Lower-Middle, and Upper-Middle Income Countries: A Systematic Review of the Literature. *Maternal and child health journal*. 2015;28:28.

There were marked differences between the budget allocations in the five countries as seen in Table 2 below. While approximately half of the budget will be used for service delivery in Bolivia and Laos, this component will not be supported at all in Bangladesh. Figure 6 shows the budget allocations across the five countries.

The proportion of funds allocated for equity related activities was not transparently reported in the budgets, while surveillance activities and coverage surveys were included as equity related activities in some of the budgets. IRC analysis of the budgets focusing on specific activities to reach unreached indicated a 44% allocation in Zambia, 6% in Pakistan, 6% in Laos and 0% in Bangladesh.

GAVI grant categories	Bangladesh	Bolivia	Laos	Pakistan	Zambia	Total
Service delivery	0%	14%	56%	9%	31%	11%
Human resources	15%	29%	5%	6%	8%	8%
Supply chain	56%	36%	17%	44%	0%	43%
Health information system	11%	9%	12%	25%	23%	21%
Community and local actors	0%	2%	6%	9%	14%	6%
Legal/Policy	2%	2%	0%	4%	0%	3%
Project management unit	16%	8%	4%	2%	23%	7%
Total Budget	33,922,732	3,202,234	7,560,863	83,447,762	9,096,176	137,229,767

Table 2: Activity and Item Allocations in HSS Budget

In terms of **implementation of HSS programs**, only the Zambia proposal included a substantial community involvement, with 27% of the budget allocated to CSOs. The Pakistan budget allocated 6% to CSOs. The remaining three proposals did not report any CSO involvement in their implementation of GAVI HSS programs. The Bangladesh HSS project will be implemented by WHO and UNICEF and the Government will only directly receive 1% of the budget (Figure 3).¹⁵

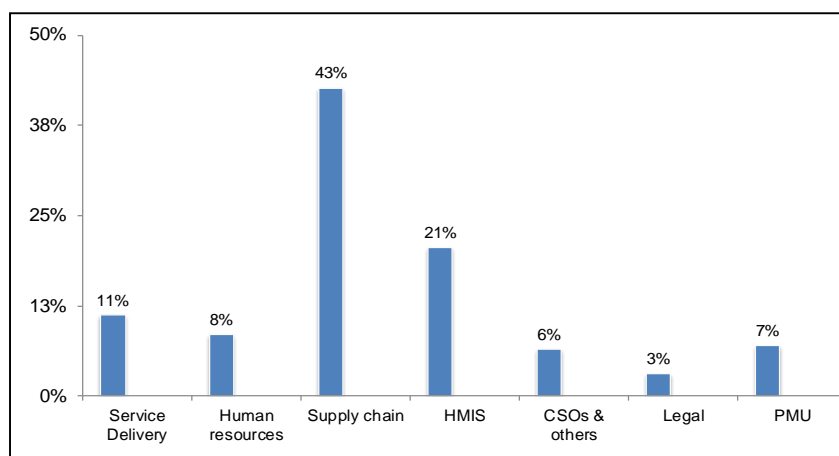


Figure 3: Budget Allocation across the 5 HSS Applications

¹⁵ Afghanistan HSS was supporting the specific component of Health information systems strengthening, so not reported in this Figure

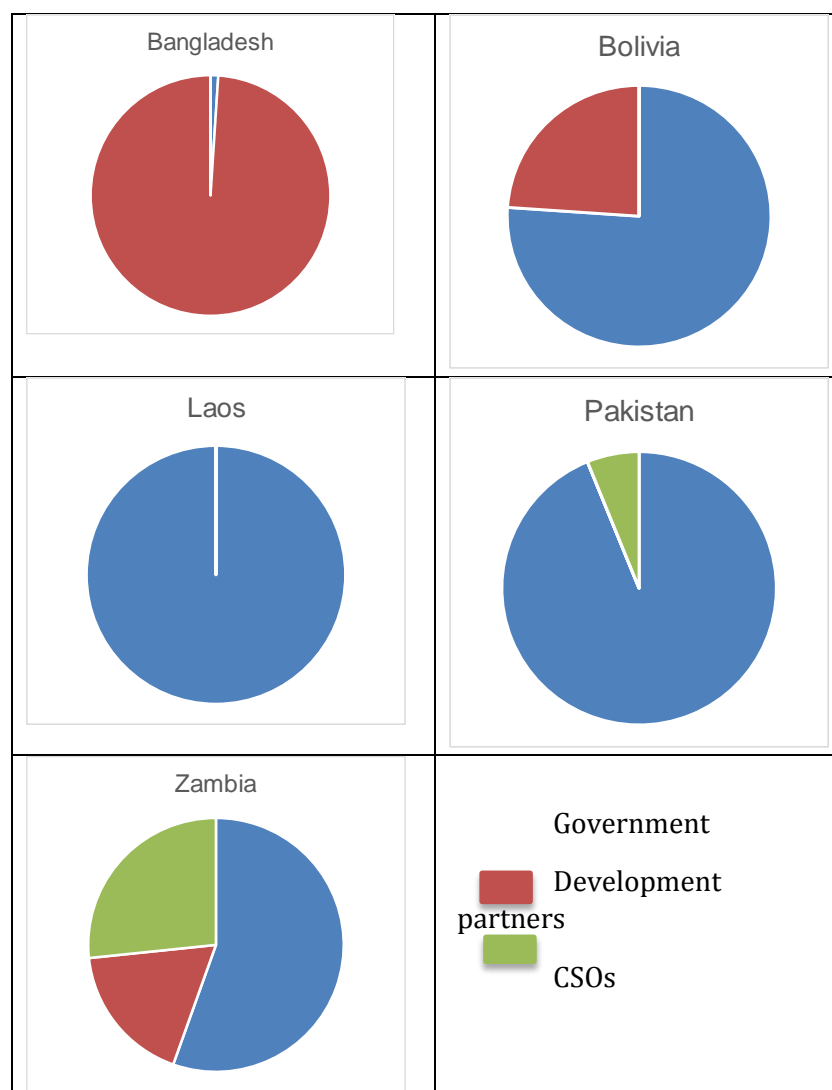


Figure 4: Implementation of the HSS programme

1.11.2 Government expenditure on immunization services

During this November IRC, seven of the reviewed countries are in the preparatory transition group; Ghana, Laos, Lesotho, Nigeria, Pakistan, South Sudan and Zambia. In the coming years, these countries are expected to increase their national budget allocations for immunization. According to data submitted to Gavi by the countries in their Annual Progress Report (APR), the Governments of Ghana and Sudan only fund 18% and 13% of total immunization expenditures, respectively. (Ref Figure 4). This must be considered too low for countries scheduled to transition from Gavi support within the next 6-10 years. However, Lesotho and Pakistan reported that 77% and 70%, respectively, were funded from Government sources.

Lesotho reported that 31% of government funds were spent on traditional vaccines, new vaccines and supplies and 46% for human resources. There was no Government spending on other critical areas of the EPI, such as cold chain or surveillance.

Financing of traditional vaccines is a good trigger to assess how countries are preparing for sustainable financing. Five countries, including conflict or post-conflict countries (Afghanistan, CAR and Sudan) are not paying for any of their traditional vaccines. Recovery

efforts in these unstable countries may shift their spending priorities. Bangladesh and Malawi are extreme examples of stable countries that do not finance their traditional vaccines (Figure 5.)

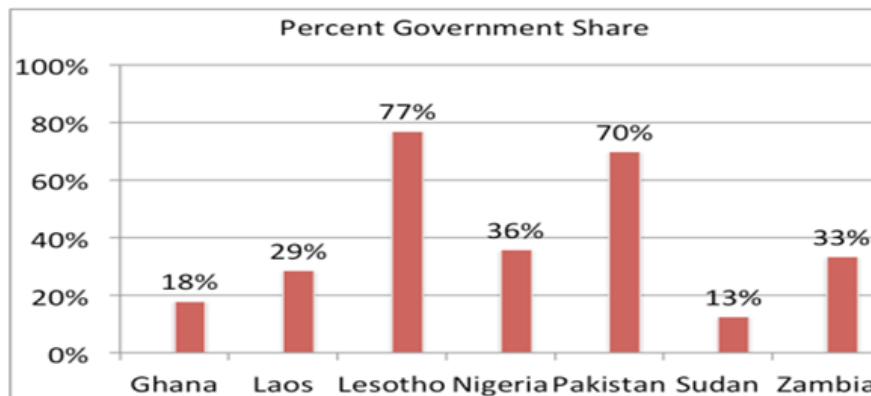


Figure 5: Government Funding Share of the total Immunization Expenditure

Recommendations

- There is a critical need to phase out the funding of recurrent costs for transitioning countries.
- Despite the clear roles of CSO in complementing immunization activities especially in reaching the hard to reach and marginalized populations, budget allocations within the HSS investments remain very low and require significant increase by applicant countries. There is a need for the guidelines to be reviewed to ensure countries pay closer and much needed attention to fully involve and fund CSO participation actively.
- There is a need by alliance partners to advocate for increased equity investments especially in countries like Bangladesh and Pakistan while macro budgets need to be made available for IRC review for HSS countries under the pool fund mechanism.

1.12 Supply Chains and the CCE Platform

1.12.1 Supply Chain Findings:

The ISCL situation in countries reviewed is generally being reported in a more complete and comprehensive manner in applications for support, although there are exceptions. The HSS guidelines in particular would benefit from being more specific in terms of defining the ISCL information countries are expected to submit. Information requested in more tabular form would make assessments of adequacy and completeness easier to compare.

Joint Appraisals for 20 of the 22 countries reviewed (No appraisal available for CAR nor Bolivia in Spanish) show:

- Only 6 countries reported inventory status. 4 inventories were up to date, 2 inventory updates were in process. (Mali, Ethiopia).
- 14 countries (70%) indicate major problems with supply chain adequacy at present, 12 of these 14 include problems at national and intermediary levels where cold rooms are required. 4 state plans for expansion, 2 countries have

sufficient capacity for the next 2-3years (Malawi, Afghanistan). This portrays a significantly different image to that indicated in Figure 1, which shows countries have almost 75% of needed capacity at present.

- 13 countries installed new supply chain equipment recently. 4 countries will use HSS funds. (Uganda, Vietnam, Nigeria and Cambodia). Lesotho also plans to use HSS funds when the application is approved.
- 5 countries were identified with stock management weaknesses. (Cambodia, Kenya, Ghana, Ethiopia, and Uganda,
- 5 countries report transport constraints. (Vietnam, Mali, Honduras, Chad, Burkina Faso).
- 6 countries have critical maintenance problems (Lesotho, Cambodia, Malawi and Uganda in particular). Ethiopia will install a maintenance facility, Kenya and Lao will complete plans, Nigeria is progressing well with maintenance measures, others not reported.
- 11 countries are seeking TA support related to ISCL.
- 7 countries plan training related to ISCL. Nigeria has already completed extensive training at all levels.
- 5 countries report HR issues. Either related to high turnover or weak capacity.
- Only 4 countries plan studies relating to wastage rates, equity of immunisation or temperature monitoring. (Afghanistan, Ethiopia, Kenya and Mali).
- 8 countries plan measures to ensure EVM/IP's are implemented. 2 Countries (Ghana and Mali) have no stated clear plan.
- JA indicates management weaknesses in 8 countries reviewed including Lesotho and budget constraints relating to ISCL in 3 countries. (Vietnam, Uganda and Honduras)

These observations raise two important issues:

- More systematic reporting of ISCL is required both in JA's and applications for support. Guidelines need to be improved to ensure this,
- EVM results may not be generating ISCL information that is well aligned with findings in JA reports, and JA reports need to systematically report a given set of ISCL related topics to include the 9 EVM Criteria, plus HR and management status before any conclusions may be drawn or adjustments made.

All 22 countries reviewed except Bolivia have conducted an EVMA within the last 4.5 years (with CAR having the oldest dated September 2011), 16 of the 22 countries have conducted an EVMA within the last 3 years, and 4 reviewed countries are planning EVMA in Q1, and Q2 of 2016. This provides the IRC with quantitative indicators of ISCL performance but can be mis-leading since EVM assessment results can be subjective and EPI program structures in

some countries do not fit well with the EVM performance template (Bangladesh, Vietnam) The EVM Tool is presently undergoing a major review and the present constraints may be addressed by 2017.

The joint appraisals usually provide good indicators of ISCL status, but the comprehensiveness and perceptions of ISCL appears to depend upon team compositions. There are instances when the ISCL information in the JA has been picked from the EVM report itself. More specific guidance on ISCL reporting is required. It is advisable that JA teams include a logistician who makes some independent observation of ISCL.

Countries do not report systematically on the progress on the implementation of EVM improvement plans. A reporting template substantially more robust than the model in the present EVM reporting template is required. It is recommended this is prepared before a JA and the logistician in the JA team verify the validity of the reported status of the implementation of the activities of the IP.

A combination of JA reports with more specific ISCL guidelines, improving quality of last EVM reports and the updated status of the implementation of improvement plans will provide a stronger foundation for the IRC assessment of supply chain readiness.

Reporting of improvements tends to remain vague (Ethiopia and Mali for example) however, and progress in strengthening supply chains other than measurable increases in vaccine storage capacity would appear to be limited and below standards required to ensure vaccines of good quality are supplied efficiently and reliably to target populations. According to EVM assessments, only 25% of countries reviewed attained an 80% level of performance in primary stores (These are stores which receive vaccines from international or domestic manufacturers) and the average performance across all criteria of EVM assessments was only 68.7%, substantially less than the WHO recommended norm of 80%. This is somewhat depicted in Figure 6 which, based upon the most recent EVM assessment findings in the countries reviewed and the WHO recommended minimum standard, indicates major shortcomings in certain key criteria (maintenance, distribution). A similar pattern was observed for countries reviewed in the March 2015 IRC. The EVM assessment does not assess human resource availability, turnover, motivation and the operational efficiency of programs that often compromise program quality. These are the root causes for most poor performing ISCL. (For example Lesotho).

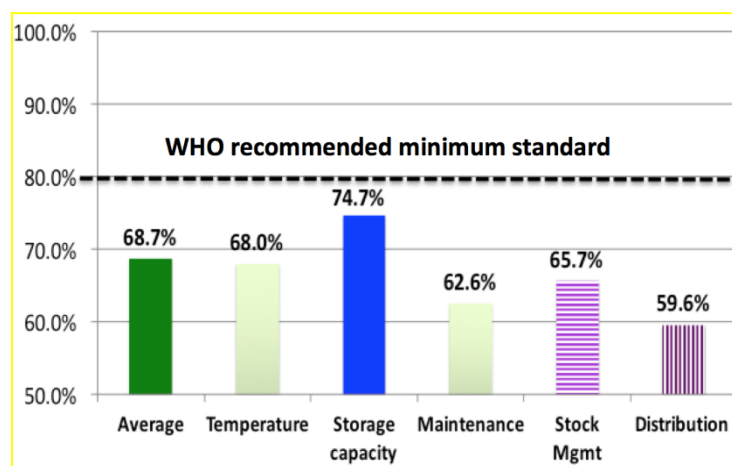


Figure 6: EVM Aggregate Performance of Countries Reviewed

Improvement would appear to be required, both in the quality of reporting ISCL performance and in the ways to improve performance.

The Gavi CCE Platform targeted for introduction in 2016 will contribute to improvements in storage capacity and, temperature monitoring at the lower distribution and service delivery points of supply chains. This should contribute to addressing equity in coverage issues and ensure that technologies are better adapted to need, resulting in an impact on reliability. However the CCE platform is not targeted to support the primary and intermediate levels of supply chains and does not contribute to the need to motivate and improve performance of immunisation service delivery personnel.

Of the seven (7) HSS applications reviewed, the application from Afghanistan related specifically to data management, whilst the Zambian application included provision for capacity building, but no equipment. Ethiopia continues the procurement of substantial quantities of equipment in the transition to supply storage and distribution management by PFSA. Bangladesh included besides upgrading of the supply chain, a large component that was related to disease surveillance purpose which component was not accepted. In Pakistan, a substantial portion (US\$ 41.00 million) of the HSS funding is kept under its 4th objective, to address the capacity constraints by building on the significant cold chain strengthening effort undertaken in HSS1.

Positive trend is the more innovative approach for designing management information systems. Countries like Afghanistan, Pakistan Kenya and Lao are putting in place more sophisticated management information systems which provide countries with real time dashboard based data-bases of stocks, stock movement, vaccine storage temperature and available storage capacity.

ISCL Recommendations:

- The CCE platform be broadened to:
 - Support equipment for primary and intermediate levels of supply chains through the inclusion of cold rooms, and centralised dashboard based temperature-monitoring systems. (60% of countries reviewed require support at national or intermediary level)
 - Motivate health providers and strengthen data quality through encouraging the adoption of mobile technology and applications for data management and providing performance incentives through phone credits.
 - Support equipment, software fees/licences for countries adopting data management systems for real time monitoring of vaccine quantities and quality in supply chains.
 - Broaden bundled equipment supply with maintenance to include outsourced maintenance of existing equipment and strengthening outsourcing management capacity.
- JA's to report, present and planned funded/unfunded situation for each of the 9 EVM assessment criteria plus the HR and Management situation in tabular form..

- Consider cost sharing of investments in supply chain equipment and vehicles in large countries through the mobilisation of matching funds through IBRD/IDA, BRAC (Bangladesh), EQUITY (Kenya) loans or similar is encouraged to encompass more countries requiring high levels of material investments. (DRC, Pakistan, Ethiopia, Nigeria, Mali)
- Provide support to develop software solutions which will encourage countries to continuously monitor in real time, vaccine stocks and movements from central stores to the point of use, know the storage capacity available to receive for any dispatched supplies , and be aware of storage temperatures at all locations in the supply chain.
- The HSS Technical assistance (TA) to encourage collaboration with a local partner as a mechanism to developing in country capacity through learning by doing and guidance or direct support through Service Level Agreements (including Maintenance/ training) for countries with suppliers of cold chain equipment and local supply chain maintenance companies .

1.12.2 Data Management

Afghanistan, Pakistan and Lao are known to be exploring or seeking new and innovative ways to promptly and reliably collect and communicate accurate immunisation statistics.

Gavi forged a unique partnership with Vodafone in 2012 to explore how mobile phone technology can help increase vaccination in sub Saharan Africa, and Afghanistan. DRC, Kenya and others are known to be using phone Apps for money transfers but no HSS or VIG applications indicate opportunities within this partnership are being availed.

However, there appears to be limited synergies between the collection, compilation and reporting of immunisation data and the systematic verification and monitoring of the quality of vaccines administered and the opportunities lost to vaccinate due to non or infrequent availability of vaccine supplies. Only three countries reviewed indicate measures are being explored to link infant vaccination records with vaccine stock quality and availability.

The use of Apps on Phone and other hand held devices to collect, communicate immunisation data and provide messaging and alerts is growing rapidly but knowledge sharing and cross adaptation from experiences in other MCH domains (nutrition, family planning, HIV etc) is insufficient. (Afghanistan)

Recognition of advantages from complementary features of phone Apps such a motivation through phone credits, location tracking through GIS or mobile tower triangulation, and multiple Apps on a single device are not adequately understood by Alliance partners at country level to guide and orient national programs.

The quality of administered vaccines or lost vaccination opportunities are not monitored in M&E frameworks in any HSS applications reviewed,

Data Management Recommendations:

- Gavi to lead and financially support an initiative that develops data management packages/modular options (Open source or otherwise) which

link infant record, immunisation data, and vaccine quality and availability in a single data management platform.

- Gavi support WHO and UNICEF to merge and streamline their existing forecasting software's so that countries use a common simple and correct tool for forecasting AND monitoring off-take against forecasts.
- The Gavi Alliance support countries and provide incentives to adopt innovative EPI data management solutions that yield improvements in data quality.

1.12.3 Distribution and Transport Network Optimization

Resources are being invested or are needed for the procurement of vehicles to replace aging fleets (Pakistan, Chad, Zambia, Vietnam, Mali, Honduras, Burkina Faso) whereas countries like Vietnam and Bangladesh distribute supplies from intermediary levels through integrated health service delivery mechanisms to peripheral storage locations.

Resources are not being invested in the improvement of transport and distribution networks except perhaps in the case of Ethiopia where the management of an integrated supply system is being outsourced to a parastatal PFSA. There is no reference to improving transport network efficiency in any application reviewed.

Current strategies do little to improve the cost effectiveness and efficiency of distribution networks and national programs and in country alliance partners are often not aware of measures to be adopted which can lead to transport network optimisation.

Stock out issues is closely related to poor demand and collection. The "Informed Push" system has demonstrated better performance and reduced stock-out. However little is done to explore this avenue through redesign of distribution systems.

Leasing storage space and leasing vehicles for campaigns was observed however. (Zambia)

Recommendations:

- The Gavi Alliance support countries to do transport network optimisation assessments and link support for vehicle procurement or leasing to findings of assessments. (Pre-requisite to HSS applications)
- Introduce direct financial incentives to countries demonstrating improvement in distribution network efficiency through vehicle tracking monitored by network optimisation service providers.
- The Gavi Alliance contract vehicle leasing service providers to model and provide outsourced lease management of vaccine supplies distribution. (Rent a Car or Riders for Health model)
- Gavi support innovative exploration / pilots of distribution system and reward reduction in stock out instances.

1.12.4 Sustainable Environment and Procurement.

Disposal of immunisation waste by burn and bury or in poorly functioning incinerators is still common place even in countries where a disposal policy may be in place. Only Nigeria and

Malawi indicate substantial resources are being invested to improve waste management practices, and 1 country (Burkina Faso), is planning to outsource waste disposal. Virtually no progress is being made to address waste management issues or improve the energy efficiency and reduce global warming contributions of distribution networks.

A large number of countries are investing substantial resources in SDD vaccine refrigerators (for example Chad and Mali) and some countries (Ethiopia, Vietnam) plan to avail of Gavi CCE Platform support that will increase the quantities of equipment and maintenance complexities at peripheral levels. 1 country (Burkina Faso) continues to procure absorption refrigerators, though none are PQS pre-qualified.

Recommendations:

- Gavi adopt the 10-Year Framework of Programmes on Sustainable Consumption and Production Patterns (10YFP), and acknowledge that SCP is one of the overarching objectives of, and essential requirements for, sustainable development.
<http://www.unep.org/10yfp/Activities/10YFPGlobalmeetings/tabid/1060074/Default.aspx>
- Gavi encourage UNICEF to join the 84-member community of 10YFP (including other UN Agencies) and adopt this “cost of ownership” approach to procurement.
- The waste management recommendations made in the IRC reports from the March 2015 review and November 2014 review and again applicable in this review are adopted.

1.13 Governance Issues

The IRC recognises the new challenges for donors in global health and the need for new engagement for aid effectiveness and coordination. It is critical that Gavi should actively contribute to the global health agenda design and implementation to make sure immunization remains a global priority and indicator to promote MDG/SDGs. Gavi could develop operational strategies to benefit from the UHC, Data quality and NCD programmes and initiatives.

Furthermore, despite the fact that countries are introducing a number of new vaccines, paying increasing share of co-financing and facing complex immunization system and policy challenges, ICC-HSCC, NRA and NITAG are still, in most countries, in their infancy stage of development. In countries utilising a SWAp, RBF, pooled funds mechanisms, specific role of Gavi in the arrangements with and linkages between HSCCs, NITAGS, the ICCs and Technical working groups are not clear enough.

Finally, HSS grants rarely request funds to support governance issues or organisational reform to support the immunisation programme. Given the many challenges in these areas countries are encouraged to explore the opportunities that may be utilised in this area.

Recommendations:

- For Pooled funding and SWAP arrangements, Gavi needs to strengthen its participation on the Joint Consultation and Coordination Committees as

well as on the Technical working group so as to ensure sufficient and appropriate attention to the complexities of achieving the desired immunisation coverage outcomes.

- Significant technical support should be provided by Gavi partners to country-led government mechanisms so they have the institutional capacity to make evidence based decisions, coordinate, monitor, regulate, guide investments and evaluate their sustainability and impact. It is also critical to ensure that the broader range of local actors and players (CSOs, Professional associations, public health and management institutes, academia, private sector etc) are effectively involved and engaged in supporting and strengthening immunization system and activities especially through the governance structures such as the ICC and NITAG.
- HSS grants rarely request funds to support governance issues or organisational reform to support the immunisation programme. Given the many challenges in these areas, countries are encouraged to explore the opportunities that may be utilised for support in this area.

1.14 Technical Assistance (TA)

The IRC notes the positive efforts being made by Gavi to institute more robust technical assistance process through the PEF. However, it further notes that coordination amongst agencies or advisors is weak and there is more competition than coordination.

Recommendations

- TA should not be a fragmented support. TA should be thought out in longer terms with stronger contributions to sustainability.
- TA should be more oriented to capacity building, transfer of knowledge and skills; and mentorship. It should be in the country context and inclusive of local technical assistance from academic sector or NGOs.

Comparative analyses of three country evaluations and new HSS applications

During this review window, the IRC also compared new HSS proposed activities with findings from previous HSS evaluations for three countries namely Bangladesh, Ethiopia and Zambia. The aim of this comparison was to assess alignment of new HSS proposals with the critical gaps identified by the evaluations of previous HSS grants implemented.

1.15 Bangladesh:

The Bangladesh first HSS proposal was approved to address health system challenges in line with Health, Nutrition, and Population Sector Program (HNPS 1996-2011) targets. The main objectives and activities were to:

To provide universal MCH services delivery through strengthened human resources management, improved logistics management, and increased community participation and demand. The main aim of the proposal was to ensure that community clinics had the functional capacity and infrastructure to deliver PHC services.

There were significant delays in funds disbursements and the country accessed the first trench of funds in 2009, which remained unspent until 2011 due to delays. The long delays necessitated reprogramming of the funds which was proposed by the country and approved by IRC in 2011. Through HSS reprogramming in 2011 the country added some around 11 new activities in line with original proposal strategic objectives.

According to FCE reports, launch of FMA initiative from Gavi side delayed disbursements. At country side, a combination of factors such as limited awareness of the FMA guidelines, challenges related to staff turnover, and concerns about the changing national health strategy as a result of a newly elected national government contributed to the delayed disbursement of HSS funds. The current FCE report in summary highlights that recruitment, health worker training, and infrastructure development for community clinics have not been carried out on time and since the HSS is midway, more evaluation findings will be available soon, however, three bottlenecks across both NVS and HSS support has been highlighted as: 1) Bottlenecks in the subnational disbursement and utilization of funds, 2) Limited vaccine storage capacity and 3) Human resource capacity and partnership.

The current proposal objectives are:

- To enhance effectiveness and sustainability of the immunization program, through stronger partnerships, coordination, management, monitoring and evaluation
- To increase the quality, safety and effectiveness of immunization service delivery through integrated PHC systems
- To improve HR development and management for immunization & related MNCH services
- To ensure effective vaccine management (EVM), in terms of Cold Chain and Supply Chain Management system

- To strengthen VPD Surveillance and Information System as an integral part of HMIS

In summary the country has planned activities to address the bottlenecks so far discovered through Full Country Evaluation initiative, in their new proposal, however, some challenges such as delays in disbursement and utilization of funds at sub national level is not visibly addressed that could be addressed from other sources since this is a general health system problem of Bangladesh.

1.16 Ethiopia:

The Ethiopia has been receiving Gavi HSS support since 2006. The objectives for HSS support to Ethiopia were to: (i) improve immunization and other primary health care services; (ii) improve access and use of effective, functioning health services, and (iii) increase equity in access and enhanced civil society engagement.

In 2014, an end grant evaluation was commissioned to assess:

- Contribution of Gavi HSS funding in Ethiopia
- HSS programme design and implementation
- Implementation of past recommendations while exploring areas not covered in past evaluations
- and grant utilisation.

Key findings indicate that HSS funds in Ethiopia has been very catalytic and substantial progress has been made but with more impact on antenatal care, skilled birth attendance, and HIV treatment than increased immunization coverage. Major portion of the HSS funds in Ethiopia has been used for equipment purchase and construction of Health facilities.

Recommendation of the evaluation has been more around design of the proposals, duplication of efforts and streamlined management of funds, however, on technical grounds; the report indicates the need for clarity of indicators and performance framework, existing problems in equity , a need for cold chain systems strengthening, problems in management and logistics of vaccines, the need to increase community participation, awareness and utilization of services by communities, enhancing the capacity of health workers especially the immunization health workers, planning, data quality issues, stagnant DTP3 coverage since 2010, high dropout rates, high stock out rates, and sustainability of HSS support.

The current application requests support for the three broader activities in line with the pooled funding plans as following:

- Improve Child Health service Delivery though engagement of community, CSO and non-state actors and strengthening of the primary level health care mainly Health Extension Program (HEP)
- Strengthening the capacity of the National Supply Chain System though strengthening Cold Chain and Supply system, upgrading the network designing and strengthening the Vaccine and Vaccination Quality Regulatory System.

- Strengthening the Monitoring and Evaluation System through strengthening the HMIS and CHIS, and performance reviews through different mechanisms.

In summary the country has planned activities to address the bottlenecks discovered through end of grant HSS evaluation. In other words, there are 15 key activities under these broader activities planned in the proposal which can basically address problems discovered during HSS evaluation with variable extents. These include areas such as Community Ownership, Equitable Access to Health Services, Improve Supply Chain and Logistics Management, Improve Resource Mobilization and Improve Research and Evidence for Decision Making. However, how operational issues will be addressed is unclear in the proposal.

1.17 Zambia:

The Zambia received first HSS support for the years 2007-2013 with a budget of over USD6,4M. The objectives for HSS support to Zambia were to:

- Contribute to addressing the human resource for health crisis through strengthening of retention mechanisms for health workers and provision of incentives to community health workers.
- To increase the transport system of the health sector for effective distribution of supplies and enhanced provision of EPI services

There have been challenges and delays in implementation mostly because of FMA, financial and data quality issues and agreeing on a Performance Framework.

In 2014, an end grant evaluation was commissioned and following challenges can be summarized from the overall findings:

Geographic Inequity: Coverage rates have been highly variable among districts since 2000

Stagnant coverage: No increases in coverage is seen but also in certain areas coverage has decreased

Wealth quintile inequalities , Weak surveillance, Poor data quality , Insufficient trained health workers , Poor coordination, need to strengthen cold chain, lack of proper micro planning and implementation of RED/REC strategy to reach satisfactory immunization goals.

Currently the country has resubmitted the proposal and requests funding for 3 years with a proposed start date of June 2016. The objectives proposed include:

- To improve the delivery of immunisation and other child health interventions in Zambia by ensuring that outreach clinics and supportive supervision are operational in target districts.
- To improve the knowledge and skills of district managers and frontline health workers on delivery and management of immunisation and other child health services.
- To develop and implement effective C4I and other child health intervention strategies through the involvement of CSOs.

- To improve the collection and utilisation of HMIS data at all levels of the health care system with special focus on district and lower levels;
- To develop and implement a Performance-Based Financing system in the target districts with the aim of improving immunisation and other child health outcomes.

In summary the country has planned certain activities to address the bottlenecks discovered through end of grant HSS evaluation. However, some key elements are missing such as training of health workers which is a key issue. In other words, the country is facing the shortage of health workers that is confirmed by evaluations but all the trainings are in form of refresher focusing on EPI staff and managers. In some other cases, for instance, under objective 2 they discuss “ through involvement of CSOs”, while there is nothing inside to use CSOs for improving immunization coverage rather the country is planning media campaigns, radio spots etc.

Conclusions

Cumulatively to date in 2015, a total of 73 countries have now been approved for NVS and 67 countries for HSS. There is a need to move rapidly from learning by doing to scaling up for HPV. There should be concerted and innovative efforts needed to address data quality issues; the decreasing visibility and active involvement of CSO/private sector; financial and programmatic sustainability issues especially amongst transitioning countries and need to develop a template for SWAP/pooled fund applications. The Secretariat needs to consider including indicators to measure system performance (aligned to the country M&E) in new Performance Framework.

Acknowledgement

The IRC acknowledges the support of the Gavi Secretariat through the A & R team, senior country managers and vaccine specialists for their invaluable inputs and assistance during the review process. The IRC also recognises with thanks the support of the WHO and UNICEF partners for the briefings and contributions across different thematic areas.

Annex 1: List of IRC Reviewers

NO.	Name	Nationality	Profession/Specialisation	Gender	French Speaking
1	Rafah Aziz	Iraq	Independent Consultant	Female	
2	Gabriel Carrasquilla	Colombia	Director, Center for Health Research, Bogota	Male	
3	John Clements	Australia	University of Melbourne, Associate Professor	Male	
4	Dora Curry	USA	Senior Technical Adviser, CARE	Female	
5	Linda Eckert	USA	Professor University of Washington (Gynaecology)	Female	
6	Ulla Griffith	UK	Lecturer, London School Tropical Medicine	Female	
7	Terence Hart	UK	Independent Consultant	Male	X
8	Philippe Jaillard	Benin/France	Agence de Medecine Preventive (AMP) Country Representative	Male	X
9	Miloud Kaddar	Algeria	Independent Consultant (ex WHO)	Male	X
10	Elsie Le Franc	Jamaica	Independent Consultant	Female	
11	Marina Madeo	Italy	Independent Consultant	Female	
12	Sandra Mounier-Jack	France/UK	Lecturer London School Hygiene and Tropical Medicine (Health Policy)	Female	X
13	Koyejo Oyerinde	USA/Nigeria	Independent Consultant	Male	
14	Bolanle Oyeledun - CHAIR	Nigeria	CEO, Center for Integrated Health Programs	Female	
15	Zeenat Patel	Canada	Independent Consultant	Female	
16	Robert Pond	USA	Independent Consultant	Male	
17	Kshem Prasad	India	Independent Consultant	Male	
18	Diana Rivington	Canada	Senior Fellow, University of Ottawa	Female	X
19	Mario Stassen	Netherlands	Independent Consultant	Male	
20	Ousmane Amadou Sy	Senegal	Independent Consultant	Male	X
21	Beena Varghese	India	Senior Health Economist Public Health Foundation of India	Female	
22	Abdul Wali	Afghanistan	Former Health Advisor Office of the President.	Male	
23	Shamsa Zafar	Pakistan	Head of Department, Centre of Excellence MNCH	Female	

Summary statistics

Gender representation: Male: 11 Female: 12

Francophone reviewers: 6 (at least a working knowledge of French)

Geographical distribution:

Africa: 5

Europe: 5

Middle East: 2

North America: 5

S.W. Asia: 3

Caribbean: 1

South America: 1

Other: 1

Annex 2: OVERVIEW OF IRC RECOMMENDATIONS

Country / Type of support		HSS	MenA routine	MenA campaign	Measles SIA	HPV demo	HPV national	Other NVS support
1	Bangladesh	Approval						
2	Bolivia	Approval						
3	Burkina Faso		Approval					
4	Cambodia					Approval		
5	CAR		Approval	Approval				
6	Chad		Approval		Approval			
7	DRC				Approval			
8	Ethiopia	Approval						
9	Ghana		Approval					
10	Honduras						Approval	
11	Kenya					Approval		
12	Lao PDR	Approval						
13	Lesotho							Rota: Resubmission
14	Malawi						Resubmission	MR: Approval
15	Mali		Approval					
16	Nigeria					Approval		
17	Pakistan	Approval						
18	Sudan		Approval					
19	Uganda			Approval				Rota: Approval
20	Vietnam							JE: Approval
21	Zambia	Approval						MR: Approval

SPECIAL REVIEW:

22	Afghanistan	DQ portion (HSS) - Resubmission						
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Annex 3: Mind the Gap: Dealing with Discrepancies between routine and survey estimates of immunisation coverage.

Background

Reliable estimates of immunization coverage should form the foundation for monitoring and evaluation of immunization programs at sub-national, national and international levels. Yet, when estimates based upon routine data are compared with estimates from household surveys, there is frequently a significant discrepancy as shown in Figure 7.

For this analysis, the most recent survey¹⁶ estimate of DTP3 coverage for each of 57 countries was compared to the estimate based upon routine data from the year covered by the survey.

Figure 8 shows that countries with a lower coverage (as measured by survey) are more likely to have a large discrepancy between the routine estimate and the survey estimate.

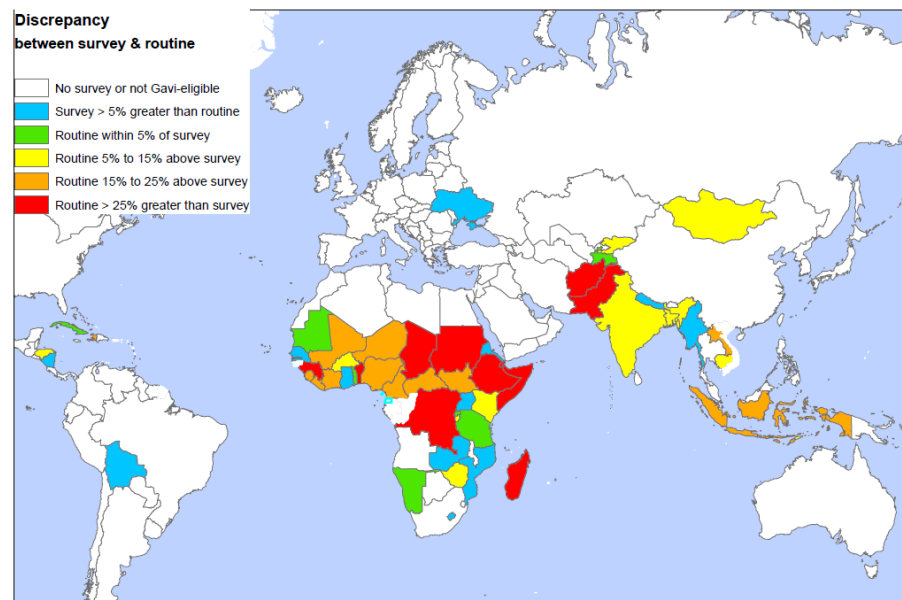


Figure 7: Routine Estimates of DTP3 minus survey estimate for the year of the most recent survey in the WUENIC database

¹⁶ Only surveys in the WHO-UNICEF WUENIC database were included. The year covered by a survey is typically the year prior to when the survey was conducted. Forty four of the 57 surveys were conducted in the last 5 years, while 8 took place in 2010, 7 in 2009 and 1 in 2008.

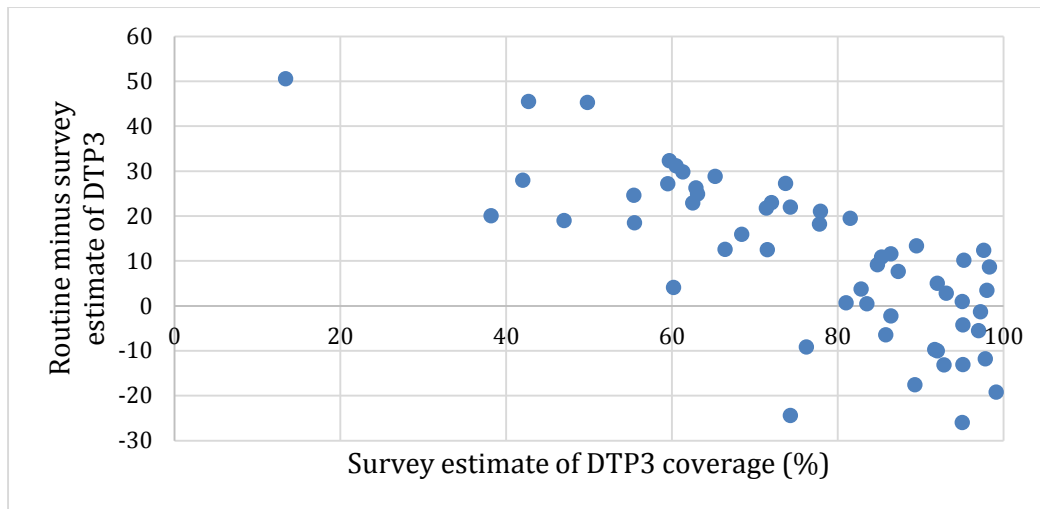


Figure 8: Association between coverage and discrepancy in estimates of DTP3 coverage. 57 Gavi supported countries, year of the most recent survey.

This association may be due to one or more of the following factors:

- Problems with routine data quality in countries with low coverage;
- Reduced accuracy of survey estimates in low coverage countries. Review of the WHO-UNICEF estimates of national immunization coverage (WUENIC) shows that for 19 of the 57 countries, the WUENIC estimate is closer to the routine estimate than to the survey estimate.¹⁷ An example, for Somalia, is given in Figure 9 below.

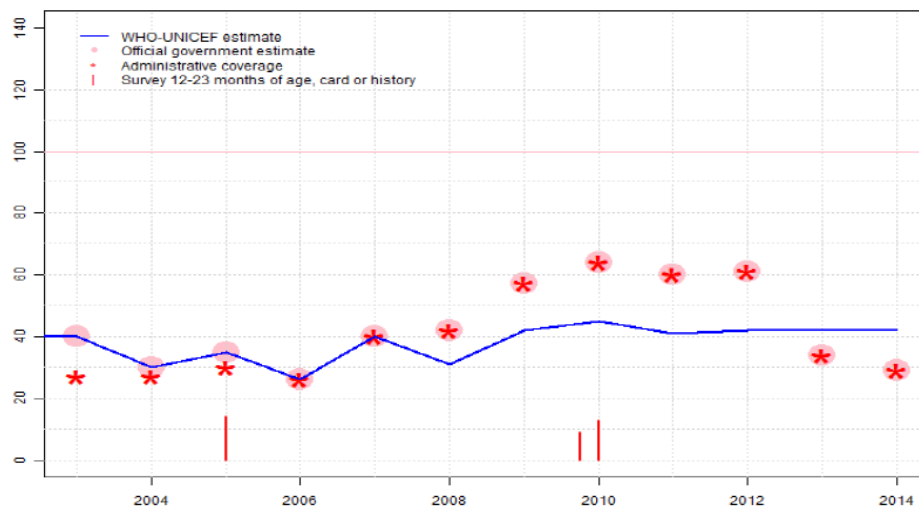


Figure 9: Trends in Official, Administrative, survey and WUENIC estimates of DTP3 coverage, Somalia

- With a survey estimate of 90% or more, there can only be a large discrepancy if the survey estimate is substantially higher than the routine

¹⁷ Due to revisions, the current WUENIC estimate given in the WUENIC database for the year of the survey is often not the same as the original WUENIC estimate for that year. Given the large number of countries each year for which substantial revisions are made of WUENIC estimates, it should be clear that the WUENIC estimates provide no more of a “gold standard” than the survey estimates.

estimate. Note that in 12 of the 57 cases (the countries in blue in Figure 7; the dots below zero on the y-axis in Figure 8), the survey estimate of coverage was higher than the routine estimate. Eritrea and Lesotho are 2 notable examples where official estimates of the target population are higher than UN estimates and the routine coverage is thus made lower.

Such examples illustrate that it would be an over-simplification to assume that discrepancies between routine estimates and survey estimates are solely a reflection of “poor data quality” (i.e. poor quality of routine data). The discrepancy may be partly the result of an inaccurate estimate of the target population (“the denominator”) or it may result from an inaccurate survey.

A case study of three countries with discrepancies greater than 20 percentage points:

To better understand how countries are addressing gaps between routine and survey estimates of immunization coverage, available documentation was reviewed from three countries for which the most recent survey estimate of DTP3 differed by more than 20 percentage points from the WUENIC estimate and more than 25 percentage points from the routine estimate: Afghanistan, Pakistan and Ethiopia, all countries reviewed by the IRC at different meetings in 2015. Table 3 summarizes the various DTP3 coverage estimates for these 3 country examples.

COUNTRY	YEAR COVERED BY THE SURVEY	DTP3 ESTIMATE		
		Survey	WUENIC	Routine
AFGHANISTAN	2010	40	66	87
	2012	60	67	92
PAKISTAN	2010	84	82	99
	2012	65	72	94
ETHIOPIA	2010	36	61	86
	2011	60	65	87

Table 3: DTP3 Coverage Estimates from the two most recent household surveys. Afghanistan and Pakistan

For each of these countries, the last two surveys and the WUENIC estimates for the years of these surveys were at least 15 percentage points less than the corresponding routine estimates. Thus, these are countries for which there is strong evidence that there are major problems with the reliability of the routine estimate. This could be due either to unreliability of the routine data (“the numerator”) or unreliability of the estimate of the target population (“the denominator”) or both. As is shown by at least one of the cases (Ethiopia), it could also be due in part to recurrent problems with the quality of surveys. Review of country documentation focused on these three aspects: numerator, denominator, and the surveys.

Afghanistan

Documents written by the NIP of Afghanistan as well as those who have reviewed it repeatedly acknowledge the discrepancy between routine and survey estimates of immunization coverage and attribute this to a combination of uncertainties about the denominator and problems with the quality of routine data. As part of its country tailored approach, Afghanistan was invited to apply this window for a supplemental HSS grant of up

to US\$ 2.3 million “with the objective to reduce the gap between administrative coverage data and survey coverage data” .¹⁸

Getting the numerator right

In Afghanistan, most vaccinations are delivered and most data are reported by very poorly remunerated workers employed by NGOs rather than by the government. There is a high turnover of these staff. Coordination and accountability of the NGO contractors is reported to be weak. This has important implications for the quality of routine data.

Among the documentation that accompanied Afghanistan’s application for a third HSS grant and its separate application for the supplement HSS grant there was no report from any assessment of the country’s routine health information system. There was no mention of any plans for an annual desk review of the quality of routine data.

Two separate, paper-based systems report routine immunization data – one managed by the HMIS unit and the other management by the EPI unit.¹⁹ Various documents repeatedly note the absence of systems for data verification²⁰ or data quality self-assessments (DQS).

Afghanistan’s approved proposal for a third HSS grant²¹ includes several activities to strengthen routine data quality²² According to the proposal narrative, Activity 4.2 was supposed to include support for DQS’s – the main data quality intervention recommended by the cMYP (2015-2019). However, for unclear reasons, the funds for the proposed DQS’s have been removed from the budget. Activity 4.3 aims for “Improving the data flow systems” and lists several proposed interventions²³ but provides no description of them and budgets a total of only US\$ 360,000 for the activity.

In October of 2015, Afghanistan submitted a proposal for a US\$ 2.3 million supplemental HSS grant for improving EPI data quality. The proposal says that it is an “EPI data quality strategic improvement plan”. To distinguish this proposal from the main HSS proposal, it can be referred to as the Data Quality Improvement Plan (DQIP). However, the proposed approach to data quality assessment is limited to data verification without any attempt to assess the root causes of any data quality problems nor desk review of data quality.

¹⁸ Afghanistan Country Tailored Approach

¹⁹ As noted by the cMYP (2015-2019), “This not only creates some duplication in data collection but also results into inconsistencies in reported figures from various sources.” The cMYP provides contradictory information about the reliability of these systems, noting at one point that “The HMIS data quality, completeness, timeliness and accuracy, is validated by a third party. These assessments demonstrate accuracy of over 90%.”

²⁰ It is notable that the 2012 DTP1 to DTP3 dropout rate, according to the most recent coverage rate was 30% while routine data suggested that it was only 8%. This suggest selective over-reporting of DTP3.

²¹ The current and previous HSS grant provided funding for 25 staff of the M and E Directorate to complete a one year diploma course to develop their skills in biostatistics, applied epidemiology, health surveys and HMIS. Funding was also allocated for vehicles, IT and infrastructure for the M and E Directorate. The Joint Appraisal notes that, “The data collection tools have been updated in January 2015, concerned staff at national level have been provided training, and now all provinces are submitting data to national level using these tools.”

²² Perhaps the most important contribution of the main HSS grant to improved data quality will come from activity 4.1 which will allocated US\$ 3 million to supportive supervision.

²³ These include improvement of the HMIS data management system, “Harmonization of EPI ... and HMIS data systems”, improving the HR data base and a study of factors favoring retention of female health workers in rural areas.

Getting the denominator right

The last national census in Afghanistan was conducted in 1978. In the cMYP as well as in the DQIP, there is considerable discussion about the challenge of estimating the size of the target population. In fact, the working assumption of the NIP and those who developed the DQIP appears to be that under-estimation of the population is the most important reason for the gap between survey estimates and routine estimates of immunization coverage.

The EPI program estimates the number of surviving infants to be 22% higher than the estimate of the Central Statistic Organization (CSO). However, even using the population estimates of the EPI program, the routine estimate of 2014 DTP1 coverage was 120% nationwide, suggesting either substantial over-reporting or major underestimation of the denominator, even by the EPI program.

The application for the main HSS proposal says it "... aims to improve the estimation of target population by RED approach to micro-planning and monitoring by using data directly at the HF and district level." In other words, more accurate denominators are to be derived through a fully decentralized process. The DQIP would provide funds for provincial EPI staff to support this decentralized process during visits to select districts. The proposal does not discuss how the resulting local estimates would be made mutually consistent or made to add up to the best national estimate of the number of surviving infants.

Getting the surveys right

During the 2010/2011 MICS, 13% of the selected clusters could not be visited due to security concerns. Due to low card retention, immunization status could be assessed based upon review of a card for only 31% of children. With other surveys availability of a card varied from 17% (in 2006) to as high as 66% (in 2013).

Gavi's third HSS grant is to fund two "coverage evaluation surveys" - one in 2016 and one in 2018. Thirty percent of the proposed DQIP would be devoted to revising and printing a new home-based record in order to improve the reliability of survey estimates.

It is notable that the findings from these surveys "... will be used to evaluate the performance of the NGOs across Afghanistan, and to inform MoPH to take corrective measures about the performance of NGOs. Twenty percent of the total budget of NGOs implementing GAVI grant contracts will be contingent on satisfactory performance on selected indicators."

Pakistan

Based upon the most recent survey (2012/2013 DHS) WUENIC estimates suggest that DTP3 coverage has been stagnant at about 70% for the last decade.

Getting the numerator right

Among the documentation that accompanied Pakistan's application for a third HSS grant there was no report from any assessment of the country's routine health information system. There was no mention of plans for an annual desk review of the quality of routine data.

In Pakistan, there are a multitude of vertical health information and surveillance systems, resulting in duplication of efforts and inefficient use of resources: DHIS/HMIS, Vertical Health Programs (LHWs, HIV AIDS, TB, EPI and Malaria). Routine EPI data are compiled

manually using a paper-based system. According to the JA report, the completeness and timeliness of reporting are not satisfactory.

The illustrative budget for the \$ 85 million HSS-3 grant includes \$2.3 million for data quality improvement. However, the specific activities have yet to be defined (support for “DQA’s” is mentioned). According to the JA report, “a comprehensive data quality improvement plan” is to be developed by Q4 2015. More discussion is warranted on means to strengthen routine data and to review the quality of routine data (“annual desk review”).

Getting the denominator right

The last census was conducted in 1998. The available documentation does not discuss any plans to reach national consensus on more reliable estimates of the target population.

Getting the surveys right

The HSS-3 grant will pay for a multitude of “Coverage evaluation surveys” to assess coverage by district and even by Union Council: The application states that first level supervisors and district level supervisors are to conduct surveys with a small sample of households (i.e. LQAS) in each Union Council at least once each year. In addition, a Third Party will conduct an external validation survey with a 30 cluster methodology in each district at least once each year. As Pakistan has over 100 districts such a survey would be quite expensive even if small sample (LQAS) methodology were employed. \$4.5 million is budgeted for these surveys but it is not clear how this was calculated or whether the cost estimate is reliable.

Ethiopia

Due to major discrepancies between various estimates, Ethiopia’s coverage with routine immunizations is highly uncertain. Not only have administrative estimates varied markedly from survey estimates but there have been marked discrepancies between surveys conducted in consecutive years. Surveys in 2011 and 2012 found DTP3 coverage to be 36% and 60% for years when the administrative estimate was 86% - 87%. Almost all independent reviews have highlighted this uncertainty.²⁴

Meanwhile, as noted by the JANS assessment, annual performance reports and strategic documents such as the new NHSP (named the “HSTP”) and the associated M&E Framework do not mention the discrepant survey findings²⁵ and suggest baseline values for immunization indicators that exceed even the baseline values provided in the cMYP and the values reported to WHO and UNICEF on the Joint Reporting Form.²⁶

²⁴ The evaluation of Gavi HSS support 2006 to 2012 (September 2014) noted that “Data quality remains a concern and is exemplified by the discordance between HMIS data and survey data ...”

- The JANS assessment (June 2015) said that “... the discrepancy between service-based (HMIS) and population-based (EDHS) data are not discussed in the HSTP (Health Sector Transformational Plan -- Ethiopia’s new NHSP for 2016-2020) and raise doubts regarding data quality.”
- The report of the High Level Donor Trip (including Gavi’s CEO; July 2015) concluded that “We remain concerned with coverage levels for immunisations which are not consistent with past coverage surveys, WHO/UNICEF estimates, and perhaps epidemiology of diseases such as measles....Improving quality of data is a top priority for Gavi’s ongoing support”

²⁵ The cMYP (2016-2020) and the 2013 Ethiopia Routine Immunization Improvement Plan, while presenting the survey estimates (see, for example Figure 2 of the cMYP), offer no explanations for the discrepancy between routine and survey estimates and proposes only “regular monitoring” and “data quality tool for every level” as the only activities to improve data quality.

²⁶ For 2014 Ethiopia reported on the JRF an administrative estimate of DTP3 coverage of 87% and an official estimate of 84%. The cMYP cites a 2014 DTP3 coverage estimate of 87%. The M&E Framework for the HSTP

Getting the numerator right

There have been considerable investments, including from Gavi HSS, in HMIS training, IT and review meetings. A national M&E strategy has been developed. Yet documents are not available with which to assess these interventions. The situation analysis in the national M&E strategy (2016 to 2020) reports that “national HMIS implementation status has reached 96%” but does not include any findings from assessment of the quality of data. An electronic data management system has been widely introduced. However, the situation analysis provides no information on the quality or even the completeness of the data. The cMYP 2016-2020 briefly notes “inadequate use of data quality assurance mechanisms at district and facility levels” and plans to “Provide data quality self-assessment and database management training to all districts”. No further findings or details of plans to strengthen data quality are included.

Among the documentation that accompanied Ethiopia’s application for a third HSS grant there was no report from any assessment of Ethiopia’s routine health information system. There is no mention of any plans for an annual desk review of the quality of routine data.

The 2014 independent evaluation of Gavi HSS support cited “...a DQA study conducted in 2010²⁷ that pointed out important issues in relation to reporting and accuracy of reported data. The same study noted that a tendency to over-report for the indicators especially DPT 3 and measles coverage was a common finding in nearly all of the reporting levels in the national HMIS system.” The evaluation concluded, “This assessment finds that [data quality] remains weak in spite of the implementation of the HMIS reporting system at all levels in the country.”

The M&E Strategic Plan (2016 – 2020) concludes “...the quality of the health information is poor in most cases and is a major challenge. It was also been noticed [that the] mostly [frequently] used data quality assurance tools are self-assessed and very brief and need to come up with comprehensive data quality assurance mechanisms with special focus and better skill.” Regarding a plan for data quality improvement, the draft M & E Strategic Plan says little more than “Data quality will be ensured by conducting data quality assurance mechanism like PRISM, RDQA and LQAS... Implementation of data quality assurance activities will be reinforced by technical assistance, supportive supervisions/ mentoring, review meetings and appropriate ICT technology.”

Given the considerable investments that have been made in the HMIS since 2010 (including a roll out of an e-HMIS to more than 3,000 facilities and health administrative levels that have access to electricity²⁸ it is unfortunate that detailed findings from a more recent assessment of the HMIS do not seem to be available. Elaboration is also needed on plans and funding for a data quality improvement plan.

Meanwhile, the JA report notes that “In 2014, the country started implementing a 28-million USD two-year (2014/2015) comprehensive routine immunization improvement plan (RIIP) with the main aim of supporting 51 high priority zones representing the large numbers of unimmunized children and having low overall immunization coverage.” Data compiled by

reports a baseline value of 91% for DTP3 coverage. Targets are for DTP3 coverage to increase from 93% in 2016 to 98% in 2020.

²⁷ Gebrekidan Mesfin, Hajira Mohammed, Habtamu Tesfaye. *Data quality and information use: A systematic review to improve evidence Ethiopia*. Addis Ababa : World Health Organization and FMOH (Planning and Policy Directorate).

²⁸ M&E Strategic Plan, Table 1

the Ethiopian HMIS suggest DTP3 coverage increased from 82% for calendar year 2014 to 93% for the 12 month period ending in 2015 .²⁹ The HMIS data suggests that number of zones achieving at least 80% penta3 coverage increased from 29% in 2013 to 48% in 2014.

Getting the denominator right

The last national population census was completed in 2007. There have been concerns of under counting and one case study noted that “...some ministry planners admit they are torn between having to use the official census data or their own differing estimates of their target populations.”³⁰ The 2012 routine immunization improvement plan notes “Variable denominator given; inconsistency the federal level and regional level figures are not matching.” However, none of the official documents available discussed any plans to develop alternative estimates of the target population.

Getting the surveys right

Table 4 and Figure 10 summarize information about coverage surveys conducted in Ethiopia since 2000. The table indicates for each survey, the year assessed (by convention, this is the year prior to the year when the survey was conducted), the number of children 12 to 23 months of age in the sample, the % of children for whom health cards were seen and the estimated % of children who received the third dose of DTP vaccine (“Survey DTP3”). Also shown is the administrative estimate of DTP3 (“Admin DTP3”) for the same year as was assessed by the survey.

The major discrepancies between the findings of surveys conducted in consecutive years suggest that it is unlikely that each of these survey estimates is reliable. In each case, the WHO/UNICEF panel concluded that the estimate from the EPI Survey was more credible than the estimate from the DHS. This warrants comment not only by those who provided technical oversight for these surveys (e.g. experts with Measure DHS) but also by researchers who insist that such surveys and mathematical modelling based upon survey estimates provide the ideal means for assessing public health outcomes³¹

²⁹ As cited in the JA report of July 2015

³⁰ Population Reference Bureau Assessment Team, April 2009. DEMOGRAPHIC DATA FOR DEVELOPMENT DECISIONMAKING Case Studies From Ethiopia and Uganda

³¹ Lim SS, Stein DB, Charrow A, Murray CJ. Tracking progress towards universal childhood immunisation and the impact of global initiatives: a systematic analysis of three-dose diphtheria, tetanus, and pertussis immunisation coverage. *Lancet* 2008; 372: 2031 - 2046

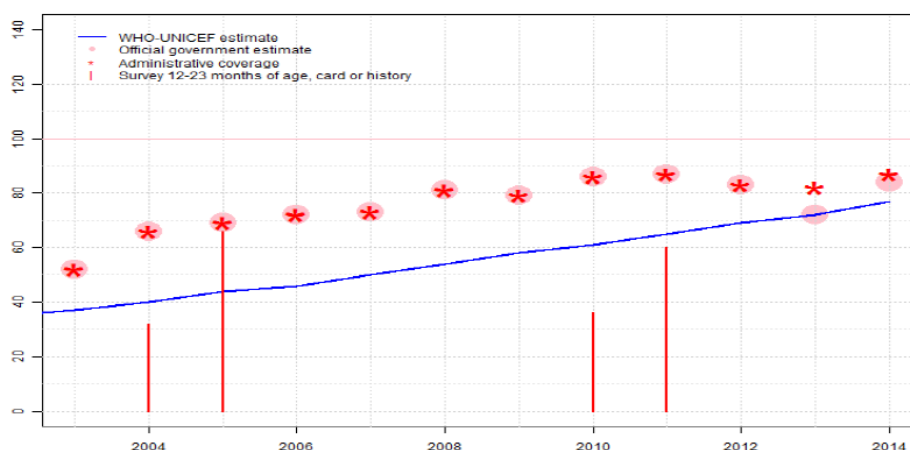


Figure 10: Trends in Official, Administrative, Survey and WUENIC estimates of DTP3 coverage, Ethiopia

Survey name	Year assessed	Sample size	Cards seen	Survey DPT3	Admin DPT3
2000 DHS	1999	2,143	27%	21%	40%
2001 EPI Survey	2000	3,564	52%	56%	42%
2005 DHS	2004	1,877	37%	32%	66%
2006 EPI Survey	2005	6,903	60%	66%	69%
2011 DHS	2010	1,927	29%	36%	86%
2012 EPI Survey	2011	3,762	47%	60%	87%

Table 4: Immunization Survey Coverage in Ethiopia, 2000-2012

Ethiopia's cMYP for 2016 to 2020 calls for EPI coverage surveys in 2016 (when a DHS is to take place) and 2018.

While Ethiopia appears to be considering other modalities to further improve its data collection processes, the hope is that during future coverage surveys it will be possible to verify immunization status by reviewing available newer data sources/tools and mothers' recall and ensure accurate reporting.