DECADE OF VACCINES
GLOBAL VACCINE ACTION PLAN

MONITORING, EVALUATION AND ACCOUNTABILITY ANNUAL REPORT 2013

DoV GVAP SECRETARIAT REPORT

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INTRODUCTION

While endorsing the Global Vaccine Action Plan (GAVP), in May 2012 the 65th World Health Assembly (WHA) requested the World Health Organization (WHO) Director General to monitor progress and report annually, using an accountability framework, to guide immunization discussions and future actions (WHA resolution 65.17). In response to this request, the Decade of Vaccines (DoV) Collaboration partners developed a Monitoring & Evaluation/Accountability (M&E/A) Framework and defined a process for an annual independent review of progress, which was presented to and noted in May 2013 by the 66th WHA (WHA report A66.19).
In accordance with the defined process, a detailed report has been prepared for review by the Strategic Advisory Group of Experts (SAGE) on Immunization DoV Working Group (WG). A report on the assessment of progress, based on the review of the detailed review by the SAGE DoV WG will be presented to SAGE, and with SAGE input form the basis of the reports to the WHO Executive Board and the WHA.

This detailed report consists of:

I. A report by the secretariat (consisting of the Bill & Melinda Gates Foundation, GAVI Alliance secretariat, UNICEF, US National Institute of Allergy and Infectious Diseases and WHO)
II. Independent submissions by DoV stakeholders

As described in the GVAP M&E/A Framework, the secretariat report has three components:

I. Monitoring Results: based on progress with achieving GVAP Goals (G) and Strategic Objectives (SO) Indicators, including a narrative report on vaccine price trends
II. Monitoring Resources Invested in Immunization
III. Documenting and Monitoring Immunization Commitments

I: Monitoring Results of GVAP Goals and Strategic Objectives Indicators

This section reports on progress against the GVAP Goals and Strategic Objectives indicators, using the operational definitions proposed in the M&E/A Framework. The information sources include: WHO-United Nations Children's Fund (UNICEF) Joint Reporting Form (JRF) database, other databases (e.g. DHS, MICS, pre-qualification database), other WHO reports (e.g. Polio Eradication Programme, Measles and Rubella Elimination Programme, surveillance reports, neonatal tetanus elimination validation reports, etc).

Data presented in this report are for 2012. With the exception of two indicators (MNT G2.1 and New Vaccines Introduction G4.3) where 2013 validated data are available. Please note that 2010 is the baseline for the majority of the indicators. For some indicators (e.g. G1.1 and G1.2 Polio) the report only refers to documents already developed by existing independent advisory committees. It has to be noted that for these areas, analysis and recommendations have been already developed and disseminated by these respective groups.

The secretariat report structure follows the GVAP outline, as adopted by the WHA. As a result, vaccination coverage data are provided in several different sections of the document, including: G3.1;

G3.2; SO3.1; SO3.2; SO4.1; SO4.2; SO4.3. Reviewers may consider reading these sections together to get a comprehensive view on progress with immunization coverage.

As requested by SAGE in November 2012, a specific narrative report was developed for SO5 on the progress with vaccine pricing, in lieu of an indicator. This report was prepared by representatives from the Bill & Melinda Gates Foundation (BMGF), MSF-*Médecins Sans Frontières*, GAVI Alliance Secretariat, the Pan American Health Organization (PAHO), UNICEF and WHO. This report provides an overview of the importance of vaccine pricing in the global context for both low-income (LIC) and middle-income countries (MIC). It summarises some of the complexities of pricing and price comparisons, the gaps in the available information, possible improvements and further actions required in this area. Individual reports on PAHO and UNICEF Pricing and Supply are provided in Annex for Pentavalent, Inactivated Polio, Rotavirus, Pneumococcal Conjugate (PCV 7, 10 and 13) and HPV vaccines.

For SO2 (Vaccine hesitancy), where the indicator were still being piloted and the feedback was suboptimal, we have supplemented the report by including a few case studies and reports that either examine causes of vaccine hesitancy or describe efforts to engage with communities in an effort to stimulate demand for immunization and consequently increase coverage.

Data quality

Immunization data are considered to be among the more reliable data in public health, especially in for LIC and MIC. However, the secretariat recognizes that there are some limitations on data quality and availability. The WHO-UNICEF JRF and the WHO-UNICEF Estimates of National Immunization Coverage (WUENIC) are the data source for many of the indicators. This report describes these two sources of data, and the data limitations. In addition, each report has an assessment of the quality of data used for the specified indicator.

We did not include all the data available but only the essential ones needed for the analysis. However, if the experts are willing to have more in-depth look at the data for coverage It is proposed to use the WHO IPAD application (it will be available for the face to face meeting in September 2013).

Word document reading tip: please use the “navigation bar” to easily access to the indicators (click on “View” and then tick the “Navigation pane” box).

II: Monitoring Resources Invested in Immunization

In order to maintain alignment with other monitoring and accountability processes that the National Health Accounts Systems will be used to monitor resources invested in immunization. This year, the report describes how the process to monitor immunization resources and provides draft examples of the types of tables and graphs that may be presented in future reports. This is work in progress and the WG is invited to provide feedback and suggest possible changes and/or additions that may be require.

III: Documenting and Monitoring Immunization Commitments

It was endorsed that we will use the for the UNSG Global Strategy for Women's and Children's Health framework to monitor immunization commitments. A process was put in place to collect immunization-specific commitments through this mechanism. This process is coordinated by the Partnership for Maternal, Neonatal and Child Health (PMNCH). The 2013 PMNCH report will be launched end September 2013 and provides preliminary, albeit limited, information on immunization commitments.

IV: Stakeholders Voluntary Reports Compilation

DoV stakeholders were requested to provide independent reports on any aspect of the GVAP that described their DoV/GVAP activities, highlighting success stories, as well as challenges and opportunities. AMP-*Agence de Médecine Préventive*, Barcelona Institute for Global Health, John Hopkins University, PATH, Sabin Vaccine Institute, and Save the Children, submitted reports. Partners' reports were included, as submitted by these organizations without any modifications by the Secretariat.

I MONITORING RESULTS: GOALS AND STRATEGIC OBJECTIVES INDICATORS

UNDERSTANDING IMMUNIZATION COVERAGE DATA: WHO-UNICEF JOINT REPORTING FORM ON IMMUNIZATION COVERAGE (JRF) AND WHO-UNICEF ESTIMATES OF NATIONAL INFANT IMMUNIZATION COVERAGE (WUENIC)

SECRETARIAT FOCAL POINT FOR DATA: MARTA GACIC, DAVID BROWN, LAURE DUMOLARD, JAN GREVENDONK

1. WHO-UNICEF Joint Reporting Form on Immunization

Since 1998, WHO and UNICEF annually collect data on national immunization systems jointly through the WHO-UNICEF JRF[1].

The Joint Reporting Form annually collects national level data on:

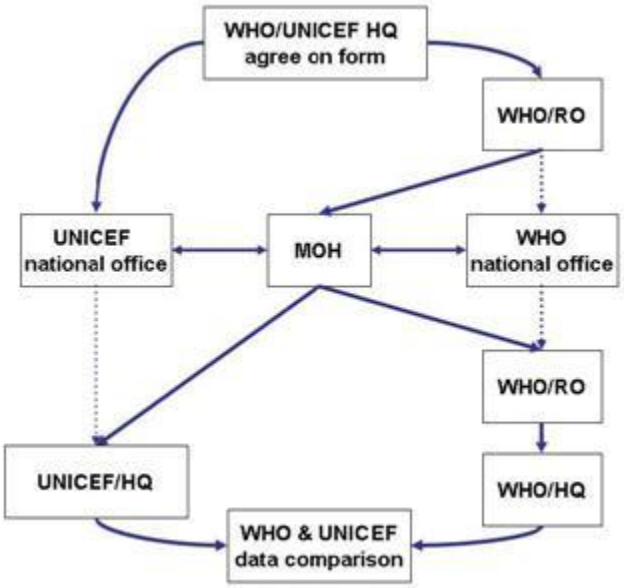
- reported cases of selected vaccine preventable diseases,
- recommended immunization schedules,
- immunization coverage,
- vaccine supply, and
- other information on the structure, policies and performance of national immunization systems.

National authorities complete the form using an excel based data-collection tool and submit the data to WHO and UNICEF during the second quarter of each year. WHO and UNICEF consolidate the replies and reconcile any differences between the two reporting channels during May. Preliminary data are available in June. Data are updated in July and periodically between August and December depending on additional information and correction reported during the year by the Member States. This permanent dialogue between WHO-UNICEF and the Member States improve both the availability and the quality of data.

The data are published on the WHO website:
http://apps.who.int/immunization_monitoring/globalsummary.

[1] http://www.who.int/immunization_monitoring/routine/joint_reporting/en/index.html

Figure 1: The Joint Reporting Form for Immunization Process



As of 23 July 2013, WHO-UNICEF received JRFs from 188 Member States, that reported data for 2012; at the official deadline of 15 April 2013, WHO- UNICEF received JRFs from139 Member States.
As at 23 July 2013, WHO and UNICEF had not received a completed JRF from Cape Verde, Finland, Monaco, Singapore, the former Yugoslav Republic of Macedonia and Turkey.

In the 188 JRFs received with data for 2012, not all sections of the JRF were completed.
- 8 Member States did not complete the NITAG section,
- 28 Member States did not provide data in the financing section,
- 11 Member States did not provide DTP3 coverage data (neither administrative nor country official estimates),
- 38 Member States did not answer to the district coverage data table related to DTP3, and
- 10 Member States did not reply to any of the two questions related to the presence of a surveillance system to monitor Rotavirus and invasive Bacterial diseases.

1.1. IMMUNIZATION COVERAGE DATA

Each year since 2000, WHO and UNICEF have jointly reviewed, prepared and published estimates of national immunization coverage for selected vaccine preventable diseases. The main sources of empirical data on immunization coverage used in this process are administrative data based on reports from service providers (e.g. health centre staff, vaccination teams, private physicians) and surveys with items on children's vaccination history.

1.1.1. Administrative data

Administrative data report the number of vaccinations administered during a given period – usually 1 month – and recorded at the service delivery point to local public health authorities who review the data and take any necessary action. The data are then aggregated and reported to the next administrative level and later aggregated, analyzed and used at the national level[2].Most countries report district and national level coverage annually to WHO and UNICEF through the JRF.

Administrative data provide timely information on programme performance, particularly when surveys may not be practical and are useful at lower administrative levels in revealing service delivery problems (e.g. vaccine shortage, poor session attendance) early on. However, coverage estimates based on administrative data are subject to numerator (number of children vaccinated) and denominator (number of children in the target population) biases.

When vaccinations are not reported by lower administrative levels or part of the population either due to delays in reporting, absent reporting or lacking information on sub-populations such as those served by the private sector, and therefore excluded from the data collection or reporting system (e.g. numerator smaller than it should be), administrative-based immunization coverage can be underestimated. Administrative-based coverage can also be overestimated when children vaccinated outside the target age group are erroneously included in the numerator.

Estimates based on administrative data can also be biased by an inaccurate denominator, especially when outdated censuses and poor population projections are used[3] or when in- or out-migration makes estimation of population is high, as in some urban areas. For instance, when coverage is high and the target population has been largely underestimated, estimated coverage can exceed 100%.

1.1.2. Survey data

Household and community-based surveys are also a common source of immunization coverage data. In these surveys, immunization history is determined either by looking at immunization records (e.g. immunization cards or child health cards) maintained in the home, asking the child's caretaker (recall) or both. The three main household survey sources are the Demographic and Health Survey (DHS) (www.measuredhs.com), the UNICEF-sponsored Multiple Indicators Cluster Survey (MICS) (www.childinfo.org/mics) and the Expanded Programme on Immunization (EPI) cluster survey (www.who.int).

Survey data allow for estimating immunization coverage even in the absence of an accurate target population size, and may also provide useful information on coverage levels among sub-populations

[2] "WHO and UNICEF estimates of national infant immunization coverage: methods and processes", A. Burton et Al. Bulletin of the World Health Organization 2009;87:535-541.
http://www.who.int/bulletin/volumes/87/7/08-053819/en/index.html

[3] "Raising Awareness Among Immunization Programme Managers to the Potential Bias Resulting from the Application of Fixed Factors to Obtain Target Population Size Estimates" Brown DW et Al.
Open Public Health Journal, 2012, 5, 15-18.
http://www.benthamscience.com/open/tophj/articles/ V005/15TOPHJ.pdf

such as those who receive services through the private sector or those who reside in urban, peri-urban or rural areas. An important disadvantage of surveys, however, is their lack of usefulness for informing timely programme interventions. For example, many coverage surveys focus data collection on children aged 12-23 months at the time of the survey, and therefore resulting coverage results reflect the immunization experience of the prior year's birth cohort as opposed to the current year's birth cohort.

Obtaining information on the latter is possible but requires more challenging and therefore costly sampling exercises. In addition, in the absence of an appropriate sampling design to obtain coverage levels at the district or lower levels, surveys may not provide useful information to inform local system performance at these levels. Other biases, such as misclassification due to inaccurate respondent recall in the absence of documented evidence of vaccination — a particular concern given low prevalences of home-based vaccination records[4] — must also be considered. Although not well documented, the length or complexity of the questionnaire may compromise the accuracy of the responses. Finally, as Burton et al (2009) highlight, both administrative and survey methods are subject to recording, computation and transcription errors as well as non-compliance with established protocols due to poor training and supervision. Systematic and purposeful data fabrication are also possible challenges.

At the global level, WHO and UNICEF collect data on immunization coverage from administrative data monitoring systems including target population, number of vaccinated children, and percent coverage for selected antigens.

As immunization coverage figures from administrative data can be biased or inaccurate, the JRF gives the opportunity to national authorities to provide estimates of what the most likely true coverage is. These official estimates may be based on data from the administrative method, from surveys, or from other sources. These official estimates are reproduced in global and regional reports as the officially reported coverage figures.

1.1.3. Electronic nominal registries

Some Member States (mostly High Income Countries (HIC) in the Americas and Europe but increasingly also Low Middle Income Countries (LMIC)) have implemented National Electronic Immunization Registries to ensure the follow up immunization status of their population at an individual level. Such registries can provide better data quality in a timely fashion and at all levels of the administrative system, facilitating the implementation of corrective actions as and when required. If all health care providers report administered doses in these registries, they can be used to obtain numerator data, without the need for aggregated periodic reporting. If registration in the immunization register is fairly exhaustive, for example through links with civil registry systems, they could produce an estimate of the denominator and thus coverage. Having the possibility to analyze disaggregated data allows for richer analysis than traditional systems are able to produce.

[4] "Child Immunization Cards: Essential Yet Underutilized in National Immunization Programmes", Brown DW. Open Vaccine J. 2012;5:1–7

2. WHO-UNICEF estimates of national infant immunization coverage (WUENIC)

Since 2000, WHO and UNICEF jointly review and prepare their own draft estimates annually, which are referred to as the WHO and UNICEF Estimates of National Immunization Coverage (WUENIC)[5].

Data on immunization coverage from all available data sources for each country and vaccine are reviewed, and estimates of the most likely coverage for each year and antigen are made from the data following an established method[67]. The time series of coverage may be adjusted if and when new sources of data become available (e.g. a new survey). Essential to this review are consultation with national authorities. Draft estimates are sent to each national authority to inform them of the results before the estimates are publicly released, and to take advantage of the local expertise that are relevant to the estimation process. Comments received from national authorities are reviewed by the WHO and UNICEF working group, and draft estimates are modified if appropriate.

The final estimates and supporting data are shared with national governments and are released annually for public use.

Statistical summaries appear in WHO and UNICEF publications:

- Immunization summary
  http://www.childinfo.org/files/immunization_summary_2012_en.pdf
- *State of the world's children*
  http://www.unicef.org/sowc/
- *The world health statistics*
  http://www.who.int/gho/publications/world_health_statistics/en/index.html

2.1. WHO-UNICEF WUENIC estimation methods

- **Country-specific**
  - All country's data are reviewed individually. Other Member States' data are never used for the estimates.
  - If national data are available from a single source, the WUENIC are based solely on that source, supplemented with linear interpolation to impute values for years for which data are not available.
  - If no data are available for the most recent estimation period, the estimate remains the same as the previous year. If new data or information subsequently become available, the relevant portion of the WUENIC time series is updated.

[5] http://www.who.int/immunization_monitoring/routine/immunization_coverage/en/index4.html

6. WHO and UNICEF estimates of national infant immunization coverage: methods and processes, A. Burton et Al. Bulletin of the World Health Organization 2009;87:535-541.
http://www.who.int/bulletin/volumes/87/7/08-053819/en/index.html

[7] A Formal Representation of the WHO and UNICEF Estimates of National Immunization Coverage: A Computational Logic Approach, Burton, A. and al,
http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0047806

- **Consistent trends and patterns**
  - If survey data tend to confirm (e.g. within ± 10 percentage points) reported coverage (administrative or country official estimate), the WUENIC are based on the country reports.
  - If multiple survey points show a fairly consistent relationship with the trend in reported data and the survey data are significantly different from reported data, the WUENIC are based on reported data calibrated to the level established by the survey data.
  - If survey data are inconsistent with reported data, the reported data show no consistent relationship with survey data and the survey data appear more reliable, coverage WUENIC are based on survey data, with interpolation between survey data points for intervening years.
  - If multiple data points are available for a given country, vaccine/dose, and year, data points are not averaged; instead, potential biases in each source are considered and an attempt is made to construct a consistent pattern over time from the data with the least potential for bias consistent with temporal trends and comparisons between vaccines.
  - If coverage patterns are inconsistent with the vaccine and dose numbers given, an attempt to identify and adjust for possible biases is made.
  - If inconsistent patterns are explained by programmatic (e.g. vaccine shortage) or contextual events (e.g. known emergencies or other incidents that may lead to an interruption in service delivery), the WUENIC reflect the impact of these events.
  - When several WUENIC are possible, alternative explanations that appear to cover the observed data are constructed and treated as competing hypotheses. Local information is considered, potential biases in the data are identified and the more likely hypothesis is selected.

- **Recall bias adjustment**

Whenever WUENIC are based primarily on survey data and the proportion of vaccinations based on parental recall is high, survey coverage levels are adjusted to compensate for inaccuracies in parental recall for multi-dose antigens (e.g. DTP, Polio vaccine, Hepatitis B vaccine and Hib vaccine) by applying the dropout between the first and third doses observed in the documented data to the vaccination history reported by the child's caretaker.

- **No coverage greater than 100%**

Coverage levels in excess of 100% are occasionally reported. While they are theoretically possible, they are usually the result of systematic error in the numerator and/or denominator, such as a mid-year change in target age groups, or inclusion of children outside the target age group in the numerator. These WUENIC are reduced to 99%.

2.1.1. WUENIC estimates weaknesses

As described above, the heuristics used constrain but do not uniquely determine the estimate. Subjectivity arises primarily in (i) the choice of rules and (ii) deciding which rule should apply in a given circumstance. There is no theoretical foundation for selecting rules and no validation of their reliability; the choices have been based on appeals to rationality, consistency and the lack of alternatives that produce more reasonable WUENIC.

Current estimates are seriously limited by the absence of any articulation of uncertainty; as presented, they appear equally precise and certain. The uncertainty in the estimates is rooted in the accuracy and

precision of the empirical data (described above) and in the choice and application of the heuristics (model-based uncertainty). Because the estimates are not based on a probability sample and multiple measures are not considered as random variants of a single population measure, we are reluctant to limit the uncertainty to the amount of variation in the empirical data. In general, we consider that any coverage level has an error of at least ±3 percentage points (not necessarily symmetrical) with perhaps a maximum of ±20 percentage points.

Beginning with the 2011 revision, estimates includes the grade of confidence (GoC) that WHO- UNICEF have in the estimate for vaccine dose for each country. The GoC reflects the degree of empirical support upon which the estimates are based. It is not a judgment of the quality of data reported by national authorities.

Finally, the quality of the estimates is determined by the quality and availability of available data. Vaccination coverage is relatively easy to measure and two methods – administrative reports and surveys – have been developed, each of which, when properly designed and implemented, provides accurate and reliable direct measures of coverage levels. Used jointly (using each measure for the same population), they provide a validation of coverage levels.

However, as described above, both methods are subject to errors. In some instances, these may be identified and corrected, as we have attempted to do. In no instance do we have complete, consistent, multiple measures for an entire country/vaccine time series. In some instances we have complete administrative data validated by periodic or occasional consistent survey findings. In others, data are available from a single source – usually administrative data – and appear internally consistent over time and across vaccines. In several Member States, administrative data and survey results are inconsistent; in others, the administrative time series is incomplete, internally inconsistent or both.

These data are supplemented with local consultations that often explain inconsistencies and anomalies and provide insight into forces that influence coverage levels. More importantly, WHO and UNICEF have worked closely with Member States to improve the quality and usefulness of coverage monitoring data systems through the conduct of Data Quality Self-Assessments and Data Quality Audits. These audits prompt corrective actions to improve the recording and reporting of administrative data. Currently, WHO is coordinating an effort to standardize methods to collect, analyze and report immunization coverage from household surveys.

GOAL 1

ACHIEVE A WORLD FREE POLIO

INDICATOR G1.1 & G1.2

G1.1: INTERUPT WILD POLIOVIRUS TRANSMISSION GLOBALLY

TARGET: 2014

G1.2: CERTIFICATION OF POLIOMYELITIS ERADICATION

TARGET: 2018

SECRETARIAT FOCAL POINT: RUDI TANGERMANN

Progress towards achievement of the polio eradication goals and interim milestones are intensely monitored, including by an Independent Monitoring Board (IMB) that reviews progress on a quarterly basis and issues a report after each of its meetings. These reports are publicly available (http://www.polioeradication.org/Aboutus/Governance/IndependentMonitoringBoard/Reports.aspx).

Hence, this report provides links to the data sources (since surveillance data are updated weekly) and summarizes the information in the Polio Eradication and End Game Strategy Plan to provide the context and the latest Global Polio Eradication Annual (2011) and Polio Eradication IMB reports for assessment of progress and recommendations for corrective action.

For definition of indicator, description of data's sources, comments on data's quality, description of results, narrative and highlights please refer to the four following documents for your review:

1. **Polio Data Monitoring**
http://www.polioeradication.org/Dataandmonitoring.aspx
This link provides real-time updates on polio cases in the world.

2. **Context , GPEI: Polio Eradication and End Game Strategy Plan 2013-2018**
http://www.polioeradication.org/Portals/0/Document/Resources/StrategyWork/PEESP_CH4_EN_US.pdf

GPEI: Polio Eradication and End Game Strategy Plan 2013-2018
Executive summary

"ADVANCES AGAINST POLIO IN 2012"

1. The year 2012 saw tremendous advances for the programme, setting up the possibility to end polio for good. Among the most significant advances is India which, in February 2012, celebrated a full year without a child paralyzed by indigenous wild poliovirus (WPV). India was arguably the most technically challenging place to eliminate polio. The country's success was due to the ability of the programme to repeatedly reach all children; the use of a new bivalent oral polio vaccine (bOPV); sustained political commitment and accountability; societal support; and the availability of resources needed to complete the job. The country remains polio-free today.

2. By the end of 2012, the total number of polio cases worldwide plunged 66% over the previous year to 223. Three of the four Member States that had re-established WPV transmission following importations (Angola, the Democratic Republic of the Congo and Sudan) did not have a single case in 2012. The fourth, Chad, has not reported a case since June 2012. To tackle cVDPVs, new, more affordable inactivated polio vaccine (IPV) options have been developed. In an important step, the Strategic Advisory Group of Experts on Immunization (SAGE), the world's chief policy guidance body for immunization, in 2012 recommended the withdrawal of the type 2 component of oral polio vaccine (OPV) as soon as possible from routine immunization programmes1 in all Member States, facilitated by the introduction of at least one dose of IPV.

3. To tackle cVDPVs, new, more affordable inactivated polio vaccine (IPV) options have been developed. In an important step, the Strategic Advisory Group of Experts on Immunization (SAGE), the world's chief policy guidance body for immunization, in 2012 recommended the withdrawal of the type 2 component of oral polio vaccine (OPV) as soon as possible from routine immunization programmes1 in all Member States, facilitated by the introduction of at least one dose of IPV.

4. In September 2012, government leaders in the endemic and donor Member States and the Secretary-General of the United Nations declared that ending polio is a top priority. This signaled the political commitment needed to effectively implement national Emergency Action Plans and capitalize on the progress to date.

5. In addition to declining cases in Afghanistan and Pakistan, evidence demonstrates that these Member States and Nigeria showed marked improvement in increasing vaccination coverage in 2012, putting them on a trajectory to interrupt transmission by the end of 2014. This progress will continue if trends persist and current security challenges do not cause a prolonged or increased impact on operations. In Pakistan, the proportion of highest-risk districts achieving the estimated target threshold of 95%2 increased from 59% in January 2012 to a peak of 74% in October 2012.

6. In Afghanistan, by the end of 2012, approximately 15 000 children remained unreachable, down from 80 000 in 2011, thanks to a combination of strategies, such as permanent polio teams operating in the key high-risk areas and intense outreach efforts with community leaders.

7. In Nigeria, although overall cases increased in 2012, case numbers had stabilized by the last quarter of the year due to revised microplans, better vaccination team selection, improved monitoring and strong oversight at the national and state levels. The proportion of very high-risk Local Government Areas in which vaccine coverage reached the target threshold increased from 10% in February 2012 to 70% in February 2013.

8. The tragic, targeted killings of health workers in late 2012 and early 2013 in Pakistan and Nigeria present a new threat to this progress. However, governments and partners have initiated a number of adjustments to improve safety in specific areas and to ensure the continuity of campaigns.

3. GPEI Annual Report 2011

http://www.polioeradication.org/Portals/0/Document/AnnualReport/AR2011/GPEI_AR2011_A4_EN.pdf

GPEI Annual Report 2011

Executive summary

"*Looking back on the second year of the Global Polio Eradication Initiative (GPEI) Strategic Plan 2010–2012, the scales are balanced between significant achievements on the one side and, on the other, some disappointing setbacks*."

Success in India was the most remarkable milestone, deemed "magnificent" by the Independent Monitoring Board (IMB) of the GPEI. Long considered one of the most challenging Member States in which to eradicate polio, India accomplished what the IMB called the "systematic enforcement of best practice" to reach over 98%of children with polio vaccine. The country freed itself of endemic polio and finally laid to rest the question of whether polio eradication is technically feasible.

Globally, polio cases fell to half the level of the previous year. In two of the four Member States with re-established transmission of polio, no cases have been reported in the Republic of South Sudan and in Angola since June 2009 and July 2011, respectively. In the other two, Chad geographically restricted polio in the second half of the year and cases plummeted in the Democratic Republic of the Congo, after aggressive response to extensive outbreaks in early 2011. All of the eight outbreaks recorded in previously polio-free Member States were successfully stopped, all but one within six months.

On the other side of the scales, the three remaining endemic Member States witnessed an unexpected and serious upsurge of polio. In Nigeria and Pakistan, the continued circulation of two wild poliovirus serotypes – and a vaccine-derived poliovirus in the former – had the ripple effect of international spread to two neighbors. In Afghanistan, the number of cases also increased, with the national programme unable to reach enough children to stop outbreaks in the insecure Southern Region. At the end of 2011, the three endemic Member States were off-track for eradicating polio.

The IMB warned in October 2011 that polio eradication would not be achieved on the programme's current trajectory. In November, an alarmed Strategic Advisory Group of Experts on immunization (SAGE) warned that failure to eradicate polio would constitute a failure of public health. By January

2012, the World Health Organization's (WHO) Executive Board had called for polio eradication to be declared a programmatic emergency for global health.

Completing polio eradication is now a global emergency because of the clear – and, as stated by SAGE – "unacceptable" consequences of failure. The children of Nigeria, Pakistan and Afghanistan bear the brunt of current polio transmission, but the consequences reach much farther. In recent years, the international spread of polio has become deadlier. Recent outbreaks on three continents –Tajikistan, Congo and China, all far from polio-endemic areas – paralyzed mostly adults. In some of these outbreaks, half the affected adults died. When the virus affects adults who have grown up in previously polio-free Member States and have received little or no vaccination, it kills far more frequently.

These consequences have triggered emergency actions among Member States and the international polio partners. The Global Polio Emergency Action Plan 2012–2013, and the revised national emergency action plans that underpin it, capture the fundamental changes that polio-affected Member States and their partners are making in their approach and structure, to ultimately bring about polio eradication.
Compounding this emergency is a 50% gap in financing needed to fully carry out the necessary activities in 2012–2013 (as of April 2012). In the first quarter of 2012, this has already dictated the scale-back of activities in 24 Member States in Asia and Africa, increasing the risk of unchecked spread if poliovirus from endemic areas enters these Member States.

The emergency eradication programme is about speed, focus and most of all accountability. From heads of state to chiefs of multilateral agencies and donors, from parent to vaccinator, every link in the chain must be tempered and strengthened to bring about a polio-free world.

4. Report of the Independent Monitoring Board of the GPEI, May 2013

- Full report, May 2013

http://www.polioeradication.org/Aboutus/Governance/IndependentMonitoringBoard/Reports.aspx

- At a glance, May 2013

http://www.polioeradication.org/Portals/0/Document/Aboutus/Governance/IMB/8IMBMeeting/8IMB_ReportSummary_EN.pdf

"The IMB makes eight recommendations" (see report for full wording):

1. The Programme must urgently construct and implement a plan to correct its crippling under-emphasis on social mobilization and communications.

2. Through the necessary trials, the Programme should (by the end of 2013) be able to conclusively answer the question: "Should the endemic Member States introduce IPV as soon as possible, or should they wait until 2015?"

3. The Polio Oversight Board should study the IMB's analysis of the current management issues. Partners' headquarters should consider these two questions: How can we work together in a more ordered and efficient way, enabling action to proceed at the speed required in a programmatic emergency? How can we be more sharply focused on what the polio-endemic Member States need

from us as a group, and how can we better coordinate efforts to provide this, including on controversial issues?

4. The Polio Oversight Board should hear candid views directly from in-country representatives of both government and partner agencies, about what they need from the partners at headquarters level.

5. The Polio Oversight Board should establish a mechanism to more frequently monitor key management information, including details of any unfilled post and its recruitment process, and should publish records of its meetings.

6. The incoming Pakistan government should seek to retain the Prime Minister's Monitoring Cell and other structures that have led polio eradication efforts so successfully during the previous government's term.

7. Nigeria should urgently finalize a more detailed operational plan to deal with the security issues that it faces, drawing on the experiences of Afghanistan and Pakistan.

8. Polio compatible cases should be routinely reported in the Programme's bulletins, reports and presentations alongside the number of confirmed cases. Further attention should be given to reducing the number of compatible cases through better surveillance. Expert review committees should receive the resources they need to support accurate diagnosis when such cases arise.

ADDITIONNAL DOCUMENTS

1. **66th World Health Assembly (WHA) – May 2013, Poliomyelitis: intensification of the global eradication initiative. Report by the Global Polio Eradication Initiative, as at 28 March 2013** http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_18-en.pdf
2. **Report of the Independent Monitoring Board of the GPEI, November 2012** http://www.polioeradication.org/Aboutus/Governance/IndependentMonitoringBoard/Reports.aspx
3. **GPEI: Polio Eradication and End Game Strategy Plan 2013-2018** http://www.polioeradication.org/Resourcelibrary/Strategyandwork/Strategicplan.aspx
4. **GPEI Key Elements of the Financial Resource Requirements 2013-2018** http://www.polioeradication.org/Resourcelibrary/Strategyandwork/Financialresourcerequirements.aspx
5. **GPEI Monitoring Framework Polio Eradication and End Game Strategy 2013-2018: Annex B (Draft document)**

GOAL 2

MEETING GLOBAL AND REGIONAL ELIMINATION TARGETS

INDICATOR G2.1

MATERNAL AND NEONATAL TETANUS ELIMINATION

TARGET 2015

SECRETARIAT FOCAL POINT: AHMADU YAKUBU

DEFINITION OF THE INDICATOR

- Maternal and Neonatal Tetanus Elimination (MNTE) is defined as an incidence of less than one case of neonatal tetanus per 1,000 live births per year in all districts or similar administrative unit of a country.
- Neonatal tetanus indicator acts as proxy for maternal tetanus

Description of validation process for NT elimination

The MNTE validation process starts with the claim of the attainment of elimination by a country. This happens after either all planned MNTE activities such as provision of Tetanus Toxoid (TT) containing vaccines through supplementary immunization activities to fill immunity gaps have been completed or when country own assessment through district level data review indicates that there is no need for additional activities and that NT rates in all districts are less than 1/1000 live births. This is followed by the pre-validation assessment, which is an intensive data review looking into core and surrogate indicators for MNT and complimented by field visits to some selected poorest performing districts based on the data review. The field trip assesses whether there is adequate evidence for the claim of elimination, and findings are consolidated to decide whether the country claim is valid. Once the risk-status of the poorest performing districts is assessed to be low for MNT, plans are then put into place for the implementation of the Lot Quality Assurance[8] – Cluster Sampling (LQA-CS) survey. It has to be noted that some Member States do not do pre validation (e.g. some states in India , Gabon etc.).

The NT LQA-CS is a type of neonatal mortality survey in which identified neonatal deaths are investigated by verbal autopsy to determine if the death was caused by tetanus. Because case fatality rate due to NT is very high (>80%), especially in the high risk populations that lack intensive medical care facilities, the NT mortality rate is assumed to approximate NT incidence. The primary elements sampled are live births delivered during a 12-month eligibility period that ends at least 4 weeks before the start of the survey. The 4-week interval between the end of the eligibility period and the start of the survey is to ensure that the outcome for all eligible live births can be determined for the entire neonatal period.

The LQA-CS survey assesses whether or not the Neonatal Tetanus Mortality Rate (NTMR) in the survey area probably exceeds 1/1000 live births during the 12-month eligibility period. It is not designed to

[8] LQA-CS survey protocol was revised in 2012 but has not been published yet.

provide a point estimate of the NTMR for the surveyed area. The number of NT deaths detected during the survey is compared to a pre-determined maximum acceptance number of NT deaths that defines whether the district “passes” (NTMR probably does not exceed 1/1000) or “fails” (NTMR is probably greater than 1/1000). This pass/fail design comes from LQA methodology.

An official notification of the survey outcome and the survey report are then communicated to the Minister of Health of the country by the World Health Organization Headquarters.

DESCRIPTION OF DATA’S SOURCES

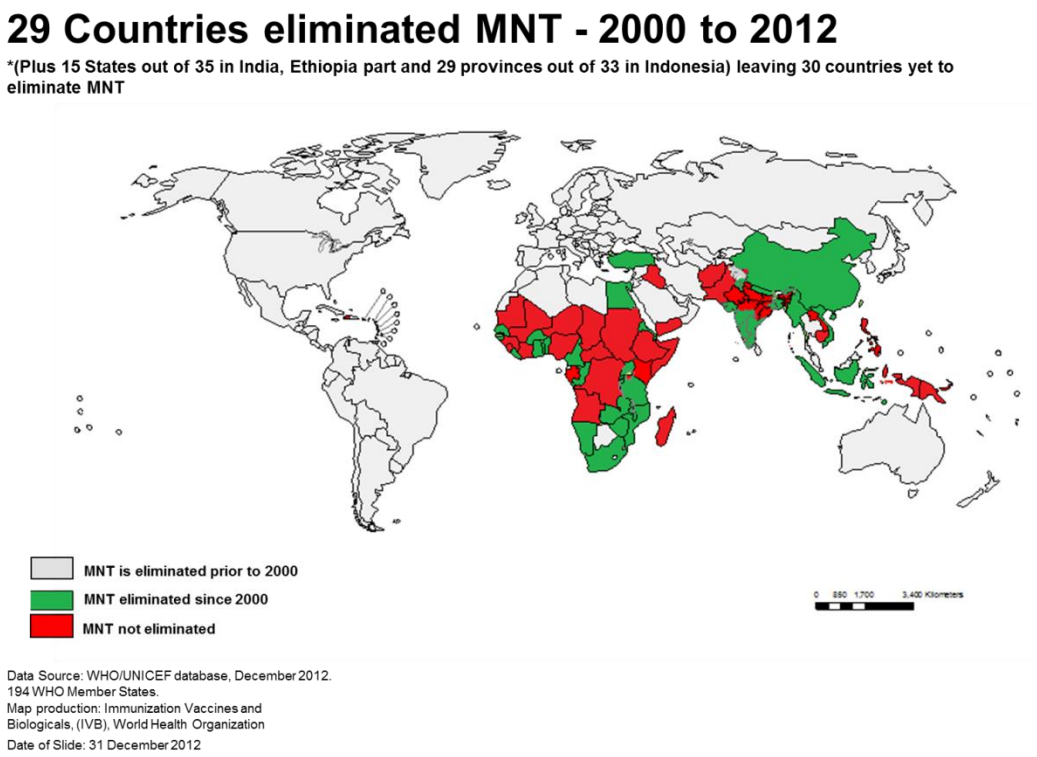
These include WHO-UNICEF joint reporting form, country Health Management Information System (HMIS) report, country surveillance reports, coverage survey reports, Demographic and Health Survey reports, Multiple Indicator Cluster Sampling survey reports and any other immunization and reproductive health programme review reports.

COMMENTS ON DATA’S QUALITY

The quality of routine administrative data by district from Member States is often questionable for many Member States, and we often rely more on survey data if that is available. However, HMIS or routine administrative data are triangulated through survey coverage and health programme review reports and these data are mainly used to assess whether the country claim is valid and whether an LQA-CS is indicated. Ability to correctly identify all births and neonatal deaths and to correctly assess whether or not the death may be due to neonatal tetanus represent some of the limitations of the LQA-CS.

DESCRIPTION OF THE RESULTS

Map 1: Member States that have validated elimination of NT (as of 31st December 2012).



Member States failing to achieve MNT elimination target (as of 31 December 2012): Afghanistan, Angola, Cambodia, Central African Republic, Chad, Congo DR, Cote d'Ivoire, Equatorial Guinea, Ethiopia, Gabon, Guinea, Haiti, India, Indonesia, Iraq, Kenya, Lao People's Democratic Republic, Madagascar, Mali, Mauritania, Niger, Nigeria, Pakistan, Papua New Guinea, Philippines, Sierra Leone, Somalia, Sudan, South Sudan and Yemen.

NARRATIVE

Maternal and neonatal tetanus is a marker of inequity, as the most vulnerable populations are affected by the disease. Almost all cases occur among the poorer segment of the population in low income Countries (LIC). Due to the nature of the disease, tetanus cannot be eradicated. In order to eliminate tetanus as a public health problem, the 42nd WHA in 1989 established a goal to eliminate maternal and neonatal tetanus. This goal was later endorsed by the World Summit for Children in 1990.

In 1999, maternal tetanus elimination was added to the WHO, UNICEF and UNFPA initiative. MNTE efforts was the focus on 59 Member States[9] that were assessed to have more than 1 NT case/ 1000 live births at the time.

Four Member States (Ghana, Liberia, Senegal and Uganda) were validated to have attained MNT elimination in 2011, in addition to partial validations in Ethiopia and Indonesia, followed by six Member States (Burkina Faso, Cameroon, China, Guinea Bissau, Tanzania and Timor Leste) in 2012.

A total of 29 out of 59 Member States are validated to have achieved the elimination status, thus the milestone for achieving elimination in 10 additional Member States by 2012 (baseline in 2010) was met. China's MNTE is a remarkable story because the country did it the "hard way" through massive investments and attention to improving health facility delivery rates and rural maternal and child health outcomes, without any mass supplementary TT vaccination campaign.

On completion of planned Supplemental Immunization Activities (SIAs) and/or improvement in clean delivery practices, pre-validation assessments were done to the validation surveys in eight Member States (Cambodia, Cameroon, China, Cote d'Ivoire, India, Indonesia, Mauritania and Sierra Leone) in 2012.

TT campaigns targeting women of reproductive age (15-49 years) were conducted in 10 Member States (Afghanistan, Angola, Democratic Republic of Congo, Ethiopia, Guinea Conakry, Madagascar, Mali, Niger, Papua New Guinea, Philippines and South Sudan). Somalia reached target women with TT vaccine as part of Mother and Child health weeks. As a result nearly 3.7 million women of reproductive age received at least 2 doses of TT vaccine during 2012 SIAs.

[9] Maternal and Neonatal Tetanus, Elimination by 2005, "Strategies for achieving and maintaining elimination", WHO 2000.

Update at 31 June 2013

- Three more Member States (Cote d'Ivoire, Iraq and Sierra Leone) were validated, thus raising the number of validated Member States to 32. In addition, three states of India passed validation survey and hence 18 out of 35 states of India were validated for MNTE.
- Lao PDR passed pre-validation assessments and is ready for validation survey. Gabon completed the survey. Equatorial Guinea will undergo the validation survey in 2013.
- Guinea Conakry, Madagascar and Philippines completed scheduled activities and are preparing for pre-validation assessment.
- During a MNTE stakeholders meeting in May 2013, development partners and stakeholders affirmed their commitment and support to the initiative till global elimination target is achieved.
- Afghanistan, Angola, Democratic Republic of Congo, Ethiopia, Haiti, Kenya, Niger, Pakistan, Sudan and South Sudan have planned TT/Td SIAs in 2013.

For Member States still failing to achieve the elimination target

- **Did they ever report zero case of NT in the past?**
  From the definition, the target is not to have zero cases, but rather to have rates below 1 NT per 1,000 live births. NT surveillance in most of the 30 remaining priority Member States is passive and has not been fully integrated into the existing active Acute Flaccid Paralysis (AFP) and measles Rubella surveillance as would have been desired. Community-based surveillance that would significantly improve the quality and sensitivity of NT surveillance is not active in most of the priority Member States. In summary, reporting zero case is not necessarily an indication of progress, but rather an indication of poor surveillance for NT.

- **What are the reasons and obstacles for not achieving the target?**
  - Limited resources including timely availability of financial resources for the high risk approach and the associated TT supplementary immunization activities as well as for health education on improvement in clean delivery and cord care practices.
  - Poor access to immunization and reproductive health services including antenatal care and clean delivery services, especially in underserved areas.
  - Sociocultural barriers and practices such as continued practice of application of harmful substance on cord.
  - Insecurity especially from armed conflicts and other insurgencies that limit access to health and other development services.
  - Other competing immunization priorities (polio, measles and other VPD outbreaks) such as getting a window of opportunity to conduct TT campaigns and often missed opportunities (non-integration of TT with other antigens). These issues are especially significant in the polio endemic Member States (Afghanistan, Nigeria and Pakistan), but in other Member States as well.

- **Have Member States shown the desired level of commitment?**
  Some of the national Governments could not keep MNTE on the priority agenda, especially due to political instability, internal conflicts, inadequate financial resources in the face of competing needs for governments' support and changes in health infrastructure - devolution. Inadequate human resources for health in terms of quantity and quality also further complicates the situation. Lack of domestic resource from national budget has impacted activities in some Member States.

- **What can be done? And by who?**
  - Strengthening partnership for sustaining financial flow, advocacy with the national Governments and other stakeholders to keep MNTE high on the agenda.
  - Use innovative approaches to reach the most disadvantaged with package of high impact interventions with integrated approaches (Mother and Child Days / Immunization Weeks) and simple appropriate technologies (TT Uniject devices).

In Member States where elimination has been validated, description on the activities Member States are taking to sustain NT elimination (includes progress with establishing district data spread sheets that meet quality criteria)

The Member States that achieved MNTE status are focusing on strengthening routine delivery of TT-containing vaccines, introducing school vaccination and expanding networks of community midwives and community health workers to broaden access to clean delivery and cord care. At the global and regional levels, efforts are being made to provide guidance to Member States on sustaining their achievements as well as following up with Member States on the need for periodic data reviews and implementation of corrective measures as may be justified by the data review to ensure that the elimination status is maintained for all Member States that achieved MNTE.

This also includes:
- Focus on school-based delivery of the vaccine as part of school health programme.
- Ensuring better linkage between antenatal care attendance and TT/Td vaccination.
- Promotion of skilled attendance at birth and discouraging harmful cord care practices.
- Supporting integrated disease surveillance including for neonatal tetanus.

HIGHLIGHTS

- Milestone for 10 additional Member States being validated as having eliminated neonatal tetanus during this decade was met.
- Additional 3.7 million women of reproductive age received 2 protective doses of TT vaccine in 10 Member States in 2012, giving a total of over 118 million women that have benefitted from the initiative since 1999.
- Four Member States conducted the pre-validation assessment and were found to have made adequate progress enable them to proceed to the validation survey stage. Additionally six Member States validated the attainment of MNTE in 2012, and three Member States (Cote d'Ivoire, Iraq and Sierra Leone) already validated in addition to three States in India in 2013.
- Delayed availability of funds in support of the implementation of activities, especially for high risk districts.
- Five Member States with persistent security and access issues – Afghanistan, Angola, Haiti, Mali and South Sudan developed MNTE national plan of actions and started activities.
- Non-availability of the most appropriate technology, the TT Uniject, for reaching the very difficult parts of Member States where its use is most appropriate in such Member States as Afghanistan, Chad, Mali, Pakistan, part of South Sudan and Yemen among others. This device will enable the programme to reach the most remote parts of Member States since lay health workers can be trained to safely administer the vaccine in their villages.

GOAL 2
MEETING GLOBAL AND REGIONAL ELIMINATION TARGETS

INDICATOR G2.2

MEASLES ELIMINATION

TARGET
4 WHO REGIONS BY 2015
5 WHO REGIONS BY 2020

SECRETARIAT FOCAL POINT: PETER STREBEL

DEFINITION OF THE INDICATOR

As defined in the "Framework for verification of measles elimination"[10]

- **Measles eradication**:

Worldwide interruption of measles virus transmission in the presence of a surveillance system that has been verified to be performing well.

- **Measles elimination**

The absence of endemic measles transmission in a defined geographical area (e.g. region or country) for ≥12 months in the presence of a well-performing surveillance system.

Note: Verification of measles elimination takes place after 36 months of interrupted endemic measles virus transmission.

- **Description of Measles elimination goals by region11**
  - PAHO: eliminated in 2002 (two years after the 2000 goal)
  - EURO: measles elimination by 2015
  - AFRO: measles elimination by 2020
  - SEARO: measles 95% mortality reduction by 2015
  - WPRO: measles elimination by 2012
  - EMRO: measles elimination by 2015

As discussed at the 63rd WHA in 2010, global measles targets for 2015[12] were proposed as milestones towards the eventual global eradication of measles. These include achievement of the Global Immunization Vision and Strategy's goal to increase vaccination coverage as well as targets for reduction of incidence and mortality:

- Exceed 90% coverage with the first dose of measles-containing vaccine nationally and exceed.
- 80% vaccination coverage in every district or equivalent administrative unit.
- Reduce annual measles incidence to less than five cases per million and maintain that level.;
- Reduce measles mortality by 95% or more in comparison with 2000 estimates.

[10] Framework for verifying elimination of measles and rubella, WER, 9, 2013, 88, 89-100
[11] Global measles and rubella strategic plan: 2012-2020, WHO
[12] Sixty-third World Health Assembly A63/18, Item 11.15, May 2010
http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_18-en.pdf

DESCRIPTION OF DATA'S SOURCES

- JRF (incidence, information on schedule and SIAs) and WUENIC coverage data: Please refer to generic note at the beginning of the report "Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC".
- Progress in global control and regional elimination of measles, 2000–2011, WER 18 January 2013 http://www.who.int/wer/2013/wer8803.pdf
- Regional progress reports on status of verification commissions (process for verification and number of Member States that are verified as having eliminated measles).
  - WPRO
    "Progress towards measles elimination in the Western Pacific Region, 2009–2012", WER, 7 June 2013, vol. 88, 23 (pp. 233–240).
    http://www.who.int/wer/2013/wer8823.pdf
    http://www.cdc.gov/mmwr/pdf/wk/mm6222.pdf
  - PAHO
    - Experts Meeting of Measles and Rubella Laboratory Network, May 7th 2013, Washington, DC, USA (report to be published).
    - International Expert Committee (IEC) for documenting and verifying the measles, rubella and CRS elimination, May 7-8, Washington, DC, USA (report to be published).
  - Other Regions: No report.

COMMENTS ON DATA'S QUALITY

- JRF and WUENIC coverage data: Please refer to generic note at the beginning of the report "Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC".
- Regional progress reports on status of verification commissions: no report from EURO, AFRO, SEARO, WPRO.

DESCRIPTION OF THE RESULTS

Please refer to the following documents:

- 2012 Measles & Rubella Initiative annual report
  http://www.who.int/immunization_delivery/adc/measles/MRI_2012_Annual_Report.pdf
- Status Report submitted to SAGE in November 2012
  http://www.who.int/immunization/sage/meetings/2012/november/1_Status_Report_Measles_Rubella_22_Oct.pdf

Table 1: Number of measles cases and incidence reported per WHO region

	Number of cases			Number of Member States reporting			Incidence per million population		
	2012	**2011**	**2010**	**2012**	**2011**	**2010**	**2012**	**2011**	**2010**
AFR	106052	194364	199174	44	46	46	118.8	223.5	235.1
AMR	88	1311	247	35	35	35	0.1	1.4	0.3
EMR	36456	35923	10072	22	20	20	59.5	59.8	17.1
EUR	26982	37073	30625	45	50	52	29.8	41.1	34.1
SEAR	46945	65161	52529	11	11	11	25.6	36.0	29.3
WPR	10722	21050	49460	26	26	25	5.8	11.5	27.2
total	227245	354882	342107	183	188	189	34.1	53.9	52.6

NARRATIVE

Summary 2012 Measles & Rubella Initiative (M&RI) annual report

The year 2012 saw important gains in measles control. The Western Pacific Region, including China, reported a 93% decline in measles cases between 2008 and 2012, bringing the region to the verge of measles elimination. It was also the year southern African Member States brought their outbreaks under control through national vaccination campaigns. Cambodia used measles supplementary immunization opportunities to identify children who were missed during routine immunization. It was also the year India, building on lessons and experience to stop transmission of polio, continued their drive to immunize 134 million children against measles through a phased campaign in stated with low routine immunization coverage, accompanied by introduction of a second dose of measles vaccine in the routine system in better performing states.

Critically, 2012 was also the year 194 Member States, through the resolution at the WHA adopting the GVAP, committed to elimination of measles and rubella in five of six WHO Regions by 2020. The M&RI provided a roadmap to achieve this goal, and released a new global strategic plan (2012-2020) for measles and rubella, building on SAGE recommendations on rubella vaccination and surveillance. The GAVI Alliance pledged to help fund the plan, offering opportunities to introduce rubella-containing vaccine to 49 Member States, funds for measles campaigns in six of the most challenging Member States, and funds to mount a response with immunization to measles outbreaks.

With progress came challenges. More than 20 million infants did not receive a routine dose of measles containing vaccine. While measles deaths have dropped by an astounding 71% since 2000, an estimated 158,000 children died of measles-related complications in 2011 —about 430 child deaths a day, from a virus that can be countered with an effective, inexpensive vaccine. A large outbreak in the DR Congo that flared to well over 130,000 cases in 2011 continued in 2012. Ukraine had the highest reported measles incidence in the world in 2012, one of several European Member States that had outbreaks in 2011 and 2012, that were related to vaccine hesitancy, putting the goal of eliminating measles in Europe by 2015 at risk. Measles outbreaks in Afghanistan, Pakistan and Somalia, demonstrated how quickly measles travels and kills when immunization services are weak and affected by conflict and civil strife.

Several supplementary immunization campaigns—a strategic investment of time and money—failed to reach the goal of 95% of children in every district.

HIGHLIGHTS

- Measles morbidity and mortality has been reduced by >90% since the introduction of Measles Vaccine.
- Measles control and elimination efforts are a major contributor to the reduction in childhood mortality and achievement of Millennium Development Goal (MDG) 4 (approximately 20% of overall reduction in child mortality is attributable to improved control and elimination of measles.
- Measles outbreaks reveal gaps in the immunization programme and highlight inequities in access to services.
- All Member States in the Americas have achieved measles elimination but remain at constant risk for importations and outbreaks until other regions achieve elimination.
- The Western Pacific Region is on track for elimination but additional efforts will be required to stop transmission before 2015.
- Based on current trends and programme performance, the 2015 global targets as well as regional elimination targets in the European (2015), Eastern Mediterranean (2015) and African (2020) Regions will not be achieved on time.
- It has to be noted that SEAR Regional Committee is expected to endorse a regional measles elimination goal this September (2013).

REFERENCES

- Framework for verifying elimination of measles and rubella, WER, 9, 2013, 88, 89-100 http://www.who.int/wer/2013/wer8809.pdf
- Global measles and rubella strategic plan: 2012-2020, WHO http://www.measlesinitiative.org
- Progress in global control and regional elimination of measles, 2000–2011, WER 18 January 2013 http://www.who.int/wer/2013/wer8803.pdf
- 2012 Measles & Rubella Initiative annual report http://www.who.int/immunization_delivery/adc/measles/MRI_2012_Annual_Report.pdf
- Status Report submitted to SAGE in Nov 2012 http://www.who.int/immunization/sage/meetings/2012/november/1_Status_Report_Measles_Rubella_22_Oct.pdf
- SAGE meeting, November 2012 – conclusions and recommendations, WER, 4 January 2013, 88th year, 1, 2013, 88, 1–16 http://www.who.int/wer/2013/wer8801.pdf
- Progress towards measles elimination in the Western Pacific Region, 2009–2012, WER, 7 June 2013, vol. 88, 23 (pp. 233–240) http://www.who.int/wer/2013/wer8823.pdf http://www.cdc.gov/mmwr/pdf/wk/mm6222.pdf
- Additional documents http://www.measlesinitiative.org/vgn-ext-templating/v/index.jsp/vgnextoid/815c081a7a593210VgnVCM10000089f0870aRCRD.html

ANNEX

Note: Terms of Reference of the SAGE Working Group on measles and rubella
http://www.who.int/immunization/sage/sage_wg_measles_rubella_nov11/en/index.html

- Please note that Prof. Narendra Arora and Prof. Helen Rees are members of the SAGE WG on M&R.
- Review progress towards 2015 global measles control targets and regional measles and rubella elimination goals.
- Prepare for regular updates and review by SAGE on progress and challenges in achieving existing measles and rubella control targets and propose necessary updating of current WHO recommendations on vaccine use (including outbreak response immunization) and surveillance strategies.
- Identify gaps in essential evidence and programme barriers to achieving measles and rubella/ congenital rubella syndrome (CRS) elimination targets and present SAGE with proposed areas for operational or basic science research.
- Advise SAGE on the appropriate timing for establishing target dates for global eradication of measles and global control or eradication targets for rubella and/or CRS.

GOAL 2
MEETING GLOBAL AND REGIONAL ELIMINATION TARGETS

INDICATOR G2.2

RUBELLA/CRS ELIMINATION

TARGET
2 WHO REGIONS BY 2015
5 WHO REGIONS BY 2020

SECRETARIAT FOCAL POINT: PETER STREBEL

DEFINITION OF THE INDICATOR

- **Rubella and CRS elimination**

The absence of endemic rubella virus transmission in a defined geographical area (e.g. region or country) for ≥12 months and the absence of CRS cases associated with endemic transmission in the presence of a well-performing surveillance system

Note: There may be a time lag (up to 9 months) in occurrence of CRS cases after interruption of rubella virus transmission has occurred. Evidence of the absence of continuing rubella transmission from CRS cases is needed because CRS cases excrete rubella virus for up to 12 months after birth. Verification of rubella elimination takes place after 36 months of interrupted rubella virus transmission.

- **Description of Rubella/CRS elimination goals by region**
  - PAHO: rubella eliminated in 2009 (one year ahead of 2010 goal)
  - EURO: rubella elimination 2015
  - AFRO: no target
  - EMRO: no target
  - SEARO: no target
  - WPRO: rubella control: target under development

DESCRIPTION OF DATA'S SOURCES

JRF and WUENCI coverage data: please refer to generic note at the beginning of the report "Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC".

COMMENTS ON DATA'S QUALITY

JRF and WUENIC coverage data: please refer to generic note at the beginning of the report. Both Rubella and CRS surveillance data are under-reported and incomplete at the global level (see Table 2 below for 2011). The PAHO is the only region with reliable rubella and CRS surveillance data. Rubella surveillance is improving in the other regions through linkage with measles surveillance.

DESCRIPTION OF THE RESULTS

Please refer to the following documents:

- 2012 Measles & Rubella Initiative annual report http://www.who.int/immunization_delivery/adc/measles/MRI_2012_Annual_Report.pdf
- Status Report submitted to SAGE in November 2012 http://www.who.int/immunization/sage/meetings/2012/november/1_Status_Report_Measles_Rubella_22_Oct.pdf

Table 2: Rubella cases and Incidence reported Member States per WHO region

WHO REGION	Number of Rubella cases			Number of member states reporting Rubella			Rubella incidence per million population		
	2012	2011	2010	2012	2011	2010	2012	2011	2010
AFRO	10809	16190	2754	39	40	37	12.1	18.6	3.3
PAH	5	9	17	35	35	35	0.0	0.0	0.0
EMR	1701	2749	1398	20	17	17	2.8	4.6	2.4
EUR	30509	9672	10551	44	47	49	33.7	10.7	11.7
SEAR	6664	9807	15276	11	10	9	3.6	5.4	8.5
WPR	44211	76022	45966	22	24	23	24.0	41.5	25.3
Total	93899	114449	75962	171	173	170	13.3	16.4	11.0

Table 3: CRS cases and Incidence reported Member States per WHO region

WHO REGION	Number of CRS cases			Number of member states reporting CRS		
	2012	2011	2010	2012	2011	2010
AFR	69	0	16	19	16	15
PAHO	0	1	0	35	35	35
EMR	20	2	5	9	9	10
EUR	60	7	2	42	47	44
SEAR	14	3	8	6	4	4
WPR	132	201	0	16	18	19
total	295	214	31	127	129	127

NARRATIVE

While PAHO region has achieved its elimination goals and a significant decline in rubella incidence has been observed in EUR, most other regions have only now initiated rubella control activities and only WPR is moving towards establishing a control goal. Meanwhile, CRS continues to be an important cause of preventable morbidity. In 2012, an estimated 103,000 children were born with congenital rubella

syndrome, leaving many deaf and blind with heart and other conditions that poor families simply cannot afford to treat.

HIGHLIGHTS

- Rubella/CRS elimination has been achieved and maintained in the Americas since 2009.
- Rubella incidence has declined by >90% in the European region since 2000 with all the Member States using combined MMR or MR vaccines.
- Among the remaining 4 WHO Regions:
    - Only the WPR is moving actively towards establishing a rubella elimination goal.
    - AFR, EMR and SEAR do not have rubella Elimination goals.
- The pace of introduction of RCV is increasing as a result of GAVI Alliance support. As of end of 2012, 134 Members Stated have introduced RCV in their Routine Immunization programme.
- Rubella and CRS remain grossly under reported particularly in Member States that have not yet introduced RCV and/or rubella control or elimination goals.
- CRS surveillance is almost non-existent outside of the Americas and selected Member States in other regions.

REFERENCES

- Framework for verifying elimination of measles and rubella, WER, 9, 2013, 88, 89-100 http://www.who.int/wer/2013/wer8809.pdf
- Progress in global control and regional elimination of measles, 2000–2011, WER 18 January 2013 http://www.who.int/wer/2013/wer8803.pdf
- Global measles and rubella strategic plan: 2012-2020, WHO http://www.measlesinitiative.org
- 2012 Measles & Rubella Initiative annual report http://www.who.int/immunization_delivery/adc/measles/MRI_2012_Annual_Report.pdf
- Status Report submitted to SAGE in November 2012 http://www.who.int/immunization/sage/meetings/2012/november/1_Status_Report_Measles_Rubella_22_Oct.pdf
- Meeting of the Strategic Advisory Group of Experts on immunization, November 2012 – conclusions and recommendations, WER, 4 January 2013, 88th year, 1, 2013, 88, 1–16 http://www.who.int/wer/2013/wer8801.pdf
- Additional documents http://www.measlesinitiative.org/vgn-ext-templating/v/index.jsp/vgnextoid/815c081a7a593210VgnVCM10000089f0870aRCRD.html

GOAL 3

MEET VACCINATION COVERAGE TARGETS IN EVERY REGION, COUNTRY AND COMMUNITY

INDICATOR G3.1

TARGET 1: REACH 90% NATIONAL COVERAGE AND 80% IN EVERY DISTRICT OR EQUIVALENT ADMINISTRATIVE UNIT WITH THREE DOSES OF DIPHTERIA-TETANUS-PERTUSSIS CONTAINING VACCINES IN ALL MEMBER STATES BY 2015

TARGET 2: REACH 90%NATIONAL COVERAGE AND 80% IN EVERY DISTRICT OF EQUIVALENT ADMINISTRATIVE UNIT FOR ALL VACCINES IN NATIONAL PROGRAMMES, UNLESS OTHERWISE RECOMMENDED IN ALL MEMBER STATES BY 2020

SECRETARIAT FOCAL POINT FOR DATA: MARTA GACIC, DAVID BROWN & LAURE DUMOLARD

DEFINITION OF THE INDICATOR

The indicator is defined as the number of Member States that have achieved national coverage ≥ 90% and coverage ≥ 80% in all districts or equivalent administrative units.

The first target is to achieve the above levels of coverage with DTP-containing vaccines in all Member States by 2015.

The second target is to achieve the above coverage for all vaccines included in the national immunization schedule.

In the current analysis, based on data available, these include the following vaccines, if they are included in the national immunization schedule:

- DTP3, Pol3 and MCV1 for all Member States.
- BCG for Member States where included in the schedule.
- HepB3, Hib3, PCV3 and rotavirus last dose (2 or 3 doses depending on the vaccine being used) for Member States where the vaccine was introduced for and used for at least 1 year and from where coverage data are available.

Coverage is taken into consideration only for the vaccines that have been introduced in the immunization schedule since at least one year before the JRF reporting year (e.g. Vaccines introduced in 2010 for coverage reported for the calendar year 2012).

It should be noted that if vaccine is in national immunization schedule for more than one year but country did not report coverage, then coverage estimates have not yet been established and therefore data are not included.

Lastly, district level administrative data are currently available only for DTP3 and MCV1 vaccines; therefore it is not possible to evaluate district level coverage level for all other vaccines. Consequently, district level data have not been presented for this indicator. The SAGE DoV WG may consider the need

for collecting district level coverage data for all vaccines, use DTP3 coverage as a proxy for geographic equity in coverage with all immunization services, or some combination of vaccines as proxies for coverage in different age groups, without necessarily estimating coverage by district for all vaccines. The difficulties in having valid estimates of district level coverage may be taken into consideration in making this decision.

DESCRIPTION OF DATA'S SOURCES

For JRF and WUENCI coverage data, please refer to generic note at the beginning of the report "Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC".

COMMENTS ON DATA'S QUALITY

WUENIC estimates are available for all the 194 Member States. For Member States who did not report coverage for 2012, WUENIC was based on previously reported data.

When WUENIC estimates are equal to administrative data reported by national authorities or when WUENIC estimates are above or equal to 90% (the Member States in this category are mainly Member States where admin data are 100 or over 100 or adjusted for private sector), then district data are considered to be valid. For 2012, 40 (20.6%) Member States have WUENIC estimates which are different from Administrative data reported by the Member States for DTP3 national coverage. However, the fact that WUENIC and country administrative coverage are the same is in itself is not a sufficient indicator of the quality of the coverage data, since the administrative or official country reports may be the only source of data from some Member States and there are no alternate sources of empiric data to question or validate these estimates. For these Member States, the district level coverage estimates need to be validated, usually by a survey in at least a sample of districts. By the definition used, DTP3 district level coverage estimates were available and considered valid in 154 Member States.

Table 4: Distribution of Member States for which DTP3 National Coverage WUENIC estimates are equal to Administrative data reported by National Authorities.

	2010 WUENIC estimates are equal to Administrative data	2011 WUENIC estimates are equal to Administrative data	2012 WUENIC estimates are equal to Administrative data
	% (n)	% (n)	% (n)
AFR	54.3 (25)	63.0 (29)	56.5 (26)
AMR	94.3 (33)	85.7 (30)	91.4 (32)
EMR	71.4 (15)	68.2 (15)	68.2 (15)
EUR	94.3 (50)	94.3 (50)	94.3 (50)
SEAR	81.8 (9)	81.8 (9)	72.7 (8)
WPR	92.6 (25)	88.9 (24)	85.2 (23)
Global	81.3 (157)	80.9 (157)	79.4 (154)

DESCRIPTION OF THE RESULTS

1. Indicator G 3.1 (target 1)

Table 5: Number of Member States by level of DTP3 national coverage rate category, by region, WUENIC, 2012

	Member States with DTP3 ≥ 90%	Member States with DTP3 70-89%	Member States with DTP3 50-69%[13]	Member States with DTP3 < 50%[14]
	N (%)	N (%)	N (%)	N (%)
AFR	18 (39.1)	21 (45.7)	3 (6.5)	4(8.7)
PAHO	26 (74.3)	8 (22.9)	1 (2.9)	0
EMR	13 (59.1)	5 (22.7)	2 (9.1)	2(9.1)
EUR	48 (90.6)	5 (9.4)	0	0
SEAR	7 (63.6)	2(18.2)	2 (18.2)	0
WPR	19 (70)	6(22.2)	2 (7.4)	0
GLOBAL	131 (68)	47 (24.2)	10 (5.2)	6 (3.1)

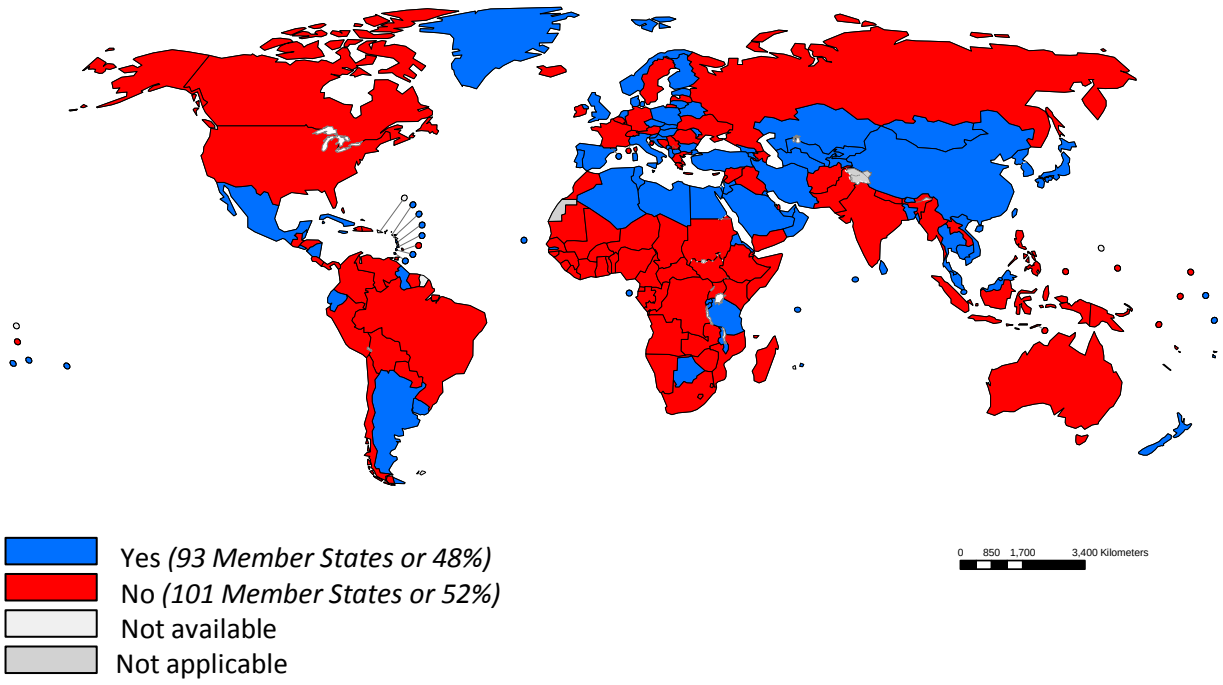
Table 6: Number of Member States achieving the target for DTP3 national coverage above or equal to 90%, and the target of all districts achieving at least 80% coverage for DTP3, per region, 2012

	WUENIC estimates are equal to Administrative data				WUENIC estimates are different from Administrative data	Total
WHO region	**DTP3 coverage national ≥ 90% & all districts ≥ 80%[15]**	**DTP3 coverage national ≥ 90% but not all districts ≥ 80%[16]**	**DTP3 coverage national ≥ 90% but no districts data available**	**DTP3 national coverage <90%**	**DTP3 district data considered as not valid**	
	N (%)	N (%)	N (%)	N (%)	N (%)	N
AFR	5 (10.9)	9 (19.6)	4 (8.7)	8 (17.4)	20 (43.5)	46
PAHO	10 (28.6)	12 (34.3)	4 (11.4)	6 (17.1)	3 (8.6)	35
EMR	7 (31.8)	3 (13.6)	3 (13.6)	2 (9.1)	7(31.8)	22
EUR	26 (49.1)	6 (11.3)	16 (30.2)	2 (3.8)	3 (5.7)	53
SEAR	3 (27.3)	3 (27.3)	1 (9.1)	1 (9.1)	3 (27.3)	11
WPR	8 (29.6)	4 (14.8)	7 (25.9)	4 (14.8)	4 (14.8)	27
GLOBAL	59 (30.4)	37 (19.1)	35 (18)	23 (11.9)	40 (20.6)	194

[13] Central African Republic, Chad, Equatorial Guinea, Nigeria, Somalia, Syrian Arab Republic (the)
[14] Ethiopia, Guinea, Haiti, Indonesia, Iraq, Papua New Guinea, South Africa, South Sudan, Timor-Leste, Vanuatu
[15] Member States with valid district coverage and meeting 2015 target
[16] Member States with valid district coverage but not meeting 2015 target

2. Indicator G 3.1 (target 2)

Map 2: Member States having achieved national coverage ≥90% for all vaccines included in the National Infant Schedule



Source: WHO-UNICEF coverage estimates 2013 revision and JRF as at 11 July 2013.
Map production: Immunization Vaccines and Biologicals, (IVB). World Health Organization
Date of slide: 16 July 2013

Table 7: Distribution of the Member States achieving ≥ 90% national coverage for all the vaccines included in their national immunization schedule per region, 2010, 2011 and 2012

	2010 National coverage ≥ 90% for all vaccines included in national schedule	2011 National coverage ≥ 90% for all vaccines included in national schedule	2012 National coverage ≥ 90% for all vaccines included in national schedule
	N (%)	N (%)	N (%)
AFR	15 (32.6)	13 (28.3)	12 (26.1)
PAHO	18 (51.4)	14 (40)	16 (45.7)
EMR	10 (47.6)	10 (45.5)	10 (45.5)
EUR	30 (56.6)	32 (60.4)	33 (62.3)
SEAR	6 (54.5)	6 (54.5)	6 (54.5)
WPR	13 (48.1)	15 (55.6)	16 (59.3)
Global	92 (47.7)	90 (46.4)	93 (47.9)

NARRATIVE

Data availability

While WHO-UNICEF estimates of national coverage are available every year and can be used to monitor progress against achievement of target coverage at the national level, the full assessment of progress against this indicator is limited by the availability of valid district level coverage data.

For DTP3, district data are considered as valid when WUENIC estimates are equal to Administrative data reported by national authorities or when WUENIC estimates are above or equal to 90%.Using this rule, only 154 Members States have valid DTP3 district level coverage estimates available.

Timely and appropriate investment and remedial action is required to ensure that this indicator can be monitored in each country if progress against the 2015 target is to be assessed. This will require that Member States improve the quality of their administrative data collection and reporting at the district level, or and/use surveys where appropriate to validate the district level coverage (especially in cases where uncertainties remain about the size of the target population by district).

National level DTP3 coverage

Globally, 131 (68%) Member States achieved DTP3 coverage ≥ 90%. However, the distribution was uneven between regions. In the African region, only 39% of regions achieved this threshold of coverage. While the proportion was higher in the South-East Asian and Eastern Mediterranean regions, the most populated Member States in these regions (e.g. India, Indonesia and Pakistan) had not achieved this threshold.

Sustenance of this level of coverage over the period of the past three years is reported in indicator SO4.2.
Among the 63 Member States with coverage <90%, six (3.1%) had coverage < 50%, whereas 10 (5.2%) had coverage between 50% and 69% and 47 (24.2%) had a coverage ≥70%.

The time trends in DTP3 coverage for Member States with DTP3 < 70% is shown in Table 8. In the majority of Member States, coverage has stagnated at low levels. A recent decline in coverage is noted in Nigeria and the Syrian Arab Republic; the recent conflict has no doubt contributed to the decline in the latter country. DTP3 coverage was over 90% in Iraq prior to 1988, since when it has fallen. Increase in coverage has been noted in Chad and Ethiopia. The newest Member State, South Sudan, is reporting increasing coverage based on administrative data in the past few years; since WUENIC are only available for 2011 and 2012, assessment of trends based on this source cannot be made.

District level DTP3 coverage

Of the 154 Member States with valid district data, 131 have WUENIC for DTP3 national coverage ≥ 90% in 2012. Among these 131 Member States, only 59 have both DTP3 national coverage ≥ 90% and all the districts ≥ 80%, this is less than a third of the total number of Member States. For 2012, 40 (20.6%) Member States have WUENIC estimates which are different from Administrative data reported by the Member States for DTP3 national coverage and therefore District data are considered as not valid. The lack of valid district level coverage estimates are an impediment to assessing progress against the 2015 target and requires urgent remedial action if progress towards this goal is to be monitored.

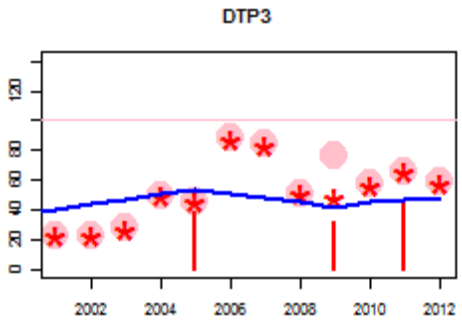
National coverage for other vaccines

In 2012, among the 61 Member States having both DTP3 and PCV3 national coverage data (vaccine introduced for at least one year), for 23 Member States DTP3 national coverage was above PCV3 coverage by more than 5% (for 13 Member States the difference is above 10%). For two Member States, PCV3 coverage was higher than DTP3 by more than 5%. In 2012, among the 27 Member States having both DTP3 and Rota last dose national coverage data (vaccine introduced for at least one year) for 15 Member States DTP3 national coverage was above Rota last dose coverage for more than 5% (for 10 Member States the difference is above 10%). For two Member States, Rota last dose coverage was higher than DTP3 by more than 5%. The causes for the difference in coverage need to be further examined at the country level as they are not apparent from the data reported through the JRF to WHO-UNICEF.

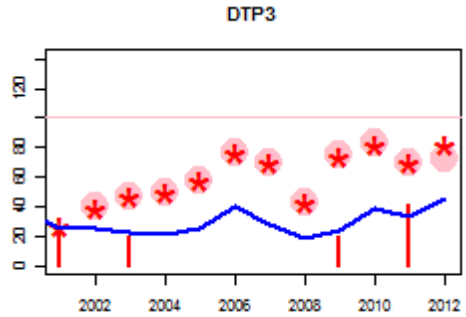
HIGHLIGHTS

- 68% (131) of the Member States have reached DTP3 national coverage ≥ 90%, only 13 of them are LIC.
- 60.9% of AFR, 40.9% of EMR and 36.4% of SEAR and 29.6% of WPR Member States did not reach the 90% target for DTP3 national coverage.
- Only 59 Member States (30%) have reached DTP3 national coverage ≥ 90% and all the districts being above 80% DTP3 coverage.
- In PAHO, 34.3% (12) of the Member States have reach DTP3 national coverage ≥ 90% but not the all the districts being above 80% target.
- In EUR, 30.2% (16) of the Member States achieving the DTP3 national coverage ≥ 90% target did not provide district level data for DTP3 coverage.

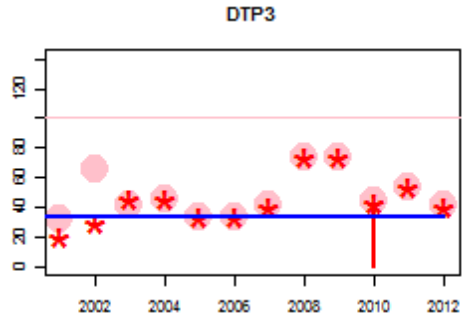
Table 8: Time trends in DTP3 coverage in Member States with DTP3 coverage < 70% in 2012



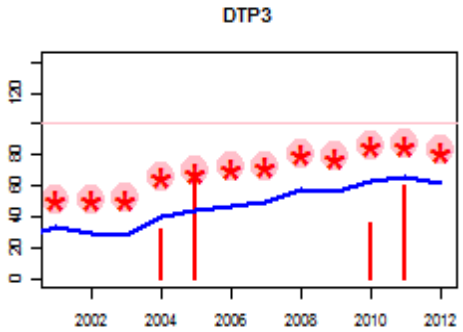
Central African Republic



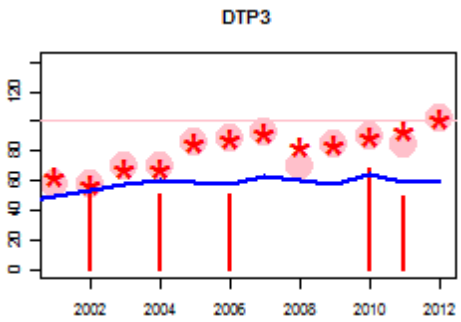
Chad



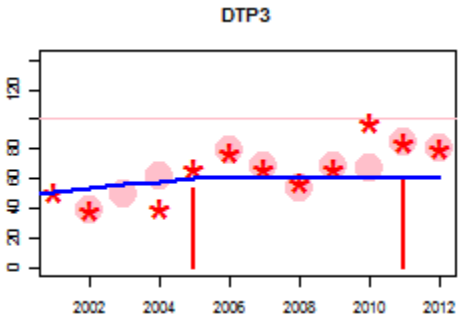
Equatorial Guinea



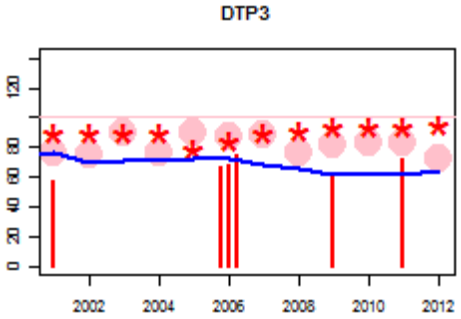
Ethiopia



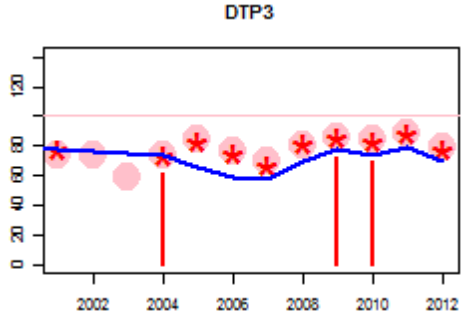
Guinea



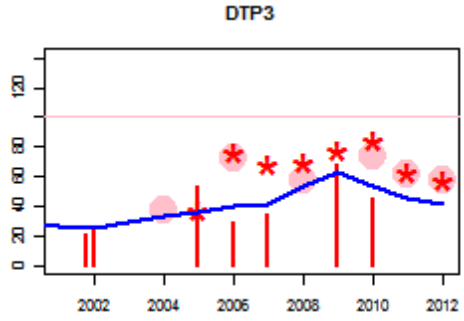
Haiti



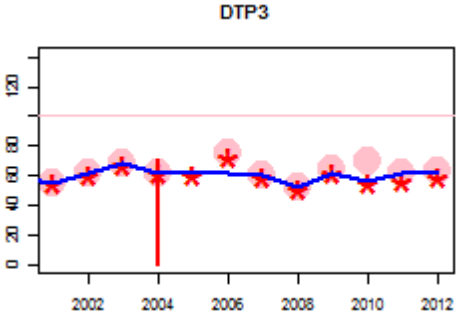
Indonesia



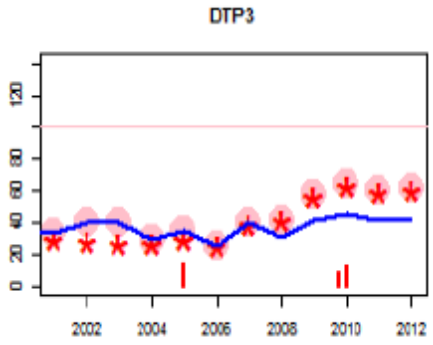
Iraq



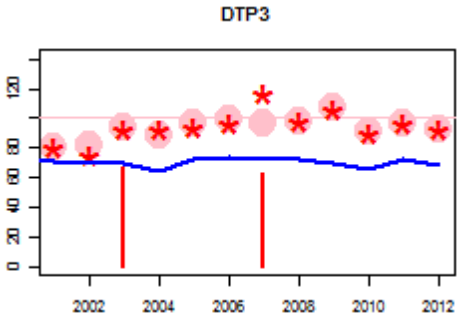
Nigeria



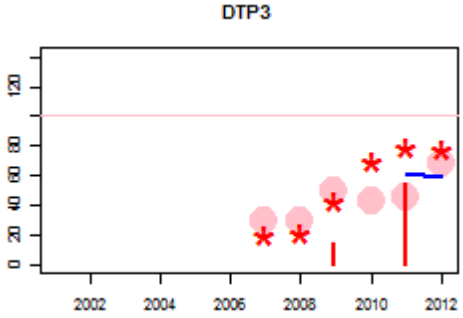
Papua New Guinea



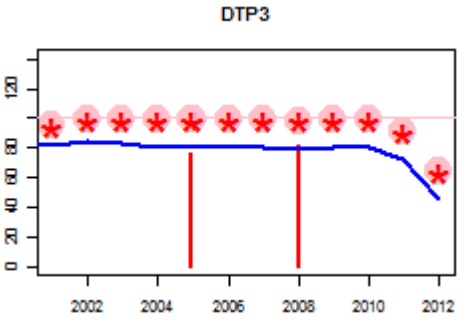
Somalia



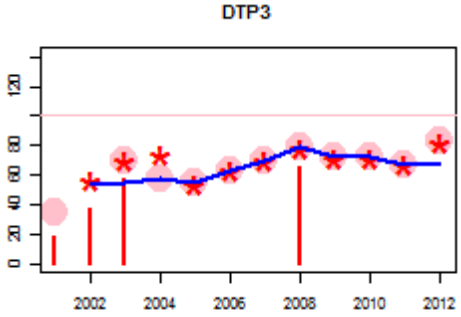
South Africa



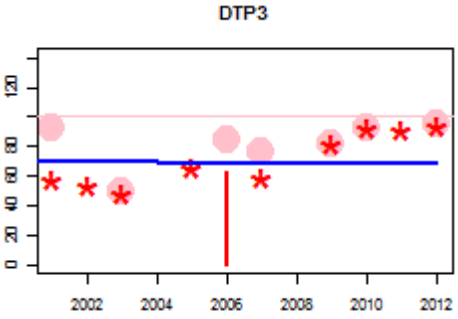
South Sudan



Syrian Arab Republic (the)



Timor-Leste



Vanuatu

Administrative coverage

Official country estimate

WUENIC

GOAL 4

DEVELOP AND INTRODUCE NEW AND IMPROVED VACCINES AND TECHNOLOGIES

INDICATOR G4.1

LICENSURE AND LAUNCH OF VACCINE OR VACCINES AGAINST ONE OR MORE MAJOR CURRENTLY NON-VACCINE PREVENTABLE DISEASES

TARGET
2020: ONE OR MORE

SECRETARIAT FOCAL POINT: DAVID WOOD & JOACHIM HOMBACH

DEFINITION OF THE INDICATOR

Licensure of the vaccine by a functional National Regulatory Authority (NRA).
Launch of the vaccine is defined as addition to the national immunization schedule in one or more LIC or MIC; 2nd generation products with significant benefits will also be considered to be a "new vaccine", as advised by the SAGE.

DESCRIPTION OF DATA'S SOURCES

- Bi-annual surveys with NRAs.
- JRF for launch of vaccine.

COMMENTS ON DATA'S QUALITY

No reporting in 2013.

DESCRIPTION OF THE RESULTS

No reporting in 2013.

NARRATIVE

Process to be used for 2014.

Any new vaccine that is considered by the SAGE DoV WG to have significant public health value would be considered towards meeting this target. However, to track progress with development of the vaccines, progress with development of the following list of seven vaccines will be actively monitored on a biennial basis: Dengue, Hepatitis C, Cytomegalovirus, Respiratory syncytial virus, Leishmania, Helminth

infections and Group A streptococcus. These vaccines were selected to represent viral, bacterial and parasitic diseases with potential for prevention through vaccination.

Incremental progress on development of vaccines will be summarized as narrative report on the seven targeted diseases listed above.

Commissioned study on this indicator to be discussed at the Global Vaccine and Immunization Research Forum (GVIRF) in March 2014.

HIGHLIGHTS

No reporting in 2013.

GOAL 4
DEVELOP AND INTRODUCE NEW AND IMPROVED VACCINES AND TECHNIOLOGIES

INDICATOR G4.2

LICENSURE AND LAUNCH OF AT LEAST ONE PLATFORM DELIVERY TECHNOLOGY

TARGET
2020: ONE OR MORE

SECRETARIAT FOCAL POINT: DAVID WOOD & JOACHIM HOMBACH

DEFINITION OF THE INDICATOR

New platform technology relates to mechanism for delivering vaccines to individuals that facilitate coverage, improves performance, or reduces cost. Licensure is to be by a functional NRA. Launch is defined by the use of the technology in the national immunization programme in one or more LIC or MIC.

DESCRIPTION OF DATA'S SOURCES

- Annual surveys with NRAs.
- JRF for launch of technology/vaccine combination.

COMMENTS ON DATA'S QUALITY

No reporting in 2013.

DESCRIPTION OF THE RESULTS

No reporting in 2013.

NARRATIVE

Process to be used for 2014.
Qualitative report on incremental progress to be commissioned and discussed at GVIRF.

HIGHLIGHTS

No reporting in 2013.

GOAL 4
DEVELOP AND INTRODUCE NEW AND IMPROVED VACCINES AND TECHNIOLOGIES

INDICATOR G4.3

NUMBER OF LOW-INCOME AND MIDDLE-INCOME COUNTRIES THAT HAVE INTRODUCED ONE OR MORE UNDERUTILIZED VACCINES

TARGET
AT LEAST 90 MEMBER STATES BY 2015
ALL LOW AND MIDDLE INCOME COUNTRIES BY 2020

SECRETARIAT FOCAL POINT: CARSTEN MANTEL & HEMANTHI DASSANAYAKE NICOLAS

DEFINITION OF THE INDICATOR

"Number of low or middle income countries (as defined by the World Bank) that have added at least one new or underutilized vaccines into their national immunization programme and sustained it for ≥12 months.

DESCRIPTION OF DATA'S SOURCES

- JRF data.
- VIMS Report: Global Vaccine Introduction, June 2013.
  The report displays data and figures on the introduction status of Hib, Pneumococcal Conjugate and Rotavirus vaccine.
  The report has been generated by the Vaccine Information Management System (VIMS) database developed and maintained by the International Vaccine Access Center (IVAC) at the Johns Hopkins Bloomberg School of Public Health and its affiliated partners and projects. Information was gathered on a regular basis from internationally recognized sources, such as UNICEF, WHO, vaccine manufacturers, ministries of health and news media.
  http://www.jhsph.edu/research/centers-and-institutes/ivac/vims/IVAC-VIMS-Report-2013-06.pdf

COMMENTS ON DATA'S QUALITY

- JRF and WUENIC coverage data: Please refer to generic note at the beginning of the report "Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC".

DESCRIPTION OF THE RESULTS

The results pertain to LIC and MIC that have added a vaccine to their national immunization programme in 2010 or 2011 and sustained its use for at least 12 months.

48 LIC or MIC introduced 54 new vaccines (Hib-containing, Pneumococcal, Rotavirus, HPV, Meningococcal C conjugate or tetravalent polysaccharide, and Yellow Fever) vaccines between January 2010 and December 2011, and have sustained the introductions for at least 12 months. Three of these 48 Member States have only introduced the vaccine in parts of the country.

Additionally, six Member States (of which four are new Member States not listed among the 54 above Member States) have conducted campaigns to administer the Meningococcal A conjugate vaccine during 2010-2011.

The above figure is the cumulative number of Member States that have introduced at least one new vaccine (Hib-containing, Pneumococcal, Rotavirus, HPV, Meningococcal, Yellow Fever) vaccines. Member States which have introduced more than one of these vaccines in the given time frame are counted only once.

Table 9: Number of Member States (by income status and by vaccine) for the forty-eight Member States that introduced at least one new vaccine from January 2010 to December 2011 (and sustained such introductions for at least 12 months)

Income Status	Hib	Pneumo	Rota	HPV	Meningococcal	YF
LIC	1	9	0	1	0	0
LMIC	5	7	3(+2)	2	0	0
UMIC	8	8 (+1)	0	2 (+1)	1 (+2)	1
Total	**14**	**24(+1)**	**3(+2)**	**5(+1)**	**1(+2)**	**1**

NB: Numbers in brackets in the table denote additional new vaccine introductions in Member States which have already introduced another new vaccine in the same period (and are thus not double-counted)

By 16 July 2013, 73 Member States had introduced at least one new vaccine: 48 in 2010-2011; 20 additional Member States in 2012; and five additional Member States by mid-2013. Data from 2013 introductions are based on the WHO/EPI information obtained from WHO regional and country immunization focal points and including information from partner agencies.

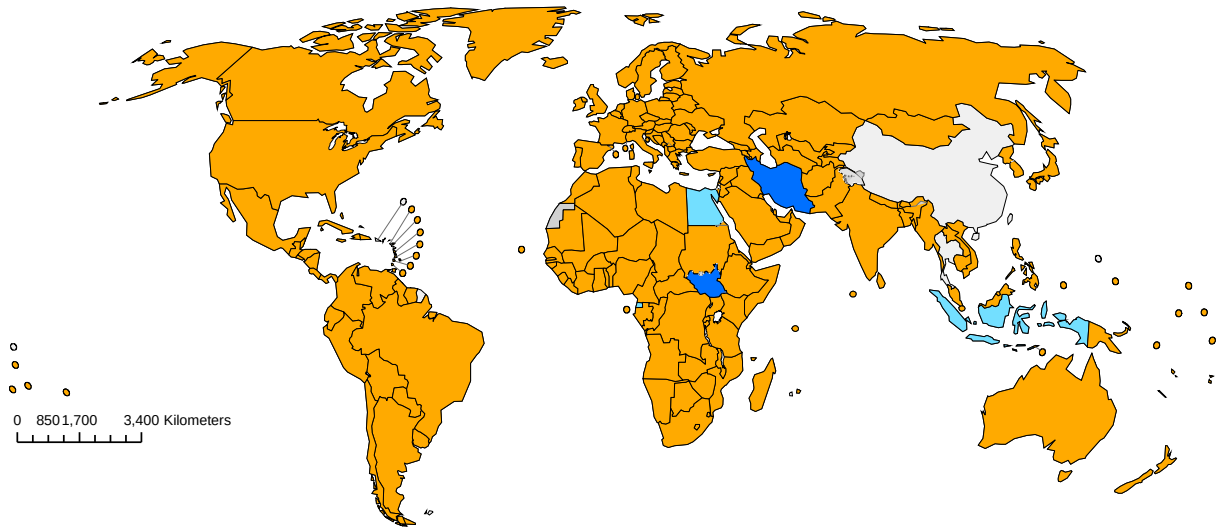
Table 10: Number of Member States that have introduced either Hib-containing, pneumococcal, rotavirus or HPV vaccines as of 16 July 2013

Country classification	Hib	Pneumo	Rota	HPV	Any one of four
GAVI-eligible	11	25 (+1)	3 (+8)	3	43/73 (59%)
Non-GAVI LMIC	2	2 (+2)	2 (+2)	1 (+1)	7/12 (58%)
Non-GAVI Upper MIC	9	1 (+3)	1 (+3)	2 (+4)	22/54 (41%)

Table 11:Number of Member States, by WHO region, that have added any new vaccine to their national immunization schedule from January 2010 to December 2011

WHO region	No. of (LIC, LMIC, UMIC) Member States / total in region	No. (%) of (LIC, LMIC, UMIC) Member States that have added a vaccine to their national schedule in 2010-2011	No. (%) of (LIC, LMIC, UMIC) Member States that have added more than one vaccine to their national schedule in 2010-2011
AFR	45/46	15 (33.3%)	0
PAHO	26/35	12 (46.2%)	3
EMR	16/22	5 (31.3%)	2
EUR	20/53	7 (35%)	1
SEAR	11/11	1 (9.1%)	0
WPR	21/27	8 (38.1%)	0

Map 3: Member States with Hib containing vaccine in the national immunization programme; and planned introductions (as of 29 May 2013)



Introduced to date *(187 Member States or 96%*)

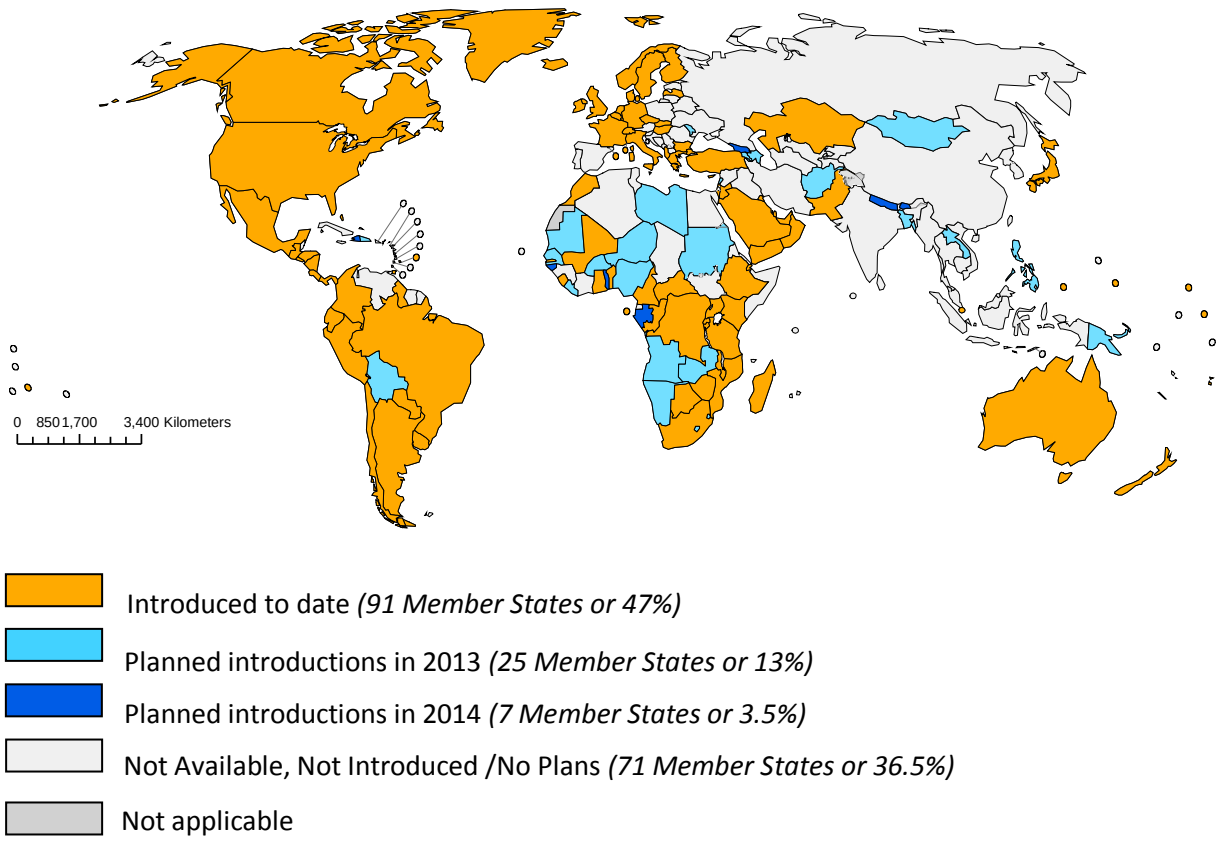
Planned introductions in 2013 *(3 Member States or 2%)*

Planned introductions in 2014 *(2 Member States or 1%)*

Not Available, Not Introduced /No Plans *(2 Member States or 1%)*

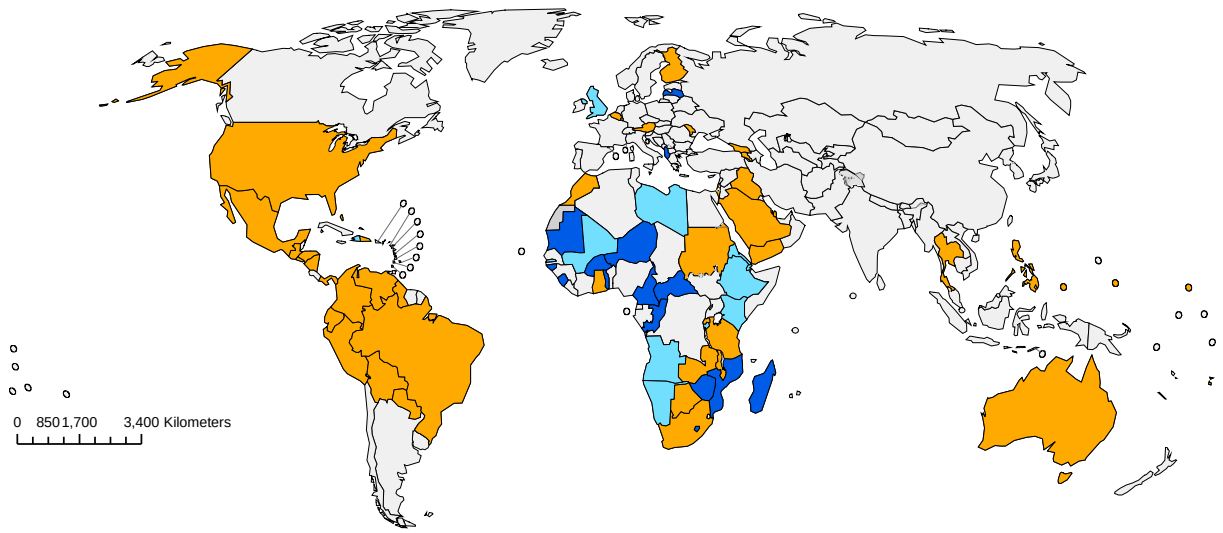
Not applicable

Map 4: Member States with pneumococcal conjugate vaccine in the national immunization programme; and planned introductions (as of 29 May 2013)



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Map 5: Member States with Rotavirus vaccine in the national immunization programme; and planned introductions (as of 29 May 2013)



Introduced to *date (46 Member States or 24%)*

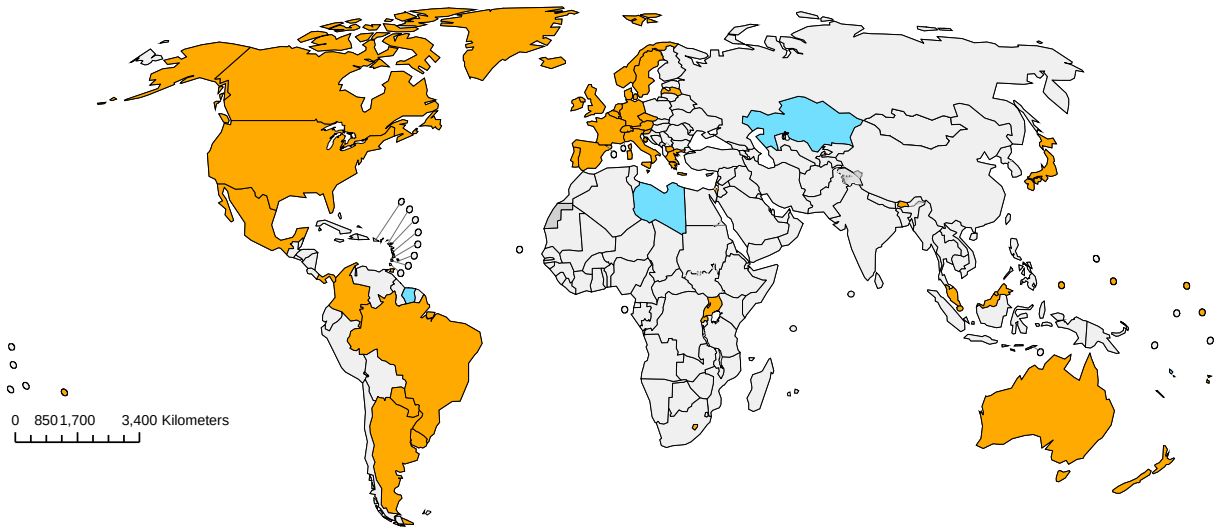
Planned introductions in 2013 *(12 Member States or 6%)*

Planned introductions in 2014 *(15 Member States or 8%)*

Not Available, Not Introduced /No Plans *(121 Member States or 62%)*

Not applicable

Map 6: Member States with HPV vaccine in the national immunization programme; and planned introductions (as of 29 May 2013)



Introduced to *date (45 Member States or 23%)*

Not Available, Not Introduced /No Plans *(145 Member States or 75%)*

Planned introductions in 2013 *(4 Member States or 2%)*

Not applicable

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

NARRATIVE

In the first two years of the decade of vaccines (2010-2011), 48 LIC and MIC added a new vaccine, in line with local disease epidemiology and priorities and sustained these vaccines for a minimum of 12 months. Since then, this number has increased steeply to 73 and it is expected that the use of these vaccines will be sustained by these Member States. Several Member States have added more than one vaccine during this same time period.

Data presented in the VIMS report (reproduced below – Figure 2) shows that the time lag between introduction of vaccines in HIC and LIC was reduced. The time period from when 50% of HIC added Hib vaccine to their national programme to when 50% of LIC did so was approximately 10 years. For pneumococcal conjugate vaccines, it is projected that this period will be just over three years. Financial support through the GAVI Alliance for vaccine procurement and other measures taken to establish and communicate the value of new vaccines have undoubtedly contributed to this outcome.

Though there have been concerns about the ability of non-GAVI eligible countries to add vaccines to their programmes, the available data suggest that an equal proportion of GAVI eligible and non-GAVI eligible LMICs added a vaccine to their schedule. Despite these data, with newer vaccines coming at a higher cost, this is one area that will need to be monitored closely, even while efforts are made to facilitate access to new vaccines and technologies in the non-GAVI LMICs.

Progress with adding vaccines to the national programme has taken place in all regions, though it has been particularly slow in SEARO, where only one of the 11 LIC and MIC added a new vaccine to their national programme.

Continued efforts will be required for the long term sustenance of vaccines in the national programmes in LIC and MIC. This will require increased investments in surveillance and impact assessment to justify the continued investments required to sustain the use of these vaccines.

HIGHLIGHTS

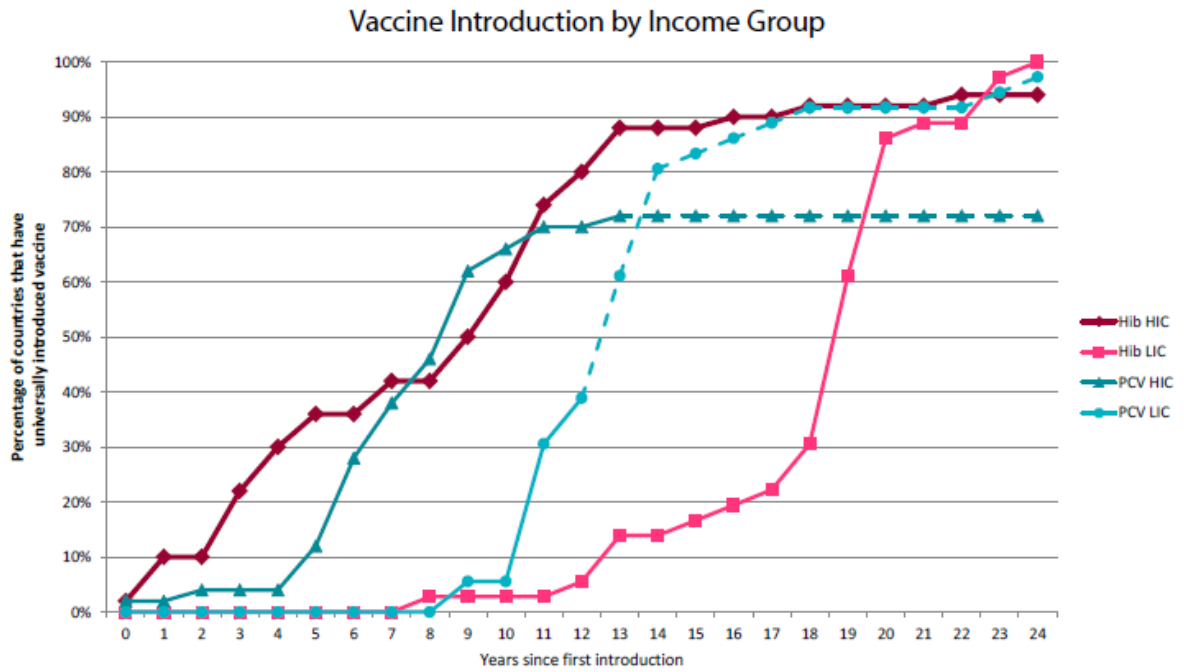
- 54 new vaccines have been introduced and sustained for their use up until mid-2013 (time of report) in 48 Member States.
- More than half (26) of the 48 Member States that introduced new vaccines in 2010-2011 with sustained use for at least 12 months are LMIC not receiving GAVI support.
- Five of the 48 Member States, plus 12 additional Member States that introduced a new vaccine in 2010-2011, have since graduated from GAVI support and efforts are needed to sustain the use of the new vaccines.
- While access to affordable vaccines is provided through the UNICEF Supply Division procurement mechanism for GAVI eligible countries, such affordable and sustained new vaccine supply is yet to be secured for all GAVI graduating countries.
- A severely constrained supply of Pneumococcal and Rotavirus vaccines is anticipated to delay planned introduction of these vaccines during the coming two to three years.

ANNEX

- VIMS Report: Global Vaccine Introduction, June 2013

http://www.jhsph.edu/research/centers-and-institutes/ivac/vims/IVAC-VIMS-Report-2013-06.pdf

Figure 2: Vaccine Introduction on Hib and Pneumococcal Conjugate Vaccines in HIC and LMIC (reproduced from VIMS 2013 report)



Note: Limited projections are available for PCV introduction in High Income Countries

A line graph showing the proportion of high and low income countries that have introduced or are projected to introduce PCV and Hib vaccine over time. Year of first introduction is 1989 for Hib vaccine and 2000 for PCV. It took 20 years for Hib vaccine to reach 70 percent of low income countries. PCV is projected to reach 70 percent of low income countries six years faster, protecting millions of children sooner from deadly pneumococcal disease.

17

GOAL 5

EXCEED THE MILLENIUM DEVELOPMENT GOAL 4 TARGET FOR REDUCING CHILD MORTALITY

INDICATOR G5

REDUCE UNDER-FIVE MORTALITY RATE

TARGET
2015: 2/3 REDUCTION COMPARED TO 1990
2020: EXCEED 2015 TARGET

Please refer to the following documents:

- Countdown to 2015, Accountability for Maternal, Newborn& Child Survival, 2013 Update Report
  http://countdown2015mnch.org/documents/2013Report/Countdown_2013-Update_noprofiles.pdf
- A Promised Renewed
  http://www.apromiserenewed.org/Dashboard.html
- UN Inter-agency Group on Child Mortality Estimation: Levels and Trends in Child Mortality, Report 2012
  http://www.childinfo.org/files/Child_Mortality_Report_2012.pdf
  http://www.childmortality.org/
- PAHO data visualized by Ramon Martinez, Global data, data for measles, pneumonias, diarrhoea
  http://healthintelligence.drupalgardens.com/content/causes-death-world-1990-2005-2010
- Global, regional, and national causes of child mortality: an updated systematic analysis for 2010 with time trends since 2000, Li Liu et al. Lancet 2012; 379:2151-61
  http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60560-1/fulltext
- Global burden of childhood pneumonia and diarrhoea, Christa L Fischer Walker et al, Lancet, Volume 381, Issue 9875, 20–26 April 2013, Pages 1405–1416
  http://www.sciencedirect.com/science/article/pii/S0140673613602226
- WHA A66/13, Monitoring the achievement of the health-related Millennium Development Goals
  http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_13-en.pdf

Extract from the Executive Summary of the "Countdown to 2015, Accountability for Maternal, Newborn& Child Survival, 2013 Update Report"

Child mortality

The global number of deaths in children under five years of age has dropped from nearly 12 million in 1990 to approximately 6.9 million in 2011. Eight Countdown Member States (Bangladesh, Brazil, China, Egypt, Lao PDR, Liberia, Mexico, and Peru) achieved reductions of at least two-thirds in their under-five mortality rate during this time period, and 22 others achieved reductions of at least half. In more than 50 Countdown Member States, the decline in child mortality has been accelerating, with a greater annual rate of reduction in 2000-2011 than in 1990-2000. However, some Countdown Member States are lagging behind. In 24 Member States – all of them, except Afghanistan, in sub-Saharan Africa – the under-five mortality rate in 2011 remained above 100 deaths per 1,000 live births. It is projected that, by 2050, one in three of the world's children will be born in sub-Saharan Africa. Efforts to improve child survival in sub-Saharan Africa must not only continue – they must be intensified. Almost two-thirds of all child deaths are the result of infectious diseases (malaria, pneumonia, diarrhoea, sepsis, measles, and AIDS) that could be prevented through cost-effective, available interventions.

As the global under-five mortality rate has fallen, the proportion of child deaths that occur in the neonatal period has increased. Neonatal deaths now account for 40% or more of all child deaths in 35 Countdown Member States, and this percentage reached 50% or higher in 12 Member States. Greater investment and attention to the newborn period, including the prevention of preterm births and stillbirths and the scale-up of effective, low-cost interventions such as antenatal corticosteroids, cord care, and kangaroo mother care, is needed if the world is to achieve MDG 4.

Vaccine-preventable causes of child death

Vaccines have the potential to play an important role in accelerating the reduction in child mortality, since several diseases that are potentially preventable through vaccination still constitute important causes of child mortality. However, we don't have updated data estimating the contribution made by VPSD control to the decrease in mortality.

The global and regional causes of child death in 2010 are summarized in the figures below (Source: Liu L et al. Lancet 2012; 379:2151-61).

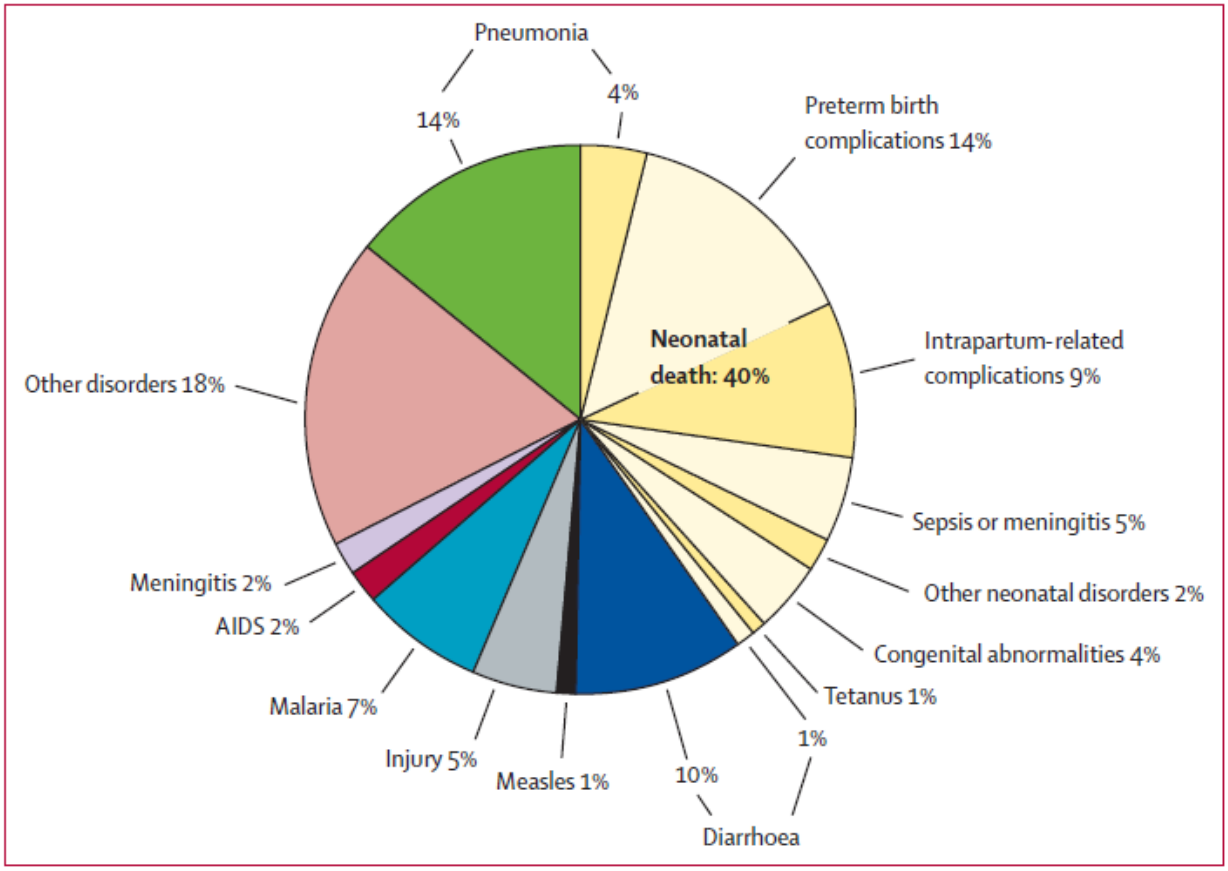


Figure 2: **Global causes of childhood deaths in 2010**
Causes that led to less than 1% of deaths are not shown.

Source: Liu et al. The Lancet 2012 ;379:2151-61

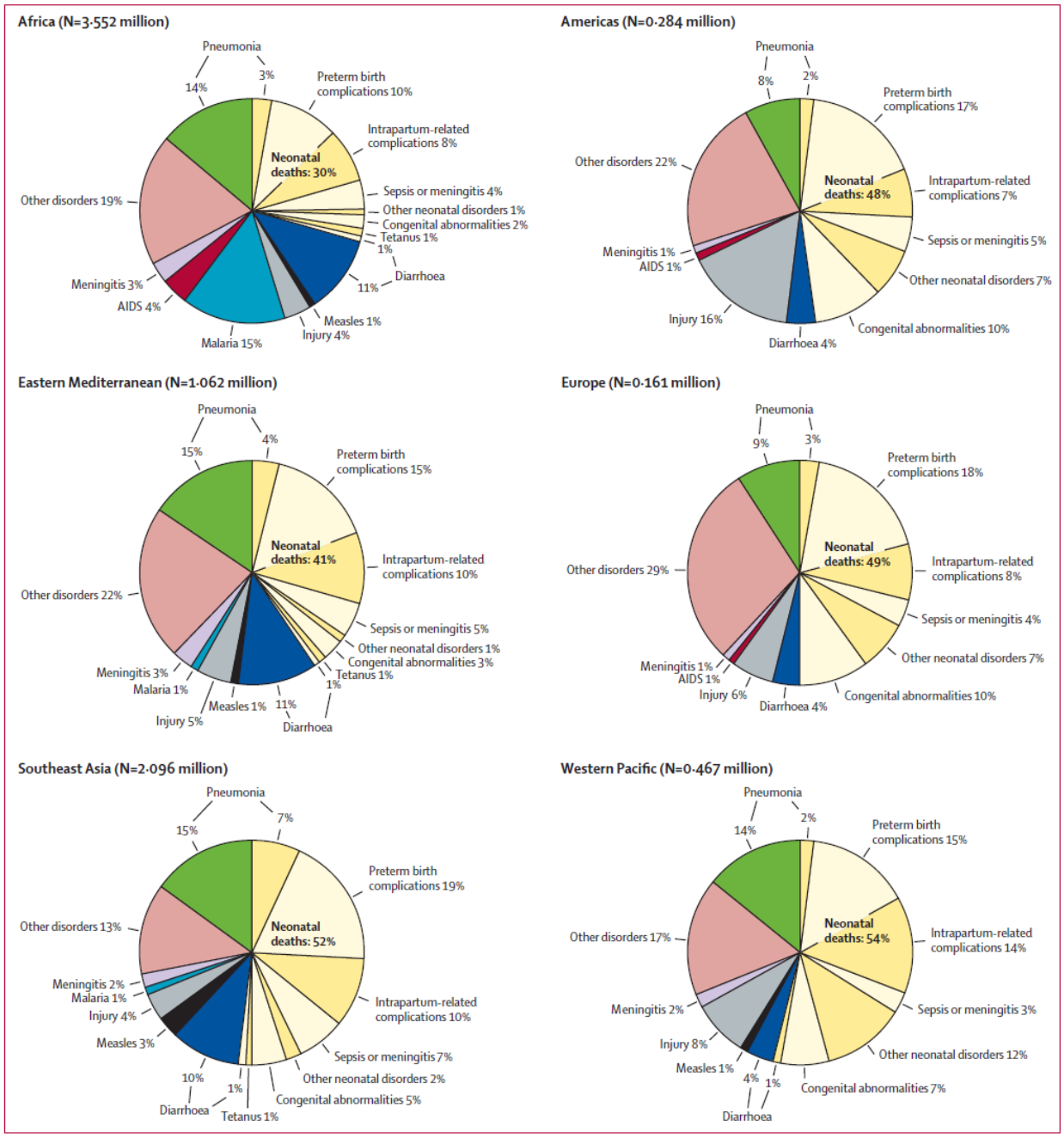


Figure 3: Regional causes of childhood deaths in 2010

Source: Liu et al. The Lancet 2012 ;379:2151-61

Measles

Despite the significant decline in measles deaths during the past decade, measles still accounts for over a 100,000 child deaths annually. This fraction of child deaths are completely preventable through vaccination. If the GVAP goals for measles elimination are met, we could expect to see close to zero deaths from measles within the decade.

Pneumonia, diarrhoea and meningitis

Pneumonia, diarrhoea and meningitis constitute important causes of child morality. In 2010 over two million children from one to 59 months of age are estimated to have died from one of these conditions. The highest burden of deaths from these conditions occur in South-East Asia and Africa, which are home to most of the Member States that are not on track to achieve MDG4. Safe and effective vaccines are available against the major pathogens causing these disease syndromes, making a large proportion of them preventable.

Nearly a third of episodes of severe diarrhoea are preventable by vaccination (e.g. rotavirus and cholera). Similarly a pathogens such as *Haemophilus influenzae* type b*, Streptococcus pneumoniae,* and influenza virus, for which safe and effective vaccines are available, account for at least a third of severe cases and two-third of deaths from pneumonia[17].

The impact of vaccination can be further magnified if the introduction of vaccines targeting the major pathogens of pneumonia and diarrhoea can be accompanied by efforts to create greater synergies to simultaneously scale up the use of other complementary interventions to reduce pneumonia and diarrhoea mortality, as outlined in the Integrated Global Action Plan for Pneumonia and Diarrhoea (GAPPD)[18].

Other potentially vaccine preventable diseases

Vaccines against other major killers of children are currently under development. Most notable of these are vaccines against malaria, which constituted 7% of the global child mortality in 2010, and 15% of child mortality in sub-Saharan Africa. The accelerated development and deployment of a safe and effective vaccine against malaria will have a major impact in reducing child mortality.

Neonatal diseases now constitute a major share of the under-five child deaths. Among neonatal deaths, neonatal sepsis and meningitis constitutes an important fraction. Maternal immunization with vaccines targeting pathogens of neonatal sepsis and meningitis, notably group B streptococcal vaccines, can potentially have a large impact in improving newborn survival, though the magnitude of the effect needs to be quantified to allow prioritization for the introduction and use of this vaccine.

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[17] Walker CL, Rudan I, Liu L, Nair H, Theodoratou E, Bhutta ZA, et al. Global burden of childhood pneumonia and diarrhoea. Lancet 2013 Apr 20;381(9875):1405-16

[18] Ending Preventable Child Deaths from Pneumonia and Diarrhoea by 2025: The Integrated Global Action Plan for Pneumonia and Diarrhoea (GAPPD) http://apps.who.int/iris/bitstream/10665/79200/1/9789241505239_eng.pdf

ANNEX

Table 12: Reducing child mortality: Progress accelerating, but newborn deaths need action, Countdown Member States, sorted by average annual rate of reduction 2000-2011†

Country or territory	Under-five mortality rate						% of under-5 deaths occurring in neonatal period (2011)
	Deaths per 1,000 live births			Average annual rate of reduction (%)			
	1990	2000	2011	1990-2011	1990-2000	2000-2011	
Rwanda	156	183	54	5.1	-1.6	11.1	42%
Botswana	53	81	26	3.4	-4.3	10.4	43%
China	49	35	15	5.8	3.3	7.9	58%
Cambodia	117	102	43	4.8	1.4	7.9	46%
Brazil	58	36	16	6.3	4.9	7.5	66%
Peru	75	39	18	6.8	6.6	7.0	51%
Egypt	86	44	21	6.7	6.6	6.8	35%
Liberia	241	164	78	5.4	3.9	6.7	36%
Senegal	136	130	65	3.5	0.4	6.4	41%
Malawi	227	164	83	4.8	3.2	6.2	35%
Lao People's Democratic Republic	148	81	42	6.0	6.0	6.0	42%
Tanzania, United Republic of	158	126	68	4.0	2.2	5.7	40%
Zambia	193	154	83	4.0	2.3	5.6	37%
Mexico	49	29	16	5.4	5.2	5.6	46%
Bangladesh	139	84	46	5.3	5.0	5.5	60%
Ethiopia	198	139	77	4.5	3.6	5.3	42%
Korea, Democratic People's Republic of	45	58	33	1.4	-2.5	5.0	52%
Niger	314	216	125	4.4	3.8	5.0	28%
Nepal	135	83	48	4.9	4.8	5.0	58%
Madagascar	161	104	62	4.6	4.4	4.8	38%
Mozambique	226	172	103	3.7	2.7	4.7	35%
Indonesia	82	53	32	4.5	4.4	4.6	49%
Morocco	81	53	33	4.3	4.3	4.3	56%
Bolivia	120	81	51	4.1	3.9	4.3	45%
South Africa	62	74	47	1.4	-1.7	4.2	43%
Guatemala	78	48	30	4.5	4.8	4.2	49%
Zimbabwe	79	106	67	0.8	-2.9	4.1	46%
Uganda	178	141	90	3.3	2.4	4.1	33%
Vietnam	50	34	22	4.0	3.9	4.1	55%
Kenya	98	113	73	1.4	-1.5	4.0	39%
Kyrgyzstan	70	47	31	4.0	3.9	4.0	48%
Azerbaijan	95	69	45	3.6	3.2	3.9	42%
Philippines	57	39	25	3.8	3.8	3.9	50%
Nigeria	214	188	124	2.6	1.3	3.8	34%
Tajikistan	114	95	63	2.8	1.9	3.7	40%
Haiti	143	102	70	3.4	3.4	3.4	36%
Eritrea	138	98	68	3.4	3.4	3.4	33%
India	114	88	61	3.0	2.6	3.3	53%
Solomon Islands	42	31	22	3.1	3.2	3.1	50%
Guinea	228	175	126	2.8	2.7	3.0	33%
South Sudan	217	165	121	2.8	2.8	2.8	29%
Lesotho	88	117	86	0.1	-2.9	2.8	46%
Turkmenistan	94	71	53	2.8	2.8	2.8	44%
Afghanistan	192	136	101	3.1	3.4	2.7	40%
Myanmar	107	84	62	2.6	2.5	2.6	47%

Table 12 (continued)

Country or territory	Under-five mortality rate						% of under-5 deaths occurring in neonatal period (2011)
	Deaths per 1,000 live births			Average annual rate of reduction (%)			
	1990	2000	2011	1990-2011	1990-2000	2000-2011	
Pakistan	122	95	72	2.5	2.5	2.5	48%
Benin	177	140	106	2.4	2.4	2.5	30%
Sierra Leone	267	241	185	1.7	1.0	2.4	27%
Yemen	126	99	77	2.4	2.4	2.4	43%
Gambia	165	130	101	2.3	2.3	2.4	36%
Equatorial Guinea	190	152	118	2.3	2.2	2.3	33%
Ghana	121	99	78	2.1	2.0	2.2	38%
Angola	243	199	158	2.1	2.0	2.1	29%
Gabon	94	82	66	1.7	1.4	2.1	39%
Comoros	122	100	79	2.0	2.0	2.1	41%
Uzbekistan	75	61	49	2.1	2.1	2.1	30%
Papua New Guinea	88	72	58	2.0	2.0	2.0	39%
Burkina Faso	208	182	146	1.7	1.4	2.0	25%
Mali	257	214	176	1.8	1.8	1.8	29%
Côte d'Ivoire	151	139	115	1.3	0.9	1.7	37%
Sudan	123	104	86	1.7	1.7	1.7	37%
Burundi	183	165	139	1.3	1.0	1.5	32%
Djibouti	122	106	90	1.5	1.4	1.5	38%
Togo	147	128	110	1.4	1.4	1.4	33%
Guinea-Bissau	210	186	161	1.3	1.2	1.3	29%
Iraq	46	43	38	0.9	0.7	1.1	54%
Chad	208	189	169	1.0	1.0	1.0	27%
Swaziland	83	114	104	-1.0	-3.2	0.9	34%
Congo	119	109	99	0.9	0.9	0.9	33%
Cameroon	145	140	127	0.6	0.4	0.8	27%
Congo, Democratic Republic of the	181	181	168	0.4	0.0	0.7	29%
Central African Republic	169	172	164	0.2	-0.2	0.5	29%
Mauritania	125	118	112	0.5	0.6	0.5	37%
São Tomé and Príncipe	96	93	89	0.4	0.4	0.4	34%
Somalia	180	180	180	0.0	0.0	0.0	29%

Source: Inter-agency Group for Child Mortality Estimation (IGME) – UNICEF, WHO, World Bank and UN Population Division, 2012.

† Negative value indicates an increase in the child mortality rate.

STRATEGIC OBJECTIVE 1

ALL MEMBER STATES COMMIT TO IMMUNIZATION AS A PRIORITY

INDICATOR SO1.1

DOMESTIC EXPENDITURES FOR IMMUNIZATION PER PERSON TARGETED

TARGET
INCREASING TREND IN COUNTRY ALLOCATION TO NATIONAL IMMUNIZATION PROGRAMMES

SECRETARIAT FOCAL POINT: CLAUDIO POLITI

DEFINITION OF THE INDICATOR

Domestic expenditures for immunization per person targeted.

Numerator: Domestic expenditures for immunization are all expenditures financed by domestic resources for immunization specific activities carried out within the routine immunization programmes. Supplementary Immunization Activities (SIAs) are excluded. Domestic expenditures are meant to include all expenditures on immunization, both for procuring vaccines and immunization delivery, from the national and subnational government budget. Extra-budgetary expenditures from development partners, out-of-pocket and private expenditures are excluded.

Denominator: For the purpose of this analysis, we use the number of live births as a common denominator.

DESCRIPTION OF DATA'S SOURCES

For JRF and WUENIC, please refer to generic note at the beginning of the report "Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC".

The JRF template includes the following immunization financing questions:

1. What amount of government funds was spent on vaccines used in routine immunization?
2. What is the total expenditure (from all sources) on vaccines used in routine immunization?
3. If total amounts are not available for the previous questions please provide an estimated percentage of total expenditure on vaccines financed by government funds.
4. What amount of government funds was spent on routine immunization?
5. What is the total expenditure (from all sources) on routine immunization?
6. If total amounts are not available for the previous question, please provide an estimated percentage of total expenditure on routine immunization financed by government funds.

In 2010, the JRF template was revised to include the indicators (see indicators 2 and 5 above) - total expenditure on vaccines from all sources and total expenditure on routine immunization from all sources, (both in absolute values). Instructions were updated to ensure harmonization of Member

States' responses. However, some Member States (between 7% and 13% in 2010-2012) report only the estimated percentage of government funding (indicators 3 and 6 above) indicating that total amounts are not available.

The indicator 1 "What amount of government funds was spent on routine immunization?" includes all recurrent, immunization-specific expenditure of routine immunization. Recurrent inputs include vaccines, injection supplies, salaries and per diems of health staff working full-time on immunization, transport, vehicles and cold chain maintenance, training, social mobilization, monitoring and surveillance.

Denominators, persons targeted (live births) are extracted from the UN, Department of Economic and Social Affairs, Population Division (2011). World Population Prospects: The 2010 Revision, CD-ROM Edition.

COMMENTS ON DATA'S QUALITY

Please refer to generic note at the beginning of the report "Understanding immunization coverage data: WHO-UNICEF JRF WUENIC".

The quality of financing data reported through the JRF mechanism is a major concern. The JRF is generally completed by national immunization programme managers or their designates, who appear to have difficulties in securing and reporting reliable immunization expenditure data. Hence, there are in fact many inconsistencies and missing data. Possible explanations are: the limitations of the national accounting systems to track immunization specific expenditure, especially those related to service delivery where costs are often shared with other programmes; lack of expertise in financial monitoring within the national immunization programmes to report expenditure information; difficulties to clearly identify the "borders" of immunization programs and what input costs to include; and lack of Member States' interest in reporting financing information.

The JRF template provides definition and instructions to report the financing indicator. However 60 Member States (31%), the majority of whom are HIC, did not report the financing indicator *in absolute values* in the last three years (2010-2012). Some of them, as mentioned above, opted to report the *estimated percentage* of government funding routine immunization.

WHO annually cross-checks the data to identify missing data and potential inconsistencies. Inconsistencies are identified by:

i. analyzing time series of financing indicators (e.g. extremely divergent values reported from one year to the other by the same country); and
ii. assessing coherence between reported expenditure for the routine immunization and expenditure for vaccines (the first one should include and be higher than the second one).

The observed time series are used to fill the missing values by assuming continuation of trends of time series or by averaging available values. For Member States with available comprehensive Multiyear Plans (cMYP), data from the costing and financing tools are also used as additional source to cross-check and to fill missing or correct inconsistent data.

Apparent mistakes like wrong currency or typing errors are also frequent and being corrected by WHO. Overall 39 values in the dataset 2010 – 2012 have been corrected and replaced by WHO estimates.

Records of inconsistencies and missing values are shared with Member States through the WHO regional Offices, however feedback for revision of data are often lacking. Checking and correcting data inconsistencies for the 2012 data, reported in the 2013 JRF is yet to be completed.

Interpretation of data should be cautious as several inconsistencies remain in the dataset: Member States reporting high fluctuations of the indicator between years or extremely high values compared to Member States in the same income range.

Response rates need also to be improved: 60 Member States (31%) reported the financing indicator for each of the past three years; 43 Member States (22%) reported for two years; 31 Member States (16%) reported only for one year and 60 Member States (31%) , mainly HIC, did not report the financing indicator in 2010-2012.

The Systems of Health Accounts (SHA) will be used from 2013 to estimate immunization specific expenditure (Please refer to Chapter II). By 2015, 75 LIC and LMIC are expected to apply the methodology and strengthen the quality of reporting JRF financing indicators.

DESCRIPTION OF THE RESULTS

Among the 60 Member States for which data on domestic expenditures are available for the last three years (2010-2013), 19 have seen their domestic expenditures steadily increasing during the period (Table 13); 10 have diminished their expenditures (Table 14).

For all the 31 other Member States there is no noticeable trend (Table 15).

Table 13: Member States for which expenditures for immunization have been steadily increasing for the past three years 2010-2012

Country	GNI per capita (US$, 2012)	WB Income classification	2010	2011	2012
Cambodia	$880	LIC	$0.9	$1.0	$3.6
Congo DR	$220	LIC	$0.0	$0.6	$1.5
Eritrea	$450	LIC	$0.5	$2.3	$2.3
Madagascar	$430	LIC	$0.6	$1.2	$1.7
Mozambique	$510	LIC	$4.2	$4.7	$5.3
Togo	$500	LIC	$22.5	$24.4	$28.6
Zimbabwe	$680	LIC	$2.7	$4.1	$4.2
Congo	$2,550	LMIC	$1.2	$5.3	$5.7
Guatemala	$3,120	LMIC	$27.8	$28.1	$62.81
India	$1,530	LMIC	$3.6	$4.0	$5.5
Papua New Guinea	$1,790	LMIC	$5.3	$8.1	$10.1
Paraguay	$3,290	LMIC	$51.9	$118.5	$214.1
Tonga	$4,240	LMIC	$14.9	$20.8	$21.3
Viet Nam	$1,400	LMIC	$5.9	$7.3	$7.9
Colombia	$6,990	UMIC	$64.4	$64.6	$102.3
Dominican Republic	$5,470	UMIC	$14.3	$19.9	$27.9
Iran IR		UMIC	$13.4	$13.5	$20.2
Venezuela	$12,470	UMIC	$51.8	$77.1	$80.4
Netherlands	$48,250	HIC	$181.7	$214.8	$254.7

LIC: Low Income Country
LMIC: Lower Middle Income Country
UMIC: Upper Middle Income Country
HIC: High Income Country

Table 14: Member States for which expenditures for immunization have been steadily diminishing for the past three years 2010-2012

Country	GNI per capita (US$, 2012)	WB Income classification	2010	2011	2012
Bangladesh	$840	LIC	$8.3	$7.9	$6.5
Benin	$750	LIC	$6.7	$5.5	$4.6
Chad	$740	LIC	$7.8	$7.7	$7.0
Tanzania	$570	LIC	$3.7	$3.6	$3.0
Sri Lanka	$2,920	LMIC	$32.7	$16.7	$0.0
Sudan	$1,450	LMIC	$2.8	$2.4	$0.6
Vanuatu	$3,080	LMIC	$17.5	$17.2	$14.8
Yemen	$1,070	LMIC	$1.4	$1.1	$1.0
Argentina		UMIC	$80.7	$67.0	$50.1
Cuba		UMIC	$199.9	$193.3	$171.7

LIC: Low Income Country
LMIC: Lower Middle Income Country
UMIC: Upper Middle Income Country
HIC: High Income Country

Table 15: Member States for which expenditures for immunization have been inconsistent for the past three years 2010-2012

Country	GNI per capita (US$, 2012)	WB Income classification	2010	2011	2012
Central African Republic	$490	LIC	$0.5	$1.1	$0.4
Guinea	$460	LIC	$0.8	$1.3	$0.0
Nepal	$700	LIC	$1.4	$4.0	$2.7
Rwanda	$570	LIC	$4.9	$4.9	$2.0
Belize	$3,710	LMIC	$54.6	$66.7	$37.6
Cameroon	$1,170	LMIC	$7.6	$8.8	$4.0
Côte d'Ivoire	$1,220	LMIC	$8.2	$5.5	$15.2
Djibouti		LMIC	$31.3	$26.7	$54.2
El Salvador	$3,580	LMIC	$99.7	$119.2	$80.3
Georgia	$3,280	LMIC	$40.6	$88.9	$21.4
Guyana	$3,410	LMIC	$86.1	$64.9	$115.9
Honduras	$2,070	LMIC	$50.1	$59.6	$40.7
Lao LPR	$1,260	LMIC	$2.3	$2.3	$1.8
Marshall Islands	$4,140	LMIC	$18.0	$27.0	$26.9
Mongolia	$3,160	LMIC	$15.9	$23.1	$20.3
Nicaragua	$1,650	LMIC	$78.5	$59.0	$60.5
Sao Tome and Principe	$1,320	LMIC	$87.6	$78.7	$123.6
Timor-Leste	$3,670	LMIC	$1.8	$0.7	$1.1
Azerbaijan	$6,050	UMIC	$35.3	$24.5	$31.1
Bulgaria	$6,870	UMIC	$244.9	$414.5	$328.1
Costa Rica	$8,740	UMIC	$475.1	$81.8	$149.4
Gabon	$10,070	UMIC	$77.2	$36.1	$38.3
Grenada	$7,110	UMIC	$53.3	$38.3	$56.9
Jamaica	$5,140	UMIC	$179.1	$68.5	$70.0
Lebanon	$9,190	UMIC	$42.9	$39.0	$51.6
Peru	$5,880	UMIC	$227.6	$152.5	$208.2
Seychelles	$11,640	UMIC	$43.3	$32.9	$70.0
Andorra		HIC	$661.4	$683.5	$475.8
Chile	$14,280	HIC	$204.2	$86.0	$260.5
Iceland	$38,710	HIC	$259.9	$256.9	$407.8
Saint Kitts and Nevis	$13,330	HIC	$29.0	$23.0	$25.0

LIC: Low Income Country
LMIC: Lower Middle Income Country
UMIC: Upper Middle Income Country
HIC: High Income Country

NARRATIVE

As would be expected, the reported domestic expenditure for immunization per person targeted vary considerably between Member States in the various income categories.

In general, domestic expenditures on immunization per live birth increase with increasing country income. Of the 60 Member States that have reported expenditure data, 19 report a consistent increase in expenditures during the three-year period 2010-2012 (Table 13). In 10 Member States, the trend seems to be downward, though in some instances the drop seems to be implausible since the declines are very steep with extremely low expenditure reported in 2012 (e.g. Sri Lanka and Sudan). This may reflect changes in accounting procedures, rather than a true decline in expenditures. Further investigations are required to verify the data from these Member States. In the remaining Member States, no specific trend could be determined over this three-year period.

The quality of reported data remains an impediment to the interpretation and use of these data as a markers of country commitment. In future, as country capacity for tracking and reporting data through the SHA is strengthened, this source of data may allow better tracking and use of expenditure data.

HIGHLIGHTS

- 31 Member States (16%) reported the financing indicator only for one year and 60 Member States (31%) mainly HIC, did not report the financing indicator.
- Data quality is variable, several inconsistencies and missing data are noted. Further data validation at country level is recommended.
- Among the 60 Member States for which data on domestic expenditures are available for the last three years (2010-2012), 19 have seen their domestic expenditures steadily increasing during the period (2012>2011>2010), and 10 have diminished their expenditures (2012<2011<2010).
- For all the 31 other Member States there is no trend as the data are inconsistent for the three-years period.
- SHA will be used from 2013 to estimate immunization specific expenditure and improve the reporting of JRF financing indicators.

STRATEGIC OBJECTIVE 1

ALL MEMBER STATES COMMIT TO IMMUNIZATION AS A PRIORITY

INDICATOR SO1.2

PRESENCE OF AN INDEPENDENT TECHNICAL ADVISORY GROUP (NITAG) THAT MEETS THE DEFINED CRITERIA

TARGET: FUNCTIONAL NITAGS IN ALL THE MEMBER STATES

SECRETARIAT FOCAL POINT: PHILIPPE DUCLOS & LAURE DUMOLARD

DEFINITION OF THE INDICATOR

A *functional NITAG* has been defined has a committee that meets all of the six following process indicators pertaining to the characteristics and functioning of the NITAG as agreed upon in 2010 by WHO and its partners involved with the strengthening of NITAGs:

1. Legislative or administrative basis for the advisory group.
2. Formal written terms of reference.
3. At least 5 different areas of expertise represented among core members.
4. At least one meeting per year.
5. Circulation of the agenda and background documents at least one week prior to meetings.
6. Mandatory disclosure of any conflict of interest.

These six indicators do not guarantee the functionality of the NITAG but have been agreed upon as a minimum set of indicators that will allow for monitoring of progress at the global level. A more comprehensive set of indicators has been developed and published to be used at national level (see Reference 1 - Blau et al. Indicators to assess National Immunization Technical Advisory Groups. Vaccine 2013;31:2653-2657).

DATA SOURCES

Process indicators related to the establishment of NITAGs are included in the WHO-UNICEF JRF since 2011 and in that year data was collected for 2010. In this summary, information from Member States regarding the existence of a NITAG, and the specific criteria are derived from the 2013 JRF and compared with JRF data from 2012 and 2011. For those Member States which did not yet submitted complete the JRF for 2013, information from the previous year's JRF was used to give a more comprehensive picture of the situation. The denominator used to calculate the proportion of NITAGs in existence is the number of Member States that completed the NITAG-related section of the JRF. The results are stratified by WHO region, World Bank national income status categories, eligibility for GAVI Alliance funding, and population size. Population figures used are those from the UN population division.

Additional information was derived from a February 2013 survey of NITAGs in the 27 European Union Member states and Norway and Iceland as part of the Vaccine European New Integrated Collaboration

Effort (VENICE) project (see Reference 2: submitted paper: Hanna Nohynek et al. National Advisory Groups and their role in immunization policy-making processes in European Member States).

DATA LIMITATIONS

These results are subject to data limitations. First, some Member States did not provide answers to the NITAG-related questions in the most recent JRF, and there is variation among the Member States that provided answers to the NITAG-related questions for the 2012 JRF and the 2013 JRF. In addition, the list of member states is not stable: for example, the Republic of South Sudan became a new member state in the Eastern Mediterranean Region (EMR) WHO region in July 2011. Second, because the analysis focused on data officially reported by the Member States, without a systematic secondary validation process with national counterparts (although this is done in some regions), it may not reflect the actual situation in the Member States. Data accuracy depends on the knowledge, recollection and interpretation capabilities of the person completing the form; since the introduction of the NITAG-related questions in the JRF is relatively recent, it is possible that some questions may have been misunderstood or misinterpreted. For example, in some regions an affirmative answer regarding the existence of a NITAG may have actually referred to an Inter-agency Coordinating Committee (ICC), a committee that coordinates and supports funding, planning, implementation and advocacy. In the 2013 and 2012 JRF, seven African Member States (Benin, Cameroon, Central African Republic, Gambia, Madagascar, Niger and Senegal) explicitly indicated having previously reported the existence of an ICC versus a NITAG. As a result it is likely that data for 2012 are more reliable than those from previous years.

Overall, 54% of Member States reported the existence of a NITAG with formal terms of reference, and 52% reported the existence of a NITAG with a formal administrative or legislative basis, among the Member States that reported data. These data should be less susceptible to reporting bias, and therefore closest to the actual number with respect to the existence of a NITAG. The number of Member States reporting the existence of a NITAG which complies with all 6 JRF indicators is also less susceptible to reporting bias.

RESULTS

As of 11 July 2013, 187 (96%) of 194 Member States had completed the 2013 JRF[19] reporting immunization related data for 2012, and 182 (94%)[20] provided a response to at least one of the NITAG-related JRF questions. Among the Member States that did not submit their JRF or their NITAG related data for 2012, Cape Verde, Finland, Marshall Islands, Russian Federation, Singapore, the former Yugoslav Republic of Macedonia, Turkey, Ukraine and the USA had reported NITAG data to last year's JRF process (e.g. data for 201)1. Data for 2011 were included in the 2012 data set for these Member States. Therefore data for 191 Member States were available for the analysis (Table 16, Table 17).

[19] Member States that have yet to submit 2013 JRF data for 2012 include Austria, Cape Verde, Finland, Monaco, Singapore, the former Yugoslav Republic of Macedonia and Turkey.

[20] Member States that have not completed the NITAG portion of JRF include Marshall Islands, Russian Federation, Serbia, Ukraine and the USA.

Table 16:**Analysis of the NITAG 2012 JRF data at global level and by WHO region**

		Region						
INDICATOR		OVERALL	AFR	AMR	EMR	EUR	SEAR	WPR
	Responding Member States/WHO Member States (%)	191/194 (98)	46/46 (100)	35/35 (100)	22/22 (100)	50/53 (94)	11/11 (100)	27/27 (100)
Existence of a NITAG	No. (%) of Member States responding	116 (61)	13 (28)	19 (54)	21 (95)	38 (76)	10 (91)	15 (56)
	% of population covered	89	57	91	98	67	99100	99
NITAG with formal terms of reference	No. Member States/No. Member States reporting existence of NITAG (%)	104/116 (90)	12/13 (92)	15/19 (79)	20/21 (95)	35/38 (92)	10/10 (100)	12/15 (80)
	% of responding Member States	54	26	43	91	70	91	44
NITAG with a legislative or administrative basis	No. Member States/No. Member States reporting existence of NITAG (%)	99/116 (85)	10/13 (77)	15/19 (79)	19/21 (90)	35/38 (92)	9/10 (90)	11/15 (73)
	% of responding Member States	52	22	43	86	70	82	41
	% of population covered	85	43	90	96	65	97	98
NITAG with ≥5 areas of expertise represented	No. Member States/No. Member States reporting existence of NITAG (%)	106/116 (91)	10/13 (77)	17/19 (89)	20/21 (95)	36/38 (95)	10/10 (100)	13/15 (87)
NITAG which met at least once in 2012	No. Member States/No. Member States reporting existence of NITAG (%)	103/116 (89)	12/13 (92)	16/19 (84)	18/21 (86)	38/38 (100)	8/10 (80)	11/15 (73)

Table 16 (continued)

		Region						
NITAG agenda and background docs distributed ≥1 week before meeting	No. Member States/No. Member States reporting existence of NITAG (%)	104/116 (90)	10/13 (77)	18/19 (95)	19/21 (90)	36/38 (95)	10/10 (100)	11/15 (73)
NITAG members required to disclose conflict of interest	No. Member States/No. Member States reporting existence of NITAG (%)	76/116 (66)	6/13 (46)	13/19 (68)	15/21 (71)	24/38 (63)	7/10 (70)	11/15 (73)
NITAG meeting all six criteria above	No. Member States/No. Member States reporting existence of NITAG (%)	63/116 (54)	3/13 (23)	13/19 (68)	13/21 (62)	22/38 (58)	5/10 (50)	7/15 (47)
	% of responding Member States	33	7	37	59	44	45	26
	% of the entire population covered	52	7	88	83	41	20	81

Table 17:**Analysis of the NITAG 2012 JRF data by World Bank income status, GAVI Alliance eligibility, and population size.**

	WB INCOME STATUS[21]			GAVI eligible countries	POPULATION SIZE[22]	
	Low N=36	Middle N=100	High N=55	N=57	Small N=97	Large N=97
Reporting Member States (% of total)	36 (100)	99 (99)	53 (96)	57 (100)	96 (99)	95 (98)
Has a NITAG No./No. reporting (%)	13/36 (36)	62/99 (63)	41/53 (77)	26/57 (46)	50/96 (52)	66/95 (69)
NITAG has formal terms of reference No./ No. reporting (%)	13/36 (36)	53/99 (54)	38/53 (72)	25/57 (44)	42/96 (44)	62/95 (65)
Legislative or administrative basis for NITAG No./ No. reporting (%)	10/36 (28)	50/99 (51)	39/53 (74)	21/57 (37)	39/96 (41)	60/95 (63)
≥5 areas of expertise represented No./ No. reporting (%)	9/36 (25)	59/99 (60)	38/53 (72)	21/57 (37)	45/96 (47)	61/95 (64)
Met at least once in 2012 No./ No. reporting (%)	10/36 (28)	53/99 (54)	40/53 (75)	20/57 (35)	42/96 (44)	61/95 (64)
Agenda/background docs distributed ≥1 week before meetings No./ No. reporting (%)	11/36 (31)	53/99 (54)	40/53 (75)	22/57 (39)	44/96 (46)	60/95 (63)
Members required to disclose conflict of interest No./ No. reporting (%)	7/36 (19)	36/99 (36)	33/53 (62)	13/57 (23)	26/96 (27)	50/95 (53)
Meet all six criteria above No./ No. reporting (%)	4/36 (11)	29/99 (29)	30/53 (57)	9/57 (16)	22/96 (23)	41/95 (43)

[21] The denominator is not the 194 WHO Member States, but 191 Member States for which the World Bank is providing the information, as of July 2013. Information on status is missing for the Cook Islands, Nauru, and Niue.

[22] Small: <7,789,876; Large: ≥7,789,876. This number was the median of the total population for the 194 Member States.

Notable progress was achieved between 2010 and 2012, and 99 (52%) Member States overall reported the existence of a NITAG with a formal legislative or administrative basis, among the Member States that reported data in the JRF NITAG section. In 2012, there were 63 Member States[23] with a NITAG that met all six process indicators including a total of 38 developing Member States. This is a 47% increase compared to 2010, when only 43 countries reported having a NITAG meeting all six process indicators.
In 2012, 11% of LIC, 29% of MIC, and 57% of HIC Member States reported having a NITAG meeting all six process criteria. Overall, 52% who live in a country with a NITAG that meets all six process indicators. 23% of Member States with smaller populations (less than the median population of all responding Member States) reported the existence of a NITAG that meets all six process indicators, compared with 43% of more populated Member States.

EMR had the highest proportion of Member States reporting the existence of a NITAG that met all six process indicators (59%) and AFR the lowest (7%). EMR had also the greatest percentage (86%) of Member States that had a NITAG based on a formal legislative decree (22% in AFR, 41% in WPR, 43% in PAHO (both regions affected by number of small Member States), 70% in EUR, and 82% in SEAR). According to a 2013 survey 85% of the 27 European Member States surveyed reported having established a NITAG (See Reference 2).

Table 16 presents the 2012 NITAG-related indicators status at the global and regional levels.

Table 17 presents the NITAG-related indicators analysis stratified by World Bank income groups, eligibility for financial support from the GAVI Alliance and population size.

More detailed information is available from Reference 3 (Duclos P, et al. Monitoring of progress in the establishment and strengthening of national immunization technical advisory groups Vaccine, 2012;30;7147-52.) and Reference 4 (Duclos P, et al. Progress in the establishment and strengthening of national immunization technical advisory groups: analysis from the 2013 WHO-UNICEF joint reporting form, data for 2012 paper submitted to Vaccine and accepted for publication).

NARRATIVE

From 2010 to 2012, there was a 47% increase of Member States reporting having a NITAG meeting all six process indicators (63 vs. 43). Despite the short period of time and considering that establishing and strengthening NITAGs is a long term process, there seems to be a constant progress in the establishment of NITAGs over the last few years.

Because the proportion of Member States with a NITAG is greater in the more populous Member States than in the less populous ones, the overall proportion of the population supported by a NITAG is substantially greater than the proportion of counties with a NITAG, both at the global and regional

[23] Afghanistan, Andorra, Argentina, Australia, Bahrain, Belgium, Bhutan, Bosnia and Herzegovina, Brazil, Canada, Chile, China, Colombia, Côte d'Ivoire, Cuba, the Czech Republic, Democratic People's Republic of Korea, Denmark, Egypt, El Salvador, Estonia, France, Germany, Honduras, Iceland, Indonesia, Iran (Islamic Republic of), Ireland, Israel, Jordan, Kazakhstan, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Mongolia, Morocco, Mozambique, Nepal, the Netherlands, New Zealand, Oman, Pakistan, Panama, Peru, Portugal, Qatar, Republic of Korea, Romania, Saudi Arabia, Singapore, Slovakia, the Sudan, Switzerland, the Syrian Arab Republic, Thailand, Tunisia, the United Kingdom of Great Britain, the United States of America, Uruguay, Uzbekistan and Zambia.

levels. In areas where regional engagement has been strong and there have been strong regional Technical Advisory Group (TAG) statements with regard to the need to strengthen NITAGs such as in PAHO, EMR, EUR and SEAR rapid progress is being achieved. The participation of NITAG Chairs at immunization and regional TAG meeting in most regions and the fostering of exchanges between NITAGs have been received very positively by all and can contribute to capacity strengthening by emulation.

Beyond progress on meeting the indicator there has been substantial quality improvement in the processes of many NITAGs, which is hard to quantify at global level but worth highlighting. Despite this progress, efforts need to be accelerated to reach the GVAP indicator of ensuring that all Member States have the support of a fully functional NITAG. Such progress is particularly necessary in the AFR and WPR regions. Essential to progress is the need for concerted advocacy from all partners, including clear communication about the difference responsibilities of NITAGs and ICCs and also a systematic communication and advocacy from all partners in support of NITAG strengthening. In this context it should be clear that introduction of new vaccines in a country does not in any way diminish the need for the establishment/strengthening of NITAGs, just the opposite.

Requiring the existence of NITAGs for future funding applications from GAVI-eligible Member States and communicating the possibility of accessing GAVI Health System Strengthening (HSS) funds to establish or strengthen NITAGs is necessary. Global and National levels communication should make it clear that the purpose of a NITAG is not only the facilitation of new vaccine introductions, but rather, the NITAG should serve as a technical resource to the government and to immunization programme managers, using their range of expertise to review the strategies and recommendations for use of vaccines in the current vaccination programs as well reviewing and synthesizing evidence to be used for making decisions regarding vaccine introduction. NITAGs could also play an important role in the immunization monitoring and accountability process at the national level, through an independent review of progress.

A special approach needs to be explored to allow small population size Member States to benefit from sub-regional or other Member States advisory groups. Small Member States, including some of the Caribbean islands, small island nations in the Western Pacific region, may not have a large enough population to justify establishment of a NITAG and/or adequate resources to support its establishment. Some of these less populated Member States, particularly those in close geographical proximity and which share cultural similarities, similar epidemiologic profiles, and have a tradition of working together on public health issues, may choose to seek guidance from a subregional decision-making mechanism, such as the former Caribbean Epidemiology Centre or Caribbean EPI Managers Meeting. Such discussions have started in the Americas for the Caribbean and in WPR for the Pacific Islands Member States.

Current challenges to the establishment of NITAGs include the need to ensure adequate expertise, independence from the government, transparency of the process, and quality review of the evidence on which recommendations are based. Meeting the six basic process indicators is the first step, and committees that meet with these criteria should continue to be strengthened. Fostering exchanges between NITAGs is an important way to facilitate support and progress. These exchanges should extend to making evidence available to other groups, such as public posting of systematic reviews. Very limited resources are available from partners to support NITAG strengthening in middle income countries, highlighting the need for these Member States to capitalize on initiatives such as SIVAC and ProVac. Efforts to establish NITAGs through professional organizations such as academies of paediatrics need to be well-coordinated with the government, to ensure that there is not a development of parallel groups.

Exploring the potential transition from polio or other VPD-specific TAGs where they exist, to NITAGs, is an important consideration. In some Member States the NITAG's mandate is broader and extends to infectious disease control.

HIGHLIGHTS

- By the end of 2012:
  - 63 Member States reported a NITAG that met six process indicators, representing a 47% increase over the 43 reported in 2010 (including 38 developing countries).
  - 99 (52%) Member States reported the existence of a NITAG with an administrative or legislative basis, a 2% increase since 2010. These Member States account for 85% of the global population.
- Where there is commitment, progress in the establishment and strengthening of NITAGs is fast.
- Progress needs to be accelerated to reach the GVAP NITAG target.
- Special approaches need should be explored to allow small Member States to benefit from sub-regional or other Member States' advisory groups.
- The existence of a NITAG should be a prerequisite for applications from GAVI-eligible countries in the future, and the possibility of accessing HSS funds for establishing and strengthening NITAGs should be considered.

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STRATEGIC OBJECTIVE 2

INDIVIDUALS AND COMMUNITIES UNDERSTAND THE VALUES OF VACCINES AND DEMAND IMMUNIZATION BOTH AS A RIGHT AND A RESPONSIBILITY

INDICATOR SO2.1

PERCENTAGE OF COUNTRIES THAT HAVE ASSESSED (OR MEASURED) THE LEVEL OF CONFIDENCE IN VACCINATION AT SUBNATIONAL LEVEL

TARGET: INCREASING TREND IN THE % OF MEMBER STATES HAVING ASSESSED THE LEVEL OF CONFIDENCE IN VACCINATION AT SUBNATIONAL LEVEL

SECRETARIAT FOCAL POINT: MELANIE SCHUSTER

DEFINITION OF THE INDICATOR

% of Member States that have assessed (or measured) the level of confidence in vaccination at subnational level.

DESCRIPTION OF DATA'S SOURCES

WHO PAHO and EUR region volunteered to pilot test the questions related to the indicator, as proposed by the SAGE WG on Vaccine Hesitancy, in their 2012 UNICEF-WHO JRF. The JRF was sent to the Member States in December 2012 and January 2013. The Member States were asked to return the completed forms by 15 April 2013. In addition self-administered questionnaires were personally distributed at the Southern & Eastern and Central African Regional immunization managers' meetings in Q1 2013.

Two questions were related to this indicator in the JRF:

- Question 1: Has there been some assessment (or measurement) of the level of confidence in vaccination at subnational level in the past?
- Question 2: If yes, please specify the type and the year the assessment has been done.

COMMENTS ON DATA'S QUALITY

As of 5 July 2013 not all Member States had returned the completed JRF. In the EUR region 48 out of 53 Member States (91%) provided data in the 2012 JRF. Member States which did not provide data in the JRF were: The Former Yugoslav Republic of Macedonia, Turkey, Austria, Finland and Monaco. In PAHO, all 35 Member States (100%) provided data in the 2012 JRF.

During the African immunization managers meeting, 14 national immunization managers were asked to complete the questionnaire. Of these, 11 provided a completed questionnaire.

Immunization managers identified what type of assessments the country did. Assessments were carried out in LIC as well, not just in HIC. The data clearly illustrated how many assessments have been done in the three regions(see Table 18).

29% of the Member States did not indicate whether or not an assessment had been done (Question 1). If an assessment had been done, not all Member States specified the type of assessment (Question 2).

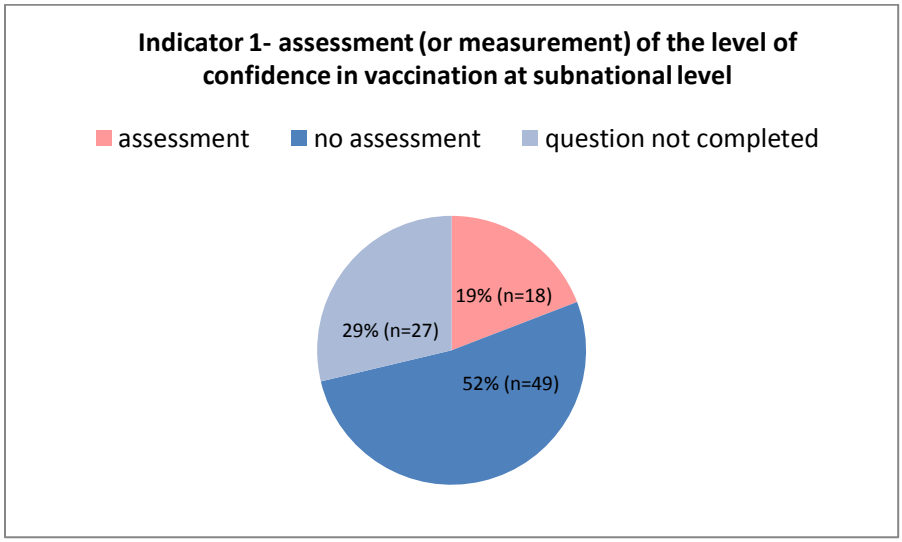
DESCRIPTION OF THE RESULTS

Table 18: Number of Member States reporting an assessment (or measurement) of the level of confidence in vaccination at subnational level

Region	EUR % (n)	PAHO % (n)	EUR and PAHO % (n)	AFR % (n)
Assessment	17 (8)	20 (7)	18 (15)	27 (3)
No assessment	35 (17)	69 (24)	49 (41)	73 (8)
Question not completed	48 (23)	11 (4)	33 (27)	0 (0)
Total	100 (48)	100 (35)	100 (83)	100 (11)

Of all participating Member States, 19% (n=18) assessed or measured the level of confidence at subnational level. (Figure 3)

Figure 3:Assessment of vaccine confidence of all participating Member States



NARRATIVE

The two vaccine confidence indicators were developed by the SAGE Vaccine Hesitancy WG. This is the first pilot test, no previous results are available.

Overall, 94 Member States representing all levels of income were included for pilot testing of the vaccine confidence indicator.

Response differed between the two methods used, with more Member States responding an assessment conducted during an immunization managers' meeting, compared to those who were asked to provide responses through the JRF (PAHO and EUR). The JRF is lengthy and time constraints might have led to incomplete submission. In addition as the questions were added to the JRF for the first time, explanations may have been lacking regarding the questions and the objectives of the indicators leading the EPI managers not involved with the topic previously to have difficulties responding. JRF format presented some variances depending on the regions, and even within a region (due to translation).

In regard to Indicator 1, the vaccine confidence assessment at a subnational level in the past, 71% of all Member States provided specific feed-back whether this was done or not in their country. 19% of participating Member States did a confidence level assessment demonstrating that vaccine confidence is an issue in their country. 52% did not do an assessment and 29% did not complete the question. For the 29% not providing feedback, it was impossible to differentiate whether no assessment was done or if the immunization manager filling in the questionnaire/JRF could not provide any answer. The reported assessments were done in Member States of all income levels. One vaccine confidence assessment was done in a LIC, 11 MIC and six HIC.

Regarding feasibility of collecting data for this indicator through the JRF, the Secretariat feels that more information is needed to draw conclusions. The Secretariat is assessing with EPI managers the difficulties they faced regarding these questions. Results should be available in September allowing the SAGE DoV WG to make recommendations regarding the process to collect information on this indicator.

HIGHLIGHTS

- This represents a first attempt to assess measurement of confidence in vaccination at national or subnational levels.
- Response rate was suboptimal, but improved when the questionnaires were administered on during immunization managers' meetings.
- It was impossible to assess whether no response equals no assessment.
- The nature of the assessments was indeterminate; the current questions and the mechanism for administering the questions and interpreting the data requires further consideration.

STRATEGIC OBJECTIVE 2
INDIVIDUALS AND COMMUNITIES UNDERSTAND THE VALUES OF VACCINES AND DEMAND IMMUNIZATION BOTH AS A RIGHT AND A RESPONSIBILITY

INDICATOR SO2.2

PERCENTAGE OF UN- AND UNDER-VACCINATED IN WHOM LACK OF CONFIDENCE WAS A FACTOR THAT INFLUENCED THEIR DECISION

TARGET: DECREASING TREND IN THE DISTRIBUTION OF % OF UN- AND UNDER-VACCINATED IN WHOM LACK OF CONFIDENCE IS A FACTOR AT THE NATIONAL LEVEL

SECRETARIAT FOCAL POINT: MELANIE SCHUSTER

DEFINITION OF THE INDICATOR

Indicator 2: % of un- and under-vaccinated in whom lack of confidence was a factor that influenced their decision.

DESCRIPTION OF DATA'S SOURCES

WHO PAHO and EUR region volunteered to pilot test the questions related to the indicator in their 2012 UNICEF-WHO JRF. The JRF was sent to the Member States in December 2012 and January 2013. The Member States were asked to return the completed forms by 15 April 2013. In addition self-administered questionnaires were personally distributed at the Southern & Eastern and Central African Regional immunization managers' meeting in Q1 2013.

Three questions were related to this indicator in the JRF:

- Question 1: What is the percentage of un- and under-vaccinated in whom lack of confidence was a factor that influenced their decision (this applies to all vaccines)?
- Question 2: Was this percentage measured or estimated?
- Question 3: Any comments or specific issues?

COMMENTS ON DATA'S QUALITY

As of 5 July 2013, not all Member States had returned the completed JRF. In the EUR region 48 out of 53 Member States (91%) provided a 2012JRF. Member States which did not provide a JRF were: the Former Yugoslav Republic of Macedonia, Turkey, Austria, Finland and Monaco. In the PAHO region, all 35 Member States (100%) provided a 2012 JRF. During the African immunization managers meeting, 14 national immunization managers were asked to complete the questionnaire. Of these, 11 completed the questionnaire.

DESCRIPTION OF THE RESULTS

Member States were asked to provide a measured or estimated percentage of un- and under-vaccinated in whom lack of confidence was a factor which influenced their decision to get vaccinated. 10% of the Member States answering the JRF provided an estimate of un-or under-vaccinated, 90% did not provide any answer to this question. Of the African Member States, 45% provided a percentage (.

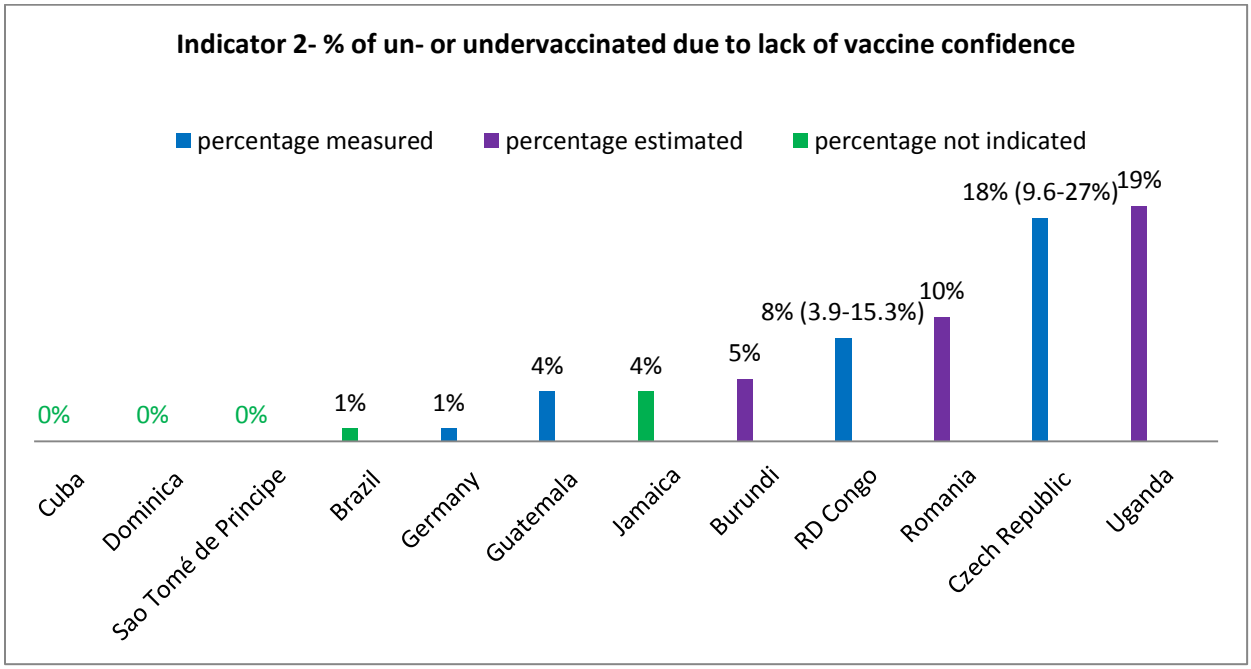
Table 19).

Table 19: Number and percentage of Member States which provided a measured or estimated percentage of un- or under-vaccinated.

Region	EUR % (n)	PAHO % (n)	EUR and PAHO % (n)	AFR % (n)
Provision of data	6 (3)	14 (5)	10 (8)	45 (5)
No provision of data	94 (45)	86 (30)	90 (75)	55 (6)
Total	100 (48)	100 (35)	100 (83)	100 (11)

Member States from three regions provided percentages, which varied between 0%- 19% of un- or under-vaccinated due to lack of confidence. Czech Republic specified that the percentages ranged from 9.6-27% according to vaccine. The DR Congo provided a range of percentages, 8% lack of confidence on a national level and percentages ranging from 3.9-15.3% in different provinces of the country (Figure 4) .

Figure 4: Percentage of measured, estimated or unknown (did not specify either from measured or estimated) of un- and under-vaccinated in whom lack of confidence was a factor that influenced their decision



NARRATIVE

The two indicators on vaccine confidence were developed by the SAGE Vaccine Hesitancy WG. This is the first pilot test, no previous results are available. Only 13 Member States provide measured or estimated percentage of un- or under-vaccinated in whom lack of confidence was a factor which influenced their decision to get vaccinated. Populations with lack of confidence in vaccinations were reported from Member States of all three levels of income, of the 13 Member States three were HIC, nine MIC and one LIC. Lack of vaccine confidence ranged from zero in Cuba, Dominica, Botswana and Sao Tomé de Principe to 19% in Uganda. Two Member States, Czech Republic and DR Congo, reported a range of percentages dependent on the type of vaccine. These results demonstrate that the lack of confidence can be significant problem in African Member States, such as Uganda which reported a population with lack of confidence of 19%. However, it was unclear how these estimates were derived and thus it was difficult to compare the responses between Member States. Comments on the indicators represented the large scope of issues around vaccine confidence, from confidence being an important issue to not being relevant at all. It further unveiled a variety of vaccine confidence determinants, from religious dimension to safety issues around the vaccine.

In regard to the JRF format, consistency and clarity is needed to receive comparable results. During this pilot test, there were variations of the questionnaire form between the two regions. Member States in the Americas might have been confused when selecting yes/no in the drop-down selection for question 2 where they should identify if the percentage with lack of confidence was measured or estimated.

HIGHLIGHTS

- Vaccine confidence assessments , as a proxy for issues with confidence, were not limited to HIC but had been done in Member States of all income levels. The pilot test demonstrates that vaccine confidence is an issue throughout the AFR, EUR and PAHO regions and that several Member States had estimated the vaccine hesitancy in the past.
- Different vaccine confidence assessments were identified and could be used for future assessments by other Member States.
- In regard to type of assessment Member States provided examples from national and subnational level, hence the question might need to be reworded to have a uniform approach which captures all types of assessments Member States provide feedback on.
- It was impossible to assess whether no response equals no assessment and therefore there is a need to continue the pilot testing to be able to evaluate the feasibility of collecting vaccine hesitancy data using the JRF process or consider alternatives. Member States that did not report in the pilot testing JRF will be contacted to understand the reason for their absence of participation (no interest for the question, absence of data etc).
- Member States could be identified having population with lack of confidence which would not be primarily assumed to have issues of vaccine confidence, such as Uganda.
- A variety of vaccine confidence determinants, from religious dimension to safety issues around the vaccine were identified by the Member States.
- It needs to be further assessed whether not providing a percentage indicates that there are no persons with lack of confidence, or if it was unfeasible for the immunization manager to provide an estimate.

STRATEGIC OBJECTIVE 2

INDIVIDUALS AND COMMUNITIES UNDERSTAND THE VALUES OF VACCINES AND DEMAND IMMUNIZATION BOTH AS A RIGHT AND A RESPONSIBILITY

CASE STUDIES

This indicator was used only on a pilot basis and the feedback received is difficult to interpret. The secretariat commissioned and identified reviews and published reports that analyze the causes of vaccine hesitancy or provide examples of initiatives or approaches used to foster greater community awareness and participation in immunization.

These case studies/reviews are appended. For the 2013 report, we highlight activities in three regions:

- AFR
    - Nigeria: Community Participation in Immunization and Polio Services: A case study of PRRINN-MNCH Community Engagement Strategy in Northern Nigeria.
- EUR
    - TIP Guide development and value, and outline the pilot and outputs (recommendations made as a result of using TIP) from Bulgaria and the current project implementation in Sweden.
- SEAR
    - Indonesia: Increasing the community Awareness about immunization through media campaign.
    - Nepal: Intensification of routine immunization and maternal health through mobilization of local participation, resources and ownership using appreciative inquiry approach.

ANNEX

- Summary of the World Immunization Week 2013.
- Reviewed articles:
    - A systematic review of interventions for reducing parental vaccine refusal and vaccine hesitancy, Alina Sadaf and al, Vaccine Journal.
    - Measuring vaccine confidence: analysis of data obtained by a media surveillance system used to analyze public concerns about vaccines, Heidi J Larson and Al, Lancet Infectious Diseases.

CASE STUDY 1: Nigeria Community Participation in Immunization and Polio Services: A case study of PRRINN-MNCH Community Engagement Strategy in Northern Nigeria

Problem

The Northern Nigerian states of Jigawa, Katsina, Yobe and Zamfara (combined population of 20 million) have some of the worst immunization coverage rates, and other health indices, in the country. The poor health indices stem from a complex interplay of demand and supply side issues. The health system, particularly primary health care, is dysfunctional and community needs are often not met, which creates a vicious cycle of distrust and underuse of health services. Immunization suffers from irregular services and supplies and low community participation. The situation is worsened by the failure of the health system to appreciate and leverage the socio-cultural dynamics within the community. Health interventions are often designed and implemented without considering community norms and concerns or the roles of various members of the community, including men, grandmothers and in-laws. Ignoring the community leads to non-acceptance and eventual failure of an otherwise technically appropriate intervention.

Intervention–The PRRINN-MNCH[24] Community Engagement Approach

The PRRINN-MNCH programme[25], funded by the UK Department for International Development (DFID) and the Government of Norway, developed and deployed a community engagement strategy centered on community volunteerism and social approval. The whole community is involved, including religious and traditional leaders, husbands, grandmothers, young women and others, in order to generate wide social approval for behavior change. Community volunteers (CV) play a vital role in sharing information and providing support and services. The participatory mobilization approach saturates the communities with health information and supports them to turn new awareness into action. The community is mobilized to take individual and collective responsibility for the immunization of their children. For example,

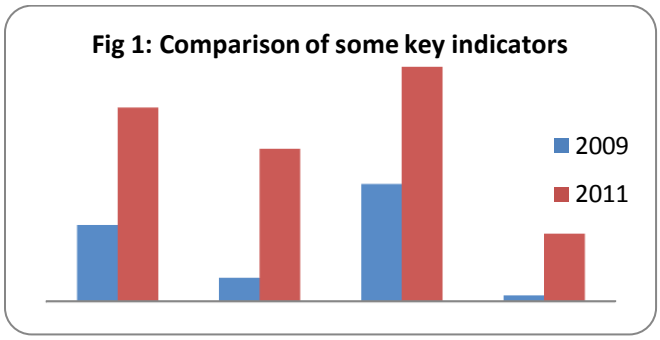
- CVs follow up to ensure actions are taken by individuals and community so there is standing permission from husbands for mothers to take children for immunization.
- Facility-in-Charges are assisted by the community to help transport vaccines to immunization sessions.
- Parents are mobilized to bring children for immunization during campaigns and on the immunization days.
- At Morning Prayer on immunization days, male CVs inform husbands to take their children to be immunized.
- Female CVs visit homes, major events (e.g. naming ceremonies) to remind mothers about immunization and trace children who dropped out or delayed immunization.
- To increase awareness, decision-making and discussion on polio, the “Majigi” (film) about polio is shown in high risk areas, followed by experience sharing and discussions on the content of the Majigi. Majigi is complemented by radio jingles, vaccination slogans, songs, mimes and body tools.

[24] Partnership for Reviving Routine Immunization in Northern Nigeria and Maternal, Newborn and Child Health Initiative

[25] *The Partnership for Reviving Routine Immunization in Northern Nigeria and Maternal, Newborn and Child Health Initiative (PRRINN-MNCH) is managed by a consortium led by Health Partners International, Save the Children International and Grid Consulting. For further details visit http://www.prrinn-mnch.org/.

RESULTS

CVs document their activities and submit them monthly to monitor and review progress. A mid-term household survey in focus LGAs[26] shows that between 2009 and 2011, OPV3 coverage increased from 26% to 66%; knowledge of the vaccination schedule increased from 8% to 52%; standing permission for vaccination increased from 40% to 80%; and fully immunized child coverage increased from 2% to 23%.



Key Lessons Learnt

- Community engagement takes time and investment.
- Face-to-face engagement is important - mass media raises awareness, but dialogue answers questions and addresses concerns; face-to-face engagement is especially important in communities where there is mistrust or suspicion.
- It is important to address other issues beyond polio (measles, maternal health or malaria) that are considered high priority by the community. This makes the focus on polio more acceptable.

[26] Findley, Uwemedimo, Doctor, Green, Adamu, Afenyadu, Changes in Maternal and Child Health Care Behaviors: Early evidence of the impact of community-based programs, PRRINN-MNCH, September 2012

CASE STUDY 2: Indonesia: "Increasing the community Awareness about immunization through media campaign"

Please refer to attached document "Info CSO, 6th Edition, December 2012" (*to be provided by the Secretariat).*

SUMMARY

In this newsletter, The Ministry of Health, Department for Health Promotion presents the activities developed using GAVI funds (CSO and HSS) to improve the participation of communities and individuals to immunization activities.

Described activities include:

- Increasing the community awareness about immunization through media campaign.
- HSS reprogramming component focus on increasing immunization coverage for 2012-2014.
- Local workshop with immunization programme managers from 58 districts where routine immunization is low to identify the problems and to address them.
- Scouts' training to the immunization activities and programmes.
- Motivating the health cadres through information communication contest.
- Midwives and health cadres and shaman training to immunization services.

6th edition, December 2012

Info GAVI

Ministry of Health Republic of Indonesia

GAVI ALLIANCE

SKIPI GAVI (021) 421 3729 SKIPI GAVI-HSS (021) 521 4884 SKIPI GAVI CSO (021) 2941 0056, 527 0929

INCREASING THE COMMUNITY AWARENESS ABOUT IMMUNIZATION THROUGH MEDIA CAMPAIGN

Reprogramming of HSS component implemented in order to improve immunization coverage and MCH, one of the goals is to improve the immunization coverage in the District / City with low immunization coverage. Various efforts will be carried out and one of the efforts is immunization campaigns through media including Public Service Announcements (PSAs). The activity was carried out by the Centre for Health Promotion. The Immunization PSAs was ran from November 22 - December 20, 2012, at MNC TV, Trans TV and TVRI and also through the Airport TV at Soekarno-Hatta Airport.

Footage of Immunization TV Ad

Immunization campaign aims to increase awareness and knowledge of the public, especially pregnant women and nursing mothers about the importance of immunization. It is necessary to promote, support and protect the immunization as a key intervention to improve health and safety of the child's life. One is the provision of access to the right information about immunization to infants in a sustainable manner. The campaign is also expected to mobilize all stakeholders to support the implementation of the immunization program.

Immunization campaign will resume in February - March 2013 before the Sub National Immunization Week (PIN) Diphtheria second round of East Java. In addition to PSAs on television, there will be also the radio spots. GAVI-CSO IBI (Indonesian Midwifes Association) will also broadcast PSAs through radio in the intervention area of South Sulawesi and West Java.

CASE STUDY 3: Development and Pilot Application of the Guide to Tailoring Immunization Programmes (TIP) in the WHO European Region

SECRETARIAT FOCAL POINT: ROBB BUTLER AND NATHALIE LIKHITE

In 2010, the SAGE stated that if the WHO European Region (EURO) cannot improve coverage of immunization among susceptible populations, the goal of measles eradication will not be possible. In response, EURO Vaccine-Preventable Diseases and Immunization Programme (VPI) developed the Guide *to Tailoring Immunization Programmes*[27] (TIP), to boost national and sub-national infant and child scheduled vaccination coverage. TIP uses participatory approaches to gain insights from caregivers and their communities, as well as key stakeholders, in order to 1) identify populations susceptible to vaccine-preventable diseases (VPD), 2) diagnose supply and demand-side barriers and motivators to vaccination, and 3) design evidence-informed responses to sustain vaccination and reach the remaining susceptible populations in EURO. This allows Member States to tailor immunization services, and in turn, assist the Region in meeting disease elimination and eradication goals.

TIP Development in Bulgaria

In February 2012, EURO requested permission to work alongside Bulgaria's National Immunization Programme (NIP) to test the TIP approach and methods, as a means for diagnosing reasons for insufficient vaccination coverage among marginalized and vulnerable populations, particularly ethnic Roma, residing in Bulgaria. Each step of the TIP guide was tested with the objectives of both 1) improving the process with which the TIP guide would be implemented in other Member States and 2) assessing the usefulness and effectiveness of the proposed TIP tools and research instruments. The collaboration was implemented via facilitated workshops, key informant interviews, consultations and primary research with local, regional and national stakeholders from government, civil society and the community, including Roma health mediators and vulnerable parents.

TIP Pilot in Sweden

In early 2013, EURO applied lessons learned from its experience in Bulgaria in Sweden. A workshop was held from 11-13 March, 2013 in Stockholm, hosted by Smittskyddsinstitutet (SMI) and European Centre for Disease Prevention and Control (ECDC), to apply the TIP diagnostic framework in view of providing input into the Swedish Immunization Programme's Strategy to Reach Hard-to-Reach Groups. Three communities were identified:

1. Anthroposophic community, in Jarna.
2. Somali community, particularly in Rinkeby and Tensta, northern Stockholm.
3. Migrant communities, with a focus on Gothemborg Northeast and Angered.

The workshop included representatives of SMI, ECDC Health Communications Unit and Karolinska, Lund and Nordic Schools of Public Health NHV, Göteborgs University staff and graduate students in public health. The use of the segmentation steps and TIP diagnostic framework received positive feedback and

[27] www.euro.who.int/__data/assets/pdf_file/0003/187347/The-Guide-to-Tailoring-Immunization-Programmes-TIP.pdf

TIP in general was effective in providing guidance on key questions to address to each identified community. Currently, insights from each community are being collected using qualitative research methods conducted with parents, community members and local immunization providers. These will be presented, analyzed and discussed in August 2013 in view of designing programmatic strategies to close the measles and rubella immunization gaps in the identified communities. These programmatic strategies will be tested in the latter part of 2013.

Please refer to three additional pdf documents sent by EURO (*to be provided by the Secretariat).*

CASE STUDY 4:

"YOU ARE THE CREATOR": USING APPRECIATIVE INQUIRY TO TRANSFORM HUMAN POTENTIAL AMONG HEALTH WORKERS, LOCAL LEADERS AND COMMUNITIES TOWARDS IMMUNIZATION, MATERNAL AND CHILD HEALTH GOALS IN NEPAL

SECRETARIAT FOCAL POINT: RAJENDRA BOHARA AND SHARAD AGARWAL

SUMMARY

- Uses an **inspirational, forward-looking, positive and 'appreciative' approach** to generating transformational change that creates the energy needed to achieve a fully immunized status.
- Strategically **targets sub-district level health and development functionaries** to unlock their inner potential to energies them to mobilize teams, resources and abilities to close the final gap between the current immunization status and being fully immunized.
- A three day workshop that takes participants through the 4Ds of AI – **Discover, Dream, Design and Deliver**.
- Creative collaborations and **mobilization of local resources** from a variety of sources is a hallmark of the process, bringing in the needed resources to reach the fully immunized status. It also involves **collective community monitoring and intelligence gathering which generates ownership** and further support the efforts.
- **Local ownership** is also generated by encouraging contribution to workshop expenses. WHO contribution is less than 20% of the costs.
- **Partnerships at all levels** are characteristic of the program, with good coordination at the national level between the MoHP and UN agencies, and in districts between the District Health officers and District Development Committee (DDC) and its members.
- **Declaring a VDC as 'fully immunized' is a deliberate and astute strategy** that provides a concrete and achievable goal, and thereby channelizes motivation, strengthens team work, and infuses rigor into tracking and monitoring systems. Combined with the motivational Appreciative Inquiry, it drives initiative, resourcefulness and result orientation. The criteria for being certified as fully immunized drives quality control, and keeps district and VDC teams nimble. Besides, the declaration event provides the needed strategic visibility and recognition to local entities, and spreads the word to other VDCs, creating a healthy peer pressure all around.
- These characteristics provide the **elements of sustainability** of the intervention. District and sub-district teams are likely to continue in the same vein not only to maintain gains in immunization, but to health as a whole, because the AI inputs infuse them with a new paradigm of their own role in the world, that they are the creators and need to take responsibility for the future. They also are likely to find the benefits of success and recognition rewarding enough to continue working for.
- **Sensitive support** to VDCs to ensure motivation is maintained in face of challenges is imperative to ensure increasing number of VDCs attain full immunization status.
- **Engagement of local actors such as school teachers** is recommended so that they be involved not only to enable contribution to immunization, but to energies the education system itself, which in Nepal is sorely needed. The returns to immunization and health would be through an aware, educated and therefore, a healthy society. Other such opportunities for inter-sectoral synergies are abounding.
- **Technology** could be used to further support the networks in place.
- Nepal has provided a strong basis for adopting a similar 'appreciative', inspirational approach to generating the drive and motivation for reaching immunization goals in other contexts /countries. Given its universal human approach, and proven evidence based principles and methods, it is likely

to be **effective in all contexts** for immunization (and health). This approach is a refreshing shift from the problem based, analytical approaches of dominant methodologies, and is efficient in that it transforms and frees rather than laboriously chip away at change.

- Given that **human systems are complex**, and require holistic, intuitive, flexible approaches such as Appreciative Inquiry are likely to be most suited. Resources and practitioners for such approaches are to be found worldwide.
- However, most critically, the Nepal experience demonstrates the importance of **marrying a sensitive tool (AI) with a robust and grounded strategy** to ensure success.

'You are the Creator'

Using Appreciative Inquiry to transform human potential among health workers, local leaders and communities towards immunization, maternal and child health goals in Nepal

June 2013, Nepal: Nara Bahadur Karki carries a chair on his back as he walks in between rows of government health and development staff in a workshop in a barely air-conditioned hall of a local NGO resource centre in Nepal's eastern-most district of Morang. 'Isn't this how we carry our burdens all the time?' he says, coach, facilitator, Appreciative Inquiry specialist and practitioner of transformational technologies, as he invites them to de-clutter their minds of beliefs and past negativities, and accept their persona as 'heroes'. 'You are the creator', he says as he provokes them to uncover their own vast undiscovered potential and forge a 'dream'. Later, he invites them to present to an avid audience at an imaginary TV show five years ahead, just how they achieved their 'dream'. The 150 participants who between them hold the responsibility for the health and development of all citizens of their district, but who have been lulled into complacency due to uninspiring supervision and challenges of terrain, vaccine supply, staff shortage, 'inconvenient' priorities of migrant and ethnic minorities in a landlocked country with a turbulent political history, emerge from the three day workshop, inspired, driven and restless with a mission to accomplish. They had committed to declare their VDC (Village Development Committee[28]) as fully immunized – and soon.

[28] Village Development Committees or VDCs as they are popularly referred to is the smallest development unit in the Nepal administrative system. The Country is divided into five regions, each of which into districts (a total of 75 districts in Nepal), and each district into VDCs. Each VDC is made up of nine Wards. Each VDC has a health facility post or sub-post which is maintained by the Health Facility Incharge who is supervised by the District Health Officer. The developmental budget of the VDC is held by the VDC Secretary who reports to the Local Development Officer (LDO) at the district level and is responsible for various activities such as infrastructure, campaigns such as the Open Defecation Free, or clean environmental efforts. While he holds considerable discretion in the spending of that budget, some of which could be for health, typically, there is not much interaction or coordination between the two.

Immunization in Nepal

The Morang workshop was the latest in a series of workshops launched by the National Immunization Program of the Ministry of Health and Population, Government of Nepal, together with WHO and UNICEF country offices, exactly a year earlier in Achham, one of the most remote and inaccessible districts of Western Nepal. Despite the difficult terrain, the EPI program in Nepal was considered to be a success and overall immunization rates were improving over the years. However, a persistent 13% of children under one year of age remained under-immunized and 3% were entirely missed by vaccination services[29] despite best efforts. To address this, and in line with the SEARO declaration of 2012-13 as the *'Year of Intensification for Routine Immunization'*, Nepal decided that one of the best ways to achieve this was through community engagement and mobilization of local ownership and resources. It announced 2013 as the *'Year of Reaching Every Child with Routine Immunization'*. However, it also acknowledged that innovation would have to be at the heart of its efforts in order to achieve success.

The Objective

With the objective of energizing district and sub-district level governmental health staff to mobilize community stakeholders to engage in reaching every child and ensuring full immunization coverage, WHO Nepal Country Office in close coordination with Government of Nepal, and UNICEF Nepal Country Office, commissioned the services of Nara Bahadur Karki, a well-known Appreciative Inquiry practitioner and life coach in Nepal.

The Strategy – Appreciative Inquiry as an Innovation

Appreciative Inquiry (AI) [30], [31],[32] is a positive, vision-oriented, asset based, inspirational approach that enables people to (co-)construct 'dreams' by revisiting past moments of excellence and life-giving

[29] National Demographic and Health Survey (NDHS 2011) as reported in '*Journey to Success';* WHO-IPD, 2012/3
[30] Locating the Energy for Change: An Introduction to Appreciative Inquiry, Elliot, C.

experiences, and then be driven by the attainment of the goals. The strength based approach generates powerful shifts within individuals where they begin to see themselves as the catalyst for change, and not as passive recipients. This induces them to take responsibility, which in turn, generates the energy for creating a vision and finding the means to meet them. External support, supervision, and monitoring become less relevant as they strive to meet their own goals, and discover the vast reserves of creativity and resourcefulness within them. They also discover empathetic listening and therefore a heightened ability to strike meaningful relationships. AI brings a psychological and metaphysical approach to human change, and relies on the power of the positive rather than an analysis of the problems. It is a practical approach that is rooted in people's past achievements and builds grounded goals. Because the shift is internal and fundamental, it generates sustainable change.

Marrying transformational approaches to routine immunization was an innovation. Nara Bahadur and other practitioners had been called upon in the past by development agencies to help facilitate processes such as maternal and child health bottleneck analysis, strategy development etc., but now he was challenged to motivate health system staff and their counterparts to take responsibility of the immunization status of their respective constituencies. It meant finding a way for staff long used to apathy and non-recognition, to be resourceful, creative and proactive. It implied asking them to be good leaders, and inspire their own teams in turn to go that extra mile (which in Nepal could be a couple of days walk) to list every child, record its full immunization status by ward, antigen, ethnic group, coordinate vaccine supply, and unfailingly hold EPI sessions and mobile clinics. It meant mobilizing mothers groups, school teachers, media persons and others and drawing the support of local leaders to advocate and monitor and mobilize funding to fill vacant health worker positions. It also implied demonstrating to senior policymakers that new approaches bring new results. It meant much more than passively administering doses to visiting children.

[31] An Introduction to Appreciative Inquiry, Taylor, J.

[32] Appreciative Inquiry: Theory and Change, Bushe, G.R. 2011, in The Routledge Companion To Organizational Change (pp 87-103), Boje, D., Burnes, B., and Hassard, J., (eds.) Oxford, UK, Routledge

Furthermore, the health functionaries needed to realize that unless they made their own health facility better equipped and 'attractive', they could be unsustainably chasing every last child in the mountains with catch up doses. Once every baby was born in a health facility, every child could be tracked for immunization. The secret to sustaining a fully immunized status lay in a smartened health facility, of which he/she was in charge. The route to a fully immunized status, therefore, lay within *him/her*, the Health Facility Incharge. This was the grand realization and essence of the 'appreciative' approach unleashed by the innovation - that the secret to success lay within them, each of them. And once they made the internal commitment to a goal, the resources mobilized, the team gathered and results started to show.

This was also where it differed from other social mobilization and community engagement programs in immunization. The issue in Nepal was not so much about 'engaging' communities (as in parents, mothers/households) to 'demand' vaccination. With nearly 90% coverage, there was a critical mass of quiet acceptance, and 'demanding' seemed unnecessary. But there was an underlying expectation that it would be simple, predictable and easy to access. The critical factor in achieving a sustainable fully immunized status was in precisely making routine immunization routine, accessible, easy and all in day's work for the community. The critical intervention therefore, lay with the health functionary, and therefore, the health system, rather than families or households. It clearly needed to fine-tune, streamline, and grease its moving parts, and invite creative collaborations with local partners, and make itself an attractive, accessible option.

The Project

This provided the basis for a national level collaboration between MoHP/Government of Nepal, WHO CO and UNICEF CO, a series of workshops were launched to invest in energizing staff to help pull up the system socks, and thereby provide uncommon holistic and intuitive local leadership. After a couple of pilots, 25 out of the 75 districts were targeted. All parties pooled resources, with WHO contributing less than 20% of the costs in addition to the facilitator. Any additional funding gaps were met by district level resources.

Apart from the Health Facility Incharge, the VDC Secretary was expected to participate. While others, such as school teachers, journalists, local leaders, armed force personnel were encouraged to participate, the engagement of the VDC Secretary, who holds the development budget for the VDC, was strategic – and another innovation in the strategy. Later, this was proven to be astute as the VDC secretaries were seen to be proactive in allocating funds and/ or mobilizing local leaders or other influencers. They were also the conduit for upward engagement of the district Local Development Officer (LDO), who could then be mobilized by the District Health Officer (DHO), and between them and other district level functionaries, they could get the attention of the District Development Officer (DDO) who was the highest authority at the district level. This multi-level partner collaboration was another pillar of the strategy.

For two out of the three days of each workshop, the facilitator would take the participants through a seamless process of examining the four Ds that mark the archetypal pillars of Appreciative Inquiry – Discover, Dream, Design and Deliver. By facilitating participants to recall and reflect on past moments of excellence and happiness, and convincing them to de-clutter their minds of negativities, he guides them into a positive frame of thinking about themselves, and 'discover' their achievements and talents. He starts with encouraging participants to interactively discover what is 'appreciable'[33] within them (e.g. the inherent talents, values and greatness in those moments) as well as inspiring lessons emerging from them, and through this 'co-search' help participants get connected to their source of life energy. He helps the participants see how they themselves hold the power to be architects of their own future, and how they carry the solutions to their challenges. He brings them to realize the power of gratitude and that simple acts of expressing gratefulness can bring happiness, connectedness, joy, inspiration, creative and intuitive thinking.

[33] The term 'appreciable' refers to both senses of its meaning: that which is worthy of praise and admiration; and that which can be augmented or increased (e.g. money in a deposit).

He then invites them to create a provocative 'dream' inspired from their past achievements, and develop a plan for achieving it. He places one condition that one of the elements of the 'dream' must be about immunization. On the third day he invites each VDC team to an imaginary TV show five years hence to present how they achieved their 'dream'. It is strategic elements such as these that make the AI workshops a cut above usual motivational processes. Rather than present their intended plan to achieve their envisioned goal, this process subtly reinforces achievement by projecting the dreams as already completed, and by placing participants in a position of glory by asking them to recount how they achieved them. It is a subtle shift, but precisely where lies the power. It is a psychological and metaphysical intervention, and therefore creates fundamental shifts in perception. The 'publicly' declared 'dreams' bind the participants into an action plan. The idea of a 'fully immunized' VDC is seeded at this stage. It also necessarily throws the participants of each VDC into a team spirit that forges a buy-in to a common dream. This is critical for the follow-up that they lead when back in their village.

After the workshop, the VDC teams (and therefore the districts) are tasked with (i) line listing every child, tracing all dropouts in each ward of every VDC and ensuring immunization is completed (ii) mobilizing schools, community leaders, mothers groups, CBOs, private hospitals in identifying and reaching every child with vaccination (iii) inviting community leaders to monitor vaccination (iv) recruiting vacant vaccinator posts with local resources (v) declaring VDC as 'fully immunized'. The district teams were expected to certify the fully immunized status with independent monitoring. A Declaration event was encouraged as a strategic opportunity for advocacy at multiple levels.

The Health Facility Incharge and the VDC secretary would typically convene a meeting of their staff, including the Female Community Health Workers (FCHVs). These FCHVs are a legacy of the Nepal health system and is a network of female volunteers who belong to the villages and wards where they serve as health volunteers providing outreach support to various health programs. They would have held this role since several years, and enjoy high credibility and acceptance by the community and mothers. The team would prepare a detailed plan on how to reach every child in every ward and collect comprehensive and accurate information on its vaccination status, and then coordinate with the vaccination teams to complete any missed doses. This also leads them to streamline the system for forecasting vaccine supply from the district cold room so that EPI vaccination sessions and mobile clinics are held at regular, scheduled dates known to the families. The FCHVs then meticulously list every child, and therefore every family, by visiting every home in their respective wards, and often creating new

registers for entering the details. In some cases they enter the same details, by hand, sorting by ward, antigen and ethnicity. The data is checked by the Health Facility Incharge and together they ensure the accuracy of the data. Health cards are issued in some cases to the families and a copy kept at the facility.

The Health Facility Incharge and VDC Secretary galvanize interest from other local influentials such as community leaders, school teachers, NGO representatives to support the mission by advocating in their respective circles, reporting on any missed children, monitoring the progress and/or double-checking the accuracy, or simply supporting the FCHVs in recording the data if they felt challenged. When reasonably satisfied on full coverage, the VDC team would invite the district officials to further verify and certify. The district EPI manager and District Health Officer would conduct an independent check and if satisfied, issue a certification. Based on this, and with further support, typically, from the VDC budget, a public declaration event would be held to celebrate the achievement.

However, the significant achievement in this process is the manner in which this work is accomplished. Often the Incharge and VDC Secretary are noted for their supportive supervision and leadership. They are seen to be far more sensitive to the challenges of the staff, and solutions are more creatively

forthcoming. Resources for incentives are more frequently mobilized. They also reach out more effectively to other stakeholders in the village and request their participation. In the successful areas, they are seen to create wide community engagement, resources and thereby ownership. This process is seen to impact not only immunization coverage and quality, but also other maternal and child services, and in principle, health.

Results, one year on

One year into the process, since the pilot in Achham in June 2012, 18 workshops have already been conducted, and another 21 in the pipeline. As many as 50 VDCs across nine districts have declared themselves fully immunized and another 20 are slated to do so in the immediate weeks. By the end of the year, all 25 districts are expected to be covered. The National Immunization program has since decided that the program be extended to 42 districts by 2014.

While the fully immunized VDCs are the final outcome indicator, several compelling process indicators present themselves equally. Large numbers of local planning committees are getting mobilized in every intervention VDC, involving 12,000 local leaders and 3000 health workers. 11,000 FCHVs are activated serving as a key bridge between the health system and communities. Increasingly wider set of stakeholders are getting engaged, a maiden experience for many. For example, the local tourism committee, never before involved in health, arranged for an elephant with banners to move around the villages announcing the efforts towards 'full immunization village' campaign and motivating communities to join in.

The Declaration events were another strategic dimension of the project. While initially it seemed that this could only be an interim target, since a fully immunized status could be immediately compromised with even one new child with a missed dose, it became clear that this event brought lot more value to the process. The high profile events, complete with speeches, dance and ceremony created a wave of their own with the media picking them up, and so also the neighboring VDCs. With each event, local leaders got their visibility, the VDC secretary looked good, the health facility in charge received public recognition by the district officials and subordinates alike. Mothers groups and FCHVs had a chance to share the glory. Willy-nilly, the message of every family's critical engagement in immunization went around. The *process* of achieving a certified fully immunized status sensitized key stakeholders from mothers and families to community leaders and village influentials. It resulted in a strengthened, sometimes fresh, tracking and monitoring systems, which taught every team the value of rigour in maintaining quality data. EPI sessions and clinics became regular as the communities became more aware of their rights to expect regular vaccination services. It induced improved team management and spirit where joint planning, division of labor and supportive supervision started to become the norm. And most of all, creativity was established as a latent (and under-used) resource. Resources were creatively mobilized through local partnership, in some cases directly through community members.[34]

It was a state of reinforced self-esteem, renewed commitment and inspiration achieved through personal transformation guided through a positive and appreciative inquiry, that shifted the mental paradigm from problem solving to envisioning a life-giving future, and that released this creative energy

[34] Example of Bhanu Village: The Health Facility Incharge raised Rs 100,000 for a birthing centre directly through community donations when the budget holder who had not attended the workshop was not cooperative enough.

among the erstwhile apathetic workers. Of significance was also that each successful VDC had the opportunity to experience, and therefore retain the memory of, synergistic team functioning and all its benefits, which was likely to continue to motivate them.

Outcomes

The outcomes are, therefore, one, that an increasing number of VDCs are indeed ensuring that all children are fully immunized, but more significantly, two, that systems are getting rigorous and quality-conscious. Three, the success is generating effective advocacy with senior officials at all levels which is likely to attract increased attention and resources. Four, momentum for *sustaining* gains is likely to be built. There is increased interest from other public health and non-health sectors and opportunities for leveraging wider impact are emerging. The intervention is attracting donor attention and those of headquarters of the UN agencies involved. The National level government counterparts are increasingly committed to the approach and mobilizing internal resources to expand the program. Inter-sectoral interest is building up at the district level where opportunities for synergy are becoming evident. Teams of managers are coming together around the EPI manager, and commitment, integrity and an appreciation of a cooperative way of functioning are becoming evident.

Discussion, Limitations and Suggestions

The program has clearly revealed the efficacy and efficiency of transformational approaches in reaching public health objectives such as expanding immunization coverage. The human dimension of public health has to be recognized as being a complex system[35] (as opposed to complicated or simple), and the irrationalities, paradoxes, inconsistencies and non-linearity of human mind and behavior recognized alongside the analytical and rational. Strategies that embrace these are needed. Holistic, intuitive, probing (rather than deterministic) approaches are needed. Appreciative Inquiry approaches are harmonious with this and should be better utilized in motivating organizations, personnel, communities

[35] The Cynefin Framework, in A Leader's Framework for Decision Making, Snowden, D.J. and Boone, M.E., Harvard Business Review, 2007

towards self-generated collective goals. AI's underlying principles work with the aspirational dimension of the human mind, and allow individuals to transform to their own anticipated future.

In terms of replicability across other contexts and countries, AI is a well-established methodology with vast resources and practitioners available worldwide that could be drawn upon within each specific context. However, it would be imperative to build a grounded and relevant strategy with clear expected outcomes to provide a robust framework within which to use AI to motivate participants. Needless to say, wide stakeholder partnership would ensure success in supporting such an approach.

At the programmatic level, the intervention is currently riding on the skill and charisma of the single facilitator, who happens to be from within the country and therefore seamlessly generates identification with his participant groups. However, for the healthy growth of the program, an expanded capacity is fast needed. While it may not be feasible to develop a second line of similar facilitators as it takes years of experience and skill to reach the ability of the current facilitator, it would be very helpful to develop a 'shadow team' of functionaries who provide follow-up support within a group of VDCs including their own, freeing the main facilitator for critical tasks. Two participants from each workshop could be competitively identified and a group of 10-12 from five to six districts could form a core first batch of trainees that go through a practical specially designed training program (workshop, observational sessions, remote mentoring etc.) to acquire some of the insights of a facilitator. The identification of the members could be through a motivational process while incentivizing those with inclination or interest along these lines.

Mobile technology holds tremendous potential for enhancing the effectiveness of the work of the FCHVs. While they have done a remarkable job of line listing and tracking every child in their respective wards, and maintaining meticulous records across various parameters, these have all been handwritten and therefore labor intensive (not to mention prone to errors). This vast and well trained network of FCHVs, which is a legacy of Nepal's health system, and which enjoys long standing trust and credibility in the community, offers potential to be armed with handheld data devices with which they directly input relevant information from the field into centralized electronic databases. Information on immunization status of drop out children could be uploaded via handsets on to a common web based platform, and the planning for mobile/EPI clinics and vaccine supply be mobilized accordingly. This could potentially be integrated with other health and nutrition indicators and could offer tremendous centralized and well

managed integrated electronic repository of services (e.g. birth registration certificates, growth monitoring, immunization status, reminder service, etc). It would be a health demographic database of every family and child throughout Nepal, and would offer tremendous potential benefits and efficiencies, not to mention further innovation. Besides, the electronically connected (and therefore accessible) FCHV network would offer its own possibilities for communicating and coordinating with, providing refresher inputs to, and horizontal linkages. Examples of mhealth[36] abound around the world which can be reviewed to inspire and creatively design an adapted application for Nepal.

While there is broad acceptance of immunization within the country, given the strong and credible interpersonal networks already in place in Nepal, FCHVs should be oriented to move the parents from a relatively passive acceptance to a sharper keenness for immunization for their children, based on a deeper understanding of its benefits. This would be an important investment into the future when the sensitized communities could be expected to sustain the programme even if the system tended to slip back. It will also be a protective layer against any skepticism against vaccine that may creep in in the future. Ultimately it is a sensitized populace that will safe guard against system lapses and sustain immunization over the generations. Armed with mobile phones, FCHVs could be much more effective in this function.

Multiple opportunities for collaboration and synergies within and across sectors towards further enhancing the impact and sustainability of the program are emerging. Involving school teachers is an on-going discussion, but is recommended not only for its direct support to the immunization program, but to the much-needed benefit it would bring to the education system in Nepal. The returns to immunization and health would be through an aware, educated and therefore, a healthy society. It is important that teachers participate in the workshop alongside the others.

District level collaboration, primarily through the District Development Committee (DDC) should be deepened. Synergy between the VDC level functionaries of the different sectors of the district (e.g. Women and Child department, Environment and Sanitation Department), should be maximized to further strengthen the network of systems supporting the FCHV in reaching out to the households. It also holds the potential for *integrated* messaging and action between sectors for communities.

It is imperative that district level monitoring is sharply maintained to ensure that undue local obstacles do not erode motivation for the teams. Sensitive and timely remote guidance would help facilitate solutions to local challenges, thereby increasing the number of VDCs that reach the fully immunized status. National level support to district teams to remain nimble would be essential. The program, while successful, does need nurturing, and this would be critical.

[36] http://www.mhealthalliance.org/media-a-resources/mpulse/122-members-highlights-zmq-and-core-group-polio-project-india-collaborate-on-mhealth-project;
http://www.who.int/nmh/events/2012/mhealth_guide.pdf;
http://www.unicef.org/infobycountry/uganda_62001.html;
http://healthunbound.org/node/3268;
http://sites.healthunbound.org/content/mobile-innovations-recording-child-vaccination-and-health-data-immunization-registers-mvac-0;
http://www.imedicalapps.com/2012/06/harnessing-mobile-phone-improve-vaccination-lower-income-countries/

Another year into implementation, it would be in a position to validate the methodology as well as crystallize areas for refinement. For example, it has yet to fully test its impact in municipalities and urban populations. Five municipalities are slated and the results will be keenly awaited.

ANNEX 1

SUMMARY OF THE WORLD IMMUNIZATION WEEK 2013

World Immunization Week (WIW) www.who.int/campaigns/immunization-week/2013/en/index.html, held in the last week of April 2013, gives countries and immunization partners around the world the opportunity to communicate the health benefits of vaccination. The ultimate goal of WIW is to protect more people – and their communities – from vaccine-preventable diseases which is aligned with GVAP SO2 and SO3. WIW was one of the three immunization related resolutions endorsed by the 2012 WHA: (i) the GVAP (ii) to formally designate the last week of April each year as World Immunization Week, and (iii) to declare the completion of Poliovirus Eradication a Programmatic Emergency for Global Public Health.

WIW is a global campaign thanks to its success at regional and national levels (beginning in the Americas in 2003) and to the commitment of dedicated individuals and groups in advocating for a simultaneous immunization week across the world. 2013 was the second year in which countries in all six WHO regions participated in WIW, with over 180 countries undertaking various activities. The global slogan was "Protect your world – get vaccinated". A range of WIW products were developed by WHO including: Campaign website in six languages; Campaign essentials – a toolkit for event organizers; Seven immunization feature stories; Fact sheet on immunization coverage; Information sheet: 10 myths and facts about vaccination; and Event registration site where visitors to the site can register their WIW events.

The Decade of Vaccines (DoV) special supplement was published in the Vaccine journal coincided with WIW 2013 www.sciencedirect.com/science/journal/0264410X/31/supp/S2. An Information Session on Immunization was also held in Geneva by DoV partners with global experts talking about how, collectively, the global community can make sure that people all over the world, even in the most hard-to-reach areas, have access to all the vaccines they need. See the webcast at www.who.int/campaigns/immunization-week/2013/webcast/en/index.html

Different geographical regions implemented activates and emphasized different themes to adapt to their specific needs, they were as follows:

- **African Vaccination Week: Save lives, Prevent disabilities, Vaccinate!**
  www.afro.who.int/en/clusters-a-programmes/ard/immunization-and-vaccines-development/events/african-vaccination-week/african-vaccination-week/african-vaccination-week-2013.html
  43 African countries implemented a range of activities including: rollout of new vaccines; vaccination campaigns integrated with other life-saving interventions such as vitamin A supplementation, deworming medicines for intestinal worms and insecticide treated nets; screening of children to ensure they are fully immunized; as well as public education and health promotion events.

  Participating countries embarked on mobilization and sensitization campaigns using traditional and social media, engaging community and religious leaders where relevant, organizing workshops for media practitioners and health workers; conducting community dialogues through panel discussions; recognizing deserving health workers through award of certificates, and sensitizing supervisors, as well

as undertaking supportive supervisory visits to vaccination sites. Activities had a common, overarching goal: to showcase the power of vaccination in protecting public health.

- **Vaccination Week in the Americas: Vaccination, a shared responsibility.**
  http://new.paho.org/vwa
  44 countries and territories participated with the aim to reach more than 44 million children and adults. Since 2003, Vaccination Week in the Americas has taken the benefits of vaccines to more than 411 million people of all ages, including more than 140 million children under five, and nearly 139 million senior citizens.

  Various launch events were held: in the "Adjacency Zone" between Belize and Guatemala; in Port-of-Prince, Haiti, focusing on vaccinating women ages 15–49 against tetanus and strengthening vaccination in low coverage areas to keep the country free of measles and rubella; in Cuba, El Salvador, Honduras, Puerto Rico, Panama, Antigua and Barbuda, the Cayman Islands, and many other countries and territories of Latin America and the Caribbean; and bi-national events in border areas including Honduras–Guatemala, Panama–Costa Rica, Panama–Colombia, and Guyana–Suriname. Participating countries deployed vaccines against diseases including polio, measles, rubella, and congenital rubella syndrome, diphtheria, mumps, whooping cough, neonatal tetanus, influenza, yellow fever, rotavirus, bacterial pneumonia, and human papillomavirus, among others. In addition, 18 countries and territories carried out supplementary activities such as deworming, vitamin A supplementation, growth monitoring, cancer screening, distribution of water filters, body-mass-index (BMI) screening, and foot care demonstrations for people with diabetes.

- **Vaccination Week in the Eastern Mediterranean: Stop measles now!**
  www.emro.who.int/vpi/vpi-news/2013-vaccination-week.html
  All 22 countries participated with the aim to increase visibility of the region's measles elimination target for 2015 and draw the attention of policy-makers, partners, medical community and the public.

  Afghanistan held the second round of National Immunization Days (NIDs) for polio eradication in conjunction with Vaccination Week. **Kuwait** held training sessions for healthcare workers. **Lebanon** implemented a measles vaccination campaign and vaccinated 630,000 children between nine months and 18 years of age. **Libya** organized a scientific seminar on the introduction of new vaccines, measles elimination and other important immunization activities. **Pakistan** (Balochistan) held vaccination campaigns for women of child-bearing age and tracked children with uncompleted vaccinations. **Somalia** introduced the 5-in-1 pentavalent vaccine. Vaccination centres and mobile teams in **Sudan** intensified their efforts to trace children with uncompleted vaccinations and communicated with parents on the importance of immunization.

- European Immunization Week**: Protect. Prevent. Immunize.**
  All 53 countries participated. In addition to the local and national events taking place across the region, the EURO launched a series of new resources for promoting immunization www.euro.who.int/en/what-we-do/health-topics/disease-prevention/vaccines-and-immunization/european-immunization-week/european-immunization-week-2013/new-immunization-resources-launched-in-eiw-2013, and guest bloggers contributed varying perspectives on the campaign site.
  EURO commissioned the development of the design frame and code for an "immunization app" for smart phones which advises parents when vaccinations of members of their family are due according to national schedules.

Slovenia conducted workshops for paediatricians and school doctors on communicating with parents about vaccination. Catch-up vaccination campaigns were launched in Austria, France and the United Kingdom. In France, all 26 regions cooperated with doctors, nurses, midwives, pharmacists and a wide variety of health- care organizations were involved. Efforts were made to reach out to populations that could have been missed, such as prisoners, young people and refugees. A film was made in sign language for the deaf. Belgium conducted a campaign using the slogan "Give measles the final jab!". European Immunization Week 2013 saw Germany and Switzerland move from paper to online vaccination records. Both countries ran humorous poster campaigns on this topic.

- **Immunization Week in South-East Asia: Intensification of routine immunization.**
  www.searo.who.int/entity/immunization/immunization_week_searo/en/index.html
  Eight countries participated. A wide variety of products were developed or adapted for country contexts. SEARO developed a new regional brand and logo, produced campaign a toolkit with key messages, planning tool, immunization factsheet for countries.
  Bhutan enhance awareness on the importance of immunization for the communities through print media. Live radio talks, question and answer sessions were organized between the health authorities and the general public to clarify any doubts on immunization. **India** organized over 124,000 immunization sessions throughout the country. Preliminary data showed that more than 2.1 million vaccinations were given to children under two years of age and over 254,000 pregnant women. **Indonesia** organized media workshops, issued press release on routine immunization and announced the rollout of pentavalent vaccine. A talk show with the Minister of Health, midwives association and religious leaders was screened on TV. **Myanmar** conducted polio immunization campaigns in Rakhine state where conflict and migration issues have reduced routine immunization coverage.

- **Immunization Week in the Western Pacific: Finish the job – No more measles for anyone.**
  www.wpro.who.int/world_immunization_week/en/
  30 countries participated in a variety of ways, from advocacy meetings with high-level officials in Viet Nam to live broadcast of children's TV shows in Korea. WPRO urged countries to intensify efforts to immunize all children, particularly those in hard-to-reach communities and remote areas. WPRO also held an exhibit highlighting the importance of immunization, and the region's progress in eliminating measles.

ANNEX 2

Article: A systematic review of interventions for reducing parental vaccine refusal and vaccine hesitancy, Alina Sadaf and al, Vaccine

In Press, Uncorrected Proof, Available online 13 July 2013.
Please refer to web link: http://www.sciencedirect.com/science/article/pii/S0264410X13009353

Abstract

Unvaccinated individuals pose a public health threat to communities. Research has identified many factors associated with parental vaccine refusal and hesitancy toward childhood and adolescent immunizations. However, data on the effectiveness of interventions to address parental refusal are limited. We conducted a systematic review of four online databases to identify interventional studies.
We used criteria recommended by the WHO's SAGE for the quality assessment of studies. Intervention categories and outcomes were evaluated for each body of evidence and confidence in overall estimates of effect was determined. There is limited evidence to guide implementation of effective strategies to deal with the emerging threat of parental vaccine refusal. There is a need for appropriately designed, executed and evaluated intervention studies to address this gap in knowledge.

Highlights

- Unvaccinated individuals put communities at risk of disease.
- Parental vaccine refusal and hesitance is an emerging issue.
- Authors conducted a systematic review for interventions to reduce refusal/hesitance.
- Authors found limited evidence on effective strategies to guide policy makers.
- There is a need for appropriately designed, executed and evaluated intervention studies.

ANNEX 3

Article: Measuring vaccine confidence: analysis of data obtained by a media surveillance system used to analyze public concerns about vaccines, Heidi J Larson and Al, Lancet Infectious Diseases

Published online 13 May 2013.
http://dx.doi.org/10.1016/S1473-3099(13)70108-7
http://www.sciencedirect.com/science/article/pii/S1473309913701087#

STRATEGIC OBJECTIVE 3

THE BENEFITS OF IMMUNIZATION ARE EQUITABLY EXTENDED TO ALL PEOPLE

INDICATOR SO3.1

PERCENTAGE OF DISTRICTS (OR EQUIVALENT ADMINISTRATIVE UNIT) WITH 80% OR GREATER COVERAGE WITH THREE DOSES OF DIPHTERIA-TETANUS-PERTUSSIS CONTAINING VACCINE

TARGET
ALL MEMBER STATES WITH ALL DISTRICTS $\geq$ 80% DTP3 COVERAGE BY 2020

SECRETARIAT FOCAL POINT FOR DATA: MARTA GACIC, DAVID BROWN, LAURE DUMOLARD & JAN GREVENDONK

DEFINITION OF THE INDICATOR

Percentage of district or equivalent administrative unit (referred to as "district" for the purposes of this report) with at least 80% of coverage for DTP3.

DESCRIPTION OF DATA'S SOURCES

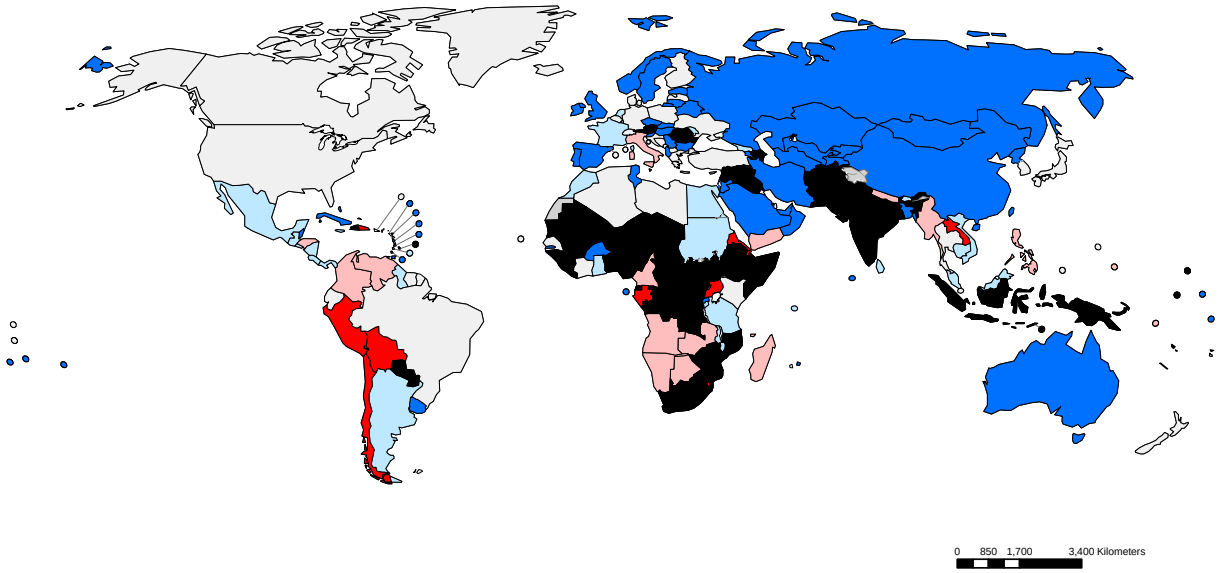
For JRF and WUENIC, please refer to generic note at the beginning of the report "Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC".

COMMENTS ON DATA'S QUALITY

Please refer to generic note at the beginning of the report "Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC" and the Goal 3 report for an assessment of the district level coverage data quality.

DESCRIPTION OF THE RESULTS

Map 7: Member States with % of districts with DTP3 coverage ≥80% for 2012 (including the Member States, where district data are considered as not valid- indicated in the hatched shading)



< 50% *(20 Member States or 10%, with 10 MS having district data considered as not valid)*

50-79 % *(27 Member States or 14% with 10 MS having district data considered as not valid)*

80-99 % *(40 Member States or 21% with 12 MS having district data considered as not valid)*

All districts *(63 Member States or 32% with 4 MS having district data considered as not valid)*

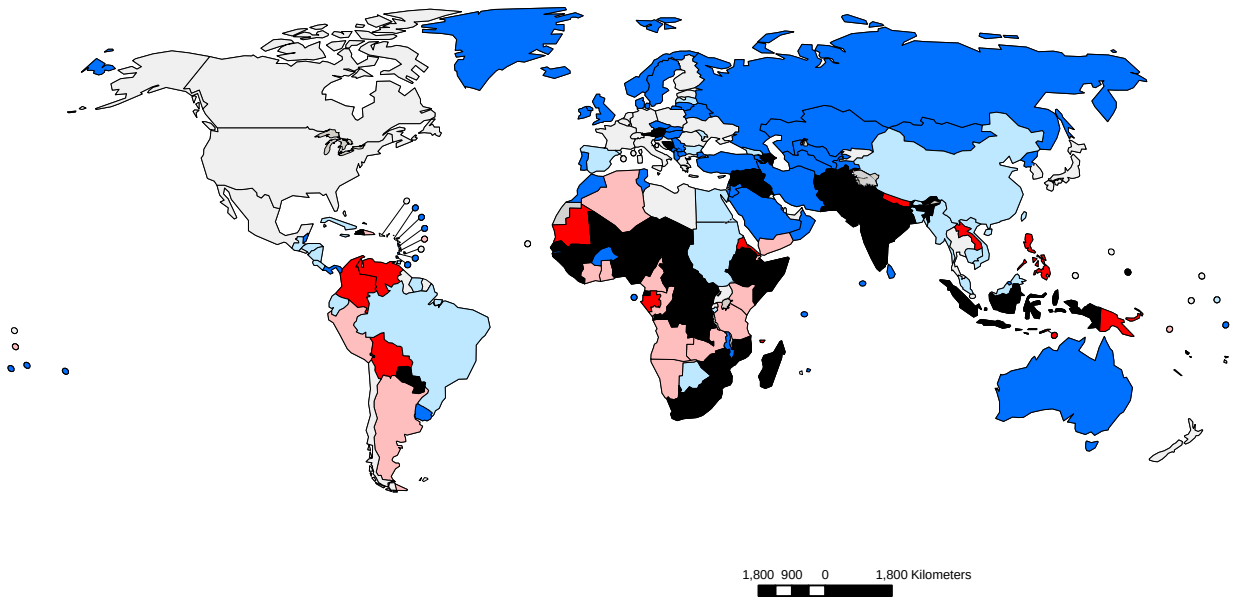
Not available *(44 Member States or 23% with 4 MS having district data considered as not valid)*

Not applicable

WHO-UNICEF estimate is less than 90% or WHO UNICEF estimates differ from Country administrative coverage *and therefore District data are considered as not valid (40 Member States or 21%)*

Source: WHO-UNICEF coverage estimates 2013 revision and JRF as at 11 July 2013.
Map production: Immunization Vaccines and Biologicals, (IVB). World Health Organization
Date of slide: 16 July 2013

Map 8: Member States with % of districts with DTP3 coverage ≥80% for 2010 (including the Member States where district data are considered as not valid – indicated in the hatched shading)



< 50% *(23 Member States or 12% with 11 MS having district data considered as not valid)*

80-99 % *(35 Member States or 18% with 6 MS having district data considered as not valid)*

50-79 % *(32 Member States or 16% with 14 MS having district data considered as not valid)*

All districts *(59 Member States or 30% with 3 MS having district data considered as not valid)*

Not available *(44 Member States or 23% with 2 MS having district data considered as not valid)*

Not applicable

WHO UNICEF estimates differ from Country administrative coverage *(36 Member States or 19%)*

Source: WHO-UNICEF coverage estimates 2013 revision. Map production: Immunization Vaccines and Biologicals, (IVB). World Health Organization

Date of slide: 23 July 2013

Table 20: Distribution of Member States per % of districts achieving ≥80% of coverage for DTP3, per region in 2012

	With valid district data										No valid district data				
	100% districts with DTP3 ≥ 80%		80-99% districts with DTP3 ≥ 80%		50-79% districts with DTP3 ≥ 80%		0-49% districts with DTP3 ≥ 80%		Total		District level data not reported		District Data available but considered as not valid		Total
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N
AFR	5	11%	5	11%	7	15%	4	9%	21	46%	5	11%	20	43%	46
PAHO	10	29%	10	29%	3	9%	4	11%	27	77%	6	17%	2	6%	35
EMR	7	32%	3	14%	1	5%	1	5%	12	55%	4	18%	6	27%	22
EUR	26	49%	5	9%	1	2%	0	0%	32	60%	19	36%	2	4%	53
SEAR	3	27%	2	18%	2	18%	0	0%	7	64%	2	18%	2	18%	11
WPR	8	30%	3	11%	3	11%	1	4%	15	56%	8	30%	4	15%	27
Total	59		28		17		10		114		44		36		194

NARRATIVE

District level data are available for 150 Member States. However, as per the definition used, District level coverage data were available and considered as valid for only 114 of the 194 Member States. Of these, DTP3 coverage was ≥ 80% in all districts in 59 Member States.

When district level data, irrespective of whether they were considered valid, were reviewed, in 20 Member States <50% of districts had achieved DTP3 ≥ 80%. These included Bolivia, Central African Republic, Chile, Djibouti, Dominican Republic, Eritrea, Gabon, Equatorial Guinea, Haiti, Lao PDR, Lesotho, Mauritania, Nigeria, Peru, Papua New Guinea, Paraguay, Somalia, South Sudan, Swaziland, and Uganda.

When the analysis was restricted to only those Member States with valid district data, in 10 Member States, <50% of districts had achieved DTP3 ≥ 80%. These included Bolivia, Chile, Djibouti, Dominican Republic, Eritrea, Gabon, Lao PDR, Peru, Swaziland and Uganda. However, it may be noted that many of the Member States with low coverage and uncertain data quality are excluded from this analysis and, therefore, it does not provide a complete picture of geographic equity in coverage.

Since the number of Member States with valid district level data varies by year, it is difficult to comment on trends.

The lack of valid district level data in several Member States in sub-Saharan Africa and in Asia are an impediment to tracking this indicator, especially in Member States where equity in coverage would be most important. The main reason for the lack of validity is that uncertainty around the actual population

estimates increases at the district levels. Therefore, coverage estimates are often crude (and sometimes misleading) tool to manage immunization programs and monitor coverage equity.

On way to remedy this would be through assessments of district level coverage. Such studies may also serve to identify and address factors that may be contributing to low local coverage. An alternative way to manage district level coverage and monitor geographical, social and ethnic inequities would be through the implementation of electronic nominal registries.

HIGHLIGHTS

- 21% (40) of Member States have WUENIC estimates differing from Administrative data.
- 10 Member States have less than 50% of their districts achieving a DTP3 coverage above 80%.
- 17 Member States have between 50% and 79% of their districts achieving a DTP3 coverage above 80%.
- In EUR, 35.8% and in WPR 29.6% of the Member States did not provide districts level data.
- Lack of valid district level data in several Member States in sub-Saharan Africa and in Asia.

STRATEGIC OBJECTIVE 3

THE BENEFITS OF IMMUNIZATION ARE EQUITABLY EXTENDED TO ALL PEOPLE

INDICATOR SO3.2

REDUCTION IN COVERAGE GAPS BETWEEN WEALTH QUINTILES AND OTHER APPROPRIATE EQUITY INDICATOR(S)

TARGET
INCREASING TREND IN EQUITY IN IMMUNIZATION COVERAGE
PROPORTION OF MEMBER STATES WITH <20% DIFFERENCE IN COVERAGE BETWEEN WEALTH QUINTILES
60% BY 2015 AND 75% BY 2020

DEFINITION OF THE INDICATOR

Diphtheria, tetanus toxoid and pertussis third dose (DTP3) immunization coverage among 1-year-olds distributed by wealth quintiles (%) for the period 2008-2011.

For the proposed period 2008-2011 (surveys 2009-2012), only 15 Member States had data available in the WHO database.

To increase the number of Member States, we included all the surveys conducted from 2008 (therefore including data of 2007), this increases the total number of Member States to 24 (Zimbabwe has conducted two surveys).

DESCRIPTION OF DATA'S SOURCES

- **WHO Health Equity Monitor Database of the Global Health Data repository.**

This database (http://apps.who.int/gho/data/node.main.HE-1540?lang=en) currently include about 30 reproductive maternal, neonatal and child health indicators disaggregated by child's sex, place of residence (rural vs. urban), wealth quintile and educational level. The data are based on international health surveys (DHS and MICS) conducted in 91 Member States, 90 of which are low or middle income Member States. Health inequality data are subject to a cautious interpretation due to several types of limitations (please refer to the "Handbook on health inequality monitoring with a special focus on low- and middle-income Member States").
http://apps.who.int/iris/bitstream/10665/85345/1/9789241548632_eng.pdf

- The survey data on equity: http://apps.who.int/gho/data/node.main.HE-1540?lang=en
- Immunization data: http://apps.who.int/gho/data/node.main.HE-1585?lang=en

Method of estimation

Data for this analysis are derived from re-analysis of DHS and MICS micro-data, which are publicly available, using the standard indicator definitions for estimating household wealth, as published in DHS

or UNICEF documentation. The analysis was done by the International Center for Analysis and Monitoring of Equity in Health and Nutrition based in the Federal University of Pelotas, Brazil.

Since estimates of household wealth and immunization coverage are only available through DHS and MICS surveys, these data cannot be generated for each country on an annual basis.

The operational definition for this indicator sets the baseline using data from any survey from 2009 or later (e.g. coverage in the 2008 birth cohort or later). The number of Member States for which the data are available from 2008 (survey 2009) is limited (14 Member States). The current analysis includes all the surveys conducted since 2008 (including then data from 2007), it does include 24 Members States (Zimbabwe has conducted two surveys in 2010 and 2011).

These data will be compared with data from subsequent surveys in future analysis. For those Member States that do not have a survey since 2009, the baseline will need to be established once these data become available.

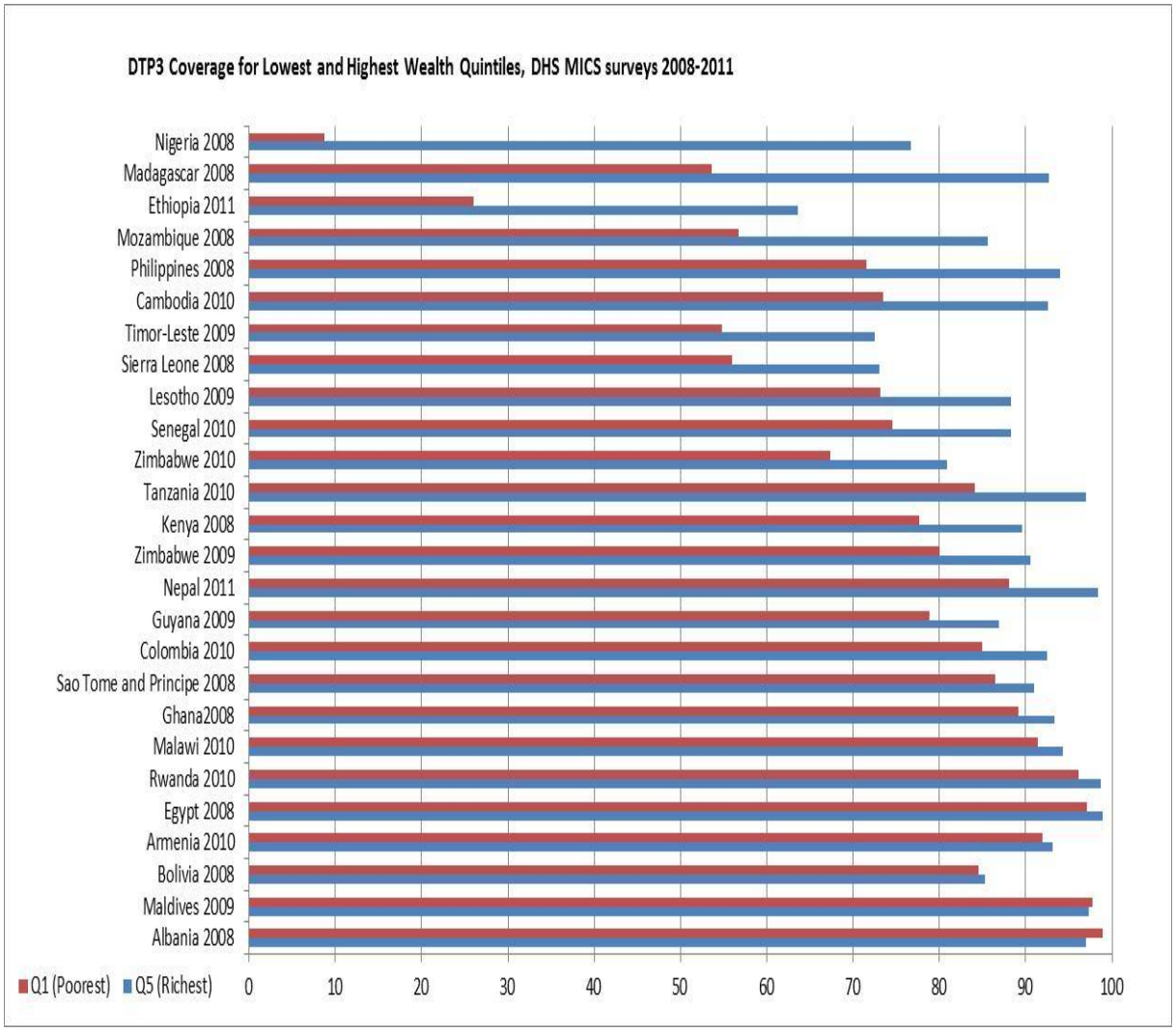
The UN Secretary General's Global Strategy for Women's and Children's Health recommends household surveys every three years for the 75 countdown Member States. Hence, we expect that at least this subset of Member States will have three sets of data during the decade to monitor reduction in coverage inequities.

COMMENTS ON DATA'S QUALITY

In general, standard indicator definitions, as published in DHS and MICS, were used. In a few cases there may be minor differences between the data reported here and in previous DHS or MICS country reports due to small discrepancies in the definition and calculation or some indicators. Detailed information about the indicator criteria applied in all WHO-defined categories is available in the WHO Indicator and Measurement Registry (http://www.who.int/gho/indicator_registry/en/).

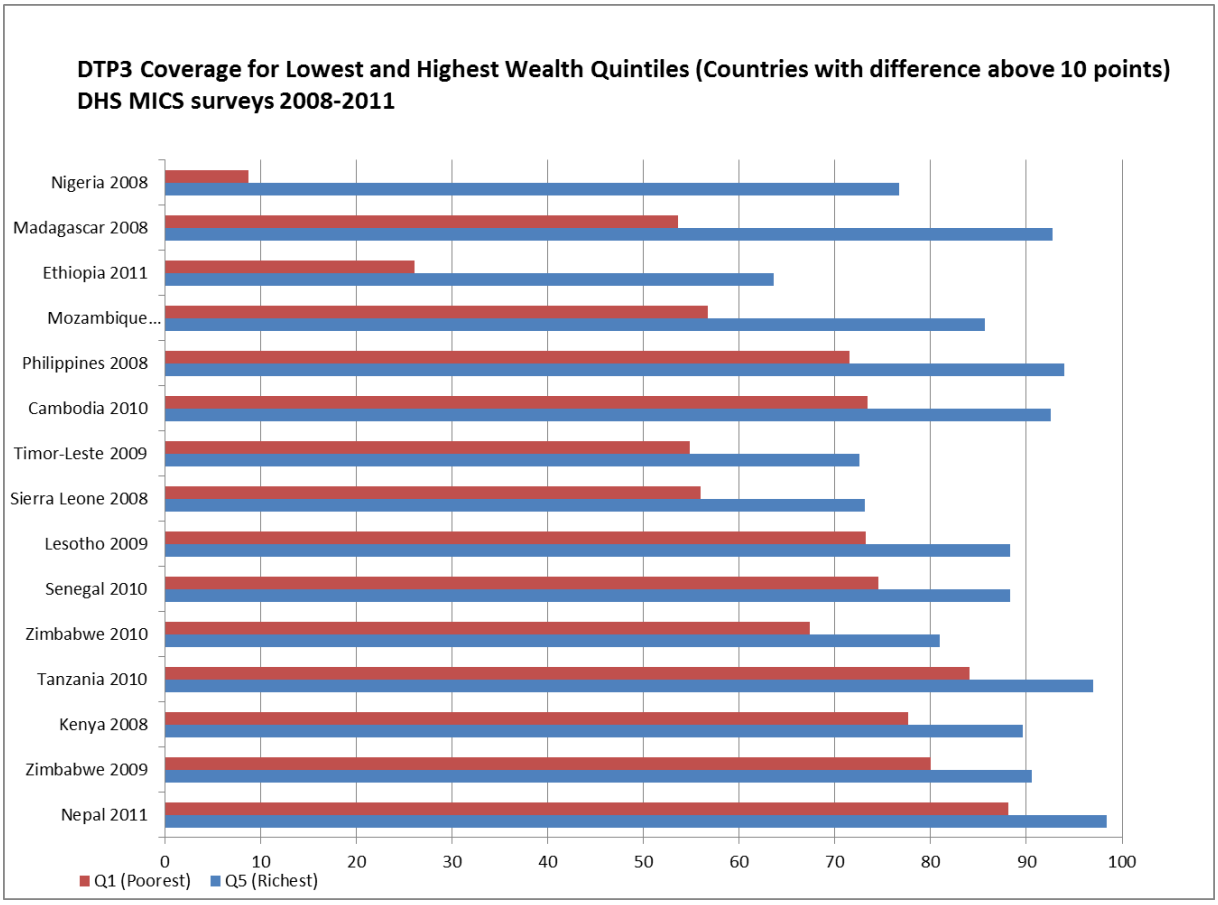
DESCRIPTION OF THE RESULTS

Figure 5: DTP3 Coverage for Lowest and Highest Wealth Quintiles 2007-2010



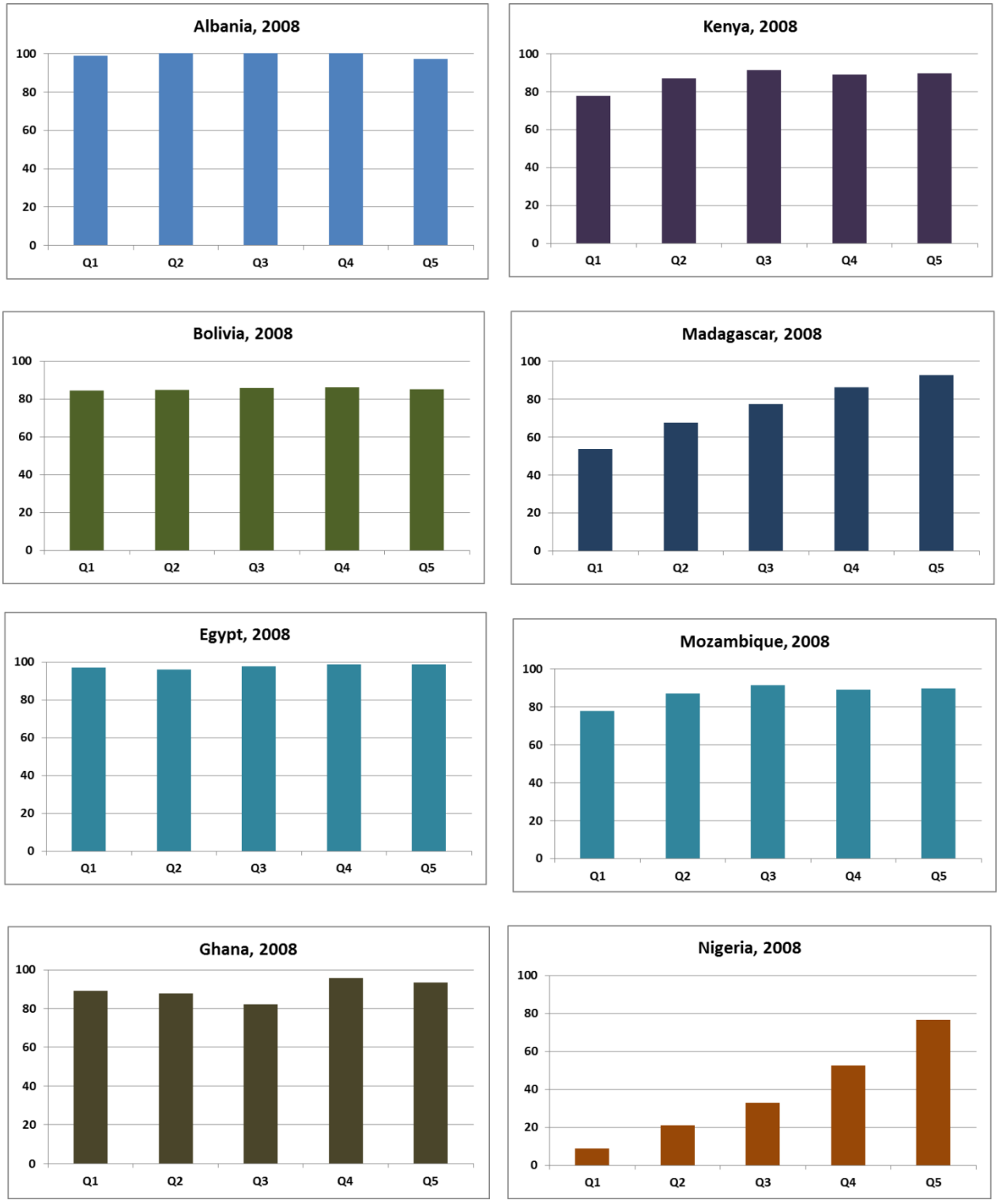
Source: DHS MICS surveys 2008-2011

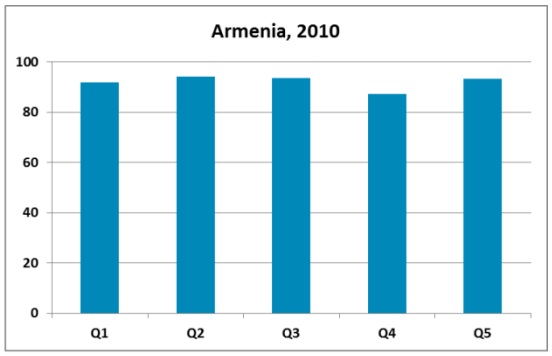
Figure 6: DTP3 Coverage for Lowest and Highest Wealth Quintiles 2007-2010, only Member States with difference above 10 points

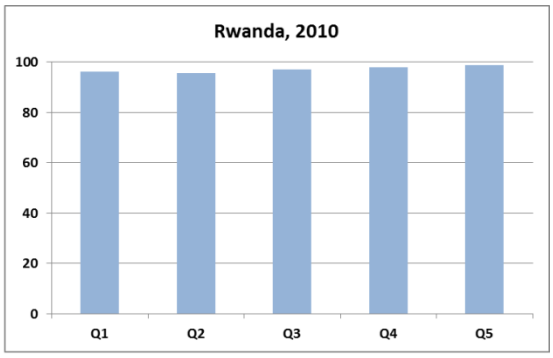


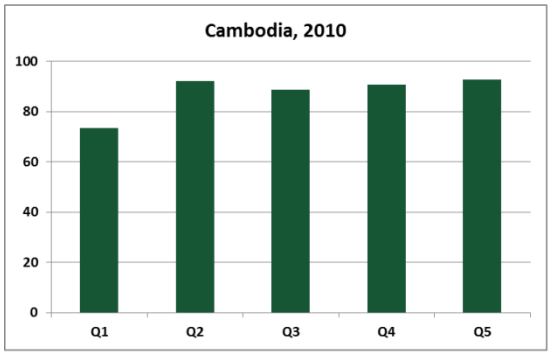
Source: DHS MICS surveys 2008-2011

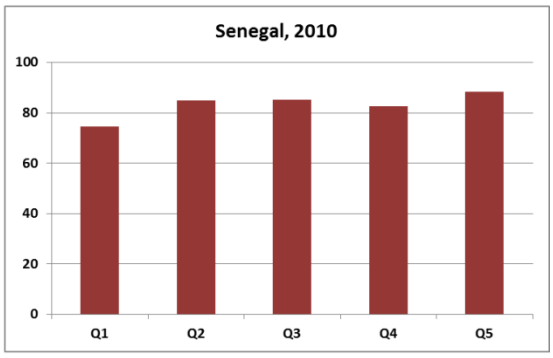
Figure 7: DTP3 national coverage by wealth quintile for all the Member States with data available between 2007-2011 (surveys 2008-2012)

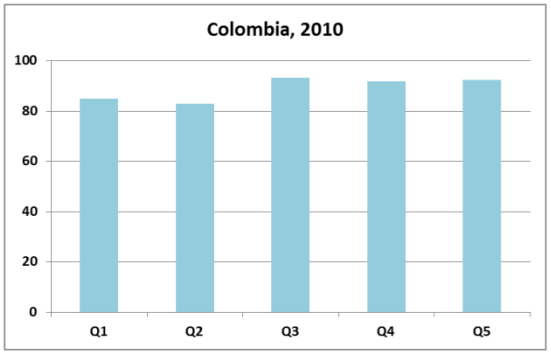


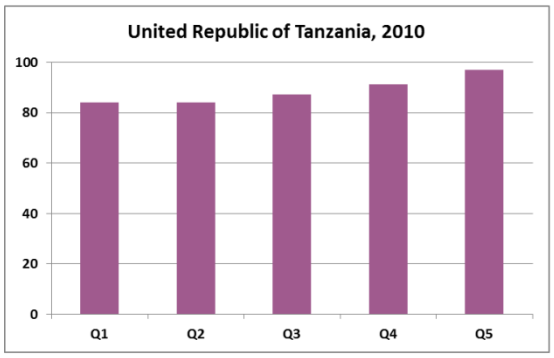

Armenia, 2010
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

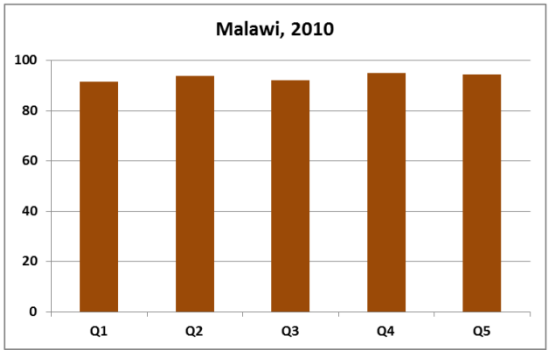

Rwanda, 2010
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

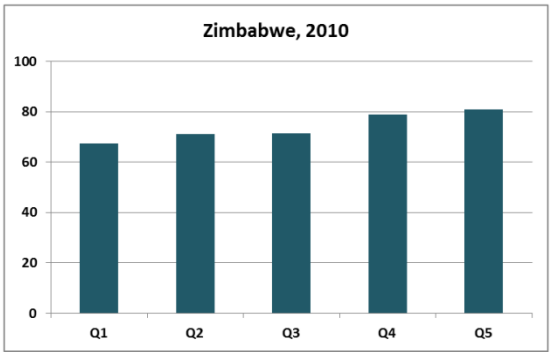

Cambodia, 2010
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

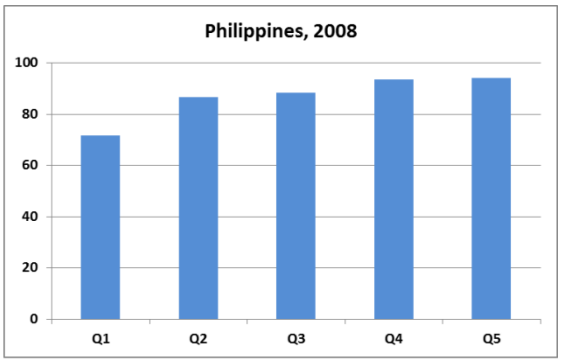

Senegal, 2010
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

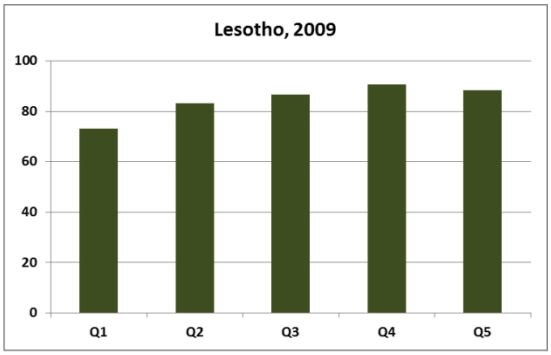

Colombia, 2010
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

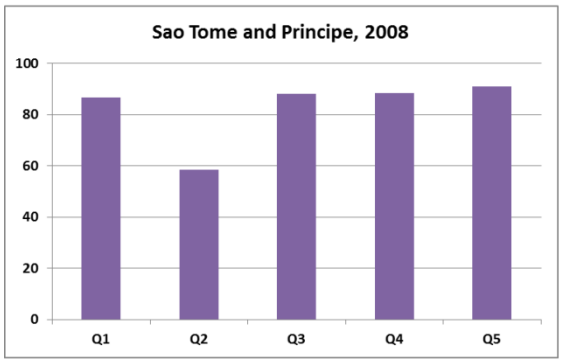

United Republic of Tanzania, 2010
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

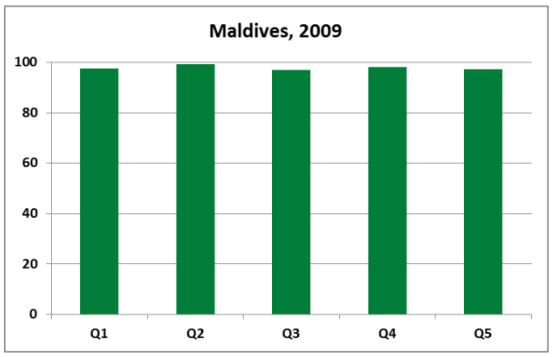

Malawi, 2010
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

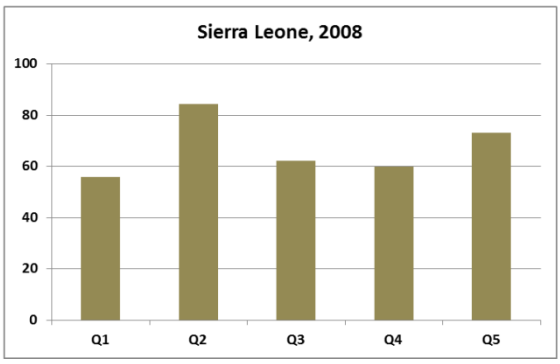

Zimbabwe, 2010
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

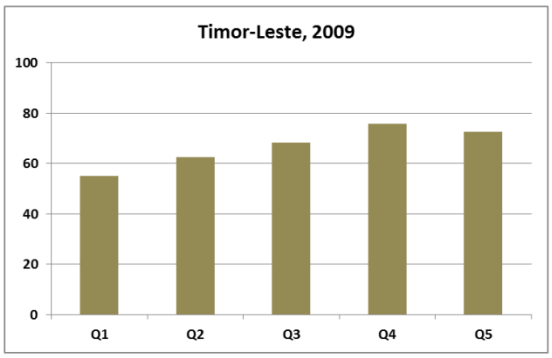

Philippines, 2008
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

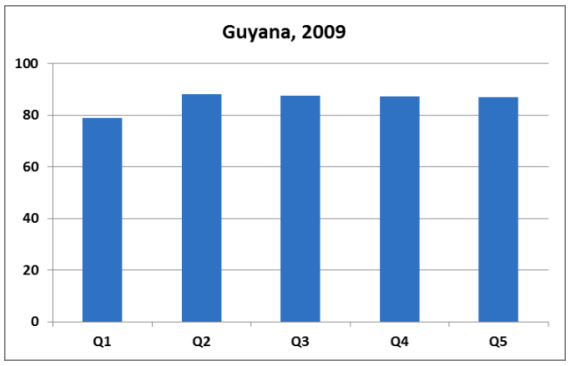

Lesotho, 2009
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

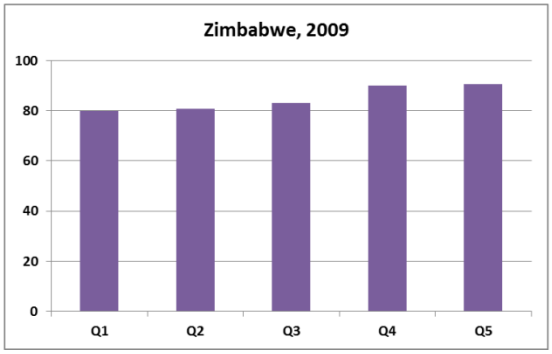

Sao Tome and Principe, 2008
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

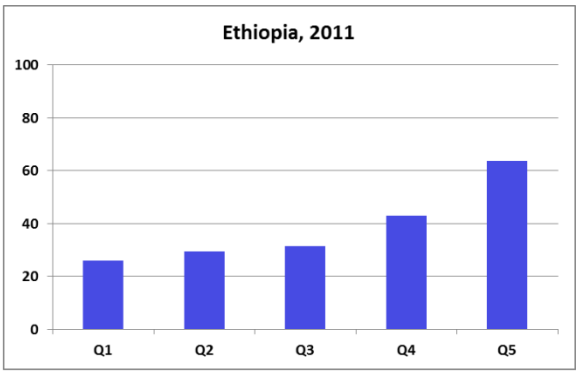

Maldives, 2009
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

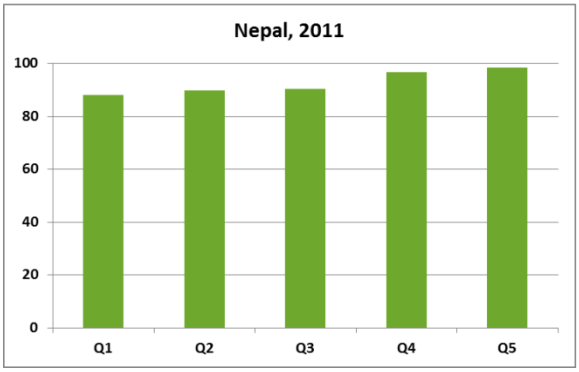

Sierra Leone, 2008
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5


Timor-Leste, 2009
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5


Guyana, 2009
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5


Zimbabwe, 2009
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5


Ethiopia, 2011
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5


Nepal, 2011
100
80
60
40
20
0
Q1
Q2
Q3
Q4
Q5

NARRATIVE

DTP3 coverage data, stratified by wealth quintiles were available for 24 Member States for the year 2007-2010 (surveys 2008-2001). These data represent the baseline for these Member States (Figure 5).

In 13 of these Member States the estimated DTP3 coverage was higher by 10% or more in the richest quintile compared to the poorest. They include Cambodia (2010), Ethiopia (2011), Kenya (2008), Lesotho (2009), Madagascar (2008), Mozambique (2008), Nepal (2011), Nigeria (2008), Philippines (2008), Senegal (2010), Sierra Leone (2008), Tanzania (2010), Timor-Leste (2009) and Zimbabwe (2009 and 2010), (see Figure 6, Figure 7). In five of these Member States, the difference was 20% or greater (Ethiopia, Madagascar Mozambique, Nigeria and Philippines).

The coverage in the poorest quintile was higher than that in the richest quintile in Albania and the Maldives.

The coverage by wealth quintile for each country is shown in the country graphs in Annex 1. These graphs indicate that the highest and lowest coverage is not necessarily in the richest and poorest quintile, respectively. While in a few Member States (e.g. Madagascar and Nigeria), house hold wealth appears to be a strong determinant of coverage with a progressive increasing coverage with increasing household wealth. In most other Member States the patterns of coverage between the different wealth quintiles are variable, without the clear progression in coverage by wealth quintile, as observed in Madagascar and Nigeria.

In general, Member States with high national coverage are likely to have less difference in coverage between wealth quintiles. Member States with less than 90% national DTP3 Member States that do not have baseline data from a recent survey are encouraged to conduct a survey to establish a baseline. Member States with differences in coverage of 10% or more are encouraged to take urgent measures to address inequities and conduct follow up surveys to document the impact of these measures.

HIGHLIGHTS

- Distribution of DTP3 national coverage by wealth quintiles is available for only 24 Member States for 2007-2010 (surveys 2008-2011).
- Except for two Member States (Albania and Maldives, both with very high national coverage), coverage was higher in the wealthiest quintile compared to the poorest quintile.
- In 14 Member States, the difference of DTP3 coverage between Wealthiest and Poorest quintile is greater than 10%.
- In 5 Member States, the difference of DTP3 coverage between Wealthiest and Poorest quintile is greater than 20%.
- In Madagascar and Nigeria a progressive increase in coverage with increasing household wealth was observed; in the remaining Member States, there was no such clear trend.

STRATEGIC OBJECTIVE 4

STRONG IMMUNIZATIONSYTEMS ARE AN INTEGRAL PART OF A WELL-FUNCTIONING HEALTH SYSTEM

INDICATOR SO4.1

DROPOUT RATE BETWEEN FIRST DOSE (DTP1) AND THIRD DOSE (DTP3) OF DIPHTERIA-TETANUS-PERTUSSIS CONTAINING VACCINES

TARGET
DECREASING TREND IN DROP-OUT RATES

SECRETARIAT FOCAL POINT FOR DATA: MARTA GACIC, DAVID BROWN & LAURE DUMOLARD

DEFINITION OF THE INDICATOR

The indicator is calculated using the formula (DTP1-DTP3)/DTP1 *100.

DESCRIPTION OF DATA'S SOURCES

Please refer to generic note "Understanding Immunization Coverage data: WHO-UNICEF JRF and WUENIC".

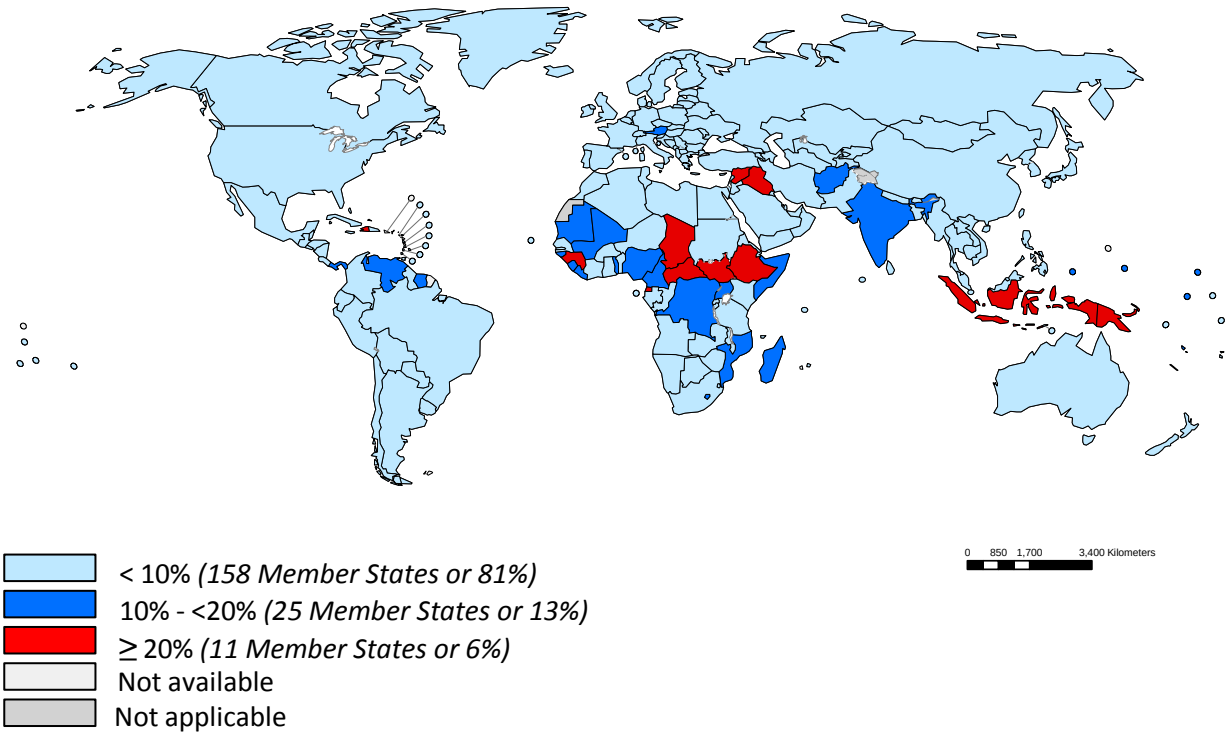
COMMENTS ON DATA'S QUALITY

Please refer to generic note "Understanding Immunization Coverage data: WHO-UNICEF JRF and WUENIC".

Data for this indicator are for 2010-2012 with the only exception of data for South Sudan being available only for 2011 and 2012.

DESCRIPTION OF THE RESULTS

Map 9: DTP1-DTP3 drop-out rate by country, 2012



Source: WHO-UNICEF coverage estimates 2013 revision and JRF as at 11 July 2013.
Map production: Immunization Vaccines and Biologicals, (IVB). World Health Organization
Date of slide: 16 July 2013

Figure 8: Member States for which the DTP1-DTP3 dropout rate ≥ 10% for the last three years 2010-2012

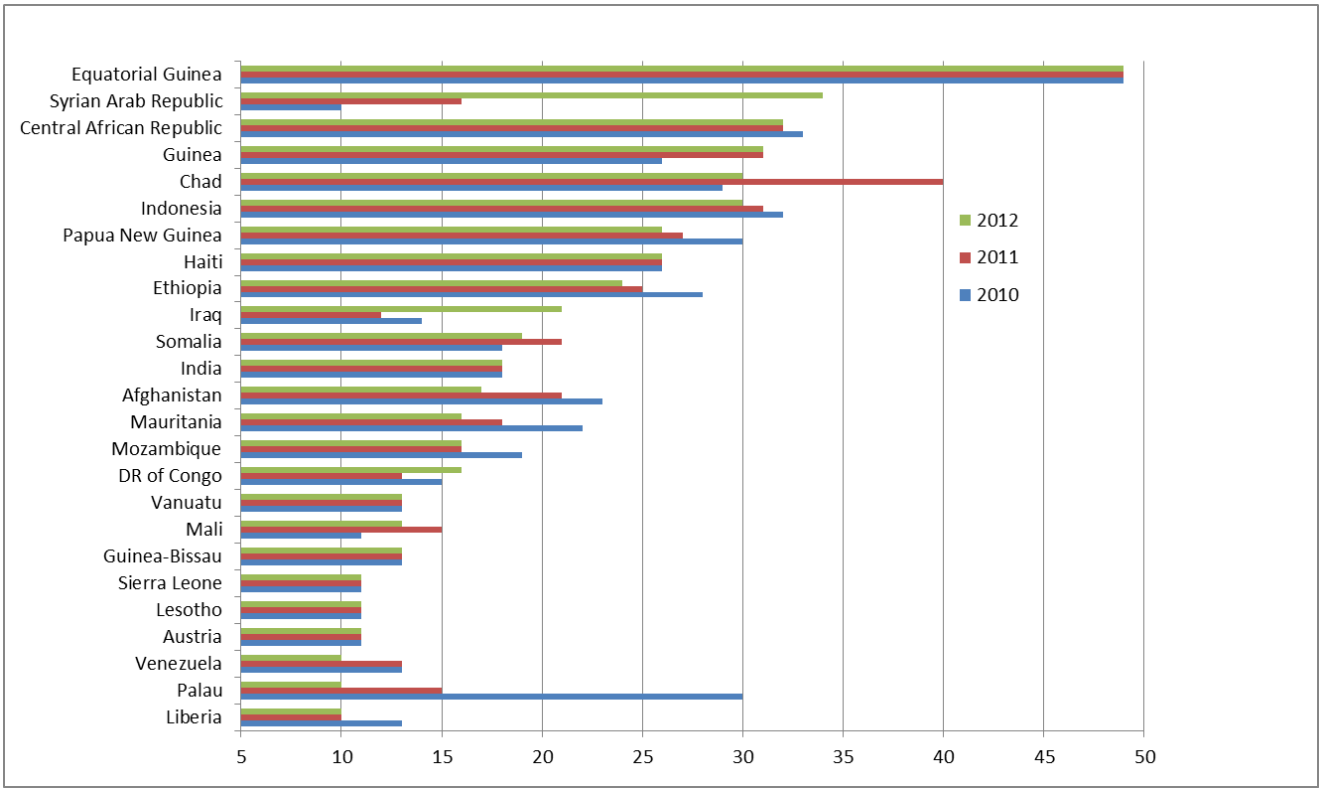


Table 21: Member States with DTP1-DTP3 dropout rate ≥10% for 2012 and showing an increasing trend for the last three years 2010-2012

Country	DTP1-DTP3 drop-out rate 2010	DTP1-DTP3 drop-out rate 2011	DTP1-DTP3 drop-out rate 2012
Cameroon	9	9	10
Suriname	3	4	11
Uganda	8	10	12
Nigeria	10	6	13
Panama	2	11	14
DR Congo	15	13	16
Micronesia	6	13	16
Marshall Islands	5	12	18
Nauru	0	0	19
Iraq	14	12	21
Syrian Arab Republic	10	16	34

Note: Member States are sorted by increasing DTP1-DTP3 dropout rate for 2012

Table 22: Member States with DTP1-DTP3 dropout rate ≥ 10% for 2012 showing a decreasing trend for the last three years 2010-2012

Country	DTP1-DTP3 drop-out rate 2010	DTP1-DTP3 drop-out rate 2011	DTP1-DTP3 drop-out rate 2012
Palau	30	15	10
Venezuela	13	13	10
Mauritania	22	18	16
Afghanistan	23	21	17
Ethiopia	28	25	24
Papua New Guinea	30	27	26
Indonesia	32	31	30

Note: Member States are sorted by increasing DTP1-DTP3 dropout rate for 2012

Table 23: Member States with DTP1-DTP3 dropout rate ≥10% for 2012 and showing a stable trend for the last three years 2010-2012

Country	DTP1-DTP3 drop-out rate 2010	DTP1-DTP3 drop-out rate 2011	DTP1-DTP3 drop-out rate 2012
Austria	11	11	11
Lesotho	11	11	11
Sierra Leone	11	11	11
Guinea-Bissau	13	13	13
Vanuatu	13	13	13
India	18	18	18
Haiti	26	26	26
Equatorial Guinea	49	49	49

Note: Member States are sorted by increasing DTP1-DTP3 dropout rate for 2012

Table 24: Member States with DTP1-DTP3 dropout rate ≥10% for 2012 and showing an inconsistent trend for the last three years 2010-2012

Country	DTP1-DTP3 drop-out rate 2010	DTP1-DTP3 drop-out rate 2011	DTP1-DTP3 drop-out rate 2012
Liberia	13	10	10
Madagascar	10	7	10
Togo	11	3	11
Mali	11	15	13
Mozambique	19	16	16
Somalia	18	21	19
Chad	29	40	30
Guinea	26	31	31
Central African Republic	33	32	32

Note: Member States are sorted by increasing DTP1-DTP3 dropout rate for 2012

NARRATIVE

In 2012, over 80% of Member States had dropout rates less than 10%. The number of Member States with dropout ≥ 10% rates have remained relatively static over the past 3 years, with 36 (18.6%) Member States in 2012, they were 35 in 2011 and 39 in 2010.

Among these 36 Member States:

- 11 had DTP1-DTP3 dropout rate ≥20%
  (Central African Republic, Chad, Equatorial Guinea, Ethiopia, Guinea, Haiti, Indonesia, Iraq, Papua New Guinea, South Sudan, Syrian Arab Republic,) and
- 25 had DTP1-DTP3 dropout rate 11-19%
  (Afghanistan, Austria, Cameroon, DR Congo, Micronesia (Federated States of), Guinea-Bissau, India, Liberia, Lesotho, Madagascar, Marshall Islands, Mali, Mozambique, Mauritania, Nigeria, Nauru, Panama, Palau, Sierra Leone, Somalia, Suriname, Togo, Uganda, Venezuela, Vanuatu).

Among the 36 Member States with a DTP1-DTP3 dropout rate ≥ 10%, 17 (47.2%) had a DTP1 national coverage above 90%, indicating that these Member States could achieve high national coverage if the reasons for the high dropout rates were identified and addressed. Among the 35 Member States for which we have the last three years data[37], 11 have seen their dropout rate increase between 2010-2012 period; 7 decrease; 8 remained stable and 9 had an inconsistent trend (see Table 21, Table 22, Table 23 and

Table 24). However, it has to be noted that sometimes the variation is minor (+/- 5%) and has to be interpreted carefully because of the data uncertainty.

Among Member States with an increasing dropout rate, a dramatic increase was observed in the Syrian Arab Republic, probably related to the ongoing conflict which originated in 2012. Significant increase in dropout rates were seen in five Member States, namely Iraq, Marshall Islands, Nauru, Panama and Suriname (three-fold increase in dropout rates between 2010 and 2012). However, most of these are Member States with small birth cohorts where small changes in numbers may have led to this observed effect. The only country where the dropout rate decreased by a factor of three was Palau; in others, the decreases were less striking.

The Member States with the highest dropout rates were also those with DTP3 < 70%. This indicates that the target populations have been able to access services, though not consistently, as a result of which the coverage with the full complement of services remains low. The fact that in many of these Member States the drop-out rates seem to be increasing or stagnating, suggests that no active measures are taken to identify causes of drop-out and address them. Identifying the causes for the dropouts and taking corrective measures could result in increases in vaccination coverage and put these Member States on track for achieving a coverage ≥ 90%.

In 2012, six Member States (Cameroon, Madagascar, Nigeria, Nauru, Suriname and Togo) had a DTP1-DTP3 drop-out rate ≥ 10% when in 2011 the dropout rate was < 10%.

[37] South Sudan data are available for 2011 and 2012.

HIGHLIGHTS

In 2012

- 36 Member States had a DTP1-DTP3 dropout rate ≥ 10%.
- 11 Member States had DTP1-DTP3 dropout rate being ≥20%.
  (Central African Republic, Chad, Equatorial Guinea, Ethiopia, Guinea, Haiti, Indonesia, Iraq, Papua New Guinea, South Sudan, Syrian Arab Republic).
- Six Member States (Cameroon, Madagascar, Nigeria, Nauru, Suriname and Togo) had a DTP1-DTP3 dropout rate ≥10% when in 2011 the dropout rate was < 10%.

STRATEGIC OBJECTIVE 4

STRONG IMMUNIZATIONSYTEMS ARE AN INTEGRAL PART OF A WELL-FUNCTIONING HEALTH SYSTEM

INDICATOR SO4.2

SUSTAINED COVERAGE OF DIPHTERIA-TETANUS-PERTUSSIS CONTAINING VACCINES 90% FOR THREE OR MORE YEARS

TARGET: ALL MEMBER STATES BY 2020

SECRETARIAT FOCAL POINT FOR DATA: MARTA GACIC, DAVID BROWN & LAURE DUMOLARD

DEFINITION OF THE INDICATOR

National coverage for DTP3 is maintained ≥ 90% for at least three consecutive years 2010, 2011 and 2012.

DESCRIPTION OF DATA'S SOURCES

Please refer to generic note " Understanding Immunization Coverage data: WHO-UNICEF Joint Reporting Form (JRF) and WHO-UNICEF Estimates of National Infant Immunization Coverage (WUENIC)".

COMMENTS ON DATA'S QUALITY

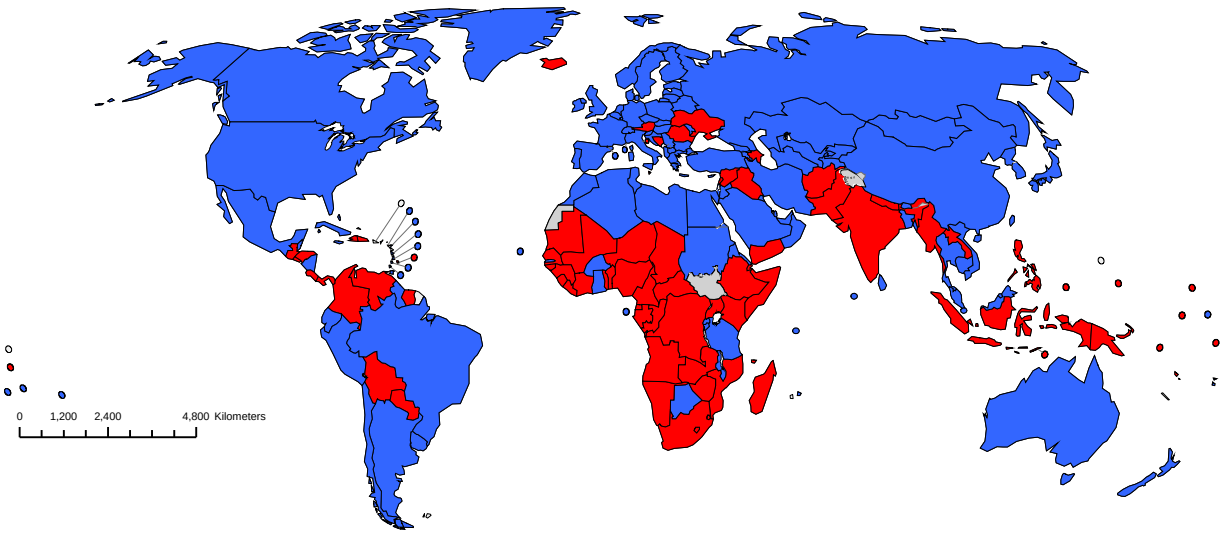
Please refer to generic note "Understanding Immunization Coverage data: WHO-UNICEF JRF and WUENIC".

As South Sudan became a WHO Member State in 2011, this country was not included in the analysis for this indicator.

In Member States where the WUENIC is based primarily on estimates from periodic coverage surveys, which may be conducted at intervals of three years or more, this is a difficult indicator to reliably measure since year-to-year changes in coverage cannot be captured on a yearly basis.

DESCRIPTION OF THE RESULTS

Map 10: Member States that have sustained a DTP3 national level coverage ≥ 90% for the last three years, 2010-2012



< 90% *(77 Member States or 40%)*

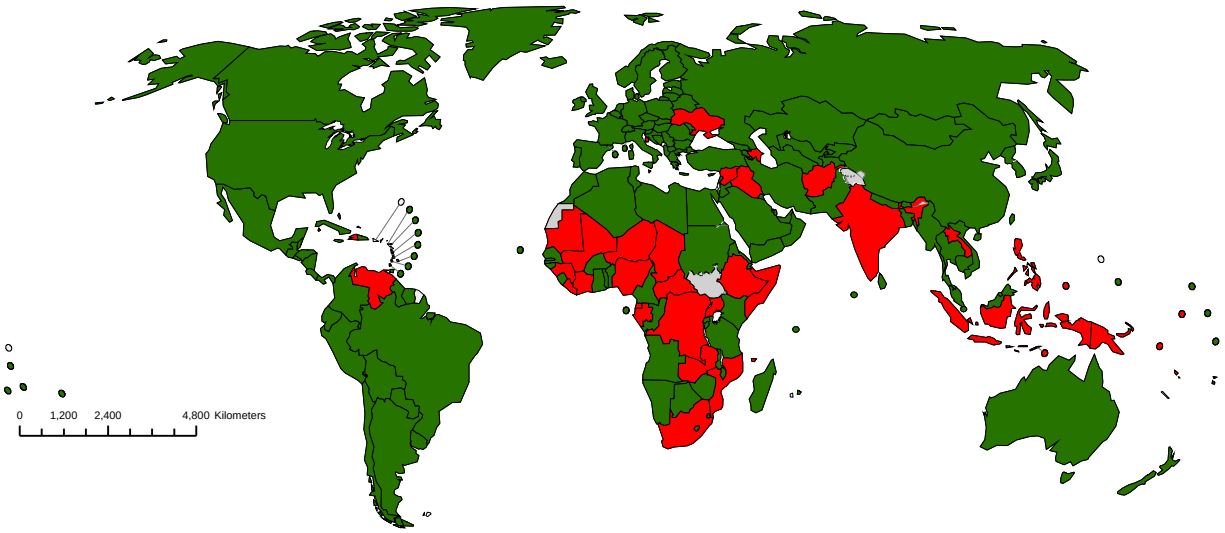
≥90% *(116 Member States or 60%)*

Not applicable

Not available

Source: WHO-UNICEF coverage estimates 2013 revision and JRF as at 11 July 2013.
Map production: Immunization Vaccines and Biologicals, (IVB). World Health Organization
Date of slide: 16 July 2013

Map 11: Member States that have sustained a DTP3 national level coverage ≥ 80% for the last three years, 2010-2012



< 80 % *(38 Member States or 20%)*
≥80 *(155 Member States or 80%)*
Not available
Not applicable

Source: WHO-UNICEF coverage estimates 2013 revision and JRF as at 11 July 2013.
Map production: Immunization Vaccines and Biologicals, (IVB). World Health Organization
Date of slide: 16 July 2013

Table 25: List of Member States that have sustained DTP3 national level coverage ≥90% for the last two years only (2011 and 2012)

Country	WHO Region	GAVI country	Income Group	DTP3 2010	DTP3 2011	DTP3 2012
Nepal	SEAR	Yes	LIC	82	92	90
Samoa	WPR		LMIC	87	91	92
Senegal	AFR	Yes	LMIC	89	92	92
Swaziland	AFR		LMIC	89	91	95
Tuvalu	WPR		UMIC	89	96	97
Malta	EUR		HIC	76	96	99

Note: Member States are sorted by increasing DTP3 coverage rate for 2012

Table 26: List of Member States that have sustained DTP3 national coverage ≥90% for 2010 and 2011 but not in 2012

Country	DTP3 2010	DTP3 2011	DTP3 2012
Nauru	99	99	79
Congo	90	90	85
Honduras	95	91	88
Iceland	96	95	89

Note: Member States are sorted by increasing DTP3 coverage rate for 2012

Table 27: List of Member States have sustained DTP3 national level coverage ≥80% but <90% for the last three years (2010-2012)

Country	WHO Region	GAVI country	Income Group	DTP3 2010	DTP3 2011	DTP3 2012
Bolivia	AMR	Yes	LMIC	80	82	80
Guinea-Bissau	AFR	Yes	LIC	80	80	80
Djibouti	EMR	Yes	LMIC	88	87	81
Micronesia	WPR		LMIC	85	84	81
Pakistan	EMR	Yes	LMIC	86	80	81
Lebanon	EMR		UMIC	81	82	82
Yemen	EMR	Yes	LMIC	87	81	82
Austria	EUR		HIC	83	83	83
Kenya	AFR	Yes	LIC	83	88	83
Lesotho	AFR	Yes	LMIC	83	83	83
Namibia	AFR		UMIC	83	82	84
Sierra Leone	AFR	Yes	LIC	84	84	84
Benin	AFR	Yes	LIC	83	85	85
Cameroon	AFR	Yes	LMIC	84	82	85
Dominican Republic	AMR		UMIC	88	84	85
Madagascar	AFR	Yes	LIC	85	89	86
Paraguay	AMR		LMIC	89	89	87
Zimbabwe	AFR	Yes	LIC	89	89	89

Note: Member States are sorted by increasing DTP3 coverage rate for 2012

NARRATIVE

116 (60%) of Member States have achieved and sustained DTP3 ≥ 90% for the past three years. There is the possibility of six additional Member States also meeting the indicator in 2013 since they have increased their coverage to 90% or more in 2011 and sustained this in 2012. Unfortunately, four Member States that had achieved DTP3 ≥ 90% in 2010 and sustained it in 2011, dropped their coverage below the 90% threshold in 2012.

18 Member States that achieved DTP3 ≥ 80% in 2010 have failed to reach the desired threshold of ≥ 90%. This indicates the need for careful examination of the causes for un- or under-immunization and for innovative approaches to making the coverage leap from the 80s to the 90s over the next few years.

In some Member States where the WUENIC is based on coverage surveys, rather than on administrative data, year-to-year changes in coverage cannot be observed and revisions are only possible after the next survey which may be three or more years after the one on which the current estimates are based. Thus, the observed coverage stagnation is not always as a result of lack of action. This is true for some of the large Member States with large numbers of unimmunized children, e.g. India, Indonesia and Nigeria.

HIGHLIGHTS

- 116 (60%) of Member States achieved and sustained a DTP3 national level coverage ≥ 90% for the last three years (2010-2012).
- Six additional Member States sustained DTP 3 ≥ 90% for the past two years.
- 51 Member States never reached DTP3 national level coverage ≥ 90% in the last three years (2010-2012).
- 30 Member States showed a decreasing trend in DTP3 national level coverage for the last three years (DTP3 national level coverage in 2012<2011 or 2012<2010).

Table 28: List of Member States not sustaining DTP3 national level coverage ≥ 90% in the last three years, 2010-2012 ***(77 Member States)***

Country	WHO Region	GAVI country	Income Group	DTP3 2010	DTP3 2011	DTP3 2012
Equatorial Guinea	AFR		HIC	33	33	33
Nigeria	AFR	Yes	LMIC	54	45	41
Somalia	EMR	Yes	LIC	45	41	42
Chad	AFR	Yes	LIC	39	33	45
Syria	EMR		LMIC	80	72	45
Central African Republic	AFR	Yes	LIC	45	47	47
Guinea	AFR	Yes	LIC	64	59	59
Haiti	AMR	Yes	LIC	60	60	60
Ethiopia	AFR	Yes	LIC	63	65	61
Papua New Guinea	WPR	Yes	LMIC	56	61	63
Indonesia	SEAR	Yes	LMIC	62	62	64
Timor-Leste	SEAR	Yes	LMIC	72	67	67
South Africa	AFR		UMIC	66	72	68
Vanuatu	WPR		LMIC	68	68	68
Iraq	EMR		LMIC	74	79	69
Afghanistan	EMR	Yes	LIC	66	68	71
RD Congo	AFR	Yes	LIC	60	74	72
India	SEAR	Yes	LMIC	72	72	72
Mali	AFR	Yes	LIC	76	72	74
Niger (the)	AFR	Yes	LIC	70	75	74
Azerbaijan	EUR	Yes	UMIC	75	77	75
Mozambique	AFR	Yes	LIC	74	76	76
Ukraine	EUR	Yes	LMIC	52	50	76
Liberia	AFR	Yes	LIC	70	77	77
Uganda	AFR	Yes	LIC	80	82	78
Zambia	AFR	Yes	LMIC	83	81	78
Lao	WPR	Yes	LMIC	74	78	79
Nauru	WPR			99	99	79
Bolivia	AMR	Yes	LMIC	80	82	80
Guinea-Bissau	AFR	Yes	LIC	80	80	80
Marshall Islands	WPR		LMIC	94	87	80
Mauritania	AFR	Yes	LIC	64	75	80
Djibouti	EMR	Yes	LMIC	88	87	81
Micronesia	WPR		LMIC	85	84	81
Pakistan	EMR	Yes	LMIC	86	80	81
Venezuela	AMR		UMIC	78	78	81
Gabon	AFR		UMIC	67	75	82
Lebanon	EMR		UMIC	81	82	82
Yemen	EMR	Yes	LMIC	87	81	82
Austria	EUR		HIC	83	83	83
Kenya	AFR	Yes	LIC	83	88	83
Lesotho	AFR	Yes	LMIC	83	83	83
Namibia	AFR		UMIC	83	82	84

Table 28 (continued)

Country	WHO Region	GAVI country	Income Group	DTP3 2010	DTP3 2011	DTP3 2012
Sierra Leone	AFR	Yes	LIC	84	84	84
Suriname	AMR		UMIC	96	86	84
Togo	AFR	Yes	LIC	86	92	84
Benin	AFR	Yes	LIC	83	85	85
Cameroon	AFR	Yes	LMIC	84	82	85
Congo (the)	AFR	Yes	LMIC	90	90	85
Dominican Republic	AMR		UMIC	88	84	85
Myanmar	SEAR	Yes	LIC	90	86	85
Panama	AMR		UMIC	94	87	85
Comoros (the)	AFR	Yes	LIC	74	83	86
Madagascar	AFR	Yes	LIC	85	89	86
Philippines	WPR		LMIC	79	80	86
Barbados	AMR		HIC	86	91	87
Paraguay	AMR		LMIC	89	89	87
Honduras	AMR	Yes	LMIC	95	91	88
Iceland	EUR		HIC	96	95	89
Palau	WPR		UMIC	69	84	89
Romania	EUR		UMIC	94	89	89
Zimbabwe	AFR	Yes	LIC	89	89	89
Nepal	SEAR	Yes	LIC	82	92	90
Solomon Islands	WPR	Yes	LMIC	79	88	90
Angola	AFR	Yes	UMIC	91	86	91
Costa Rica	AMR		UMIC	88	85	91
Bosnia and Herzegovina	EUR		UMIC	89	88	92
Colombia	AMR		UMIC	88	85	92
El Salvador	AMR		LMIC	92	89	92
Samoa	WPR		LMIC	87	91	92
Senegal	AFR	Yes	LMIC	89	92	92
Côte d'Ivoire	AFR	Yes	LMIC	85	62	94
Swaziland	AFR		LMIC	89	91	95
Guatemala	AMR		LMIC	94	88	96
San Marino	EUR		HIC	79	86	96
Tuvalu	WPR		UMIC	89	96	97
Malta	EUR		HIC	76	96	99

Table 29: List of Member States that have never reached DTP3 national level coverage ≥ 90% in the last three years, 2010-2012 ***(51 Member States)***

Country	WHO Region	GAVI country	Income Group	DTP3 2010	DTP3 2011	DTP3 2012
Equatorial Guinea	AFR		HIC	33	33	33
Nigeria	AFR	Yes	LMIC	54	45	41
Somalia	EMR	Yes	LIC	45	41	42
Chad	AFR	Yes	LIC	39	33	45
Syria	EMR		LMIC	80	72	45
Central African Republic	AFR	Yes	LIC	45	47	47
Guinea	AFR	Yes	LIC	64	59	59
Haiti	AMR	Yes	LIC	60	60	60
Ethiopia	AFR	Yes	LIC	63	65	61
Papua New Guinea	WPR	Yes	LMIC	56	61	63
Indonesia	SEAR	Yes	LMIC	62	62	64
Timor-Leste	SEAR	Yes	LMIC	72	67	67
South Africa	AFR		UMIC	66	72	68
Vanuatu	WPR		LMIC	68	68	68
Iraq	EMR		LMIC	74	79	69
Afghanistan	EMR	Yes	LIC	66	68	71
DR Congo	AFR	Yes	LIC	60	74	72
India	SEAR	Yes	LMIC	72	72	72
Mali	AFR	Yes	LIC	76	72	74
Niger (the)	AFR	Yes	LIC	70	75	74
Azerbaijan	EUR	Yes	UMIC	75	77	75
Mozambique	AFR	Yes	LIC	74	76	76
Ukraine	EUR	Yes	LMIC	52	50	76
Liberia	AFR	Yes	LIC	70	77	77
Uganda	AFR	Yes	LIC	80	82	78
Zambia	AFR	Yes	LMIC	83	81	78
Lao	WPR	Yes	LMIC	74	78	79
Bolivia	AMR	Yes	LMIC	80	82	80
Guinea-Bissau	AFR	Yes	LIC	80	80	80
Mauritania	AFR	Yes	LIC	64	75	80
Djibouti	EMR	Yes	LMIC	88	87	81
Micronesia	WPR		LMIC	85	84	81
Pakistan	EMR	Yes	LMIC	86	80	81
Venezuela	AMR		UMIC	78	78	81
Gabon	AFR		UMIC	67	75	82
Lebanon	EMR		UMIC	81	82	82
Yemen	EMR	Yes	LMIC	87	81	82
Austria	EUR		HIC	83	83	83
Kenya	AFR	Yes	LIC	83	88	83
Lesotho	AFR	Yes	LMIC	83	83	83
Namibia	AFR		UMIC	83	82	84
Sierra Leone	AFR	Yes	LIC	84	84	84
Benin	AFR	Yes	LIC	83	85	85

Table 29 (continued)

Country	WHO Region	GAVI country	Income Group	DTP3 2010	DTP3 2011	DTP3 2012
Cameroon	AFR	Yes	LMIC	84	82	85
Dominican Republic	AMR		UMIC	88	84	85
Comoros	AFR	Yes	LIC	74	83	86
Madagascar	AFR	Yes	LIC	85	89	86
Philippines	WPR		LMIC	79	80	86
Paraguay	AMR		LMIC	89	89	87
Palau	WPR		UMIC	69	84	89
Zimbabwe	AFR	Yes	LIC	89	89	89

Table 30: List of Member States showing an increasing trend in DTP3 national level coverage for the last three years (DTP3 national level coverage in 2012>2011 or 2012>2010) ***(42 Member States)***

Country	WHO Region	GAVI country	Income Group	DTP3 2010	DTP3 2011	DTP3 2012
Chad	AFR	Yes	LIC	39	33	45
Papua New Guinea	WPR	Yes	LMIC	56	61	63
Indonesia	SEAR	Yes	LMIC	62	62	64
Afghanistan	EMR	Yes	LIC	66	68	71
Ukraine	EUR	Yes	LMIC	52	50	76
Lao	WPR	Yes	LMIC	74	78	79
Mauritania	AFR	Yes	LIC	64	75	80
Venezuela	AMR		UMIC	78	78	81
Gabon	AFR		UMIC	67	75	82
Namibia	AFR		UMIC	83	82	84
Cameroon	AFR	Yes	LMIC	84	82	85
Comoros	AFR	Yes	LIC	74	83	86
Philippines	WPR		LMIC	79	80	86
Palau	WPR		UMIC	69	84	89
Solomon Islands	WPR	Yes	LMIC	79	88	90
Costa Rica	AMR		UMIC	88	85	91
Bosnia and Herzegovina	EUR		UMIC	89	88	92
Colombia	AMR		UMIC	88	85	92
Samoa	WPR		LMIC	87	91	92
Trinidad and Tobago	AMR		HIC	90	90	92
UR Tanzania	AFR	Yes	LIC	91	90	92
Côte d'Ivoire	AFR	Yes	LMIC	85	62	94
Denmark	EUR		HIC	90	91	94
Cambodia	WPR	Yes	LIC	92	94	95
Norway	EUR		HIC	93	94	95
Peru	AMR		UMIC	93	91	95
Swaziland	AFR		LMIC	89	91	95
DPR Korea (the)	SEAR	Yes	LIC	93	94	96
Guatemala	AMR		LMIC	94	88	96
San Marino	EUR		HIC	79	86	96
Bhutan	SEAR	Yes	LMIC	91	95	97
Guyana	AMR	Yes	LMIC	95	93	97
Italy	EUR		HIC	96	96	97
Tuvalu	WPR		UMIC	89	96	97
UK	EUR		HIC	94	95	97
Viet Nam	WPR	Yes	LMIC	93	95	97
Belize	AMR		LMIC	96	95	98
Gambia (the)	AFR	Yes	LIC	97	96	98
Rwanda	AFR	Yes	LIC	97	97	98
Maldives	SEAR		UMIC	96	96	99
Malta	EUR		HIC	76	96	99
Mexico	AMR		UMIC	95	97	99

Table 31: List of Member States showing a decreasing trend in DTP3 national level coverage for the last three years (DTP3 national level coverage in 2012<2011 or 2012<2010) ***(30 Member States)***

Country	WHO Region	GAVI country	Income Group	DTP3 2010	DTP3 2011	DTP3 2012
Nigeria	AFR	Yes	LMIC	54	45	41
Syria	EMR		LMIC	80	72	45
Ethiopia	AFR	Yes	LIC	63	65	61
Iraq	EMR		LMIC	74	79	69
Uganda	AFR	Yes	LIC	80	82	78
Zambia	AFR	Yes	LMIC	83	81	78
Nauru	WPR			99	99	79
Marshall Islands (the)	WPR		LMIC	94	87	80
Djibouti	EMR	Yes	LMIC	88	87	81
Micronesia	WPR		LMIC	85	84	81
Suriname	AMR		UMIC	96	86	84
Togo	AFR	Yes	LIC	86	92	84
Congo (the)	AFR	Yes	LMIC	90	90	85
Myanmar	SEAR	Yes	LIC	90	86	85
Panama	AMR		UMIC	94	87	85
Paraguay	AMR		LMIC	89	89	87
Honduras	AMR	Yes	LMIC	95	91	88
Iceland	EUR		HIC	96	95	89
Brunei Darussalam	WPR		HIC	95	97	90
Burkina Faso	AFR	Yes	LIC	91	91	90
Chile	AMR		UMIC	92	94	90
Argentina	AMR		UMIC	94	92	91
Qatar	EMR		HIC	97	93	92
Egypt	EMR		LMIC	97	96	93
Brazil	AMR		UMIC	98	99	94
Tonga	WPR		LMIC	99	99	95
Dominica	AMR		UMIC	98	98	97
Tunisia	EMR		UMIC	98	98	97
Oman	EMR		HIC	99	99	98
Seychelles	AFR		UMIC	99	99	98

STRATEGIC OBJECTIVE 4

STRONG IMMUNIZATION SYTEMS ARE AN INTEGRAL PART OF A WELL-FUNCTIONING HEALTH SYSTEM

INDICATOR SO4.3

IMMUNIZATION COVERAGE DATA ASSESSED AS HIGH QUALITY BY WHO AND UNICEF

TARGET: ALL MEMBER STATES HAVE HIGH QUALITY IMMUNIZATION COVERAGE DATA BY 2020

SECRETARIAT FOCAL POINT: MARTA GACIC-DOBO, DAVID BROWN & ANTHONY BURTON

DEFINITION OF THE INDICATOR

In the absence of any other source of information to make a judgment of the quality of the coverage data, the WUENIC Grade of Confidence (GoC) for DTP3 coverage is used as a proxy for this indicator.

The WUENIC are based on data and information that are of varying, and, in some instances, unknown quality.

Beginning with the 2011 revision, WHO-UNICEF describes the GoC WHO-UNICEF have in the WUENIC. This assessment is made for the estimates of national coverage for BCG, DTP1[38], DTP3[39], Pol3[40], MCV[41], HepB3[42], Hib3[43], RotaC[44], and PcV3[45] for each country each year. As there is no underlying probability model upon which the estimates are based, WHO-UNICEF are unable to present classical measures of uncertainty, e.g., confidence intervals. Moreover, WHO-UNICEF have chosen not to make subjective estimates of plausibility/certainty ranges around the coverage. The GoC reflects the degree of empirical support upon which the estimates are based. It is not a judgment of the quality of data reported by national authorities.

DESCRIPTION OF DATA'S SOURCES

Administrative and official coverage estimates reported on WHO-UNICEF JRF. Coverage survey results, births, surviving infants from "United Nations, Population Division. The World Population Prospects - the 2010 revision", New York, 2013.

[38] First dose of DTP vaccine
[39] Third dose of DTP vaccine
[40] Third dose of polio vaccine
[41] First dose of measles containing vaccine
[42] Third dose of hepatitis B vaccine
[43] Third dose of Hib vaccine
[44] Last dose (second or third, depending on the vaccine) of rotavirus vaccine
[45] Third dose of Pneumococcal Conjugate Vaccine

COMMENTS ON DATA'S QUALITY

High GoC (3) is assigned when WUENIC is supported by reported data[R+], coverage recalculated with an independent denominator from the World Population Prospects(D+), and at least one supporting survey within two years [S+]. While well supported, the estimate still carries a risk of being wrong.

Moderate GoC (2) is assigned when estimate is supported by at least one data source; [R+], [S+], or [D+]; and no data source, [R-], [D-], or [S-], challenges the estimate.

Low GoC (1) is assigned when there are no directly supporting data; or data from at least one source; [R-], [D-], [S-]; challenge the estimate.

All estimates should be used with caution and should be assessed in light of the objective for which they are being used.

DESCRIPTION OF THE RESULTS

Table 32: Distribution of Member States by GoC for DTP3 Coverage Estimates for 2010-2012

	Country 2012 % (n)	Country 2011 % (n)	Country 2010 % (n)
Low GoC	56.7 (110)	53.6 (104)	49.2 (95)
Moderate GoC	39.7 (77)	38.7 (75)	44 (85)
High GoC	3.6 (7)	7.7 (15)	6.7 (13)
Total	100 (194)	100 (194)	100 (193)

Table 33: Distribution of Member States above and below National DTP3 coverage of 90% (WUENIC) by GoC for Coverage Estimates for 2012

	DTP3 ≥90% % (n)	DTP3 <90% % (n)
Low GoC	51.9 (68)	66.7 (42)
Moderate GoC	45 (59)	28.6 (18)
High GoC	3.1 (4)	4.8 (3)
Total	100 (131)	100(63)

NARRATIVE

It is important to understand that the GoC is not a data quality indicator *per se*.The GoC Indicator reflects only the confidence WHO-UNICEF have in the WUENIC estimates. However, when the GoC is high we can consider that data are of good quality, since the coverage estimates from more than one source are consistent with each other. On the other hand, the data quality may be very high even though it is from a single source (e.g. in Member States with well-functioning and accurate nominal registries), but may receive a low GoC if they did not report their data to WHO, or a medium GoC if their data were not supported by data from a recent survey.

For Member States where DTP3 national coverage WUENIC estimates are ≥ 90% a large proportion are assigned a medium GoC, possibly because a fewer number of these Member States conduct surveys, in addition to administrative reports, to estimate immunization coverage.

The use of the GoC is a suboptimal indicator of the quality of coverage estimates from the Member States and attempts are required to find a more suitable alternate for assessing quality.

HIGHLIGHTS

- The GoC related to the WUENIC is a suboptimal but it is the only currently available indicator to assess coverage data quality from all Member States.
- At least half of the Member States have additional data supporting the reported coverage estimates, with no contradictory estimates from any other source.
- For only 3.6% of the Member States, WHO-UNICEF have a high GoC for DTP3 coverage data.

STRATEGIC OBJECTIVE 4

STRONG IMMUNIZATIONSYTEMS ARE AN INTEGRAL PART OF A WELL-FUNCTIONING HEALTH SYSTEM

INDICATOR SO4.4

NUMBER OF MEMBER STATES WITH CASE-BASED SURVEILLANCE FOR VACCINE PREVENTABLE DISEASES

MEASLES

TARGET: 100% OF MEMBER STATES FOR POLIO AND MEASLES SURVEILLANCE BY 2015

SECRETARIAT FOCAL POINT: MEASLES: PETER STREBEL

DEFINITION OF THE INDICATOR

Availability at the national level of a database (or line listing) of each reported measles (or rubella) case with key demographic variables as well as laboratory results and final case classification.

DESCRIPTION OF DATA'S SOURCES

- Monthly surveillance reports to WHO.
- JRF and WUENIC coverage data: please refer to generic note at the beginning of the report "Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC".

COMMENTS ON DATA'S QUALITY

- JRF and WUENIC coverage data: Please refer to generic note at the beginning of the report.
- Surveillance data can be biased by under-reporting because not all patients with measles seek care, not all of those who seek care are reported by healthcare workers, and some reports of cases may not reach the central level. The proportion of true cases that are reported varies from fewer than 5% to up to 50%, depending on multiple reasons such as disease incidence, overall quality of the surveillance system and communications activities.
- Surveillance systems capture measles deaths even less than measles cases. The gap largely comes about because a measles-associated death is defined as any death occurring in the four to six weeks after rash onset that is not clearly due to other causes (e.g. trauma), while cases reported through the surveillance system typically are seen in the first few days after rash onset. Most of the measles-associated deaths are from respiratory causes (e.g. croup, pneumonia), diarrhoea or encephalitis. Often, at the time of death, the earlier episode of measles may be forgotten or is not noted on the death certificate.

DESCRIPTION OF THE RESULTS

Please refer to following documents:

- 2012 Measles & Rubella Initiative annual report http://www.who.int/immunization_delivery/adc/measles/MRI_2012_Annual_Report.pdf
- Progress in global control and regional elimination of measles, 2000–2011, WER 18 January 2013 http://www.who.int/wer/2013/wer8803.pdf
- Status Report submitted to SAGE in November 2012 http://www.who.int/immunization/sage/meetings/2012/november/1_Status_Report_Measles_Rubella_22_Oct.pdf
- Report on the 10th WHO Global Measles Rubella Laboratory Network Meeting WHO Headquarters, Geneva, Switzerland, 25 - 27 June 2012 (not publicly available)
- Report on the 11th WHO Global Measles Rubella Laboratory Network Meeting, 2013, Geneva (draft).

Please refer to Tables summarizing measles, rubella and CRS cases and incidence in respective indicators.

NARRATIVE

Summary 2012 Measles & Rubella Initiative (M&RI) annual report

The epidemiological standards for epidemiological surveillance for measles and rubella are based on case-based surveillance with laboratory confirmation, in-depth outbreak investigations, and identification of viral genotypes from every outbreak. National integrated measles and rubella surveillance systems must cover each nation completely, and perform with sufficient sensitivity to detect any ongoing transmission. Surveillance data should then be used to improve programme performance. The indicator the M&RI uses to track surveillance performance is the number and proportion of Member States with measles incidence of less than five cases per million population.

Surveillance for measles and rubella has steadily improved globally. It has demonstrated the reduction in measles cases, even as surveillance has become more sensitive in more Member States, including laboratory confirmation through the WHO Measles and Rubella Laboratory Network.

The improvements global measles surveillance over time are notable. Between 2000 and 2011, the number of Member States annually reporting measles surveillance data to WHO increased from 169 (88%) to 188 (97%). Between 2004 and 2011, the number of Member States using the recommended case-based surveillance increased from 120 (62%) to 183 (94%). From 2000 to 2011, the number of Member States with access to standardized quality controlled measles testing by the WHO Measles and Rubella Laboratory Network increased from 71 (37%) to 191 (98%).

Laboratory supported case-based surveillance

Case-based measles surveillance has been established in 183 Member States (94%) with 11 Member States[46] still to implement it nationwide. The WHO Global Measles and Rubella Laboratory Network includes 690 laboratories organized in a tiered structure that provides diagnostic and virus

[46] Algeria, Comoros, Guinea-Bissau, Mauritius, Seychelles, Sao Tome and Principe, Somalia, South Sudan, San Marino, India, Thailand

characterization capacity. The critical role of the laboratory network is under recognized and increasing efforts are being made to showcase its value for money. The laboratory network needs to be scaled up in some large Member States (e.g. India and Indonesia) and expanded to include the remaining Member States. There is a shortfall of US$ 1 million in 2013 for enhancing rubella molecular surveillance which is required for monitoring progress towards rubella elimination.

Performance indicators repeatedly show that the field investigation component of measles and rubella surveillance is lagging behind and some Member States with elimination goals (e.g. in the EUR) are not reporting measles and rubella case-based data to the EURO. Guidelines are being developed for establishing sentinel CRS surveillance and the capacity for technical assistance is being expanded through training both regional and country focal points as well as a pool of consultants in a standard approach for conducting assessments of national surveillance systems. Combining measles/rubella surveillance reviews with AFP surveillance and new vaccine surveillance assessments will allow more frequent focus on this critical component of the programme. There is a need for updated guidance and standard procedures for conducting integrated VPD surveillance reviews. In addition, there is the opportunity and expectation that measles/rubella surveillance will take over some of the costs to maintain the AFP surveillance network (e.g. salaries for surveillance officers who currently do surveillance for measles and other VPDs as well as polio).

Financial and human resource to conduct country-wide, case-based surveillance with laboratory confirmation of cases remains inadequate. Filling the resource gaps will require stronger commitments and contributions from the Member States, failing which the verification of measles elimination may be a jeopardy for lack of meeting the surveillance quality indicators.

HIGHLIGHTS

- 184/194 Member States have established measles case-based surveillance.
- 183/194 Member States have access to diagnostic services for Measles and Rubella/CRS as part of the WHO Measles/Rubella Global Lab Network.
- Rubella cases and, to an even greater extent, CRS cases are grossly under-reported.
- Significant resource gaps exist to support high quality case-based surveillance for Measles, Rubella and CRS.

REFERENCES

- Global measles and rubella strategic plan: 2012-2020, WHO http://www.measlesinitiative.org
- Progress in global control and regional elimination of measles, 2000–2011, WER 18 January 2013 http://www.who.int/wer/2013/wer8803.pdf
- 2012 Measles & Rubella Initiative (M&RI) annual report http://www.who.int/immunization_delivery/adc/measles/MRI_2012_Annual_Report.pdf
- Status Report submitted to SAGE in November 2012 http://www.who.int/immunization/sage/meetings/2012/november/1_Status_Report_Measles_Rubella_22_Oct.pdf
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- Meeting of SAGE, November 2012 – conclusions and recommendations, WER, 4 January 2013, 88th year, 1, 2013, 88, 1–16.
  http://www.who.int/wer/2013/wer8801.pdf

Additional documents

- http://www.measlesinitiative.org/vgn-ext-templating/v/index.jsp/vgnextoid/815c081a7a593210VgnVCM10000089f0870aRCRD.html
- http://www.who.int/immunization_monitoring/laboratory_measles_resources/en/

STRATEGIC OBJECTIVE 4
STRONG IMMUNIZATIONSYTEMS ARE AN INTEGRAL PART OF A WELL-FUNCTIONING HEALTH SYSTEM

INDICATOR SO4.4
NUMBER OF COUNTRIES WITH CASE-BASED SURVEILLANCE FOR VACCINE PREVENTABLE DISEASES

TARGET: 75% OF LOW AND MIDDLE INCOME COUNTRIES FOR SENTINEL SITE SURVEILLANCE BY 2020

WHO FOCAL POINT: SENTINEL SURVEILLANCE: MARY AGOCS & SINGH SIMARJIT

DEFINITION OF THE INDICATOR

The number of countries that report conducting case-based surveillance, including laboratory confirmation for rotavirus and invasive bacterial vaccine preventable diseases (IB-VPD), at one or more hospital-based sentinel sites, data from which are included in the WHO data bases.

DESCRIPTION OF DATA'S SOURCES

- Data reported annually through the WHO-UNICEF JRF ; and
- Data reported by sentinel sites participating in a WHO-coordinated surveillance network.

Joint Reporting Form

The current JRF requests information on the presence of surveillance systems for rotavirus and IB-VPD, including laboratory confirmation of cases through two questions:

1. "Is there a surveillance system in place for invasive bacterial diseases (for example bacterial meningitis, sepsis or bacteraemic pneumonia), in which suspected cases are confirmed by laboratory and surveillance data could provide information to allow evaluation of the impact of vaccination against Hib and/or Pneumococcus?"
2. "Is there a surveillance system for rotavirus diarrhoea, in which cases are cases are confirmed by laboratory and surveillance data could provide information to allow evaluation of the impact of vaccination against rotavirus?"

Responses to these questions provide information as to whether countries have a surveillance system in place, though not all the sites may be reporting data to WHO. The sites that do not participate in the WHO-coordinated surveillance network currently do not report surveillance data to WHO.

WHO-Coordinated Sentinel Hospital Surveillance Networks

WHO works closely with Member States to coordinate hospital-based sentinel surveillance for invasive bacterial diseases and rotavirus diarrhoea.[47] The surveillance focuses primarily on children < 5 years if age and the specific pathogens targeted include *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Neisseria meningitides* in children with suspected pneumonia, meningitis or sepsis and rotavirus in children with hospitalized diarrhoea. All WHO-coordinated sites use standard case definitions[4849] and

[47] New and Underutilized Vaccine Implementation (NUVI): Monitoring and Surveillance (http://www.who.int/nuvi/surveillance/en/)

[48] Case definitions: Invasive Bacterial Vaccine Preventable Diseases (http://www.who.int/nuvi/surveillance/IB-VPD_Case_Defs.pdf)

laboratory methods[50] and report data to the respective WHO regional offices monthly or quarterly; the regional data are consolidated every six months into a global data base and global surveillance bulletins are published every six months. Member states participating in this network are mainly LIC and MIC who receive direct technical assistance from WHO. GAVI-eligible countries also receive financial support.

COMMENTS ON DATA'S QUALITY

Several HIC or MIC did not report on this indicator in the JRF, including countries such as the USA and Canada from where there are published reports on incidence of rotavirus and invasive bacterial diseases prior to and after use of vaccine.

There are also a few discrepancies in reporting of JRF data , since a few countries that participate in the WHO-coordinated surveillance and provide surveillance data to WHO, reported that they did not conduct surveillance in the JRF (described in the results section). In countries that do not participate in the WHO-coordinated surveillance, it is difficult to verify the JRF responses.

For sites participating in the WHO-coordinated surveillance network, regular site visits are conducted and an external laboratory quality assurance system has been put in place to establish and sustain high quality surveillance. However, gaps do exist in the quality and completeness of the data conducted at these sites and steps are being taken to continuously monitor and address gaps in quality of data.

For sites not participating in the WHO coordinated network, WHO does not currently have the resources or capacity to assess surveillance quality.

DESCRIPTION OF THE RESULTS

Joint Reporting Form

In 2012, for IB-VPD:

- 129 (67%) Member States noted that they had a surveillance system in place for invasive bacterial diseases (for example, bacterial meningitis, bacteraemic pneumonia, or sepsis).
- 43 (22%) Member States noted that they did not have such a surveillance system.
- 22 (11%) Member States replied that this question was not applicable (4 Member States) or did not reply (18 Member States).

In 2012, for rotavirus:

- 101 (52%) Member States noted that they had a surveillance system in place for rotavirus diarrhoea with suspect cases confirmed by laboratory and surveillance data.
- 71 (37%) Member States noted that they did not have such a surveillance system.
- 22 (11%) replied that this question was not applicable (three Member States) or did not reply (19 Member States).

[49] Rotavirus diarrhoea: case definitions (http://www.who.int/nuvi/surveillance/RV_Case_Defs.pdf)

[50] NUVI: resources for monitoring and surveillance
http://www.who.int/nuvi/surveillance/resources/en/index.html

Table 34: Countries reporting that they conduct sentinel site surveillance for rotavirus diarrhoea and IB-VPD in JRF, by WHO region

WHO Region	Total number Member States	Member States with rotavirus surveillance	Member States with IB-VPD surveillance
AFR	46	28	35
PAHO	35	23	25
EMR	22	14	15
EUR	53	23	35
SEAR	11	3	5
WPR	27	10	14
Total	194	101	129

The number of countries in the World Bank LIC and MIC categories that reported conducting surveillance for rotavirus diarrhoea and IB-VPD are shown in Table 2. Among LIC, 20 and 26, respectively, reported conducting rotavirus and IB-VPD surveillance. Among MIC, 57 and 65, respectively, reported conducting rotavirus and IB-VPD surveillance. Of the 73 GAVI-eligible (including GAVI graduates), 47 and 52, respectively, reported conducting rotavirus and IB-VPD surveillance, respectively.

Table 35: The income category of countries reporting that they conduct sentinel site surveillance for rotavirus diarrhoea and IB-VPD

Income category	Total countries	No. with rotavirus surveillance	No. with IB-VPD surveillance
LIC	36	20	26
MIC	101	57	65
GAVI	73	47	52

Overall, of the 137 LIC and MIC, 77 (56%) reported conducting rotavirus surveillance and 91 (66%) reported conducting IB-VPD surveillance. Data on the number reporting data to WHO are provided in the section below.

WHO-Coordinated Sentinel Hospital Surveillance Networks

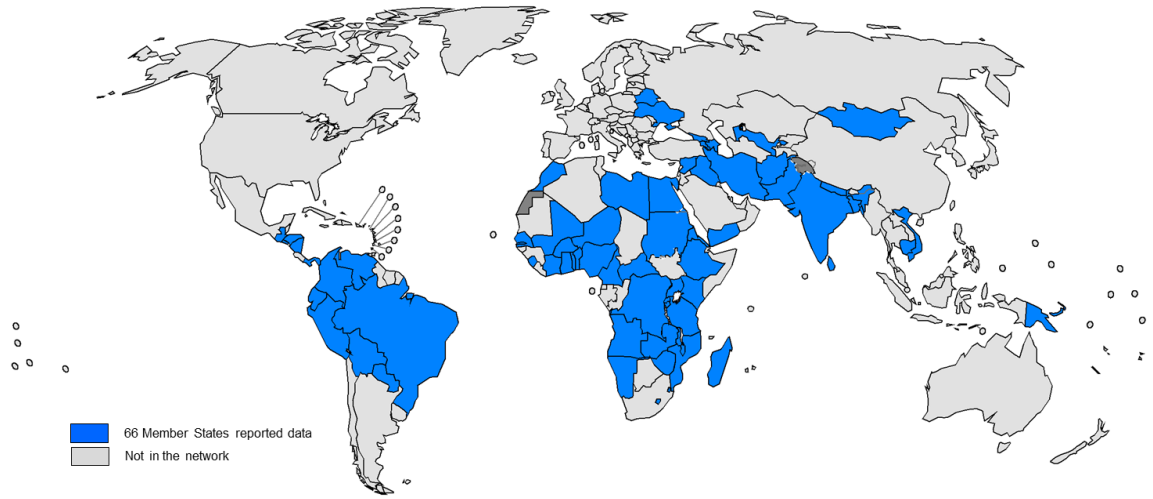
The
Table 36 and the
Map 12 and

Map 13below shows the number of countries reporting rotavirus and IB-VPD surveillance data to WHO in 2012.

Table 36:Number of countries, by WHO region, that reported rotavirus diarrhoea and IB-VPD surveillance data to WHO in 2012.

WHO Region	Number of countries reporting rotavirus data to WHO in 2012	Number of countries reporting IB-VPD data to WHO in 2012
AFR	20	30
PAHO	15	12
EMR	8	10
EUR	6	6
SEAR	4	4
WPR	7	4
Total	**60**	**66**

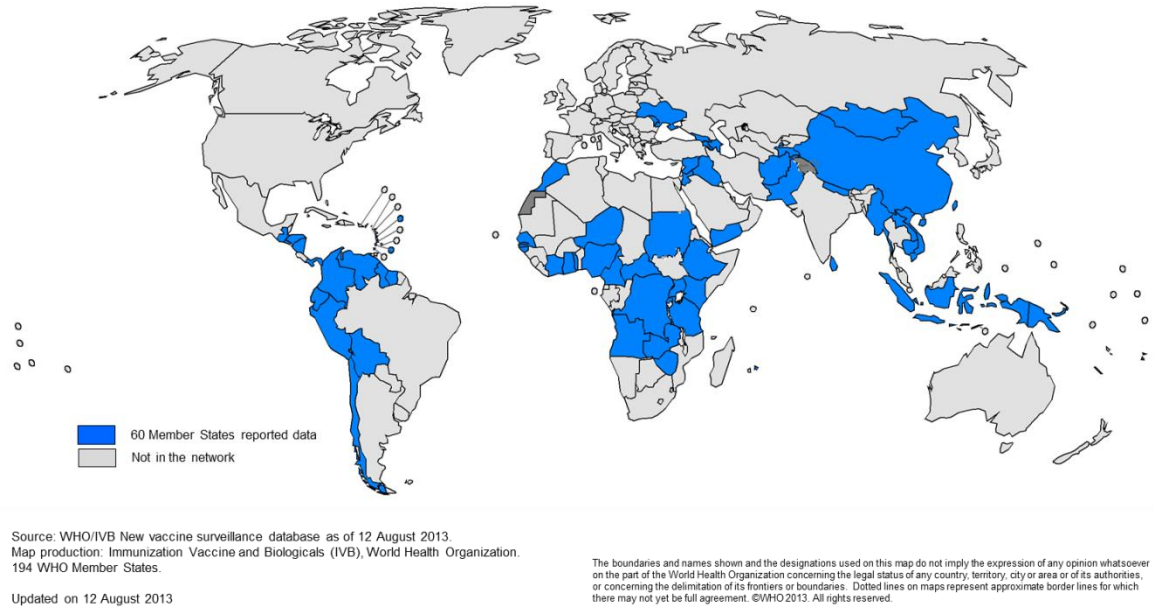
Map 12: Member states that reported data to the WHO-Coordinated Invasive Bacterial Vaccine Preventable Diseases (IB-VPD) Surveillance Network for 2012



Source: WHO/IVB New vaccine surveillance database as of 12 August 2013.
Map production: Immunization Vaccine and Biologicals (IVB), World Health Organization.
194 WHO Member States.

Updated on 12 August 2013

Map 13: Member states that reported data to the WHO-Coordinated Global Rotavirus Surveillance Network for 2012



In 2012, 60 countries (all LIC and MIC) reported rotavirus surveillance data to WHO. Among these 60 Member States, three (Indonesia, Nepal and Tajikistan) stated that they did not have rotavirus surveillance in place in their JRF, whereas four (China, Sri Lanka, El Salvador and Ukraine) did not respond to this JRF question.

In 2012, 66 countries reported IB-VPD surveillance data to WHO. Of these, three (Afghanistan, Brazil and Egypt) reported they did not have surveillance, one (Libya) stated that the question was not applicable, and three (Sri Lanka, El Salvador and Ukraine) did not provide any response in the JRF.

NARRATIVE

Globally, 129 (67%) Member States reported having a case-based surveillance system for IB-VPD, including laboratory confirmation of cases. Of these, 66 Member States reported data to WHO in 2012. For rotavirus, 101 (52%) of Member States reported having surveillance in place, with 60 reporting data to WHO in 2012. Discrepancies were noted between the responses on existence of surveillance reported in the JRF and actual reporting of surveillance data to WHO via other means.

While this reflects that there are ongoing surveillance for diseases targeted by new vaccines, the nature and quality of the surveillance in a large number of LIC and MIC that do not participate in the WHO-coordinated surveillance network is unknown. While resources exist to support the GAVI-eligible countries to assess and improve surveillance quality, existing resources will not allow support for and quality assessment of surveillance in the remaining MIC.

The WHO-coordinated sentinel site surveillance for rotavirus diarrhoea and IB-VPD was established in 2008, though the network has evolved during this period and the quality assurance processes have only been recently fully established. At the same time, with an increasing number of LIC and MIC countries having introduced new vaccines, the primary surveillance objective has moved from generating data for

decision-making to monitoring the impact of vaccination. In order to assess whether the current surveillance strategy is fit for purpose and will meet the evolving needs and to inform measures that may be taken to further improve the two sentinel surveillance networks, WHO under the guidance of a technical advisory group launched a strategic review of the two sentinel hospital surveillance networks.

The objectives of this review are to: (1) assess whether and to what extent the original objectives of the surveillance network have been met, and (2) critically assess whether the current surveillance strategy is fit for purpose to meet the evolving surveillance objectives and specifically to determine whether and how the surveillance may be used for document vaccination impact. The review is being conducted by an independent group of experts and will culminate in a meeting during the week of 16 September 2013. The assessment and recommendations from this review will be presented to SAGE in November 2013.

HIGHLIGHTS

- Globally, 129 (67%) Member States reported having an IB-VPD case-based surveillance system in place, using laboratory confirmation of cases, on the most recent JRF. They included 91 LIC and MIC. 66 countries reported data to WHO in 2012. For rotavirus, 101 (52%) of countries (77 LIC and MIC) have such a system in place, with 60 reporting data to WHO in 2012.
- SO 4.4 indicator does not include 'laboratory-confirmation' of cases. Including this phrase would be important to ensure reliable high-quality data are produced and to strengthen global laboratory capacity to conducted surveillance for VPDs.
- While WHO has established a system for assessing surveillance quality in GAVI eligible countries participating in the WHO coordinated network, there is currently no system in place to assess surveillance quality in the remaining countries.
- The combined technical and logistical advances in immunizations and development of a sentinel site surveillance infrastructure for viral and bacterial diseases via the rotavirus and IB VPD surveillance networks makes this an opportune time to build upon these achievements to further enhance other VPD case-based surveillance activities.

STRATEGIC OBJECTIVE 5

IMMUNIZATION PROGRAMMES HAVE SUSTAINABLE ACCESS TO PREDICTABLE FUNDING, QUALITY SUPPLY AND INNOVATIVE TECHNOLOGIES

INDICATOR SO5

PERCENTAGE OF DOSES OF VACCINE USED WORLDWIDE THAT ARE ASSURED QUALITY

TARGET: 100% OF DOSES VACCINES BY 2020

SECRETARIAT FOCAL POINT: DAVID WOOD, LAHOUARI BELGHARBI AND NORA DELLEPIANE

DEFINITION OF THE INDICATOR

While acknowledging that manufacturers are responsible for the quality of the vaccines they produce, WHO published a definition for "vaccines of assured quality" which depends on the existence of a competent and functional regulatory authority to regulate the product as assessed by an external expert team using widely agreed indicators. A vaccine of assured quality is defined as one that consistently meets appropriate levels of purity, potency, safety and efficacy as judged through an independent review system competent to take an evidence-based decision on the product for a specified population in a specific context. Such a review system makes use of all available information, such as licensing dossiers, surveillance of field performance, lot-by-lot scrutiny, appropriate laboratory testing, current Good Manufacturing Practice, inspection of manufacturers, and evaluation of clinical trials, and the responsibility is generally assumed by a national regulatory authority. This definition implies that, faced with the same risk/benefit, any competent authority would come to the same decision. The definition also indicates clear pathways to improve vaccine quality by strengthening national regulatory authorities and WHO is actively engaged in this task. By insisting on competent regulatory oversight, while recognizing the role of risk analysis in the selection of vaccines for use, WHO strongly reiterates the need for a single standard of quality. Only vaccine of assured quality should be considered for use in national immunization programs on the basis of the risk/benefit ratio for the particular population.

At the end of 2012 there were 44 vaccine-producing Member States. Manufacturers in these Member States, through exports, supply all Member States. A functional National Regulatory Authority (NRA) will make a risk/benefit decision on a national basis, and risks and benefits for the same product may vary between Member States. WHO provides a service – prequalification of vaccines – to additionally assess whether a vaccine already approved by a functional NRA is suitable for use, through UN procurement, in target populations (typically in high disease burden settings) outside of the producing country. The list of prequalified vaccines, published by WHO, is used by a third group of Member States – self-procuring Member States – to source vaccines of assured quality.

There are thus two components to the indicator. First, the number of prequalified vaccines which are of assured quality and are suitable for use, through UN procurement procedures, in high disease burden Member States. Secondly, the proportion of the global population that is directly provided with regulatory oversight by a functional NRA, as assessed by WHO. The percentage of doses worldwide that are of assured quality is defined as the proportion of the global population that uses vaccines either directly regulated by a functional NRA or prequalified vaccines through UN supply.

DESCRIPTION OF DATA'S SOURCES

The information on the number of prequalified vaccines is from a database maintained by the WHO Vaccine Prequalification Secretariat. The list of prequalified vaccines is published on the WHO website.
The information on the percentage of doses of assured quality provided by WHO is sourced from the WHO-UNICEF JRF, correlated with the worldwide national immunization coverage and the data gathered from the routine WHO NRA assessments and follow up conducted in the Member States. Member States data sources are the National Immunization Programme (NEPIs), the vaccine manufacturers, NRAs and the National Control Laboratories (NCLs).

COMMENTS ON DATA'S QUALITY

For the doses of assured quality, WHO compiles information through a routine review twice a year and with a quality management system applied using common terminology and process to gather and provide analysis for this indicator. Currently 2% of data are unknown. To assess data quality, WHO gathers additional information from six groups of sources: 1) vaccine produced by manufacturers, 2) vaccine released by NRA/NCL, 3) vaccine procured, 4) vaccine distributed to the programme, 5) vaccine used (including wastage rate), and 6) vaccine administered (doses effectively used to vaccinate each targeted population.

A new database is currently under development that will target the number of vaccines doses produced by manufacturers and the number of doses released by NRAs/NCls for all EPI vaccines. The prototype is under testing and it will target all 44 vaccine producing Member States. This will help to improve accuracy of the information.

DESCRIPTION OF THE RESULTS

Table 37: Number of Prequalified vaccines in 2010 and 2012

Vaccine	PQ 2010	PQ 2012
BCG	4	4
DTwP	3	3
Measles	4	4
MR	1	1
MMR	4	4
DTwP-Hepatitis B-Hib	2	4
DTwP-Hepatitis B+Hib	2	3
Pneumococcal conjugate	3	3
Rotavirus	3	3
HPV	2	2
Other vaccines	83	94

Figure 9: Proportion of global population provided with functional regulatory oversight for vaccines

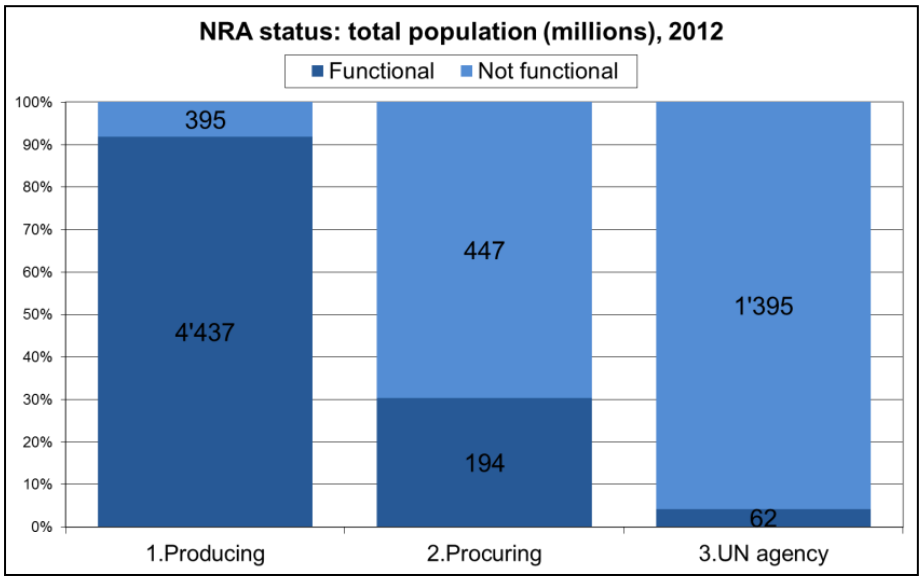
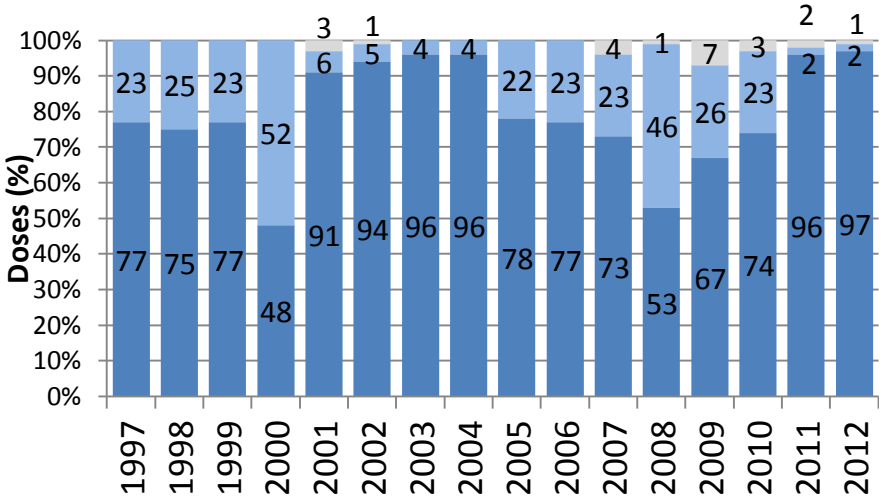


Figure 10: Percentage of assured (dark blue) /non-assured (light blue) quality vaccines used worldwide (%) 1997- 2012 (Grey shade is for unknown quality)



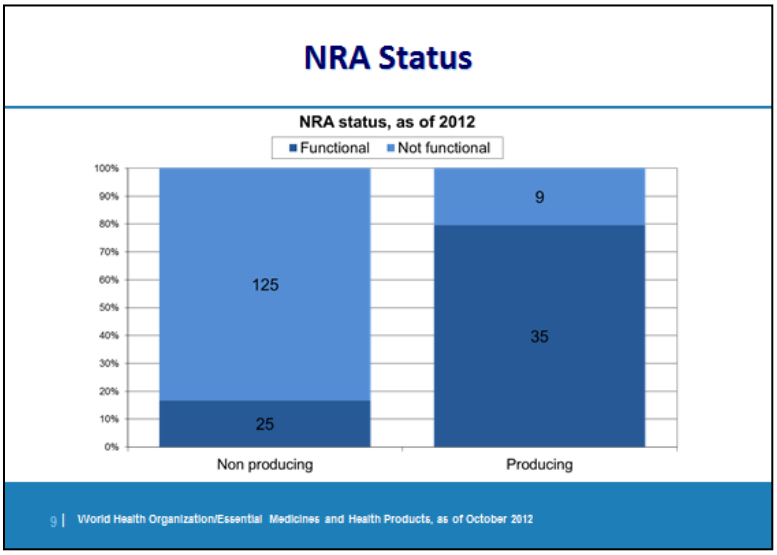
NARRATIVE

Since 2009, India and China, two Member States with large populations and large capacity to produce different type of vaccines accelerate their efforts to strengthen their vaccines regulatory oversights. India is one of the major suppliers of prequalified vaccines already having a functional NRA. The NRA of China became functional in early 2011. China has a great potential to become another major supplier of prequalified vaccines. Continuous efforts by these Member States to meet the highest quality standards has been documented and reflect major commitments by their respective government. This was translated in a massive recruitment of regulatory staff and increased budget (US$ 500 million to US$ 1

billion used in each country) between 2008 and 2012. Moreover each of these governments has committed additional support in their respective national strategic five years plan.

Additional Member States have made efforts to develop and/or sustain their regulatory system in order to maintain stringent oversight on quality of vaccines produced, used locally or exported. By end of 2012, 23 out of 44 vaccine producing Member States produced one or more WHO prequalified vaccines.

Figure 11: Functionality of NRA in producing and non-producing Member States



At end 2012, 68% (4.693 million) of the global population is provided with direct oversight by functional NRAs (60 Member States).The 32% that are not regulated by a functional NRA have access to WHO prequalified vaccines. Overall, 97% of the global doses of vaccines used in national immunization programmes are of assured quality.

As of July 2013 all vaccines produced are sourced from 44 vaccine producing Member States from which 35 Member States have been assessed as having a functional NRA. Knowing there is permanent change in the market profile, and increased investment from major pharmaceutical companies to build or establish vaccine plants in developing emerging markets, there is a risk that vaccine production investment happens in Member States where there is no, or a poorly functional, regulatory system. In order to mitigate that risk WHO is stratifying its support to Member States into three groups, by risk to vaccine quality: a) high risk group where yearly monitoring should be performed with a formal assessment every two to three years since failure of the regulatory system would jeopardize sources of prequalified vaccines, b) medium risk where continuous monitoring is expected every 2-5 years however there is no impact or threat on current prequalified vaccines, and c) low rick where regulatory oversight should be monitored between five to seven years and there is no vaccine prequalified or no major supply risk for national immunization programmes.

For prequalified vaccines, there were several quality issues identified during 2012 at bulk and final product manufacturing levels that impacted on the supply of PQ pentavalent vaccines. Future security of the supply of the MMR vaccine will be impacted by the decision of one manufacturer to stop the

manufacture of the mumps component. Supply will continue until 2015 when the already produced bulks are likely to be exhausted.

HIGHLIGHTS

- Major vaccine suppliers, China and India, have maintained their regulatory oversight for vaccines at a functional level to ensure quality of vaccines.
- All vaccines are sourced from 44 vaccine producing Member States from which 35 have a functional regulatory system, as monitored by WHO.
- The number of prequalified vaccines has grown compared to the GVAP baseline in 2010.
- Continuity of supply of key prequalified vaccines (e.g. pentavalent vaccines) has been problematic, leading to vaccine shortages in some Member States.
- 97% of the total of vaccines doses used globally is of assured quality as of December 2012 .

STRATEGIC OBJECTIVE 5:

IMMUNIZATION PROGRAMMES HAVE SUSTAINABLE ACCESS TO PREDICTABLE FUNDING, QUALITY SUPPLY AND INNOVATIVE TECHNOLOGIES

VACCINE PRICING

SECRETARIAT FOCAL POINT: MILOUD KADDAR

Executive Summary

The price of vaccines, especially for the new or underutilized vaccines, is an important determinant of their introduction and sustained use in LIC and MIC. However, the price of vaccines, despite some significant reductions, varies significantly between countries. There are currently limited sources of data available to monitor vaccine prices particularly outside of the pooled procurement of vaccines conducted by PAHO and UNICEF.

The inclusion of a Vaccine Price indicator as part of the WHA annual report on progress of the GVAP implementation will facilitate global dialogue among partners and with countries on this issue and will promote improved data availability and quality.

WHO facilitated discussions between interested partners in vaccine pricing to reach consensus on the scope of this first narrative report; to propose a methodology for monitoring vaccine prices; and possible areas for reporting in the future. Key observations and points presented in this report include:
Vaccine pricing is dependent on the market conditions (supply costs and demand dynamics); stakeholders' strategies and practices (market access approaches; procurement mechanisms and systems; funding mechanisms; products characteristics and preferences). Considerable inconsistencies and ambiguities of pricing policies and practices remain for different categories of countries (e.g. GAVI supported vs. non-GAVI supported).

The biggest vaccine price data gap is with non-GAVI, non-UNICEF and non-PAHO MIC. More than 45 MIC are currently self-procuring some vaccines and are not eligible for GAVI support or pricing. There is currently minimal comparable information for self-procuring LIC and MIC. There have been a number of improvement in the availability and transparency of pricing data from both PAHO and UNICEF with publication of historical and current pricing. Taking into account these factors and developments, it becomes clear that analyzing and monitoring vaccine price trends is a challenging task but an important priority.

This report provides an overview of the importance of vaccine pricing in the global context for both LIC and MIC. It summarizes some of the complexities of pricing and price comparisons, the gaps in the currently available information, possible improvements and further actions required in this area through the DOV and GVAP. Individual reports on PAHO and UNICEF Pricing and Supply are provided in Annex for Pentavalent, Inactivated Polio, Rotavirus, Pneumococcal Conjugate (PCV 7, 10 and 13) and HPV vaccines.

The SAGE GVAP working group is asked to provide advice on:

- Approach and methods used in this report (country matrix, types of prices, etc).

- Selection of vaccines to be included in the future annual reports.
- List of specific priority areas to be addressed in future reports.
- How to strengthen and improve the provision of vaccine price data and information.
- Potential dissemination and use of this vaccine price indicator and report to facilitate global and country dialogue on vaccine development and access.

As more comparable data are collected and collated over the decade greater transparency will be possible adding to the improvement of reporting through the annual narrative and allowing more discernible trends and impacts to be evaluated.

1. Context and objective

The price of vaccines, especially for the new or underutilized vaccines is an important determinant for their introduction and sustained use in LIC and MIC. However, the price of vaccine may vary between countries, depending on the market conditions (production costs, demand dynamics) and stakeholders' strategies (market access approaches, procurement mechanisms, funding and contracting conditions). Hence, instead of establishing a single indicator, a decision was taken to start by preparing a narrative report on the basis of which one or more indicators that would facilitate tracking of vaccine prices may be considered.

The inclusion of a Vaccine Price indicator as part of the WHA annual report on progress of the GVAP implementation will facilitate global dialogue among partners and with countries on this issue and will promote improved data availability and quality.

The WHA 66/19 document noted "In addition to the indicators for the GVAP, a report on trends in vaccine prices, classified according to the procurement mechanisms used, will be presented for review by the SAGE. The SAGE will also be requested to advise on an appropriate indicator for monitoring such price trends". As a result the WHO facilitated discussion between interested partners in vaccine pricing to reach consensus on the scope of this first narrative report and propose a methodology for monitoring vaccine prices and possible areas for reporting in future narratives. The results of this process and the proposed methodology for annual reporting are included in this report and its appendices. This report provides an overview of the importance of vaccine pricing in the global context for both LIC and MIC. It summarises some of the complexities of pricing and price comparisons, the gaps in the currently available information, possible improvements and further actions required in this area through the DOV and GVAP. Individual reports on PAHO and UNICEF Pricing and Supply are provided in the Annex for Pentavalent, Inactivated Polio, Rotavirus, Pneumococcal Conjugate (PCV 7, 10 and 13) and HPV Vaccines.

Some of the key observations and points presented in this paper are that there has been substantive progress at PAHO and UNICEF in terms of vaccine price data made publicly available. The vaccine price data gap is with non-GAVI, non-UNICEF and non-PAHO countries, more than 45 MIC are currently self-procuring some vaccines and are not eligible for GAVI support or pricing.[51] Considerable inconsistencies and ambiguities of pricing policies and practices remain for different categories of countries (e.g. GAVI

[51] Kaddar M, Schmitt S, Makinen M, Milstien J. Global support for new vaccine implementation in middle-income countries. Vaccine 2013 April 18; 31 Suppl 2:B81-B96 [online].
Available at:< http://www.ncbi.nlm.nih.gov/pubmed/23598496> [Accessed July 2013].

supported vs. non-GAVI supported). Taking into account these factors and developments, it becomes clear that analyzing and monitoring vaccine price trends is a challenging task but an important priority.
Vaccine pricing data availability is not currently optimal for all countries. Data and information are published for the two pooled procurement facilities available to some countries. The PAHO Revolving Fund publishes Weighted Average Prices (WAP) for its Member States and actual prices for some sole supply vaccines. UNICEF Supply Division publishes awarded prices under established Long Term Arrangements (LTA), which cover largely LICs and some LMICs. UNICEF SD will, in the future, publish awarded prices following a tender, albeit outside of the LTA framework, including for MICs. There is currently minimal comparable information for self-procuring countries, including self-procuring LIC and MIC.

Some data availability improvements were made in the past two years. Specifically UNICEF published historical pricing by supplier for LIC and GAVI-eligible countries in 2011, expanded this to publish current prices in 2012 and additionally awarded pricing for these groups in 2013. PAHO has made its pricing lists more easily accessible on its website and with the product differentiation of the new vaccines, it is possible not only to determine a WAP but also the actual prices for some monopoly supplied vaccines.

2. Importance of Vaccine Price

Vaccine prices are one of the main drivers of immunization costs; they have been roughly estimated to be up to 50% of the total cost of the GVAP and are becoming the biggest proportion of costs for national EPI programmes. Vaccine pricing is one of the key obstacles to implementation of new vaccines by non-donor supported MIC.[1] Sustainability of new vaccines implementation for countries graduating from development partner support are an identified concern as more countries move into this category and access to pooled negotiated prices for donor countries becomes more challenging. GAVI has secured a certain level of commitments from some suppliers for maintaining the GAVI price level for graduating countries for particular periods (indicated in

Table 39).

Monitoring vaccine pricing and developing activities to optimise and facilitate vaccine affordability, supply security and sustainability to all countries will provide a measure of success of the GVAP. It will facilitate global dialogue on this issue, and will promote improved data availability and quality.

3. Vaccine Market and Pricing Complexity

The vaccine market is quite unique, it has very distinct features which increase the complexity of assessing and understanding pricing and its context[52]. The vaccine market is made up of individual markets, each with their own specificities, particularly on the supply side. Key features of the overall market include:

1. Vaccines are biological products, manufactured in a highly regulated environment to ensure quality and are vulnerable to supply failure;
2. Vaccine manufacturing is a high-risk business with characteristics such as long-cycle time and expensive to manufacture, large capital investments, extremely vulnerable to demand fluctuations and perceptions, etc. These risks contribute to the overall vaccine price;
3. Vaccines are administered to otherwise healthy individuals; therefore, quality and safety are of utmost importance and risk aversion is therefore, appropriately, very high;
4. There are very few manufacturers of vaccines that meet international standards of quality established by WHO. Many of the individual vaccine markets are monopolies or oligopolies either by product or presentation. Parallel monopoly markets are a particular feature of new vaccines;
5. Vaccines are predominantly funded by governments and development partners rather than individuals, especially for the major proportion of LIC and MIC populations;
6. The vaccine market is relatively small when compared to the global pharmaceutical sales (between 2% and 3%) but it has a rapid annual growth. The vaccine market has tripled in value from US$ 5 billion in 2000 to almost US$ 24 billion in 2013 and is projected to rise to almost US$ 100 billion by 2025. Five large multi-national corporations make up to 80% of the global market. Vaccine production is becoming a profitable and promising niche for the pharmaceutical industry, attracting an increasing number of research-based companies;
7. Some of the new vaccines are being implemented in HIC at almost the same time as development partner supported countries (a sign of market convergence);
8. Traditional vaccines are provided to different countries in different presentations. There are significant distinctions (market divergence) between the vaccines provided to HIC and development partner supported as well as most of the MIC;
9. There are two large pooled purchasers of vaccines with UNICEF procuring some or all vaccines on behalf of up to 100 countries per year and PAHO procuring for around 40 Member States. Both organizations share many common strategies and features but have some specific principles and practices;
10. Some manufacturers, development partner, global agencies such as GAVI and UNICEF support the concept of vaccines tiered pricing where the lowest price is provided to development partners supported and/or LIC;

[52] Frank A. Sloan: *The Economics of Vaccines*. The Oxford Handbook of the Economics of the Biopharmaceutical Industry. 2012,
Postma MJ, Standaert BA: *Economics of vaccines revisited*: Hum Vaccin Immunother. 2013 Jan 30;9(5)

11. Emerging market vaccine manufacturers play an important role in meeting the demand, particularly for traditional and underutilized vaccines, in lowering the price through competitive entry, and in providing increased production capacity, including through arrangements with multinational manufacturers. Emerging market vaccine manufacturers' use of pricing structures such a tiered pricing is somewhat limited;
12. In many individual vaccine markets there is a tenuous balance between demand and available supply which requires constant management and communication. In some cases, individual (self-) procuring countries are essentially competing for the limited supply with the large procuring entities.

Pricing is influenced by a number of factors on both the demand and the supply side of the market. On the demand side: burden of disease, target population, volume, presentation and formulation preference, sources of funding forecast accuracy, service delivery, regulation, procurement mechanisms and processes, transaction costs and system readiness to incorporate a vaccine into a national programme play a role. On the supply side: availability of supply, production technology and capacity, level of competition, product characteristics, predictability of demand and funding, influence of payers and global health initiatives, are but some of the many factors in addition to the market access strategies of individual vaccine suppliers.

An IFPMA Pricing Policy Paper 2008[53] included the following statement: "all research-based vaccines companies fully respect competition policies, laws and regulations worldwide. An individual company's prices, whether for older or newer vaccines, are based on many factors, including among others, market competition, differential income levels in different markets and the special needs of populations in poor countries".

Vaccine pricing has become more complex for all stakeholders. There has been a shift from standardised annual transactional procurement to more strategic complex and longer term procurement and financial arrangements for vaccines. Global examples include the Advance Market Commitment (AMC) for Pneumococcal Vaccine, GSK Rotavirus agreement with UNICEF and more recently the HPV commitments for GAVI eligible countries with UNICEF. Even for a few of the older traditional vaccines some strategies have been employed which secure supply (for example through multi-year contracts or other pertinent arrangements) but at the same time, this makes the comprehension of price components and contractual terms less evident. Development partners, CSOs, manufacturers, procurement partners and Member States are often pursuing different and sometimes conflicting objectives regarding pricing of vaccines.

Some confidentiality contractual conditions such as: bundling, discounts, rebates, assured volumes, contracted price change triggers, etc. are considered important to the industry for commercial reasons. These contractual provisions are designed to secure better pricing and secure supply but at the same time establish sophisticated contracts and mask the actual price of vaccines. Product price comparability is complex. Comparing the prices between two procurement systems such as between UNICEF and PAHO, between UNICEF and a self-procuring country or PAHO and a self-procuring country requires a more in-depth knowledge of the context and procurement systems and actual practices for each reported contractual price.

[53] www.ifpma.org

Although a contract may include other complexities including or in addition to those noted above, the negotiated and published prices of UNICEF and PAHO with the supplier are to the port of export of the vaccine, with the price of the vaccine applying to all countries or donors eligible to access it. However, individual country pricing and contracting can be more complex. Individual country prices could include international and domestic transport, insurance, storage, taxes, duties and other supply chain components and costs. Some countries may also include other goods and services into the supply contract which would then be reflected in the price. Some examples include, but are not limited to, the provision of cold chain equipment, training of country staff, surveillance system support, promotional and advocacy materials. Direct price comparison between different procurement systems therefore requires the disaggregation of the inclusions of the reported prices and, where possible, the quantification or, at a minimum, the qualification of these inclusions.

The complexities of vaccine pricing make comparability from different sources a challenge to reporting vaccine pricing and trends. As more comparable data are collected and collated in the coming years, greater transparency will be possible adding to the improvement of reporting through the annual narrative and allowing more discernible trends and impacts to be evaluated.

4. WHO Facilitated Working Group for Vaccine Pricing

A special working group was established to determine the scope and contents of the narrative report and to propose possible indicators that may be used to track vaccine prices in future. The working group included representatives from WHO, UNICEF, GAVI Secretariat, PAHO, Médecins Sans Frontières and the Bill & Melinda Gates Foundation. Other partners were consulted on some key points and the group benefited from the stakeholder consultations that had been conducted by the WHO Vaccine Product Price and Procurement (V3P) Project which WHO has been implementing since 2011. A summary of the deliberations and justifications for the recommendations of the group is included in Annex to this report, full minutes from each meeting are available if required.

Summary of Recommendations

All partners were in agreement on the importance of including a price indicator in the GVAP monitoring and evaluation and accountability framework.
The working group concluded that:

- A country matrix including all LIC and MIC should be developed;
- The vaccines for inclusion should be selected, taking into account their reflection of GVAP's goals and both the current and proposed priorities throughout the GVAP time period;
- Current data sources are UNICEF actual prices for LIC and GAVI eligible countries, and PAHO WAP for member states;
- Possible data sources for Member States outside of the pooled procurement mechanisms which includes approximately 47 partially or fully self-procuring MIC could be made available through initiatives such as the WHO V3P project, the WHO-UNICEF JRF and partners such as MSF;
- The price data points should include manufacturers' prices at export point per vaccine and per presentation for the country matrix groups (lowest, highest and WAP) with a base line set at 2010, and should include where possible price trends from 2001 (the start of GAVI support);
- The context and complexity of vaccine pricing should be provided in the WHA annual report and it would be possible to focus the narrative on a particular aspect or vaccine each year to serve as an information source to the audience;
- Vaccine market information (both supply and demand) is important to the context of each vaccine. The sources and mechanisms of financing also effects pricing and should be reflected;
- In future, when data would be available from countries outside of the pooled procurement systems, it would be important to contextualize the data and information to allow for greater comparability and minimize misinterpretation and simplification; more complex calculations and indicators could be required.

5. Current and Future Data and Information Sources

Table 38: Country Matrix and Current Availability of Pricing Data

Country Groups	Price Data Publically Available
Low Income Countries (LIC)	
UNICEF[54]/GAVI	Low/High and WAP
PAHO*[55]	WAP (or Actual Price for monopoly supply)
Self-Procuring	No, very limited and partial on country web sites. No information publicly available in comparable form
Middle Income Countries (MIC)	
UNICEF/GAVI	Low/High and WAP
UNICEF/ GAVI Graduating/Graduated	Low/High and WAP
UNICEF Non GAVI	Limited, details not currently published
PAHO*	WAP (or Actual Price for monopoly supply)
Self-Procuring	No, very limited and partial on country web sites. No information publicly available in comparable form

*While the matrix separates country groups by World Bank Income Status, PAHO does not differentiate pricing using this method. Therefore, the PAHO prices will be indicated as one price for both groups.

As noted, the currently available published data sources for vaccine pricing are from UNICEF and PAHO. UNICEF publishes the supplier-specific awarded price per dose, product, and calendar year, based on multi-year LTAs. Depending on the allocation of a product and supplier to a particular Member State, the Member State (or development partner) pays the actual price for the particular product. For specific ad hoc demand, predominantly for MIC, UNICEF is issuing individual tenders. To date, UNICEF has not published prices awarded outside of established LTAs but is working to do so in the near future. In 2013, UNICEF has issued a pooled procurement tender for Pneumococcal, Rotavirus and Human HPV vaccines for these non GAVI eligible MIC[56] but the results of this initiative are yet to be announced.

In addition, GAVI has secured some commitments to pricing for graduating countries for some vaccines after these countries graduate GAVI financial support. Some of these commitments have already been realized through actual procurement and contracting through UNICEF, as the primary procurement agency on behalf of GAVI. Other commitments have been made outside of a formal procurement process. These are summarized in

[54] UNICEF pricing available at: http://www.unicef.org/supply/index_57476.html
[55] PAHO pricing available at: www.paho.org
[56] Available at http://www.unicef.org/supply/index_67101.html

Table 39. Some assurance has yet to be secured for certain products such as for HPV vaccine, which is currently excluded from extension of the GAVI price to graduating countries.

Table 39: Published Supplier Commitments to Pricing for GAVI Graduating Countries as of July 2013[57]

Current GAVI Supported Vaccine	WHO Prequalified Suppliers	Published Graduating Country Price Commitment	Timing
Pentavalent Vaccine (DTwPHepBHib)	Biological E	No published commitment	
	Crucell	Same price for GAVI eligible Countries procured through UNICEF	Until 2020
	GSK	No published commitment	
	LG Life Sciences	No published commitment	
	Serum Institute of India	No published commitment	
Pneumococcal Conjugate Vaccine (PCV)	Pfizer	Access to the tail price under the terms and conditions of the AMC for all Phase II GAVI-eligible countries, which includes all current graduating countries procuring through UNICEF.	Until at least 2020
	GSK	Access to the tail price under the terms and conditions of the AMC for all Phase II GAVI-eligible countries, which includes all current graduating countries procuring through UNICEF	Until at least 2020
Rotavirus Vaccine (RV)	GSK	Same price for GAVI eligible countries (1.88 EURO) procured through UNICEF for graduated countries approved for GAVI support for rotavirus prior to 2012	Under current contract until 2016
	Merck	No published commitment	
Human Papillomavirus Vaccine (HPV)	GSK	No published commitment	
	Merck	No published commitment	

Source: GAVI Secretariat www.gavialliance.org

Sanofi Pasteur and its affiliate Shanta Biotech have indicated they would offer GAVI prices for all GAVI vaccines they supply to graduating countries procured through the GAVI procurement agency (UNICEF).[8] The prices indicated through the arrangements noted in

[57] www.gavialliance.org

Table 39 will be available for procurement of these vaccines with government funds through UNICEF as the GAVI primary procurement agent. However, these negotiations are vaccine and supplier specific and do not currently include all vaccines and suppliers. As such, this group of countries (GAVI graduating/graduated) will remain a distinct group in the proposed country matrix for the GVAP indicator.

PAHO pricing is based on a WAP for vaccines where multiple suppliers are contracted. Countries pay the WAP, not the individual supplier price for vaccines. For the parallel monopoly markets apparent in the new vaccines such as Pneumococcal, Rotavirus and HPV vaccines, the prices paid by PAHO countries are relative to the actual vaccine supplied.

Outside of these two pooled procurement systems, there is limited comparable data on self-procuring country prices available. Due to the complexity of comparability noted previously it is not sufficient to utilize any published data at face value. Such data are unlikely to be directly comparable with the published price to export port of UNICEF and PAHO. While some trends in pricing could be extrapolated from some individual country data, these data do not in general indicate contractual or delivery terms, which may have changed during the period.

Initiatives have been launched to improve vaccine price transparency, particularly for self-procuring countries, and to provide this data in a comparable format on a published platform. The WHO V3P project[58] is currently piloting a mechanism which will allow countries to provide data to a web-based platform which could then be collated and published. The data will include quantitative and qualitative information to improve comparability and allow users to have a greater understanding of pricing in its context. WHO is also investigating the use of the JRF as one possible method for countries to report vaccines pricing on an annual basis, while the comparability of this information across countries could be limited between countries and years, it could provide broader information on general trends.

During the Decade of Vaccines period and the reporting under the GVAP M&E/A framework it is anticipated that there would be further discussion and efforts to improve the availability of vaccine pricing data which would lead more effective monitoring and targeted activities. Support in required to ensure that such activities are prioritized, funded and undertaken.

6. Selected Individual Vaccine Market Trends for Matrix Countries

Individual reports on PAHO and UNICEF Pricing and Supply are provided in Annex for Pentavalent, Inactivated Polio, Rotavirus, Pneumococcal Conjugate (PCV 7, 10 and 13) and HPV vaccines. The following is a brief summary of key information provided for the purposes of monitoring vaccine pricing under the proposed matrix. There are a number of gaps to the matrix which subsequent reports will endeavor to fill.

[58] http://www.who.int/immunization_supply/procurement/v3p/en/index.html

Table 40: Vaccine Price Table (Data Provided by UNICEF and PAHO) in USD

VACCINE AND MATRIX GROUP	PRESENTATION	YEAR AND PRICE					
Inactivate Polio Vaccine		2001	2006	2010	2011	2012	2013[7]
PAHO Actual – Low							2.90[6]
PAHO Actual – High							4.14[6]
PAHO WAP				4.50	5.50	5.98	
UNICEF MIC - Actual Low				3.40		3.30	
UNICEF MIC - Actual High				3.80		3.30	
DTwPHepBHib Pentavalent Vaccine		2001	2006	2010	2011	2012	2013
UNICEF/GAVI – Low	Liquid 1 dose		3.63	2.70	2.25	2.50	1.95
	Lyo 2 dose	3.50	3.60	2.25	2.25	2.95	1.97
	Liquid 10 dose				1.75	1.60[1]	1.19[1]
UNICEF/GAVI – High	Liquid 1 dose	-	3.63	3.20	3.20	3.20	2.70
	Lyo 2 dose	3.50	3.60[1]	2.95	2.95	2.95	2.95
	Liquid 10 dose				2.11[5]	2.11[5]	2.11[5]
PAHO WAP	Liquid 1 dose			3.30	3.19	2.99	2.85
	Lyo 1 dose	3.50	3.99	3.20	2.95	2.88	2.52
	Liquid 10 dose						2.20
UNICEF MIC Actual – Low	Unspecified Presentation			2.97		2.30	
UNICEF MIC Actual – High	Unspecified Presentation			5.40		5.40	
Pneumococcal Conjugate Vaccine		2001	2006	2010	2011	2012	2013
PAHO	PCV7		53.00	20.00			
	PCV 10				14.85	14.24	14.12
	PCV 13					16.34	15.84
AMC UNICEF	PCV 10 or 13[2]			3.50	3.50	3.50	
UNICEF MIC Actual (NON AMC)	PCV 10			19.00		16.00	
Human Papilloma Vaccine		2001	2006	2010	2011	2012	2013
PAHO (Actual)	Bivalent			18.95	14.00	13.48	13.08
	Quadrivalent					14.25	13.79
UNICEF/GAVI (Actual)	Bivalent (2-dose vial)						4.60
	Quadrivalent						4.50
Rotavirus Vaccine		2001	2006	2010	2011	2012	2013
PAHO (Actual)	2 Dose Course			7.50	7.50	6.88	6.50
	3 Dose Course			5.15	5.25	5.25	5.15
UNICEF/GAVI (Actual)	2 Dose Course					2.52[1,3]	2.52[1,3]
	3 Dose Course					5.00[4]	5.00

All prices listed are CIP or FCA *2010 Incoterms. For more information see International Chamber of Commerce, http://www.iccwbo.org/products-and-services/trade-facilitation/incoterms-2010/

[1] Unspecified special conditions Apply.
[2] The price consists of a co-payment (the Tail Price) of a maximum of UD$ 3.50) funded by a country or GAVI and a subsidy of the difference between UD$ 7.00 and the Tail Price funded by the donors of the Advance Market Commitment (AMC) (total price US$ 7.00/dose). Prices are based on a 10 year supply commitment and a volume guarantee as well as other terms as defined in the AMC legal framework .(http://www.gavialliance.org/funding/pneumococcal-amc/amc-legal-agreements/). During 2013, the AMC funding for doses procured under the contracts entered in 2010 is expected to be fully disbursed, where after the Tail Price will apply. For contracts entered more recently, the price of US$ 7.00 continues to apply.[3] Price is contracted at €1.88 (converted to US$ 2.52 as of March 2012).
[4] Price is for a single country. Free of charge doses will be made available by 2015-2016, provided a certain quantity is procured at the price of US$ 5.00.
[5] Price is based on Incoterms CPT – destinations in India
[6] Price of US$ 2.90 is from a manufacturer in The Netherlands, US$ 4.14 is from Belgium
[7] All 2013 price subject to change through the course of the year, final prices for 2013 will be reported again in 2014.

Inactivated Polio (IPV)

In the PAHO region, IPV is mostly supplied for risk groups. PAHO is procuring IPV for 17 Member States in 2013; only one country is using the vaccine for the routine schedule. The prices as indicated in

Table 40 show in increase in the WAP from 2010 to 2012, the actual prices from two suppliers for 2013 show a variance of 30%.

UNICEF is currently procuring very limited quantities of IPV (approx. 200,000 - 300,000 doses per year) for two MIC. No LIC nor GAVI country currently procure IPV. The two price points provided by UNICEF for 2010 and 2012 indicate a 3% reduction in the lowest price and a 15% reduction in the highest price. There are currently four manufacturers with pre-qualified products, with one pipeline manufacturer expected to have WHO-prequalified IPV in single and multi-dose vial presentations in early 2014. However, one manufacturer has recently had their production suspended by WHO and there is no information on when production will start again.

It is considered the IPV market will change considerably in the course of the DoV due to the SAGE recommendation, potential GAVI support and to the GPEI strategy which will significantly increase demand.

Demand may also increase for combination vaccines containing IPV particularly in MIC; it is proposed to include these vaccines in the GVAP price Indicator as they become available.

Pentavalent Vaccine (DTwPHepBHib)

The Pentavalent market has been volatile for the last years with multiple suspensions and some delisting of products from WHO pre-qualification. After several years of fragile supply, the situation is now stabilizing. PAHO predominantly procure the liquid single dose presentation while UNICEF procures 1 dose, 2 dose and 10 dose presentations. The market preference has shifted from the original lyophilized formulation to the liquid formulations. Price per dose is on the whole decreasing due to increased competition and active engagement of donors and emerging market manufacturers. The 10 dose presentation is the lowest price per dose. The differential between highest and lowest price for non-GAVI MIC procurement through UNICEF is significant. This market is likely to change in the future with the advent of a whole-cell pertussis hexavalent vaccine and the GPEI strategy.

Pneumococcal Conjugate Vaccine (PCV)

From 2006 to 2010, PAHO procured the PCV7 presentation of this vaccine. Seven Member States previously using PCV7 changed to PCV10, currently eight Member States procure this product from PAHO. PCV13 is procured for 13 PAHO Member States, three Member States are GAVI eligible and have access through PAHO and UNICEF to the AMC price.

In 2010, UNICEF procured PCV vaccine for 11 Member States, 10 GAVI-supported countries and one non-GAVI-supported MIC. In 2012, UNICEF procured PCV vaccine for 28 countries, including one non-GAVI-supported MIC. PCV is a parallel monopoly market, while there are currently two manufacturers with pre-qualified products available, they are not easily interchangeable. New entrants are expected in the market at the earliest in 2016/2017.

The market is further defined by the AMC. Prices have been established through UNICEF in line with the terms and conditions of the AMC with an initial price of US$ 7 per dose and a tail price cap of US$ 3.50 per dose. For vaccine doses contracted in 2010, in 2013 the AMC funding will have been fully disbursed for PCV13 through the price of US$ 7.00, and therefore Tail Prices will be accessed. As an outcome of

the most recent tender, the tail price for PCV13 is reduced as of mid-2013 to US$ 3.40 per dose and will be further reduced to U$D 3.30 per dose in 2014 onward; for PCV10 the Tail Price for doses on contracts entered into in 2010 and 2011 remains at US$ 3.50, to be accessed from 2014, whereas the 3rd supply agreement will see a reduced price of US$ 3.40 per dose from 2014. The AMC is available for all GAVI and GAVI graduating countries. It is therefore difficult to directly compare the AMC price with the PAHO price.

Human Papillomavirus Vaccine (HPV)

HPV is a parallel monopoly market. The two currently available WHO-prequalified products include both a bivalent and quadrivalent presentation. Both products are available in single dose form and the GSK product is also WHO prequalified in a 2 dose presentation which could help to lower the price. A second generation of HPV is under development. No other manufacturer is expected to enter this market before 2016. Both HPV vaccines, the bivalent and quadrivalent are available through PAHO. PAHO started procuring the bivalent for one Member State in 2010. The quadrivalent has been procured since 2012. In 2013, eight countries and territories procuring through PAHO are providing HPV as part of universal coverage.

UNICEF has not procured HPV vaccine prior to 2013. The recent tender on behalf of GAVI-supported countries achieved a price of US$ 4.50 per dose for the quadrivalent from Merck and US$ 4.60 for the bivalent from GSK for GAVI eligible countries from 2013. These prices will not be available to GAVI graduating countries or MIC. Further negotiations could result in an outcome for these groups in terms of price commitment.

A number of countries, particularly GAVI graduating and MIC, have entered into agreements for donated supply of HPV from suppliers and affiliated foundations for periods of up to five years. These agreements have generated demand for the vaccines and include commitment from the governments to fund the vaccine after the donation period. The price offered after the donation period may not be specified.
Currently the pooled procurement market for either presentation of HPV is small but is expected to increase significantly during the DoV due to the availability of GAVI funding for selected countries.

Rotavirus Vaccine (RV)

RV is a dual monopoly market with two WHO prequalified products, one requiring a 2 dose course and the other a 3-doses course. Prices should therefore be considered in relation to the number of vaccines required per course. There is strong country preference for the 2 dose course vaccine, which has led to issues with supply that are predicted to continue until 2015. New entrants are expected in the market from 2015/2016.

PAHO Member States started procuring RV in 2008. In 2013, 11 countries/territories are procuring GSK 2 dose course vaccine while two countries and one small Caribbean island are procuring the Merck 3 dose course vaccine. PAHO indicate no other Member States are interested in the 3 dose course presentation in the region.

UNICEF started procuring RV in 2011. In 2012 UNICEF procured RV vaccine for nine GAVI-supported countries. As of mid-2013, UNICEF has not procured RV on behalf of non-GAVI eligible countries. UNICEF is currently procuring the Merck 3 dose course for four countries. GSK has agreed to extend the UNICEF/GAVI pricing to GAVI graduating countries that have implemented RV with GAVI support but not those that did not take up this opportunity. Special contracting and/or payment terms apply to the UNICEF listed prices for GAVI countries.

The variance in price for the Merck product between UNICEF and PAHO is not considerable but for the GSK product the PAHO price is more than two and a half times the UNICEF/GAVI price.

7. Recommendations and Future Reporting Focus

Vaccine price Indicator

The vaccine price indicator team proposes to report annually on a price trends of selection of vaccines for a matrix of countries (further detailed are in the annex of this indicator). The greater the number of vaccines to be reported on increases the reporting requirements on the key partners in this area. The working team proposed the following vaccines based on:

a. Markers of high importance in public health impact including new and expensive vaccines.
b. Their impact on under five mortality.
c. Taking into account their reflection of GVAP goals and strategic objectives.

The recommendations to the SAGE DoV WG are:

- IPV (recognizing G1 of achieving a world free of poliomyelitis and the potential changes in the polio immunization market during the course of the decade);
- Pentavalent vaccine (recognizing G5 of reducing child mortality);
- PCV (recognizing G4 introducing new vaccines and G5 reducing child mortality);
- Rotavirus (recognizing G4 of introducing new vaccines and G5 reducing child mortality);
- HPV (recognizing G4 introducing new vaccines, G5 reducing mortality and SO3 which includes expanding the traditional target population and considering gender dimension).

The group discussed the value of whether or not to include measles or measles containing vaccines. The rationale for inclusion of MR and MMR vaccines in GVAP price tracking efforts is based on the following considerations:

- Measles and rubella are targeted for elimination in five out of six WHO Regions by 2020 and adequate vaccine access and supply is an absolute requirement for achieving this goal;
- With the GAVI investment to support countries to introduce MR vaccine over the next five years, there will be a shift away from single antigen M vaccine to MR vaccine (in GAVI eligible countries) and MMR vaccine in all other countries (e.g. PAHO countries);
- Currently the MR and MMR vaccine supply situation is tenuous due to the fact that there are few prequalified MR/MMR vaccines – MR (only SII) and MMR (SII, Sanofi, GSK and MSD – however only SII and Sanofi provide 10d vials);
- With limited competition in the medium term, there is potential for significant price increases for MR and MMR vaccines thereby increasing the cost of reaching the GVAP MR elimination goals;
- Tracking MR and MMR price may be a good way to prevent and manage any significant price increase.

Vaccine of regional importance such as YF, JE and Typhoid, were also proposed but the group felt that these should be discussed by and with the SAGE WG for future inclusion.

As demand for the vaccines increases and with improved data availability over the coming years greater comparability will be possible and some conclusions may be able to be drawn regarding the impact of some policies and activities (both on the supply and demand sides) on specific vaccine supply and pricing.

Future Reports

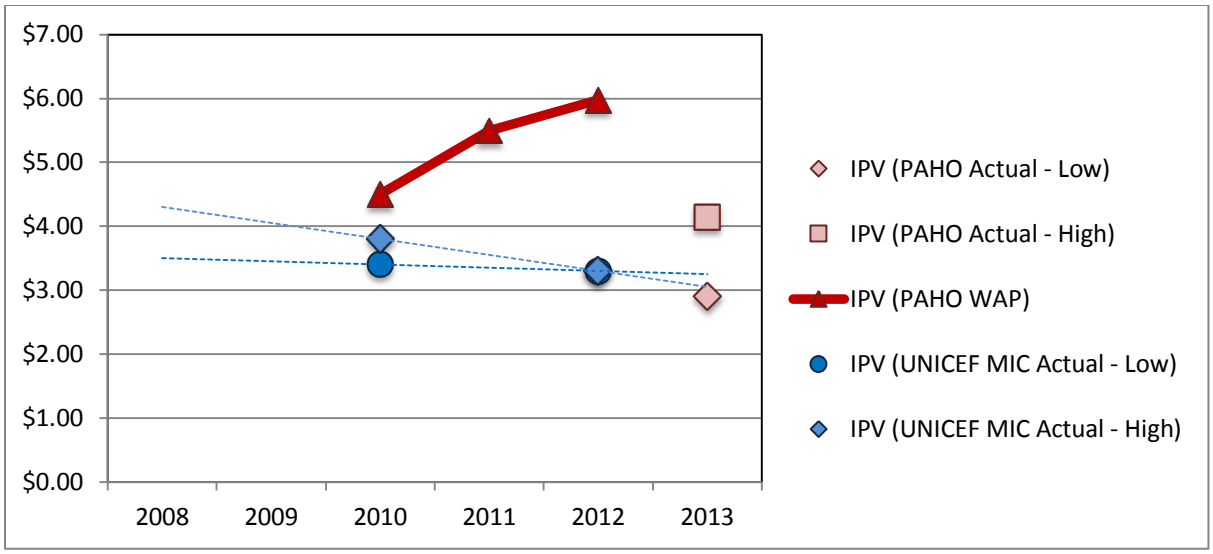
The vaccine price indicator team considered that the matrix of data for countries on specific vaccines could be provided on an annual basis to the GVAP monitoring and accountability report. It is also important to strengthen and improve the provision of vaccine price data and provide context to these data.
It is therefore proposed that an annual vaccine price indicator report could focus on priority areas including:

- Individual challenging vaccine markets on the supply or demand side.
- Prices in MIC especially in self-procuring non-GAVI eligible countries.
- Priority vaccines for a target period, e.g. the roll out of IPV from 2015, Measles elimination in give out of six WHO Regions by 2020.
- Financing impacts: the role of development partners in effecting prices e.g. GAVI market shaping activities and strategic goals in reducing WAP.
- The role of pooled procurement on supply and effecting price changes.
- The impact of initiatives such as AMC, UNICEF MIC strategy, V3P and others on vaccine prices.
- The role of vaccine manufacturers from developing countries on the impact on supply and pricing.
- The impact on access and prices of the new supply strategies developed by research based companies.
- Ability of the purchaser to influence pricing through new contracting and financing approaches.

<u>Annex One – Individual Vaccine Reports</u>
Data Provided by UNICEF and PAHO and compiled by WHO. All prices are in US$.

Inactivated Polio Vaccines (IPV)

Figure 12: IPV Pricing from UNICEF and PAHO



Pooled Procurement

In the PAHO region, IPV is mostly supplied for at risk groups. PAHO is procuring IPV for 17 Member States in 2013; only one Member State is using the vaccine for the routine schedule. Between 2010 and 2013, 17-19 Member States have procured the vaccine regularly. The prices as indicated in the chart above show an increase in the WAP from 2010 to 2012. The actual prices from two suppliers for 2013 show a variance of 30%.

UNICEF is currently procuring very limited quantities of IPV (approx. 200,000 - 300,000 doses per year) for two MICs. UNICEF issues an annual tender for this demand. The two price points provided by UNICEF for 2010 and 2012 indicate a 3% reduction in the lowest price and a 15% reduction in the highest price.

Supply Considerations

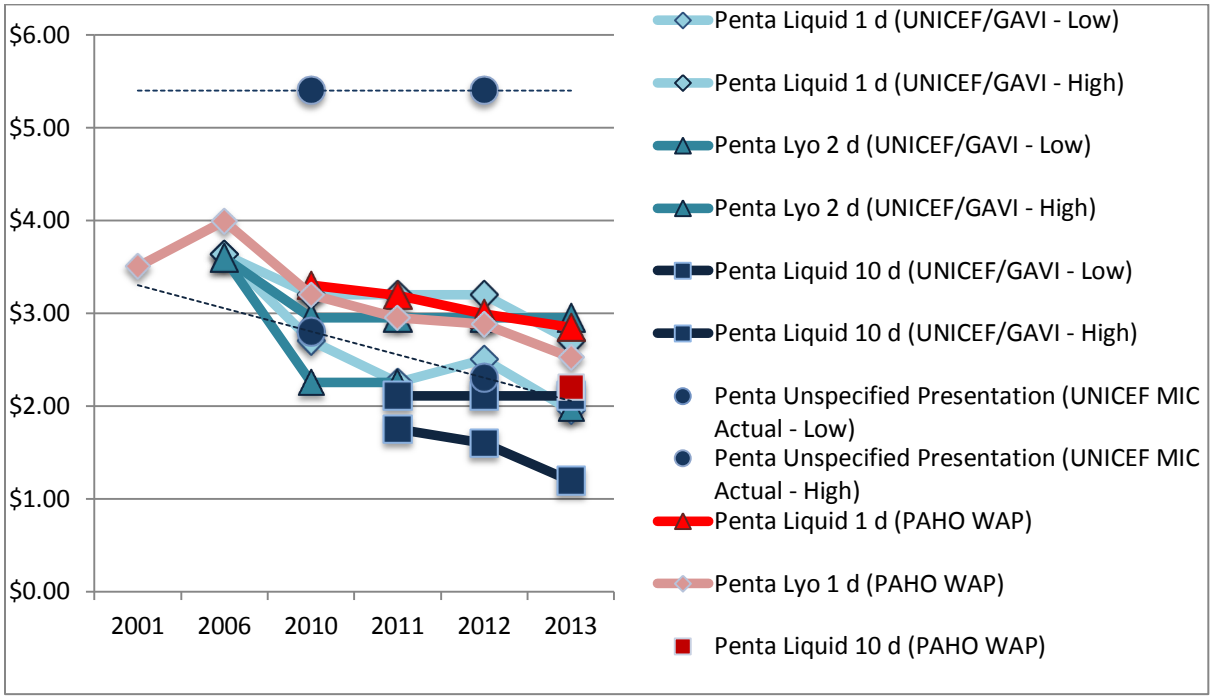
There are currently four manufacturers with pre-qualified products, with one pipeline manufacturer expected to have WHO-prequalified IPV in single and multi-dose vial presentations in early 2014. However, one manufacturer has recently had their production suspended by WHO and there is no information on when production will start again.

In 2013 PAHO has contracts with two suppliers; it notes that while the total quantity requested annually has been fulfilled, however, delays have occurred from manufacturers awarded. The supply is fragile in terms of timely supply.

Both PAHO and UNICEF anticipate changes in the IPV market following the GPEI strategy which will significantly increase demand. Demand may also increase for combination vaccines containing IPV particularly in MIC.

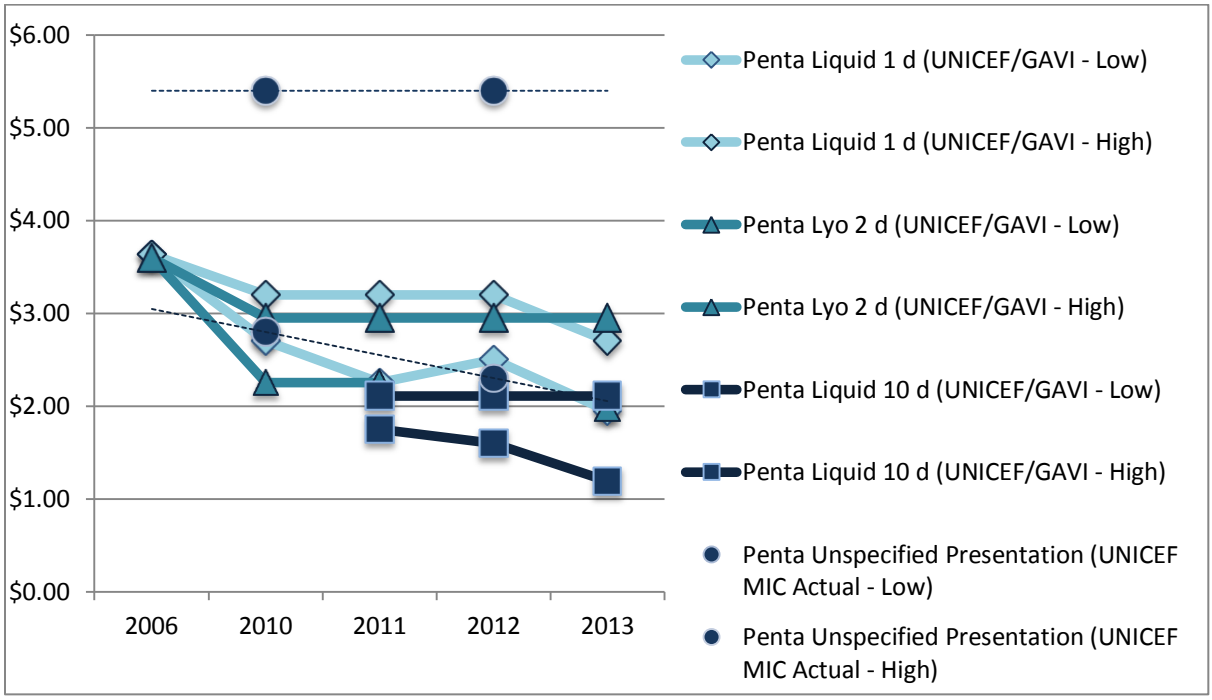
DTP-HepB/Hib Vaccines (Pentavalent)

Figure 13: DTwPHepBHib Vaccines (Pentavalent) Pricing



Special conditions apply for UNICEF/GAVI – Low prices (Liquid 10 dose) in 2012 and 2013.
UNICEF/GAVI – High prices (Liquid 10 dose) for 2011, 2012 and 2013 are based on Incoterms CPT – destinations in India.

Figure 14: DTwPHepBHib Vaccines (Pentavalent) Pricing UNICEF/GAVI and UNICEF MIC



Special conditions apply for UNICEF/GAVI – Low prices (Liquid 10 dose) in 2012 and 2013.
UNICEF/GAVI – High prices (Liquid 10 dose) for 2011, 2012 and 2013 are based on Incoterms CPT – destinations in India.

Figure 15: DTwPHepBHib Vaccines (Pentavalent) Comparison of prices 2006/2013 (Liquid 1 d, Lyophilized 2 d); 2010/2012 (Unspecified Presentation)

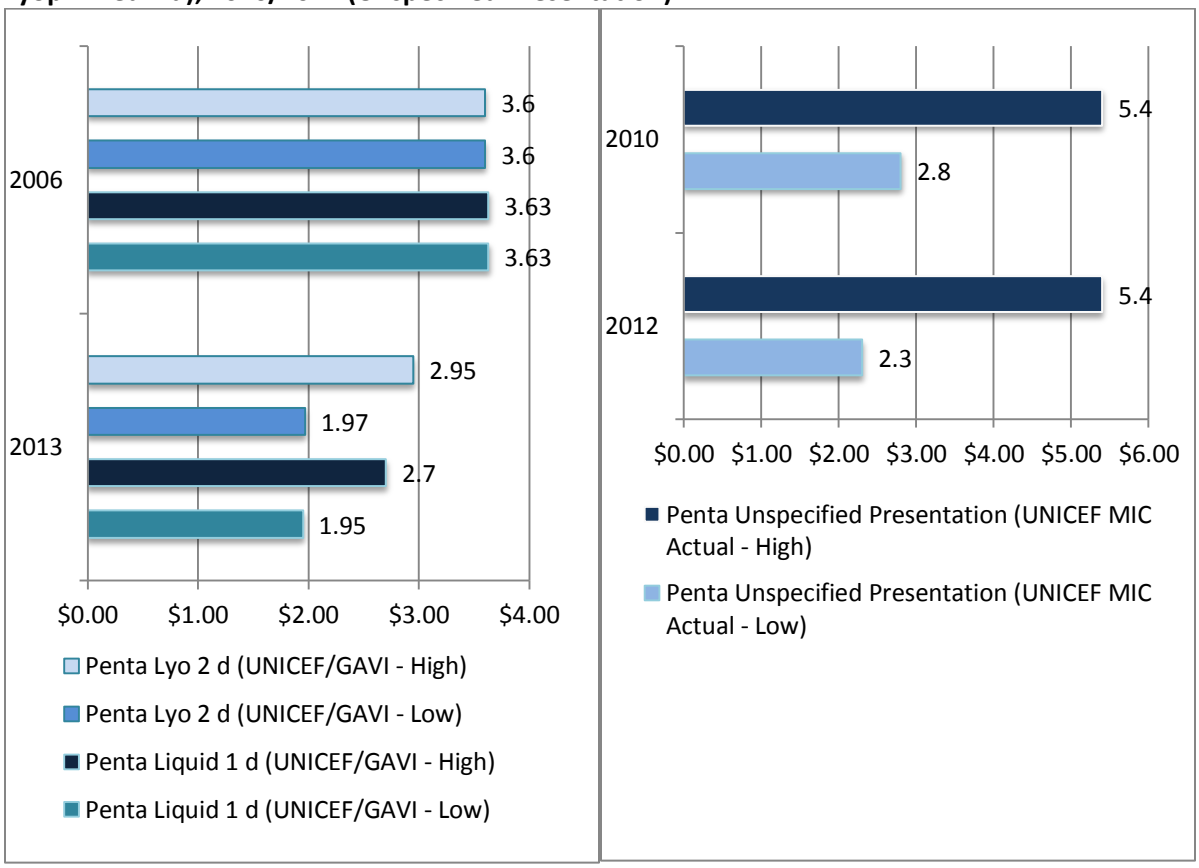
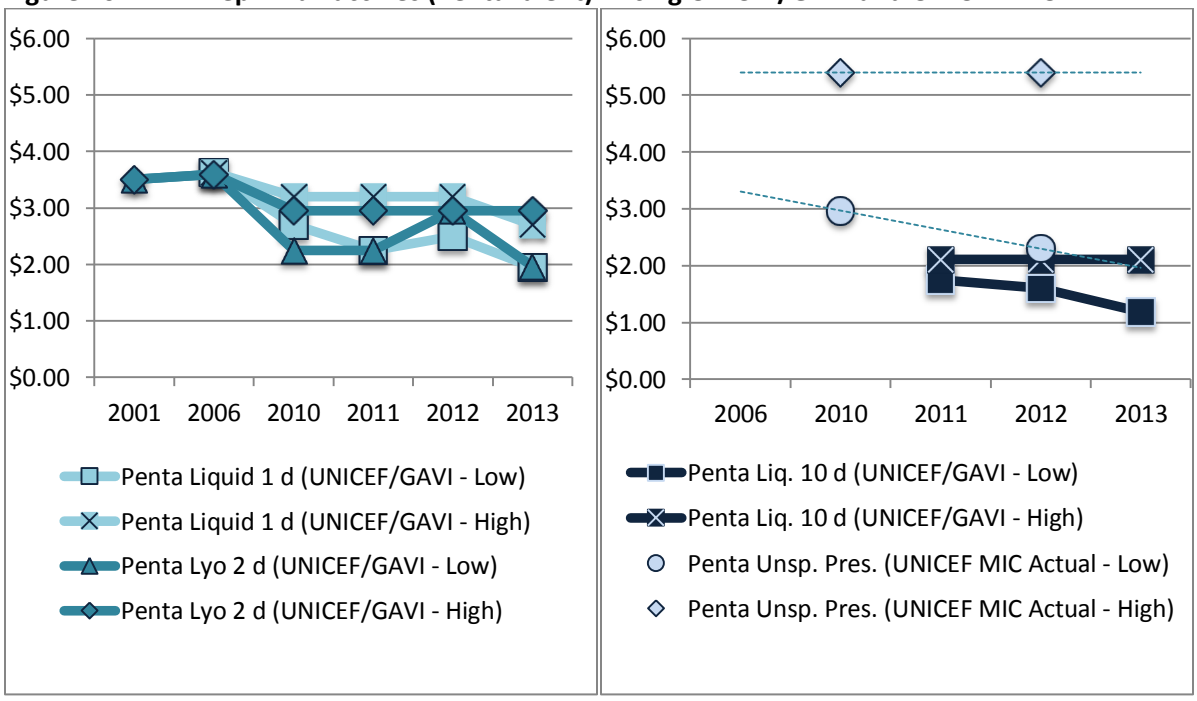
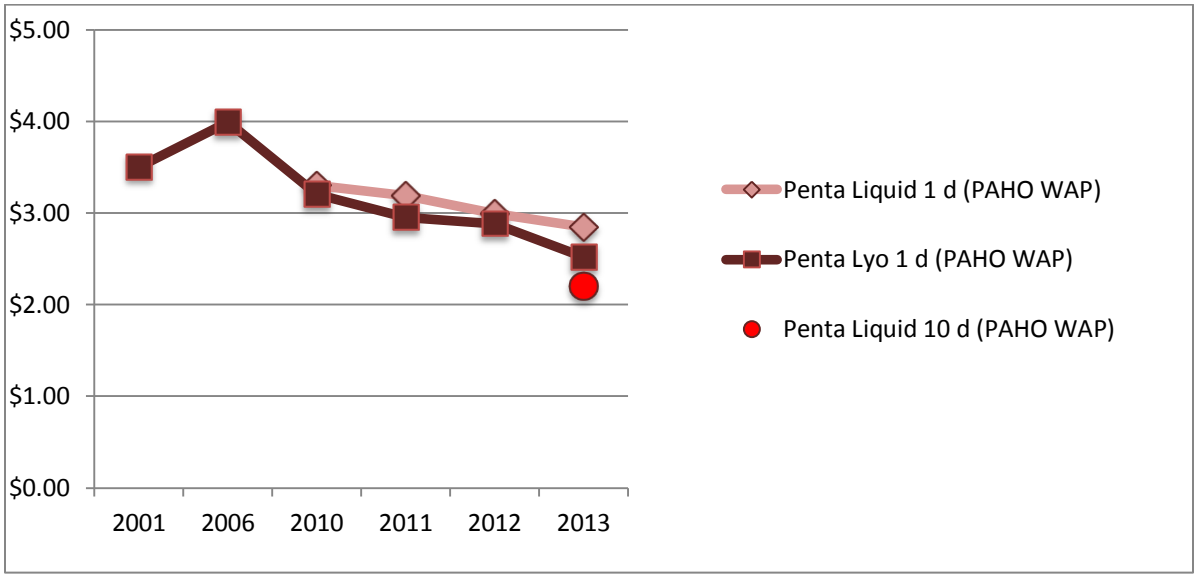


Figure 16: DTwPHepBHib Vaccines (Pentavalent) Pricing UNICEF/GAVI and UNICEF MIC



Special conditions apply for UNICEF/GAVI – Low prices (Liquid 10 dose) in 2012 and 2013.
UNICEF/GAVI – High prices (Liquid 10 dose) for 2011, 2012 and 2013 are based on Incoterms CPT – destinations in India.

Figure 17: DTwPHepBHib Vaccines (Pentavalent) Pricing PAHO



Pooled Procurement

PAHO procures predominantly the single dose presentation of pentavalent. In 2001 and 2006 only one supplier was available but since 2010 three suppliers are under contract. A price is available for the 10 dose presentation as it was requested by one Member State in 2013 but procurement is yet to occur. In 2006, 30 Member State procured the single dose lyophilized presentation while seven procure the liquid single dose. In 2013, 22 countries are now procuring the liquid presentation while a few small islands in the Caribbean procure low volumes of the single dose lyophilized vaccine.

Pentavalent vaccine is now used in almost all GAVI-supported countries and is continuing to roll-out in MIC procuring through UNICEF. UNICEF procures 1 dose, 2 dose and 10 dose presentations in liquid and lyophilized forms. The demand is largely for fully liquid vaccine and a preference for multi-dose vials.

In 2010, UNICEF procured a total of 97.5 million doses of pentavalent vaccine for 65 countries, of which 95.7 million doses were for 56 GAVI-supported countries and 1.8 million doses for 9 non-GAVI-supported countries. In 2012, UNICEF procured a total of 171 million doses of pentavalent vaccine for 72 countries, of which 162 million doses were for 62 GAVI-supported countries and 9 million doses for 10 non-GAVI-supported countries. The demand for GAVI-supported countries through UNICEF is now stabilizing around 200 million doses per year; the demand for non-GAVI-supported countries through UNICEF Procurement Services has fluctuated and is now approximately 10-15 million doses per year.

The prices provided in the above Figure 17 indicate large variation in the lowest and highest price for non-GAVI MIC procurement of pentavalent through UNICEF, but as the presentation is not specified, this could also be a factor in the differential.

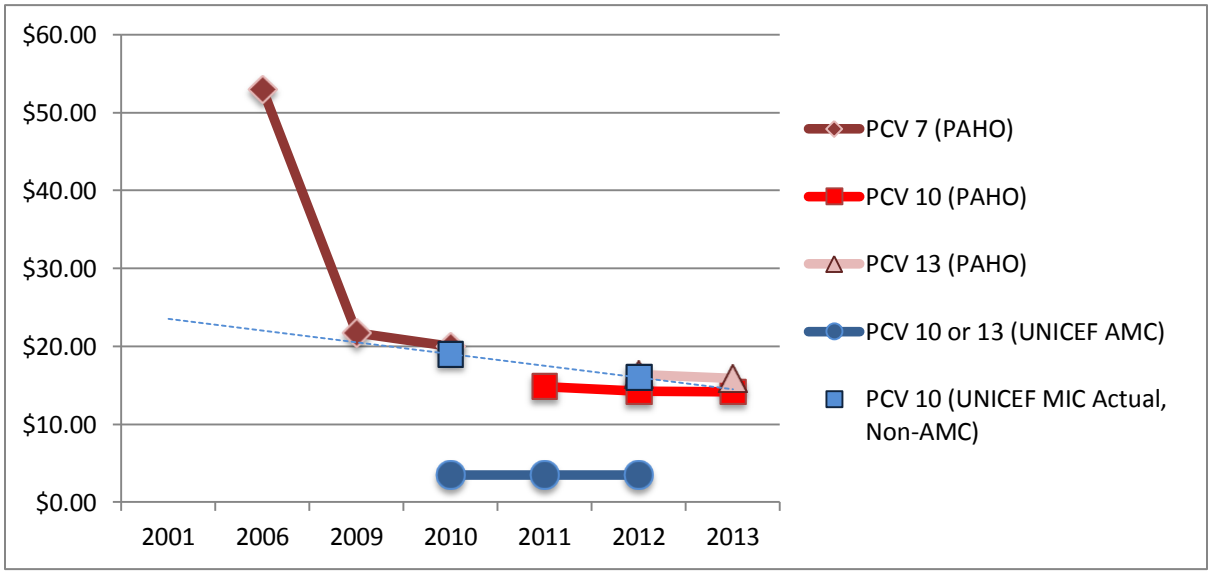
The pricing for both GAVI-supported and non-GAVI-supported markets through UNICEF is decreasing due both to competition and availability of multi-dose vials.

Supply Considerations

The Pentavalent market has been volatile for the last years with multiple suspensions and some delisting of products from WHO pre-qualification. After several years of fragile supply, the situation is now stabilizing. UNICEF, together with partners, is actively pursuing supply security policy by awarding multiple manufacturers to mitigate supply failures. There are currently five manufacturers with pre-qualified products and a robust pipeline for future products. PAHO anticipates more stable supply in the coming years but also anticipates a shift to whole-cell hexavalent (DTwPHepBHibIPV) once this product becomes available.

Pneumococcal Conjugate Vaccines (PCV)

Figure 18: PCV 7, 10 and 13 Pricing PAHO, UNICEF AMC and UNICEF MIC



The price for AMC UNICEF (PCV 10 or 13 vaccine) consists of a co-payment of a maximum of US$ 3.50 (the Tail Price), funded by a country or GAVI and a subsidy up to US$ 7.00 funded by the AMC development partners . Prices are based on a 10 year supply commitment and a volume guarantee as well as other terms as defined in the AMC legal framework (http://www.gavialliance.org/funding/pneumococcal-amc/amc-legal-agreements/).
The price for PCV 10 is for one Member State only.

Pooled Procurement

From 2006 to 2010, PAHO procured the PCV7 presentation of this vaccine, in 2006 the price was US$ 53 per dose for two Member States, by 2010 13 Member States were procuring PCV7 at a price of US$ 20. Seven Member States previously using PCV7 changed to PCV10, in 2013, eight Member States procure this product from PAHO at a price of 14.12 US$. PCV13 is procured for 16 PAHO Member States, three Member States are GAVI-eligible and have access to the GAVI/AMC price. The remaining 10 Member States currently procure at a price of US$ 15.84 which is a 3% price reduction on the 2012 price.

UNICEF procured in 2010 a total of 8.4 million doses of PCV vaccine for 11 Member States, of which 8.3 million doses were for 10 GAVI-supported countries and 0.1 million doses for one non-GAVI-supported

country. In 2012, UNICEF procured a total of 58.8 million doses of PCV vaccine for 28 countries, of which 58.7 million doses were for 27 GAVI-supported countries and 0.1 million doses for one non-GAVI-supported country. Demand from GAVI-supported continues to increase with new country approvals and currently 51 GAVI-supported countries have been approved for financial support, reaching a total annual requirement of around 150 million doses when fully introduced. In addition, nine more Member States are expected to apply and introduce before 2016. At this point in time (mid-2013), only one non-GAVI supported country is regularly procuring PCV through UNICEF and first procurements are in the process for two more non-GAVI-supported countries.

Supply Considerations

PCV is a duopoly market with some supply, logistics and administration issues. While there are currently two manufacturers with pre-qualified products available they are not easily interchangeable. New entrants are expected in the market at the earliest expected 2016/2017.

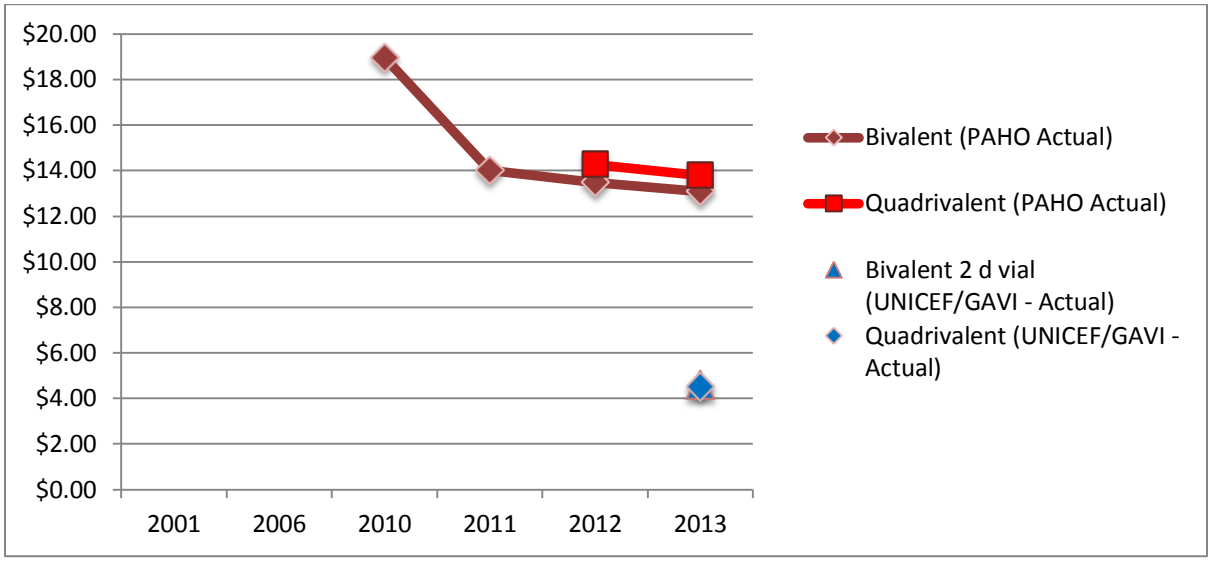
The PCV market for GAVI supported countries is regulated by AMC prices established through UNICEF in line with the terms and conditions of the AMC. This requires an initial price to be co-funded by development partners, GAVI and countries at a price of US$ 7 per dose and – when the AMC donor funds allocated to the specific agreement has been fully disbursed - a tail price capped at US$ 3.50 per dose. The first doses will be procured at the Tail Price for PCV13 in 2013, with a reduction in the tail price for PCV13 in mid-2013 from US$ 3.50 to US$ 3.40 per dose across all contracts and to be further reduced to US$ 3.30 per dose in 2014 onward; for PCV10 the tail price for doses on the third supply agreement will be US $3.40 per dose whereas vaccines procured under contracts entered into earlier will continue to be priced at US$ 3.50. The AMC is available for all GAVI and GAVI graduating countries. UNICEF has issued tenders and entered into supply arrangements for PCV under the AMC with a duration of up to 12 years.

As of end 2012, awards have been made covering a long-term demand of 1,460 million doses, to reach 146 million doses annually from 2016. Sufficient supply is available for first deliveries to 19 countries in 2013. However, timing of introduction depends on country readiness, including meeting local requirements for registration. Three to five countries will need to postpone introduction to 2014 to ensure sustainability. Due to production issues with one vaccine, limited availability in the second half of 2013 and first half of 2014 necessitates strict global management of doses and stocks.[59]

[59] UNICEF presentation on Access and Supply NUVI Meeting June 2013 Dominican Republic

Human Papillomavirus Vaccines (HPV)

Figure 19: PAHO and UNICEF Pricing for HPV



Pooled Procurement

UNICEF has not procured HPV vaccine prior to 2013. Following a recent tender, prices have been established at a price of US$ 4.50 per dose Merck quadrivalent and US$ 4.60 for GSK bivalent, for GAVI eligible countries from 2013, these prices will not be available to GAVI graduating countries or MIC. Both HPV vaccines, the bivalent and quadrivalent are available through PAHO. PAHO started procuring the bivalent for one country in 2010. The quadrivalent has been procured since 2012. In 2013, 8 countries and territories procuring through PAHO are currently providing HPV as part of universal coverage.

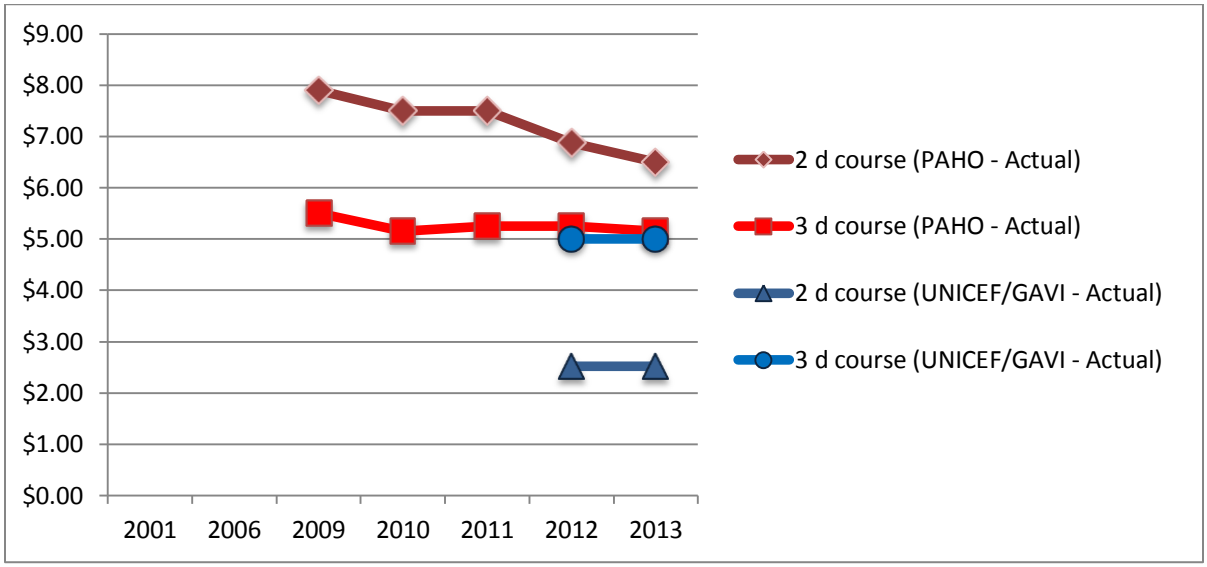
Supply Considerations

HPV is a parallel monopoly market; the two currently available WHO-prequalified products include both a bivalent and quadrivalent presentation. Both products are available in single dose form and the GSK product is also WHO prequalified in a 2 dose presentation which could help to lower the price. Currently the pooled procurement market for either presentation of HPV is small but is expected to increase significantly due to the availability of GAVI funding for selected countries.

Second generation of HPV are under development by both multinationals and emerging manufacturers, but not expected to be on the market before 2016.

Rotavirus Vaccine (RV)

Figure 20: Rotavirus PAHO and UNICEF/GAVI Pricing (prices indicated per dose)



Special conditions apply for the UNICEF/GAVI Actual price (2 dose course). The price is contracted at EUR 1.88 (converted to US$ 2.52 as of March 2012).
The UNICEF/GAVI Actual price applying for 2012 (3 dose course) is for a single country UNICEF procure this vaccine now for four countries. Free of charge doses will be made available by 2015-2016, provided a certain quantity is procured at the price of US$ 5.00.

Pooled Procurement

The variance in price for the Merck product between UNICEF and PAHO is not considerable but for the GSK product the PAHO price is more than two and a half times the UNICEF/GAVI price. PAHO countries started procuring RV in 2009. 11 countries/territories are procuring GSK 2 dose course vaccine while two countries and one small Caribbean island are procuring the Merck 3-doses course vaccine.

UNICEF started procuring RV in 2011. In 2012, UNICEF procured a total of 12.3 million doses of RV vaccine for nine GAVI-supported countries. Demand continues to increase from GAVI supported countries, with 29 countries currently approved with an annual requirement of around 18 million courses, with 10 more countries expected to apply and introduce before 2016. As of mid-2013, UNICEF has not procured RV on behalf of non-GAVI eligible countries. GSK has agreed to extend the UNICEF/GAVI price to GAVI graduating countries that have implemented RV with GAVI support but not those that did not take up this opportunity. Based on contracts entered into in 2012 and 2013, prices have come down for GAVI supported countries. Special contracting and/or payment terms have been applied. No price has been established yet for non-GAVI countries.

Supply Considerations

RV is a parallel monopoly market: there are two WHO prequalified products one requiring a 2 dose course and the other a three dose course. Prices should therefore be considered in relation to the

number of vaccines required per course. PAHO indicate no other countries are interested in the Merck 3 dose vaccine in the region. UNICEF has issued a five-year tender for RV (2012-2016) with awards to two manufacturers. Supply is scaling up with an anticipated 10 million courses expected to be made available in 2013 from manufacturers with pre-qualified vaccines and increasing to around 18 million courses in 2014, up by 80%. Due to a strong country product preference for one vaccine and the scaling up of capacity throughout the year, supply continues to be limited and constrained throughout 2013 and 2014 for the vaccine with a 2-dose schedule. Additional supply remains available for vaccine with a 3-dose schedule. New entrants are expected in the market from 2015/2016.

ANNEX TWO: Summary of Discussions of the WHO Facilitated Working Group on Establishing a Price Indicator and Narrative Report to the SAGE Working Group on GVAP Monitoring and Accountability Framework

From February to May 2013, the vaccine price indicator group held three teleconferences and one face to face meeting. The attendees varied but all notes were provided and comments included from the following participants (listed alphabetically).

Aurelia Nguyen (GAVI Secretariat)
Claudio Politi (WHO HQ)
Daniel Rodriguez (PAHO)
Gian Gandhi (UNICEF)
Jennifer Cohn (MSF)
John Yang (BMGF)
Kamel Senouci (WHO)
Kate Elder (MSF)
Melissa Malhame (GAVI Secretariat)
Meredith Shirey (UNICEF)
Michael Hinsch (WHO HQ)
Miloud Kaddar (WHO HQ)
Santiago Cornejo (GAVI Secretariat)
Sarah Schmitt (WHO HQ)
Shirley Quesada (PAHO)
Thomas Cherian (WHO HQ)

The following participants provided inputs to the development of this report.

Daniel Rodriguez (PAHO)
Jennifer Cohn (MSF)
Kate Elder (MSF)
Melissa Malhame (GAVI Secretariat)
Meredith Shirey (UNICEF)
Michael Hinsch (WHO HQ)
Miloud Kaddar (WHO HQ)
Philipp Kalpaxis (UNICEF)
Sarah Schmitt (WHO HQ)

The scope of the group considerations included:

1. Which **Countries** should be included in the data and information reporting;
2. Which **Vaccines** should be included in the data and information reporting;
3. What **source of data** are currently available and what are the limitations of this data;
4. What **additional sources of data** should be included or developed during the DoV course;
5. What **information** should an indicator/indicators provide;
6. What **contextual** information is required for interpretation and use of the data.

The main recommendations on the points above as a result of the deliberations were as follows:

1. Countries

A countries matrix should be developed to allow for comparability across specific groups of countries, the matric would include separating countries by World Bank Gross National Income Status (GNI), GAVI Eligibility and Vaccine Procurement Method. The countries should include all LIC, LMIC and UMIC. It was noted that PAHO do not differentiate countries based on World Bank GNI status so therefore for both LIC and MIC utilizing the PAHO procurement mechanism the prices would be the same.

2. Vaccines

The group considered all currently available vaccines and settled on the following recommendations. Due to the potential quantity of data that may be required for reporting on all vaccines it was recommended the following vaccines be included:

- IPV (recognizing G1 achieving a world free of poliomyelitis and the potential changes in the polio immunization market during the course of the decade).
- Pentavalent vaccine (recognizing G5 reducing child mortality).
- PCV (recognizing G4 introducing new vaccines).
- Rotavirus (recognizing G4 introducing new vaccines and G5 reducing child mortality).
- HPV (recognizing G4 introducing new vaccines and SO3 reaching other age groups).

The group discussed about the value of whether or not to include measles or measles containing vaccines. The rationale for inclusion of MR and MMR vaccines in GVAP price tracking efforts is based on the following considerations:

- Measles and rubella are targeted for elimination in five out of six WHO Regions by 2020 and adequate vaccine supply is an absolute requirement for achieving this goal.
- With the GAVI investment to support countries to introduce MR vaccine over the next five years, there could be a shift away from single antigen M vaccine to MR vaccine (in GAVI eligible countries) and MMR vaccine in all other countries (e.g. PAHO countries).
- Currently the MR and MMR vaccine supply situation is tenuous due to the fact that there are few prequalified MR/MMR vaccines – MR (only SII) and MMR (SII, Sanofi, GSK and MSD – however only SII and Sanofi provide 10d vials).
- With limited competition in the medium term, there is potential for significant price increases for MR and MMR vaccines thereby increasing the cost of reaching the GVAP MR elimination goals.
- Tracking MR and MMR price maybe a good way to prevent and manage any significant price increase.

Vaccine of regional importance such as YF, JE and Typhoid, were also proposed but the group felt that these should be discussed with the SAGE working group for future inclusion.

3. Currently Available Data

Comparable vaccine pricing data are only currently available from UNICEF and from PAHO. The PAHO data are for all PAHO Member States, UNICEF data are available for LIC and GAVI eligible countries but limited data are currently available for non-GAVI eligible MIC procuring through UNICEF. Non-supplier nor presentation specific data was provided by UNICEF for the Pentavalent vaccine and PCV for this report.

4. Additional Future Data Sources

Initiatives have been launched to improve vaccine price transparency, particularly for self-procuring countries, and to provide this data in a comparable format on a published platform. The WHO V3P project[60] is currently piloting a mechanism which will allow countries to provide data to a web-based platform which could then be collated and published. The data will include quantitative and qualitative information to improve comparability and allow users to have a greater understanding of pricing in its context. WHO is also investigating the use of the JRF as one possible method for countries to report vaccines pricing on an annual basis, while the comparability of this information across countries could be limited between countries and years, it could provide broader information on general trends. During the period of the Decade of Vaccines and the reporting under the GVAP M&E/A framework it is anticipated that there would be further discussion and efforts to improve the availability of vaccine pricing data which would lead more effective monitoring and targeted activities.

5. Pricing Information

Prices should be by product, supplier and by presentation. Wherever possible be to a comparable point such as from PAHO and UNICEF the prices published are to port of manufacturer export. The prices should be converted to US dollars. Price trends from 2001 where possible should be provided as this was a key date in immunization with the advent of GAVI funding, the base line however should be set at 2010 the start of the decade. Prices should be reported annually for all vaccines proposed, conditions pertaining to the prices should be wherever possible identified to allow for greater comparability and understanding.

6. Pricing Context

Pricing is a factor of the market dynamics for each product and the context of the procurement and funding. These factors should be adequately explained in each narrative report for each vaccine in order to provide greater clarity, transparency and comparability. The proposal to focus each narrative report on a particular area of pricing, supply or vaccine market will provide an opportunity to improve the dialogue on this area.

[60] http://www.who.int/immunization_supply/procurement/v3p/en/index.html

STRATEGIC OBJECTIVE 6

COUNTRY, REGIONAL AND GLOBAL RESEARCH AND DEVELOPMENT INNOVATIONS AND DEVELOPMENT INNOVATIONS MAXIMIZE THE BENEFITS OF IMMUNIZATION

INDICATOR SO6.1

PROGRESS TOWARDS DEVELOPMENT OF HIV, TB AND MALARIA VACCINES

TARGET: PROOF OF CONCEPT FOR A VACCINE THAT SHOWS GREATER OR EQUAL TO 75% EFFICACY FOR HIV/AIDS, TUBERCULOSIS, OR MALARIA VACCINES

SECRETARIAT FOCAL POINT: JOACHIM HOMBACH AND LEE HALL

DEFINITION OF THE INDICATOR

Number of HIV, TB and malaria vaccine clinical trials assessing clinical efficacy completed and with results reported over the last two years.

DESCRIPTION OF DATA'S SOURCES

WHO clinical trial registry platform International Clinical Trials Registry Platform (ICTRP); publications in relation to results.

COMMENTS ON DATA'S QUALITY

No reporting in 2013.

DESCRIPTION OF THE RESULTS

No reporting in 2013.

NARRATIVE

Process to be used to report in 2014: qualitative reports to be commissioned for HIV, TB and malaria separately and to be discussed at the Global Vaccine and Immunization Research Forum (GVIRF) in March 2014.

HIGHLIGHTS

No reporting in 2013

STRATEGIC OBJECTIVE 6

COUNTRY, REGIONAL AND GLOBAL RESEARCH AND DEVELOPMENT INNOVATIONS AND DEVELOPMENT INNOVATIONS MAXIMIZE THE BENEFITS OF IMMUNIZATION

INDICATOR SO6.2

PROGRESS TOWARDS A UNIVERSAL INFLUENZA VACCINE (PROTECTING AGAINST DRIFT AND SHIFT VARIANTS)

TARGET: AT LEAST ONE VACCINE PROVIDING BROAD SPECTRUM PROTECTION AGAINST INFLEUNZA A VIRUS LICENSED

SECRETARIAT FOCAL POINT: JOACHIM HOMBACH AND LEE HALL

DEFINITION OF THE INDICATOR

Number of influenza clinical trials assessing clinically the breath of protection completed and reported over the last two years.

DESCRIPTION OF DATA'S SOURCES

WHO clinical trial registry platform ICTRP; publications in relation to results.

COMMENTS ON DATA'S QUALITY

No reporting in 2013.

DESCRIPTION OF THE RESULTS

No reporting in 2013.

NARRATIVE:

Process to be used to report in 2014: qualitative report to be commissioned and discussed at the Global Vaccine and Immunization Research Forum (GVIRF) in March 2014.

HIGHLIGHTS

No reporting in 2013.

STRATEGIC OBJECTIVE 6

COUNTRY, REGIONAL AND GLOBAL RESEARCH AND DEVELOPMENT INNOVATIONS AND DEVELOPMENT INNOVATIONS MAXIMIZE THE BENEFITS OF IMMUNIZATION

INDICATOR SO6.3

PROGRESS TOWARDS INSTITUTIONAL AND TECHNICAL CAPACITY TO CARRY OUT VACCINE CLINICAL TRIALS

TARGET: EVERY REGION HAS A SOLID BASE OF MEMBER STATES COMPETENT IN HOSTING AND MANGING VACCINE TRIALS

SECRETARIAT FOCAL POINT: JOACHIM HOMBACH AND LEE HALL

DEFINITION OF THE INDICATOR

Number of Member States per WHO region having reported conduct of a vaccine clinical trial that meets quality standards.

It should be noted that there is no real quality criteria; but only the minimum amount of trial information that must appear in a register in order for a given trial to be considered fully registered (http://www.who.int/ictrp/network/trds/en/index.html).

DESCRIPTION OF DATA'S SOURCES

WHO clinical trial registry platform, counting clinical trials active or recruiting over the last two years.

COMMENTS ON DATA'S QUALITY

No reporting in 2013.

DESCRIPTION OF THE RESULTS

No reporting in 2013.

NARRATIVE

Process to be used to report in 2014: qualitative report to be commissioned and discussed at the Global Vaccine and Immunization Research Forum (GVIRF) in March 2014.

HIGHLIGHTS

No reporting in 2013

STRATEGIC OBJECTIVE 6

COUNTRY, REGIONAL AND GLOBAL RESEARCH AND DEVELOPMENT INNOVATIONS AND DEVELOPMENT INNOVATIONS MAXIMIZE THE BENEFITS OF IMMUNIZATION

INDICATOR SO6.4

NUMBER OF VACCINES THAT HAVE EITHER BEEN RE-LICENSED OR LICENSED FOR USE IN A CONTROLLED-TEMPERATURE CHAIN AT TEMPERATURES ABOVE THE TRADITIONAL 2-8°C RANGE

NO TARGET

SECRETARIAT FOCAL POINT: MICHEL ZAFFRAN & SIMONA ZIPURSKY

DEFINITION OF THE INDICATOR

This indicator measures the number of vaccines used in low and middle income Member States that are licensed for use in a controlled temperature chain (CTC) at ambient temperatures of up to 40^{o}C.
CTC is defined as:

- Allowing vaccines to be kept and administered at ambient temperatures, up to 40^{o}C, as per the conditions specified on their label.
- For one, limited period of time (length of time will vary by antigen and setting) immediately preceding administration.
- Up until this excursion, the vaccine should continue to be kept in the traditional 2-8^{o}C cold chain.

DESCRIPTION OF DATA'S SOURCES

Types of data and sources are as follows:

a) OUTCOME: Revised vaccine product inserts allowing for use of the vaccine at ambient temperatures up to 40^{o}C accessed from one or more of the following sources:
    a. WHO Vaccine Pre-Qualification Database
    b. Manufacturer Websites
    c. Hardcopies of product inserts
b) PROCESS: Public announcements made by vaccine companies of ongoing studies to assess feasibility of using their vaccines in a CTC:
    a. Journal articles
    b. Media reports
    c. Conference presentations
c) PROCESS: Private correspondence and information disclosed to WHO under non-disclosure agreements:
    a. Email correspondence
    b. Meeting minutes

COMMENTS ON DATA'S QUALITY

The information used for this report is not collected on a regular basis or a formal process. This has been done specifically for the DoV GVAP Secretariat annual report. The data used in this report is highly reliable and generally obtained first hand directly by WHO staff. Once a label variation has been approved, the information is publicly available on multiple websites and in print, and can be cross referenced to confirm accuracy.

It generally takes two to five years to obtain a CTC label variation for a vaccine. Therefore it is equally important to track progress and not just results to ensure we are on track to achieve this indicator. However, much of the information on progress is confidential and is shared with WHO under non-disclosure agreements. While this data are highly reliable, it can only be reported on in broad strokes and cannot be verified as it is not in the public domain.

RESULTS

On 27 October 2012, the Indian regulatory granted their approval for the use of MenAfriVac in a CTC, allowing the vaccine to be stored at temperatures of up to 40°C for up to four days, and kept for six hours at up to 40°C after reconstitution, provided the VVM is still good, and the expiry date has not been reached. This is the first vaccine used by the EPI program to obtain such a label; a milestone for the program. WHO has also prequalified the vaccine with this variation.

Following the regulatory approval, and utilizing guidance developed through WHO's Immunization Practices Advisory Committee, the first use of MenAfriVac in a CTC was conducted in Banikoara, in Northern Benin. Over the course of the 2012 Meningitis A vaccine Banikoara over 155,000 people were vaccinated using the vaccine in a CTC. Over 98% of health care workers said that, if given the choice, they would prefer to conduct their next campaign using the CTC approach.

In addition, four manufacturers have indicated that they have started tests and/or analysis to obtain CTC labels for their vaccines. These include vaccines against Yellow Fever, HPV and Hepatitis B.

NARRATIVE

Many of the vaccines used in immunization programmes today are actually more heat stable than their current label reflects. Keeping vaccines in a 2-8^{o}C cold is frequently extremely difficult if not impossible in settings with limited cold chain and ice pack production capacity. In addition, in settings where the cold chain cannot be reliably maintained, freeze sensitive vaccines—many of which are stable at higher temperatures—risk being damaged by accidental exposure to sub-zero temperatures.

The CTC approach aims to take advantage of this existing stability and without requiring any reformulation enable the use of vaccines outside the standard 2-8^{o}C range, endorsed through regulatory processes. The regulatory approval will allow for 'on-label' use and is important for ensuring the vaccines remain potent and safe throughout their lifecycle. This will allow Member States the flexibility to implement new or innovative vaccination strategies, not constrained by cold chain limitations, in order to reach more people, reduce costs or maximize the use of health care workers' time.
The work in this area follows four complimentary, inter-linked streams, outlined below.

- **Vaccines:** *Exploring and defining regulatory pathways to license specific vaccines for higher temperature by regulators and WHO's pre-qualification team*
- **Member States:** *Development and field testing of operational guidelines for CTC decision-making and implementation at the country level , in collaboration with WHO regional offices*
- **Technologies:** *Ensuring proven technologies are available to support the implementation of a CTC, including peak temperature threshold indicators*
- **Incentives:** *Defining mechanisms to incentivize the licensing of products to reflect their true stability, including ensuring Member States have access to product information and the ability to preferentially select products that meet their needs*

The initial focus of this work is on vaccines used in campaigns and delivered through special strategies (e.g. HPV, Hep B birth dose).

In order to ensure regulators are ready to grant variations to vaccine labels when companies request them, and do so based on a solid set of scientifically vetted principles, a regulatory forum to draft Scientific Considerations for Regulating Vaccines in a CTC was established. The first meeting of the drafting group was hosted by Health Canada, leaders in this area, 4-6 December 2012. Regulators from Brazil, Canada, France, Germany, Korea, Thailand, the USA attended, along with five vaccine manufacturers (from both developing and developed Member States). The results of the drafting group meeting will be published as a reference article in the journal Biologicals after a follow up meeting in June 2013 in Germany and will be released by WHO as Scientific Advice to regulators, bringing legitimacy and scientific rigor to CTC vaccine regulation.

To achieve a revision to the existing product label, close collaboration with manufacturers, regulatory experts and WHO staff will be essential. The data that is necessary for these types of variations does not readily exist and will need to be generated for each vaccine for which a new license is sought.

It is hoped that through this work a pathway is charted and manufacturers start conducting studies to enable them to label vaccines to reflect their true stability during the development process. However, for this to be possible, the public sector will need to develop a mechanism to incentivize manufacturers who produce vaccines that, like in the case of CTC, are designed to meet country needs. This likely requires a shift in our metrics from cost of dose purchase to cost of dose delivered.

HIGHLIGHTS

- First vaccine licensed for use in a CTC pre-qualified by WHO (MenAfricaVac).
- Over 155,000 people vaccinated using the CTC approach in Benin.
- By end of 2012, four manufacturers had launched CTC studies.
- Co-led by Health Canada and the Paul Ehrlich Institute, guidance for regulating vaccines in a CTC was started.
- The ability to incentivize manufacturers to develop vaccines to meet country constraints remains a challenge.

STRATEGIC OBJECTIVE 6

COUNTRY, REGIONAL AND GLOBAL RESEARCH AND DEVELOPMENT INNOVATIONS AND DEVELOPMENT INNOVATIONS MAXIMIZE THE BENEFITS OF IMMUNIZATION

INDICATOR SO6.5

NUMBER OF VACCINE DELIVERY TECNOLOGIES (DEVICES AND EQUIPMENT) THAT HAVE RECEIVED WHO PRE-QUALIFICATION AGAINST THE 2010 BASELINE

NO TARGET

SECRETARIAT FOCAL POINT: DENIS MAIRE

DEFINITION OF THE INDICATOR

The WHO Performance, Quality and Safety (PQS) project, was introduced in 2006 and prequalifies a range of cold chain equipment, injection devices and other products needed for safe and effective vaccine delivery (http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/).It became gradually functional through a transition period from the previous Product Information Sheet (PIS) system. This scheme has become entirely live online in 2010, year of the baseline data.

The indicator is the measure of the number of products that have been WHO PQS prequalified as of 31 December 2012 in comparison to the number of prequalified products as of 31 December 2010, which was 160 products. It does not take into account the number of products that might have entered the list and been withdrawn in the interim period. Therefore it is just the difference between two data points.

DESCRIPTION OF DATA'S SOURCES

Numbers are drawn from the PQS secretariat database records. PQS maintains three registers in its database, companies, laboratories and products. Each time a manufacturer submit a dossier for a product, this is recorded in the database. When this product reaches the stage of prequalification, this product is published directly from the database to the online PQS website. The database can produce reports of all products including their status as prequalified, suspended (temporarily taken out of the list for unresolved issues) or withdrawn (definitely taken out from the list). Each change of status is automatically dated.

COMMENTS ON DATA'S QUALITY

The data reflect the difference between the number of products that were listed in the PQS as prequalified on 31 December 2010 and those as of 31 December 2012. The record of the date after each change of product's status allows a time monitoring of the prequalification process.

DESCRIPTION OF THE RESULTS

The number of products prequalified as of 31 December 2012 were 216 products (see Table 41).
The baseline number in 2010 included 163 products (see Table 41).
A total of new products was then 53 corresponding to a 32.5% increase between 2010 and 2012 (see details in

Table 42).

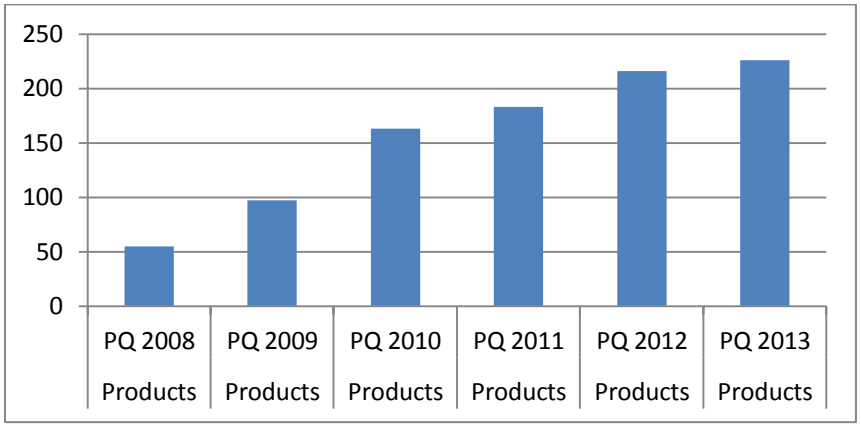
Table 41: Number of products newly prequalified during 2012

Product Name	Total with PQ in 2012
refrigerators and freezers	20
cold boxes and vaccine carriers	3
coolant packs	3
temperature monitoring devices	6
injection devices for immunization	4
Total	36

Table 42: Number of prequalified products at the end of each year from 2008 to 2013

Description	Number of Prequalified Products					
	2008	**2009**	**2010**	**2011**	**2012**	**2013**
Cold rooms and related equipment	0	1	3	3	3	3
Refrigerators and freezers	0	8	14	23	33	35
Cold boxes and vaccine carriers	0	2	31	32	34	36
Water-packs	0	1	15	16	18	17
Temperature monitoring devices	7	10	11	12	17	22
AD syringes for immunization.	21	31	30	27	29	33
Waste management equipment	5	9	10	10	10	10
Therapeutic injection devices	22	35	49	60	72	78
Total	55	97	163	183	216	234

Figure 21: Number of prequalified products as of 11 July 2013 (each year only remaining prequalified products as of 31 December of that year)



NARRATIVE

The QSS unit established the Performance, Quality and Safety (PQS) scheme for the prequalification of equipment and devices in 2006. This scheme selects immunization equipment eligible for purchase by UN agencies. It requires the industry to comply with criteria of performance, quality and safety for their products to be established by independent and WHO accredited laboratories. As more Member States are now indicating the PQS prequalification in their tender for the procurement of immunization equipment, the PQS now goes beyond UN purchase.

One of the key aims of the PQS is to bring WHO, UNICEF and other immunization stakeholders into a more productive relationship with users, key partners and industry. The intention is to create a product development, improvement and innovation cycle comprised of three steps.

- Step 1. Establish and /or adopt international standards to provide a framework of reference for the design, development and production of each product.
- Step 2. For each type of product, develop and maintain technical specifications and related test procedures that adequately reflect programmatic and operational needs.
- Step 3. Monitor products post-market in order to assess performance, quality and safety characteristics over a products life cycle from the perspective of the user, and monitor its suitability for programmatic and operational needs.

The intention is to build a system that will operate effectively over the long term and to provide procurement agencies with a list of reliable immunization equipment and devices, each proven to meet user needs. At the same time the system must encourage the continuous improvement of existing products, whilst remaining open to innovation.

Documentation: During these past years, performance specifications and test procedures have been revised to fit to this new scheme and better reflect the changes that have occurred in the industry. This work has been done in close collaboration with UNICEF Supply Division, manufacturers and laboratories.

There are now 34 sets of specification/verification documentation covering various categories of equipment as follows:

9 categories of equipment:

- E001: cold rooms & freezer rooms (extended to large volume rooms)
- E003: refrigerators and freezers – nine subcategories
- E004: cold box and vaccine carrier – five subcategories
- E005: coolant packs
- E006: Temperature monitoring devices – 13 subcategories
- E007: Accessories
- E008: Auto-disable injection devices – two subcategories
- E010: waste management – two subcategories
- E013: Reuse prevention injection devices for therapeutic use and vaccine reconstitution

Between December 2010 and December 2012, eight sub-categories of devices have been created incorporating new types of products into the PQS scheme, reflecting the rapid evolution of technologies in the field of vaccine cold chain.

Database: Major progress has been made in instituting the PQS web based database. It is now functional and an online catalogue is made available to the public and regularly updated..
http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx

Laboratories: Accredited laboratories covering all technical areas are published. Clients have now the choice between 11 laboratories. Efforts are made to identify other facilities in order to bring closer laboratories to manufacturers.

PQS Review: The current prequalification of products is mainly based on the documentation that manufacturers can provide according to specifications and verification protocols. In turn, the evaluation of a product follows the procedures described in the relevant standard operating procedures. In addition to the prequalification of devices, PQS organizes an annual review of all dossiers. This annual review is meant to update all documentation related to manufactures and products. This review is implemented by external experts and is the opportunity to examine at the same time the performance of the programme.

Innovation: Efforts are now focusing on expanding to products that were not included in the past but that are necessary to adapt to the changing environment looking at responding to a substantial increase of volume of vaccines to be stored as well as improved technologies to monitor the temperature at which vaccines are stored.

The prequalification process is sufficiently flexible to allow innovations, but represents the most demanding aspect of the PQS work. Member States are now much more demanding in terms of justifying the quality of the vaccines they use, which put pressure on the management of logistics to adopt procedures and technologies that will monitor and demonstrate the vaccine quality at any point in time. Another aspect is the increased volume of vaccines to be dealt with due to the introduction of new vaccines. These two aspects are considered by the PQS programme in looking at innovative technologies that will best respond to these new requirements. However, it requires more efforts in field studies and field monitoring of new products. Due to the limited resources of PQS these activities have to be implemented as a collaborative work with partners including IVB units, NGOs, UN

Organizations such as UNICEF, the industry and relevant testing laboratories. Those tasks are to be part of a long term vision to be shared with all partners.

Such newly introduced products include the following:

1. 30-day electronic temperature monitoring device for refrigerators

This device has been conceived specifically to record temperature in refrigerators at the health facility level to complement the use of alcohol stem thermometers. It permits the health worker to retrieve any temperature excursions (temperature records beyond 2 to 8 degree Celsius) on a LCD screen without the need of a computer or other accessories for a period of a 30-day cycle.

2. 20-day electronic shipping indicator new generation

This single-use device is meant to record all temperature excursions during transit of any international shipment. As the previous device, data can be retrieved on LCD screen. Both devices have options for computer download and automatic pdf report generation with temperature graphs presentation.

3. Centralized temperature monitoring systems

These systems are for use in large storage facilities with reliable power source and internet or mobile phone connectivity. It allows remote temperature monitoring of several cold/freezer rooms in a centralized location with options of SMS or email alerts.

4. AD jet injector

These injection devices are the new generation of jet injectors using single-use auto-disabling cartridges.

5. Solar direct drive refrigerators (without battery)

This new technology has the great advantage to eliminate the need of a battery to store energy. The battery with its short life had been identified as a real impediment to the long use of this type of appliances where electricity is not available.

6. Long holdover refrigerators

Refrigerators with this technology are characterized by their capacity of having a long holdover time allowing them to maintain an inside temperature between 2 to 8 degrees during several days without power.

7. Long term passive containers

Although none of these containers are yet prequalified, it is foreseen that they will be able to keep vaccine storage at a correct temperature for 10 to 35 days without recharge of frozen coolant. Preliminary testing is promising and should lead to prequalification by the end of the year.

Products: The Prequalification of equipment and devices is now running at an increased pace as more and more products are submitted for prequalification. Procurement agencies have now (as of 11 July 2013) the choice between 234 PQS prequalified products from 53 manufacturers. On 31 December 2010 the list counted 163 prequalified products while as of the 31 December 2012 this list was up to 216 products corresponding to a 32.5% increase. If the number of withdrawn products is taken into account, the number of dossiers processed between 2010 and 2012 accused an increase of 43%. The PQS pdf catalogue not only provides information on prequalified products but gives guidance on how to select products according to field conditions.

The increased number of products submitted is putting more pressure on the PQS to process all dossiers in a timely fashion. The PQS met its objective in having all prequalification applications evaluated in a deadline of 8 weeks despite the significant increase of the number of these applications.

II TRACKING RESOURCES INVESTED IN IMMUNIZATION

Tracking Expenditures for Immunization Using and Single Country Platform

Background

As per the M&E/A Framework presented to and noted by the Sixty-sixth World Health Assembly in May 2013, resources invested in immunization will be tracked and monitored on a yearly basis throughout the decade, using the framework of the OECD/EUROSTAT/WHO System of Health Accounts 2011. This implies an emphasis on strengthening country capacity and creating a single platform for collecting and analysing all health expenditures, including those on priority diseases or programmes like immunization. This effort intends to unify under a single platform other resource-tracking initiatives, such as those being undertaken using health accounts, and those for (i) the Commission on Information and Accountability for Women's and Children's Health (COIA) and (ii) the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Activities to track resources are underway to evaluate funding flows to support immunization in 10 countries.

Why track expenditure for immunization?
Over the last few years there has been a substantial increase in funds for national immunization programs. However, evidence suggests that impact on coverage rates is slow and that resources are not reaching front line providers[61]. Immunization activities continue to be underfunded, and financing sustainability is of concern. Tracking countries immunization expenditures on a routine basis within the framework of A System of Health Accounts 2011 (SHA2011) would help countries enhance accountability mechanisms and practices, and to assess whether resources are sufficient and best used to improve efficiency, equity, and sustainability.

What are the current opportunities for tracking immunization expenditure in the country?
Immunization expenditure tracking could be leveraged by other country level resource tracking efforts, such as the COIA platform. COIA recommended that, by 2015, countries would track and report at a minimum, two aggregate resource indicators: (i) total health expenditure, and (ii) total reproductive, maternal, newborn and child health (RMNCH) expenditure, both by financing source, and per capita.

What is System of Health Accounts 2011[62] (SHA 2011)?
SHA 2011 tracks all health spending in a given country over a defined period of time regardless of the entity or institution that financed and managed that spending. SHA generates consistent and comprehensive data on health spending in a country, which in turn can contribute to evidence-based policy-making. SHA can be used as a monitoring and evaluation tool to track changes in policy priorities and if the introduction of reforms and new programs resulted in changes in health resources allocation and expenditure.

The SHA analysts can provide information about health financing and health sector governance. What is the total envelope of health spending? Who are the main financiers of health spending – governments,

[61] Brenzel, L. (2008), "Immunization Resource Tracking Exercise: Case Study on the Republic of Tajikistan" The World Bank, Washington DC.
https://openknowledge.worldbank.org/bitstream/handle/10986/8116/445100ESW0P0901Case0Study0June02008.pdf?sequence=1

[62] OECD, Eurostat, WHO (2011), A System of Health Accounts, OECD Publishing. doi: 10.1787/9789264116016-en

donors, household, or other private sector actors? What agencies or entities are responsible for making programmatic decisions over health spending? What kinds of services and goods do the funds purchase? How is health spending distributed across different providers of health services? The SHA methodology yields information that can be used to address such questions by collecting and analysing data on health spending from donors, nongovernmental organizations (NGOs), private companies, insurance providers, government entities and households, which each contribute to health spending. Data from all of these different sources are cross-checked to avoid double counting and to produce an accurate estimate of current and capital spending in a country over a fixed time period, typically a fiscal year.

Why use a single country platform to track expenditures for immunization?

The rise of global health initiatives had generated a demand for disease-specific expenditure tracking. Resource tracking exercises like National Aids Spending Assessments (NASA), reproductive and child health, malaria, tuberculosis, and more recently, non- communicable disease were supported in a fashion similar to health accounts but often not done every year. Program managers (e.g. for HIV, TB, malaria, immunization, tobacco) in countries were asked to report to the global alliances on their country's spending, but vertical, parallel reporting with inconsistencies in treatment of shared costs like expenditures in health facilities has at times led to the awkward but not unexpected phenomenon of the sum of disease-specific expenditures exceeding the total health expenditure of a country for that year. Not using a single platform and methodology to measure spending on immunization within and across countries one gets: i) less robust, less technically rigorous and less consistent estimates; ii) no comparability of immunization expenditure across countries and over time; and iii) data collection will be multiple, a labour intensive and potentially distracting to national staff.

Such challenges may become magnified as recently established initiatives like COIA, Decade of Vaccines, and Family Planning 2020 launch their own resource tracking activities and as the GFATM new funding model requires documentation by grant renewal countries of requisite counterpart financing in HIV, tuberculosis and malaria. To address these concerns the 2013 it was proposed that the Decade of Vaccines/Global Vaccine Action Plan resources tacking be done though SHA2011. By doing so DoV/GVAP, aims to promote coordination, improve accountability, and reduced reporting burden on countries.

The release of the new global standard on reporting health expenditures, System of Health Accounts 2011 provides an opportunity to synergize the resource tracking work of the different initiatives using a single country platform.

What is the approach to Harmonizing Resource Tracking of Health Expenditure at the Global and Country Level?

WHO and partners are in the process of institutionalizing and setting up a harmonized country platform for collecting data, by automating where possible, the collection and mapping of the data, and by analysing results and trends, so that expenditures can be reported and used yearly with more technical rigour and to decrease the load on the national staff. Advantages of doing this at the country level include:

i. It is more technically rigorous in that there is a standard way to allocate expenditures by diseases.
ii. It will ensure that there will be an internally consistent estimate with current and capital health expenditure.
iii. Robust and timely health expenditure data for the development and assessment of health sector strategic plans.

iv. Use of a consistent platform that integrates data collection of immunization expenditures in existing routine health information system ensures comparability of country data over time.
v. Minimize multiple parallel data collection initiatives that are labour intensive and potentially distracting to national staff. Making reporting more frequent and reduce errors, allowing the process to focus on the reporting of data and its use for national planning purposes.
vi. Yearly production of health expenditure data as part of the health information system. The data will be relevant to inform policy choices, the development of national policies and strategic plans, all based on comprehensive evidence.

What are the risk and challenges?
There is an influx of stakeholders that want to track resources flows in the area of their initiative. SHA2011, the global standard for health expenditure reporting, with its distributional table by beneficiary (disease), should be the organizing technical framework for reporting that is a public good. Resource flow tracking efforts on the ground should be harmonized for more technical rigour and to decrease the demands on national staff.

Examinations of the roadmaps that have been submitted by the countries demonstrate that there is limited or no funding going to resource tracking activities. Although intended to be catalytic in nature, the amounts being allocated can scarcely 'catalyse'. Resource allocation to enable countries to SHA2011 is an investment that is often overlooked. We hope that by harmonizing efforts and pooling together investments for resource tracking by GFATM, DoV and other initiatives under SHA2011 this will benefit the countries and produces one set of numbers for reporting by all. We are attempting to bring in other resources, namely by trying to get other resource-tracking initiatives to pool their funds into one effort in the country. This has now been agreed upon with the GFATM. More negotiations are needed on family planning and immunization resource tracking.

Ensure access to all relevant data from stakeholders in country. In particular the private sector to get accurate estimates of the total extent of health expenditures.

What is the way forward/next steps?
- Continue technical assistance to institutionalize a harmonized country platform for collecting expenditure data, and build capacity at the country level.
- Improve accountability processes in the country having health account teams in the Ministry of Health partnering with parliamentarians and civil society to use expenditure data for policy planning.
- In order to facilitate resource tracking for health in countries, continue to work closely with IHP+ to ensure country compacts between governments and all major development partners address transparent reporting of expenditures by external partners.

What are the proofs of concepts so far?
- The health accounts methodology has been in place since 2000, and over 120 countries have implemented it at least once.
- The methodology (system of health accounts 2011 – SHA 2011) has been revised to better respond to the type of health expenditure data demanded. It is also the new global standard for reporting expenditures. Half a dozen countries have started working their latest health accounts using the new methodology and set of tools with success. For example, the Democratic Republic of Congo will present results produced and analysed with the help of the new tools in June 2013; Burkina Faso will

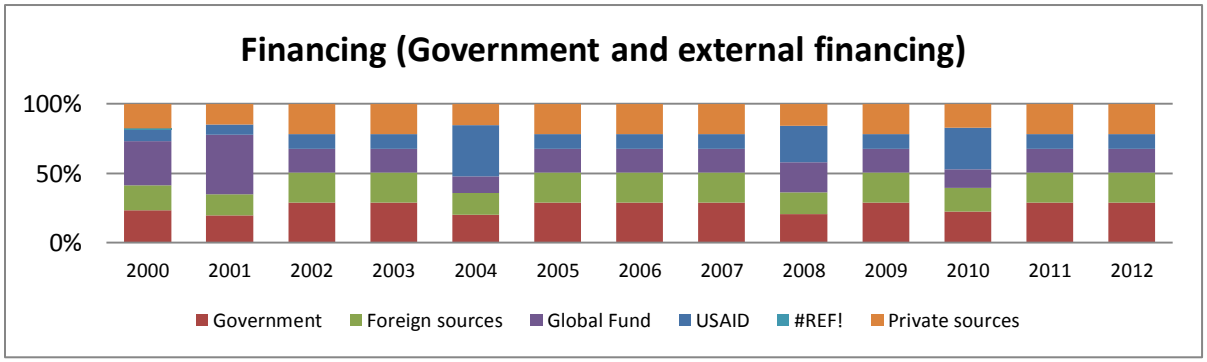
support an ECOWAS partner country and share its experience and knowledge in SHA 2011 implementation (including the tools).

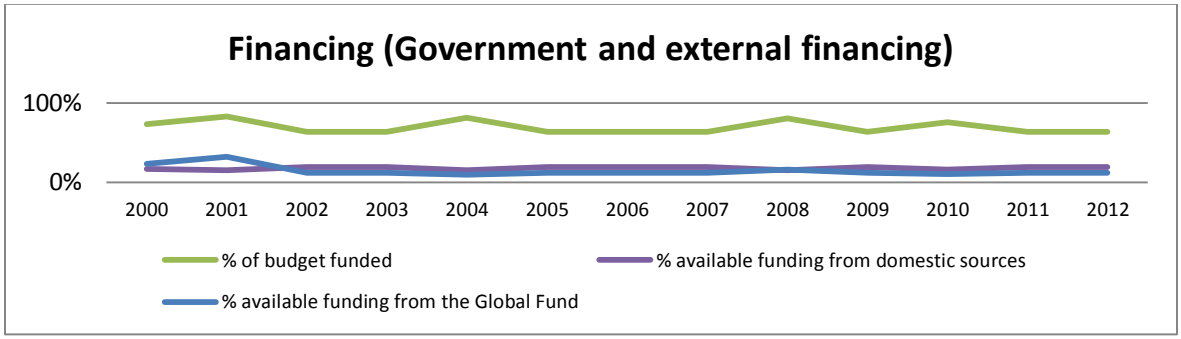
What is the WHO doing?

- WHO has developed methodology and tools. The SHA 2011 revision was done in collaboration with the OECD and Eurostat over a period of three years, including consultations with country experts. The tools were set up by Abt Associates' HS2020 project, with funding from USAID.
- WHO further adapted and enhanced to take into account the latest SHA 2011 methodology, as well as strengthening the institutionalization support that the tools could bring on the data production phase of health accounts. WHO is collaborating with health accounts teams of the planning departments in ministries of health of Member States for 10 years, and has established effective collaborative relationships with most experts in countries.

Draft outline of the proposed outputs to be presented in future reports (work in progress)

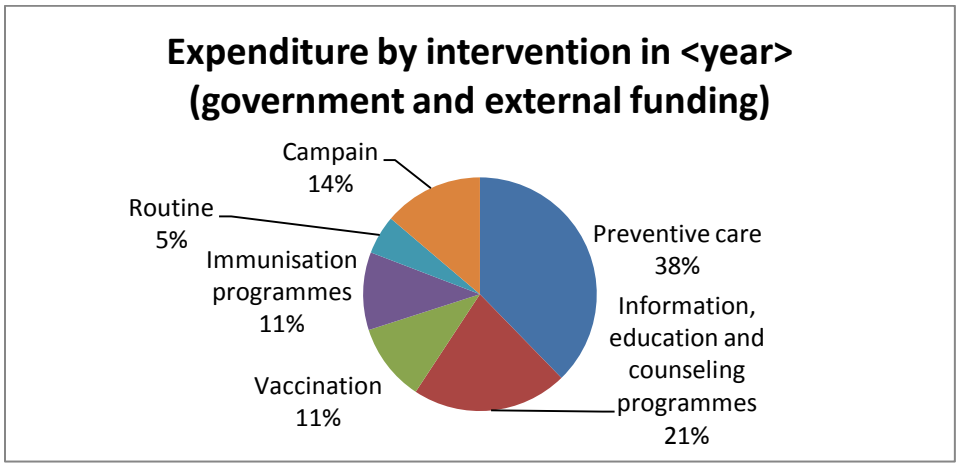
Origins of Funds for immunization expenditure (million US$)	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Government	37	37	37	37	39	41	43	45	47	49	52	54	57
central government	21	21	21	21	22	23	24	26	27	28	30	31	33
regional governments	11	11	11	11	11	12	12	13	13	14	15	16	16
local governments	5	5	5	5	6	6	6	6	7	7	7	8	8
loans	-	-	-	-	-	-	-	-	-	-	-	-	-
Foreign sources	28	28	28	28	29	31	32	34	36	38	39	41	43
Global Fund	50	80	22	22	24	25	26	27	50	30	32	33	35
USAID	13	13	13	13	70	15	16	16	60	18	70	20	21
Other foreign sources	23	23	23	23	25	26	27	28	30	31	33	34	36
Private sources	28	28	28	28	29	31	32	34	36	38	39	41	43
TOTAL expenditure on immunization	216	246	189	189	254	208	218	229	305	253	317	279	293
% available funding from domestic sources	17%	15%	19%	19%	15%	19%	19%	19%	15%	19%	16%	19%	19%
% available funding from the Global Fund	23%	32%	12%	12%	9%	12%	12%	12%	16%	12%	10%	12%	12%
TOTAL budget	295	295	295	295	310	325	342	359	377	395	415	436	458
% of budget funded	73%	83%	64%	64%	82%	64%	64%	64%	81%	64%	76%	64%	64%





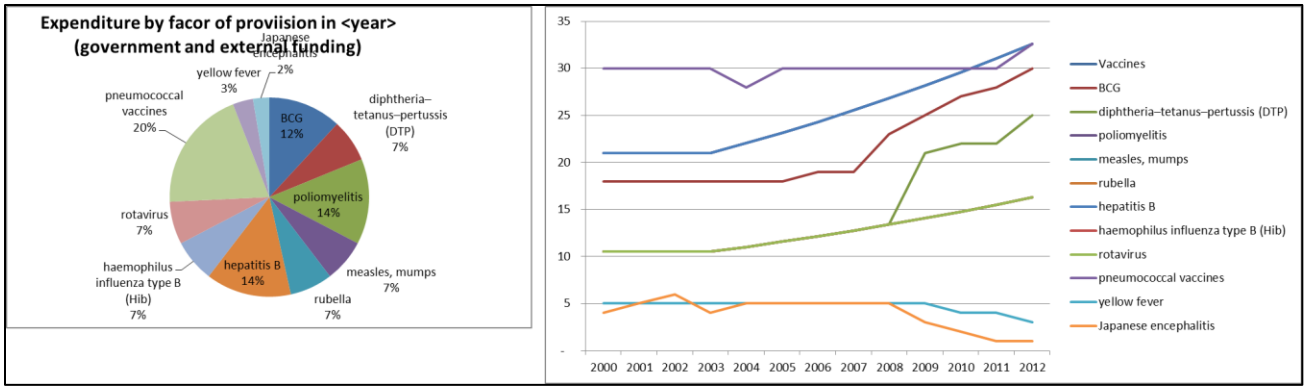
TOTAL expenditure on immunization by health care function

	Uses of Funds - million US$ (Government and external financing)	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
HC.5	Medical goods (non-specified by function)													
HC.5.1	Pharmaceuticals and other medical non-durable goods													
HC.5.1.1	Prescribed medicines													
HC.5.1.2	Over-the-counter medicines													
HC.5.1.3	Other medical non-durable goods													
HC.6	Preventive care	37	37	37	37	39	41	43	45	47	49	52	54	57
HC.6.1	Information, education and counseling programmes	21	21	21	21	22	23	24	26	27	28	30	31	33
HC.6.1.1	Vaccination	11	11	11	11	11	12	12	13	13	14	15	16	16
HC.6.2	Immunisation programmes	11	11	11	11	11	12	12	13	13	14	15	16	16
HC.6.2.1	Routine	5	5	5	5	6	6	6	6	7	7	7	8	8
HC.6.2.2	Campain	13	13	13	13	14	15	16	16	17	18	19	20	21
HC.7	Governance, and health system and financing administration	21	21	21	21	22	23	24	26	27	28	30	31	33
HC.7.1	Governance and Health system administration	11	11	11	11	11	12	12	13	13	14	15	16	16
HC.7.1.1	Planning & Management	11	11	11	11	11	12	12	13	13	14	15	16	16
HC.7.1.2	Monitoring & Evaluation (M&E)	11	11	11	11	11	12	12	13	13	14	15	16	16
HC.7.1.3	Procurement & supply management	11	11	11	11	11	12	12	13	13	14	15	16	16
	TOTAL expenditure on immunization	160	160	160	160	168	177	186	195	205	215	226	237	249



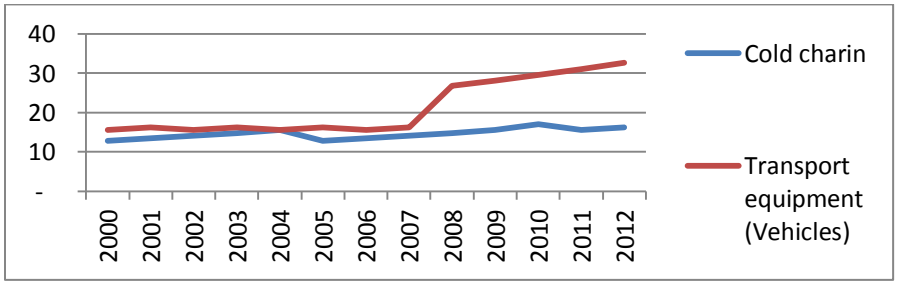
TOTAL expenditure on immunization by factor of provision

	Uses of Funds - million US$ (Government and external financing)	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
FP.3.2	Health care goods													
FP.3.2.1	Pharmaceuticals													
FP.3.2.1.5	Vaccines	21	21	21	21	22	23	24	26	27	28	30	31	33
FP.3.2.1.5.1	BCG	18	18	18	18	18	18	19	19	23	25	27	28	30
FP.3.2.1.5.2	diphtheria–tetanus–pertussis (DTP)	11	11	11	11	11	12	12	13	13	21	22	22	25
FP.3.2.1.5.3	poliomyelitis	21	21	21	21	22	23	24	26	27	28	30	31	33
FP.3.2.1.5.4	measles, mumps	11	11	11	11	11	12	12	13	13	14	15	16	16
FP.3.2.1.5.5	rubella	11	11	11	11	11	12	12	13	13	14	15	16	16
FP.3.2.1.5.6	hepatitis B	21	21	21	21	22	23	24	26	27	28	30	31	33
FP.3.2.1.5.7	haemophilus influenza type B (Hib)	11	11	11	11	11	12	12	13	13	14	15	16	16
FP.3.2.1.5.8	rotavirus	11	11	11	11	11	12	12	13	13	14	15	16	16
FP.3.2.1.5.9	pneumococcal vaccines	30	30	30	30	28	30	30	30	30	30	30	30	33
FP.3.2.1.5.10	yellow fever	5	5	5	5	5	5	5	5	5	5	4	4	3
FP.3.2.1.5.11	Japanese encephalitis	4	5	6	4	5	5	5	5	5	3	2	1	1
FP.3.2.2	Other health care goods													
FP.3.2.2.3	Injection supplies													
	TOTAL expenditure on immunization	2,173	2,175	2,177	2,176	2,181	2,190	2,199	2,206	2,218	2,234	2,243	2,251	2,266



TOTAL capital expenditure on immunization

	Uses of Funds - million US$ (Government and external financing)	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
HK.1.1.2.1	Medical equipment													
HK.1.1.2.1.1	Cold charin	13	13	14	15	16	13	13	14	15	16	17	16	16
HK.1.1.2.2	Transport equipment (Vehicles)	16	16	16	16	16	16	16	16	27	28	30	31	33
	Other?													
	TOTAL capital expenditure on immunization	28	30	30	31	31	29	29	30	42	44	47	47	49



III DOCUMENTING AND MONITORING COMMITMENTS FOR IMMUNIZATION

This document aims to provide an overview of the commitments made towards DoV/GAVP, the process agreed by SAGE to make commitments, a summary of the process in place to monitor immunization commitments made under the UNSG Global Strategy for Women and Children's Health, and proposes some discussion points for the face to face meeting in September.

COMMITMENTS TO DoV/GVAP

On 25 May 212, the WHA discussed the GVAP and its accompanying resolution. Many statements of support were made during the discussions, including statements from more than thirty Member States and organizations like the International Federation of the Red Cross and Red Crescent Societies, Médecins Sans Frontières (MSF/Doctors Without Borders), Save the Children, UNICEF, the GAVI Alliance and the International Federation of Pharmaceutical Manufacturers & Associations. At the end of the discussion, all 194 Member States voted to endorse the GVAP resolution.

In September 2012, the leadership of the Decade of Vaccines Collaboration made a commitment to implement the GVAP in the context of the UNSG Global Strategy (www.everywomaneverychild.org/commitments/all-commitments/entry/1/283).
They also recognized that the ultimate success of the GVAP depends on country ownership and the continued engagement of all stakeholders, including academics, civil society, private sector, development partners and implementers, who are committed to the DoV common goal.

During the May 2013 WHA, Member States reaffirmed their commitment to the GVAP vision and took note of the monitoring and evaluation/accountability framework and process to be used to assess and report the progress annually to the WHO Governing Bodies.

World Immunization Week (last week of April) provides an excellent opportunity to work with all stakeholders at the global, region and country level to increase awareness about immunization, advocate for increasing commitments for immunization and announcement of commitments. An example of this was the Vaccine Summit that took place 24-25 April 2013 (www.globalvaccinesummit.org), where US$ 4 billion for 2013-2018 that was pledged for polio in the context of the DoV (www.polioeradication.org/tabid/488/iid/291/Default.aspx).

GUIDING PRINCIPLES TO MAKE COMMITMENTS TOWARDS THE DoV AND GVAP

During their November 2012 meeting, SAGE reviewed the process to monitoring commitments for the DoV, and agreed to use the same framework as that used for documenting towards the UNSG Global Strategy for Women's and Children's Health (www.everywomaneverychild.org/take-action/make-a-commitment). However, while the framework and process for documenting commitments may remain the same, the nature of commitments earmarked for immunization need to be fairly explicit to allow tracking of commitments that specifically address immunization. The SAGE reviewed and endorsed the guidelines used for immunization making commitments towards the UNSG Global Strategy for Women's and Children's Health

(www.who.int/immunization/sage/meetings/2012/november/3_EWECimmunization_commitment_guidelines.pdf), and the examples of the type of commitments that could be made towards DoV.

Ideally commitments should be tangible and concrete, and represent activities or actions that can be reported back on. Where possible, it would be helpful, if the commitments were linked to one or more of the UNSG Global Strategy's goals (www.who.int/pmnch/activities/advocacy/fulldocument_globalstrategy/en/index1.html, www.who.int/pmnch/activities/advocacy/fulldocument_globalstrategy/en/index5.html) and/or one or more of the 11 Commission on Information and Accountability for Women's and Children's Health (CoIA) indicators (www.who.int/woman_child_accountability/progress_information/recommendation2/en).

Preferably they would be connected to items included in existing monitoring mechanisms that can allow for independent tracking of data in relation to the commitment. They should be specific, measurable, achievable, realistic and time specific, in order to easily determine the progress made against them and, if possible, the source of funding should be mentioned for non-financial commitments to avoid double counting. It is important for immunization commitments made to be registered under the UNSG Global Strategy. The UNSG Global Strategy is the only framework that allows us to monitor commitments made by private sector, academia and CSOs.

MONITORING COMMITMENTS MADE FOR IMMUNIZATION

The iERG requested that PMNCH produce a report that documents and monitors stakeholders' commitments to the UNSG Global Strategy for Women and Children's Health. In 2014, the fourth year of the strategy, there is a growing recognition that the nature of commitments made are changing (e.g., based around specific -- often thematic -- initiatives and calls to action), the steep rise in their number, and the need to move the focus from analysis of commitments themselves to monitoring their implementation. Also under consideration is whether the focus should be moving to countries (e.g. country score cards), as opposed to a global focus on commitments.

In 2011, prior to the establishment of the iERG, PMNCH produced its first report (www.who.int/pmnch/media/press/2011/2011_pmnch_report/en/index.html) on the content and estimated value of the commitments to the Global Strategy, using self-reported data. The ensuing PMNCH 2012 (www.who.int/pmnch/knowledge/publications/2012_pmnch_report/en/index.html) and 2013 reports (the latter is forthcoming in September 2013) continued this approach, considering all the new commitments made since the Sep 2010 launch of the Global Strategy. The reports progressively moved to a greater focus on attempting to measure the implementation of these individual commitments; at present, there are 293 commitment-makers, which is nearly triple the number from the original 111 at the time of the Global Strategy launch in 2010. The WHA DoV Annual Progress Report is shared with PMNCH so they can include progress against this commitment in their report.

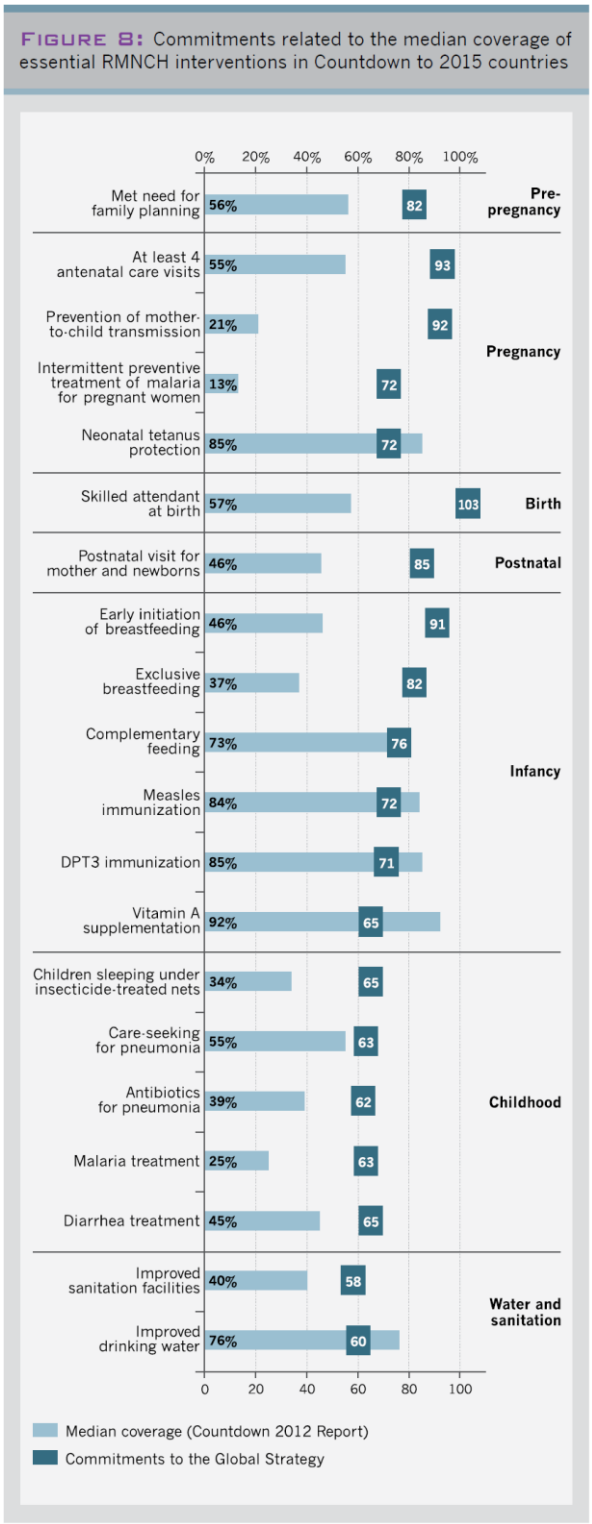
The 2012 PMNCH report shows (see Figure 22, PMNCH Report Figure 8)) that most commitments that focus on specific interventions address critical gaps, but some key interventions with low coverage still receive limited attention. In the 2012 questionnaire, 138 respondents (84%) reported that they focus on specific RMNCH interventions in their commitments, while others provide general support to women's and children's health. Many commitments, focusing either on policy, service and product delivery, advocacy or other issues, target gaps in coverage of these essential interventions. Figure 22 (PMNCH

Report Figure 8) relates the number of commitments focusing on specific interventions with the median coverage of these interventions. There is evidence that key development partners have increased their funding for reproductive health and that this trend will continue. The trends show an evolution since 2011. For example, areas such as elimination of mother-to-child transmission of HIV, postnatal care visits and exclusive breastfeeding were identified as areas receiving only limited support in the PMNCH 2011 report. However, some areas recognized as major threats to maternal and child health attracted fewer commitments: diarrhoea, pneumonia and malaria were the target of fewer than 50% of respondents.

PMNCH support for global accountability processes and platforms:

- Countdown to 2015: PMNCH acts as secretariat and co-lead of the Communications and Events sub-committee of Countdown to 2015, responsible for ensuring that Countdown evidence and messages reach policy-makers and other relevant audiences via the creation of tailored products, events, and dissemination of Countdown messages and products.
- Commission on Information and Accountability: PMNCH acts as the coordinating platform for the Advocacy and Action group of the Commission on Information and Accountability for Women's and Children's Health workplan.

Figure 22: Commitments related to the median coverage of essential RMNCH interventions in Countdown to 2015



ISSUES FOR DISCUSSION

Challenges with documenting and monitoring commitments include:

- Difficulties in capturing commitments from a number of groups of stakeholders.
- Commitments are often generic and not specific to vaccines.
- Lack of specificity of many of the commitments made, which renders the monitoring process difficult.
- Monitoring is currently based on self-reporting, which tends to lead to emphasis on “good news” and little/or no reporting on “bad news”.
- Reports are often incomplete and assessment as to the extent to which the commitments are being met is difficult.
- Need to move the focus from analysis of commitments themselves to monitoring their implementation, ideally in countries as part of their national plans.
- Significant intensity of resources employed by PMNCH in the current approach (US$ 750,000 plus staff time).

IV INDEPENDENT SUBMISSIONS FROM OTHER STAKEHOLDERS

AMP: Delivering on Promises for More than 40 Years in Africa and Beyond

Since its creation in 1972, the Agence de Médecine Préventive (AMP) has been committed to supporting developing countries to improve their immunization programs, services, and systems. Along with our public- and private-sector partners, we aim to: enhance scientific knowledge in support of evidence-based health policies; support the introduction and use of vaccines; strengthen immunization service delivery and logistics; develop human and institutional capacity through tailor-made training programs; and promote innovation in field vaccinology.

AMP is the fruit of the vision of two remarkable men: Jacques Monod, the Nobel Prize-winning French biologist and director of the Pasteur Institute, and Charles Mérieux, an entrepreneur and visionary physician. In 1972, they set out to address a serious public health problem: the insufficient use of vaccines in Africa. They created AMP with the goal of bringing immunization technology and knowledge to the continent, and Philippe Stoeckel was placed in charge.

In February 1973, AMP was invited by the Organization pour la Coordination et la Coopération pour la lutte contre les Grandes Endémies (OCCGE) to set up an office in Bobo-Dioulasso, Burkina Faso (then "Upper Volta"). The goal was to work closely with local organizations in sub-Saharan Africa to provide training to staff and to adapt diagnostic techniques, medical practices, and vaccine delivery methods to the local context.

Since its early years, AMP has expanded the scope and reach of its activities, working on other health issues elsewhere in Africa as well as in Latin America, Southeast Asia, and Eastern Europe. Current activity areas include vaccinology research, health and immunization services strengthening, health policy and institutional development, and human resources for health.
In keeping with the spirit of its founders, AMP continues to focus on sustainable, evidence-based solutions to local health challenges that have a long-term impact. This is achieved through close collaboration with government officials and local public and private actors.

This report presents some recent success stories, milestones, and innovative features of a selection of AMP's current 40 or so projects, implemented in nearly 30 countries.

Success Story 1: SIVAC

Since 2008, AMP has directed the SIVAC Initiative in partnership with the International Vaccine Institute in Seoul, South Korea, and funding from the Bill & Melinda Gates Foundation (BMGF). SIVAC promotes evidence-informed decision-making on immunization through the creation and strengthening of National Immunization Technical Advisory Groups (NITAGs) in low- and middle-income countries (LMICs), in collaboration with the World Health Organization (WHO), the International Vaccine Institute, and partners.

NITAGs make evidence-based recommendations to ministries of health (MOHs) on all issues related to vaccines and immunization. Since 2008, SIVAC has supported NITAG creation in Côte d'Ivoire,

Kazakhstan, Kyrgyzstan, Mongolia, and Mozambique, and with its partner the West African Health Organization (WAHO) in Benin and Senegal. Many countries already have nascent NITAGs that can benefit from strengthening through implementation of best practice guidelines; SIVAC has worked to achieve this goal in Indonesia, Lebanon, Nepal, Tunisia, and Vietnam.

SIVAC also collaborates with WHO to organize joint workshops to improve collaboration between NITAGs and national regulatory authorities (in charge of the assessment, licensure, control, and surveillance of biological medicinal products), the latest being one in the EMRO region in 2012.

In December 2012, SIVAC's efforts were rewarded when the Health Policy and Institutional Development unit of AMP – which is in charge of SIVAC – was designated a World Health Organization Collaborating Centre (WHO CC) on evidence-informed immunization policy-making. The WHO CC has three objectives: to support countries to accelerate the implementation of new NITAGs; to provide assistance for operational and institutional strengthening; and to facilitate interaction between NITAGs.

Success Story 2: LOGIVAC

Another example of how AMP is delivering on promises is the LOGIVAC project, jointly implemented by AMP and WHO with funding from the BMGF. Launched in 2010, LOGIVAC provides technical support to improve health logistics, the vaccine supply chain, and vaccine management in sub-Saharan Africa through certified training, recognition of professional health logisticians, and the establishment of a reference and resource center.

Recent highlights include the implementation of the EVM+HERMES process in Benin to support the MOH to optimize the vaccine supply chain with the input of several partners (2012). Another was the introduction of the first-ever training degree program in health logistics in sub-Saharan Africa, developed by AMP, WHO, the Regional Institute of Public Health (IRSP) in Ouidah, Benin, and Institute Bioforce.

Launched early 2013, the training brought together 24 students from eight Francophone African countries (Benin, Burkina Faso, Burundi, Democratic Republic of the Congo, Chad, Madagascar, Niger, and Togo) mainly from public health programs like the Expanded Program on Immunization (EPI), drug procurement agencies, and national reference laboratories.

The one-year course provides comprehensive training in health supply chain management, which has been specifically developed for staff working in sub-Saharan Africa. It features classroom learning (held at IRSP) and distance learning, as well as an internship at the end of the academic year to apply lessons learned in a professional context. Upon completion, participants receive a bachelor's degree from the University of Abomey-Calavi.

Following the success of the first edition of the training, LOGIVAC is now gearing up to launch the second edition, scheduled for November 2013.

Success Story 3: Adverse events monitoring for the yellow fever vaccine initiative

The yellow fever vaccine initiative sought to accelerate protection of persons living in sub-Saharan African through mass immunization campaigns. However, large scale use of vaccine in populations not experiencing current epidemics had not been conducted previously. A key issue related to this effort was whether African populations experienced a rate of adverse events following immunization no higher than that seen in other populations, given different age structure, higher malnutrition and the existence of underlying conditions such as HIV infection and malaria. Yellow fever, as a live virus, may cause acute viscerotropic or neurotropic disease, which may be serious or fatal.

AMP worked with WHO to establish AEFI surveillance in target countries. Many of these countries had no experience of AEFI surveillance and thus AMP, WHO, and national ministries of health had to develop systems from scratch. This included the formation of national expert committees with formal terms of reference, extensive training of field workers, implementation of hospital surveillance, and development of laboratory capacity.

The results of this effort recently were published in Vaccine. We found no increased risk of AEFIs in the vaccinated population, affirming the strategy used in the yellow fever vaccine initiative. Longer term, the expert committees have remained in place and now support other vaccine introductions, such as MenAfriVac. As more vaccines are developed for use primarily in developing countries (e.g., malaria, dengue, shigella), the need for AEFI surveillance capacity in African countries will continue to increase.

Submitted by Sabrina Gaber
Agence de Médecine Préventive
164 rue de Vaugirard, 75015 Paris, France
sgaber@aamp.org

Barcelona Institute for Global Health: Assessment of progress against the GVAP goals and strategic objectives

As part of the Decade of Vaccines Collaboration (DoVC) Secretariat, ISGlobal coordinated the work of the stakeholders involved in the elaboration of the GVAP throughout the process of drafting and approval of the plan. This degree of implication helped ISGlobal acknowledged the large extent to what inclusion of all partners was promoted, and its role in the success of the initiative. Therefore, the Institute hopes this will continue in the upcoming steps of implementation of the GVAP.

Regarding progress against the GVAP's goals and strategic objectives, given ISGlobal's mission and tasks the Institute wishes to report the work done in the following areas:

- **Goal 4: Develop and introduce new and improved vaccines and technologies**
- **Strategic Objective 6: Country, regional and global research and development innovations maximize the benefits of immunization**

Goal 4: Develop and introduce new and improved vaccines and technologies

ISGlobal, together with its research centre, the Barcelona Centre for International Health Research (CRESIB) and in collaboration with its local partner in Mozambique, the Manhiça Health Research Centre (CISM), has contributed to introduction and improvement of vaccines in the following areas:

- **Malaria vaccine candidate RTS,S**

ISGlobal, together with the CISM, has uninterruptedly worked in the development of the malaria vaccine candidate RTS,S for more than a decade. **Currently, ISGlobal participates in the phase III clinical trial of the vaccine candidate, together with 10 other sites in 7 Sub-Saharan countries**. Final results of this trial are expected in 2014, and a recommendation by the World Health Organization will likely follow in 2015. If positive, this recommendation will open the way for the implementation of a vaccine against a parasitic disease for the first time ever. ISGlobal also coordinates a research consortium devoted to the understanding of the protective immune responses elicited by the RTS,S vaccine. The initiative comprises 15 international institutions that analyze the samples collected in the phase III clinical trial of this vaccine candidate in three different work areas: statistics and data management, humoral immunology and cellular immunology.

The RTS,S vaccine, developed by GlaxoSmithKline and primarily financed by the Bill & Melinda Gates Foundation and the PATH Malaria Vaccine Initiative, shows the success of public-private cooperation and is an example of how research can contribute to the development of the most vulnerable countries in the world.

- **Haemophilus influenzae type b (Hib) conjugate vaccine**

Although the Haemophilus influenzae type b (Hib) conjugate vaccine has dramatically reduced invasive Hib disease worldwide, data on protection against pneumonia and in children with HIV are limited. Researchers from the CISM have evaluated the impact of the introduction of the Hib conjugate vaccine in a rural, high-HIV prevalence area of the country in 2009. The results of the study, led by Betuel Sigaúque, were published in The Journal of Pediatrics in July 2013.

Between 2006 and 2011, the researchers conducted hospital-based surveillance for invasive Hib disease and clinical pneumonia (classified as severe and very severe) among children under 5. Incidences calculated using population denominators were then compared between baseline (2006-2008) and post-Hib conjugate vaccination (2010-2011).
In children under 1 and under 5 years of age, significant reductions were observed in rates of both invasive Hib disease (91% and 85%, respectively) and very severe pneumonia (29% and 34%, respectively). "We have demonstrated important reductions in invasive disease and pneumonia following the introduction of the Hib conjugate vaccine in an area with a high prevalence of HIV. Continued surveillance is needed to monitor the long-term effects of this vaccine, particularly among children with HIV", said Dr. Sigaúque, the principal investigator of this study.

- **Cervical Cancer and Human Papillomavirus Infection**

Since 2001 ISGlobal's research centre, CRESIB, in collaboration the CISM and other organizations has conducted studies in Mozambique in order to:

- Determine the genotype distribution of HPV infections
- Identify the Vaccine-related HPV genotypes in women with and without cervical cancer
- Describe the prevalence and the etiology of Sexually Transmitted Infections and the prevalence of cervical neoplasia among Women from a Rural Area of Southern Mozambique.

The CISM is supporting the Mozambican Ministry of Health (MISAU) by conducting operational research in Mozambique to inform decisions about how to introduce the HPV vaccine. The CISM has been appointed by the MISAU as the managing organization of the HPV demonstration programme, following GAVI's approval of a HPV demonstration project in Mozambique.

The CISM and ISGlobal are currently assessing the feasibility and acceptability of implementing a HPV vaccination program among adolescent girls in rural and urban areas of Mozambique.

Strategic Objective 6: Country, regional and global research and development innovations maximize the benefits of immunization

The activities described above highlight the strong relation between ISGlobal and its local partner in Mozambique, the Manhiça Health Research Centre (CISM). This relation is the result of ISGlobal's commitment to the promotion of country research as a means to maximize the benefits of immunization. It also shows the importance given to regional research, since the CISM has also participated in multi-country research projects. To this regard, the main research activities carried out during 2012, in collaboration with CRESIB- included:

- Presentation of the results of the Phase III clinical trial of the RTS,S malaria vaccine candidate
- Involvement in the Phase IIb multi–site trial (Kenya, south Africa, Mozambique) to test the safety and efficacy in new-borns of a new tuberculosis vaccine candidate (AERAs 402), in collaboration with the TB Vaccine consortium and the AERAs initiative.
- Involvement in two major grants awarded to CRESIB (National institutes of health and 7th Framework Programme) to study the immunologic response of the RTS,S malaria vaccine candidate in children under 5 years of age.
- Initial phase of the evaluation of the pneumococcal vaccine impact in children under 5 years old, in collaboration with the Ministry of health.

Support has also been boosted in the field of training. The Manhiça senior Research fellowships programme was launched in 2012 to attract and retain national experienced researchers and to support PhD and Master students internationally. In addition, the CISM continued to host medical students and graduate students from the Eduardo Mondlane University, Spanish universities and other international academic institutions.

Submitted by Laia Bertran
Project Manager
Barcelona Institute for Global Health
Hospital Clínic - Universitat de Barcelona
Carrer Rosselló 132, 08036Barcelona, Spain
laia.bertran@isglobal.org

International Vaccine Access Center (IVAC), Johns Hopkins Bloomberg School of Public Health, GVAP Progress Report Summary, 26 July 2013

GAVP Strategic Objective 1: All Countries Commit to Immunization as a Priority.

Summary Action from GVAP: Inform and Engage Opinion Leaders on the Value of Immunization.
Featured Contributions from IVAC:

1) Beginning in 2010, a team IVAC embarked on the development of methods to estimate the economic benefits of immunization that may result during the Decade of Vaccines from investments to improve access in the world's poorest countries. In two papers[63] in the June 9, 2011 issue of Health Affairs, research from IVAC showed that increasing access to and coverage with new and existing vaccines can yield substantial health and economic benefits. Using projections of immunization coverage from the Global Immunization Vision and Strategy, and disease burden estimates provided by several collaborating groups, we have been able to estimate a range of costs associated with treatment for vaccine-preventable diseases, lost wages for caretakers of sick children and longer-term productivity losses due to premature death or disability resulting from infection.

   The "Decade of Vaccines Economics" (DoVE) study is ongoing and has expanded to include additional vaccines, examine a variety of uptake and coverage scenarios and refine the disease burden figures that form a basis for economic projections. Since its inception, data from the DoVE study has reached thousands of decision-makers from both development partner countries and countries with high burdens of vaccine-preventable disease. Information generated by DoVE has been featured at the 2012 Child Survival Summit held in Washington, DC, which was co-hosted by the governments of Ethiopia, India and the United States; in G8 meeting publications and at the first ever Nigerian National Vaccine Summit in April, 2012 (some of the infographics generated through DoVE are at the end of this document – to use these in the GVAP report, please contact Julie Younkin – jbuss@jhsph.edu).

2) In April 2012 IVAC helped support Nigeria's first National Vaccine Summit to build political will and value of vaccines at the highest levels down to the community level. Actions were developed to help address barriers to routine immunization that were in part informed by a landscape analysis conducted by IVAC. As a result of the summit, there was stronger commitment to reaching vaccine targets and an emphasis built on accountability. Working closely with government of Nigeria, development partners and other stakeholders, IVAC contributed to the development of an accountability framework and engagement of the stakeholders to "own" and implement the framework. A pilot test of the measurement of accountability interventions is underway.

[63] **Access the full-text articles here:**
- Ozawa et al.
http://content.healthaffairs.org/cgi/content/full/30/6/1010?ijkey=aCQyO80nhG4zw&keytype=ref&siteid=healthaff
- Stack et al.
http://content.healthaffairs.org/cgi/content/full/30/6/1021?ijkey=2aMaZBnnJqWz6&keytype=ref&siteid=healthaff

GVAP Strategic Objective 2: Individuals and communities understand the value of vaccines and demand immunization as both their right and responsibility.

Summary Action from GVAP: Build capacity.

1) Since 2011, IVAC and its partner Global Health Strategies in New Delhi, India, have been working with vaccine experts, pediatricians, bureaucrats and others to build the case for the introduction of Hib vaccines, PCV and RV by establishing a strong indigenous base of evidence and developing a cadre of Indian scientific experts equipped to advise and influence evidence based policy. We have worked with experts and the media to cultivate sustainable policy, political and media support for the introduction of new vaccines at both the national level and in 6 states. We've accomplished this through the development of training workshops and courses held by INCLEN and Child Health Foundation of India and symposia sponsored by members of a technical coalition facilitated through the project. To date nearly 100 scientists, public health professionals and bureaucrats from 14 states have attended either a national level (Dec 2012) or state level (January 2013) training course on comprehensive pneumonia and diarrhoea control. An additional 235 stakeholders have attended vaccine symposia, and 45 CSOs have been engaged. Several parliamentarian briefings have also been held. The voices of those that have attended our technical briefings have been represented in more than 100 print media pieces in 2012 and multiple TV appearances. This effort has helped engage local experts to build the case for immunization and gain confidence in assessing erroneous claims by a small yet vocal anti-vaccine lobby.

2) Our World Pneumonia Day Small Grants for Advocacy Program supported a number of different initiatives in education, training health workers, and engaging CSOs. One example includes scientific and advocacy workshops in the Philippines. The Philippine Foundation for Vaccination convened two workshops – one primarily scientific and another focused on advocacy – in the weeks leading up to World Pneumonia Day. One of the activities organized was the Third Clinical Vaccinology Course on Pneumonia Prevention, attended by more than 50 health professionals.

3) An advocacy training workshop on pneumonia was also held at the University of the Philippines in Manila. The Philippine Foundation for Vaccination invited 50 stakeholders from public and private institutions whose advocacy for disease prevention, particularly pneumonia, was paramount. The workshop focused on the use of advocacy as a tool for public health campaigning and gave participants an opportunity to design and evaluate advocacy strategies to increase public awareness about pneumonia.

Special Note: IVAC administratively managed the Small Grants Program, with support from partners in 2012 including the GAVI Alliance and the Global Alliance for Clean Cookstoves.

GVAP Strategic Objective 6: Country, regional and global research and development innovations maximize the benefits of immunization.

Summary Action from GVAP: Establish platforms for exchange of information on immunization research and consensus building.

IVAC organized a roundtable discussion on a topic that was previously receiving insufficient attention, yet impacted countries, donors and manufacturers: primary containers. The discussions of more than

40 experts from partner, donor, manufacturer and country perspectives helped identify important tradeoffs including vaccine coverage, affordability and safety that should be considered when making decisions about type and size of vial or container. Blogs, presentations and a policy brief were developed to call for more specific guidelines to ensure that decisions which impact each of these areas are made appropriately.

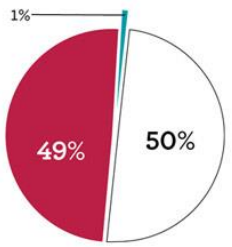
Annexes: IVAC

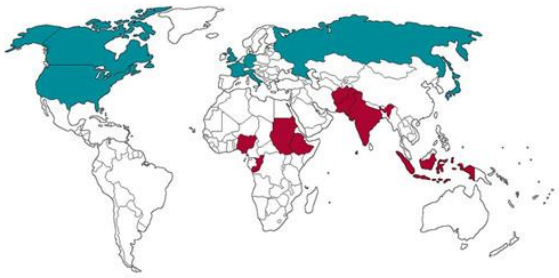
Infographics:

1. Featured in 2 G8 publications in 2012
2. Produced together with the Gates Foundation around the 2012 Child Survival Summit Call to Action in Washington, DC
3. Produced at IVAC combining DoVE estimates with work from IVAC's Nigeria team to analyze barriers to routine immunization in Nigeria (a project conducted in close collaboration with the Nigerian MOH and other Nigerian partners)

Submitted by Lois Privor-Dumm
IVAC, Johns Hopkins Bloomberg School of Public Health
lprivord@jhsph.edu

CHILD MORTALITY: A GLOBAL COMPARISON*





G8 countries | 8 countries with the most child deaths | Remaining 180 countries

* Black R, Cousens S, Johnson H, et al. Global, regional, and national causes of child mortality in 2008: a systematic analysis. The Lancet. 2010 June; 375(9730):1969-1987.

OVER THE NEXT DECADE, SCALING UP VACCINE* COVERAGE[iii] to 90% in 8 COUNTRIES** with the most child deaths

AVERT U.S. $99 BILLION in COSTS and ECONOMIC LOSSES[iii]

= THE GDP of QATAR[x]

OR

952 MILLION BARRELS of CRUDE OIL[xi]

OR

FEED 362 MILLION POOR CHILDREN for an ENTIRE YEAR[xii]

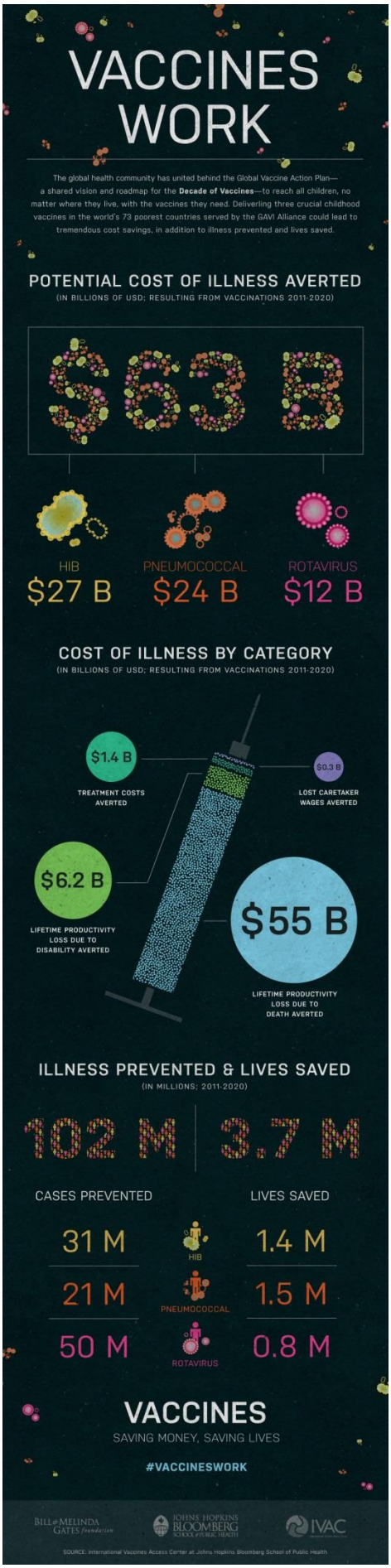
SAVE OVER 3.8 MILLION CHILDREN[iii]

= 100,000 LIVES

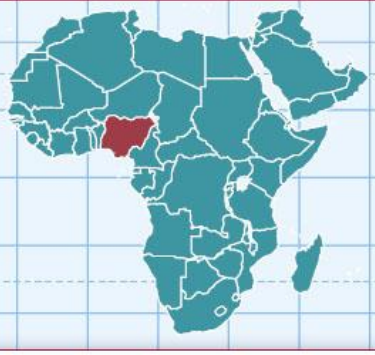
= MORE THAN THE NUMBER of CHILDREN in the UNITED KINGDOM[xiii]

*Hib, malaria, measles, pertussis, pneumococcal and rotavirus vaccines, 2011-2020

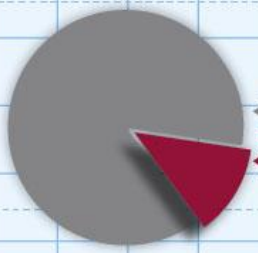
**India, Nigeria, Democratic Republic of Congo, Pakistan, Ethiopia, Afghanistan, Indonesia and Sudan (China not included)


VACCINES WORK
The global health community has united behind the Global Vaccine Action Plan—a shared vision and roadmap for the Decade of Vaccines—to reach all children, no matter where they live, with the vaccines they need. Delivering three crucial childhood vaccines in the world's 73 poorest countries served by the GAVI Alliance could lead to tremendous cost savings, in addition to illness prevented and lives saved.
POTENTIAL COST OF ILLNESS AVERTED
(IN BILLIONS OF USD; RESULTING FROM VACCINATIONS 2011-2020)
$63 B
HIB
$27 B
PNEUMOCOCCAL
$24 B
ROTAVIRUS
$12 B
COST OF ILLNESS BY CATEGORY
(IN BILLIONS OF USD; RESULTING FROM VACCINATIONS 2011-2020)
$1.4 B
TREATMENT COSTS AVERTED
$0.3 B
LOST CARETAKER WAGES AVERTED
$6.2 B
LIFETIME PRODUCTIVITY LOSS DUE TO DISABILITY AVERTED
$55 B
LIFETIME PRODUCTIVITY LOSS DUE TO DEATH AVERTED
ILLNESS PREVENTED & LIVES SAVED
(IN MILLIONS; 2011-2020)
102 M
CASES PREVENTED
3.7 M
LIVES SAVED
31 M
HIB
1.4 M
21 M
PNEUMOCOCCAL
1.5 M
50 M
ROTAVIRUS
0.8 M
VACCINES
SAVING MONEY, SAVING LIVES
#VACCINESWORK
BILL & MELINDA GATES foundation
JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH
IVAC
SOURCE: International Vaccines Access Center at Johns Hopkins Bloomberg School of Public Health

NIGERIA: Breaking Down Barriers to Immunization Coverage



ANNUAL DEATHS of children under age 5[1]



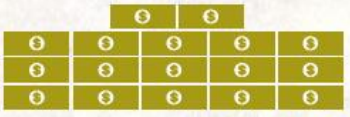
For every **CHILD** under age 5 that dies in the U.S. of the leading vaccine-preventable diseases*, **1,744** die in Nigeria[1]—about 35 school buses full of children.

*pneumonia, diarrhea, whooping cough, tetanus, measles, and meningitis

U.S. = NIGERIA

SCALING UP TO **90%** VACCINE COVERAGE* IN NIGERIA

*Hib, Pneumococcal, Rotavirus, Measles, Pertussis



WILL AVERT U.S. **$17 BILLION** IN ECONOMIC LOSSES

$ = $1 BILLION

WILL SAVE MORE THAN **600,000 LIVES** OVER THE NEXT 10 YEARS[2]

= 100,000 LIVES

TAKING AIM AT CHILD DEATHS: Best Bets for Scaling Up Immunization Coverage[3]

IMPACT ↑

HIGHER	Results-based financing Recurrent vaccine budget	Vehicle distribution Conditional cash transfers	Transportation contracts Maintenance contracts Flexible funding, donor guarantees, state-level basket funds
	Performance tracking	Management training Transition of donor-funded projects to state agencies	Satellite cold chain storage facilities, solar refrigerators Political advocacy, state health agency support
LOWER	Independent data checks Health care vouchers	Mobile immunization units SMS reminders to parents	SMS reminders to staff

LOWER ← FEASIBILITY → HIGHER

Financing and Vaccine Security | Transport | Cold Chain | Performance Management | Advocacy and Leadership | Demand Creation

[1] World Health Organization Child Mortality Estimates for 2008. www.thelancet.com/journals/lancet/article/PIIS0140-6736%2810%2960549-1/fulltext
[2] Stack, M. L., Ozawa, S., et al. (2011). "Estimated Economic Benefits During The 'Decade Of Vaccines' Include Treatment Savings, Gains In Labor Productivity." Health Affairs 30(6): 1021-1028.
[3] Wonodi, C., Stokes-Prindle, C., et al. (2012). "Landscape Analysis of Routine Immunization in Nigeria." IVAC.

PATH: Actively Contributing Toward GVAP Implementation

PATH is an international nonprofit organization that transforms global health through innovation. We take an entrepreneurial approach to developing and delivering high-impact, low-cost solutions, from lifesaving vaccines, drugs, diagnostics, and devices to collaborative programs with communities. Through our work in more than 70 countries, PATH and our partners empower people to achieve their full potential.

Vaccines and immunization are a core focus of PATH's work. Our vaccines and immunization portfolio represents our largest suite of projects and the largest share of PATH's spending. Our work ranges from vaccine research and development to support for country introduction and scale-up to ensure optimal uptake of vaccines in some of the world's most challenging settings. PATH's activities include:

- More than 50 active vaccine and immunization projects in 66 countries targeting human papillomavirus (HPV), influenza, Japanese encephalitis, malaria, meningitis A, pneumococcus, polio, and rotavirus.
- US$115 million in 2012 expenditures on our vaccine- and immunization-related projects.
- Over 230 PATH staff dedicated to projects focused on vaccines and immunization.
- More than118 million direct and indirect beneficiaries reached by PATH in 2012.

PATH's vaccine and immunization activities align with the Global Vaccine Action Plan (GVAP) guiding principles. Our work is built around increasing country ownership, growing partnerships, ensuring the equity and sustainability of immunization services, integrating work across health systems, and developing innovative products and processes to provide solutions to immunization programs globally.

Driving progress on GVAP strategic objectives in 2012–2013

PATH's vaccine and immunization portfolio works toward progress on all six GVAP strategic objectives by reinforcing the entire chain of vaccine development, optimization, and sustainable introduction.

Strategic objective 1: All countries commit to immunization as a priority

PATH develops and disseminates the evidence base on the public health value of vaccines, supports mechanisms for collaboration and peer-to-peer exchanges, and strengthens country capacity to make appropriate and evidence-based decisions on the introduction and sustained use of vaccines. Examples of our work:

- PATH engaged with civil society, pediatric, and parliamentary networks in Africa and globally to raise awareness and discuss the value of immunization.
- When Tanzania sought to introduce rotavirus and pneumococcal vaccines concurrently, PATH facilitated the planning of a country-to-country technical exchange with Ghana, the first developing country to simultaneously introduce these vaccines.
- Global and national policymakers have benefitted from PATH's activities and research in making critical immunization policy decisions, including a rotavirus vaccine schedule change in South Africa and a decision by the World Health Organization (WHO) to allow the MenAfriVac™ vaccine to travel in a controlled temperature chain.

Strategic objective 2: Individuals and communities understand the value of vaccines and demand immunization as both their right and responsibility

PATH has a strong foundation in advocacy, communications, and outreach activities in support of immunization with global, regional, national, and subnational audiences. Examples of our work:

- PATH convened a working group to develop a health worker assessment protocol to evaluate the acceptability and ease of use of rotavirus delivery devices. Results will inform the delivery device to be used for a new bovine reassortant rotavirus vaccine, improving vaccine delivery in the field.
- PATH teams conducted regional training sessions in Kenya and Senegal on advocacy techniques in support of immunization and methods to evaluate the cost-effectiveness of new vaccine introductions.

Strategic objective 3: The benefits of immunization are equitably extended to all people

PATH works to remove barriers to immunization, whether economic, social, or geographic. Examples of our work:

- PATH is supporting GAVI Alliance partners in reinvigorating their efforts to address immunization-related inequities through the development of a reference document and supporting tools for country implementers.
- As part of our support to the GAVI Alliance, PATH has provided a variety of procedural, communications, and technical assistance to facilitate the introduction of HPV, rotavirus, and pneumococcal vaccines in GAVI-eligible countries, bringing the benefits of these new vaccines to developing countries on an accelerated timeframe.

Strategic objective 4: Strong immunization systems are an integral part of a well-functioning health system

PATH drives comprehensive approaches to combat the unique complexities of health issues such as diarrhoeal disease and cervical cancer. We advance the development and delivery of vaccines as well as other proven health interventions to provide the most cost-effective, sustainable, and appropriate options for prevention, surveillance, and treatment. Examples of our work:

- PATH worked to strengthen the global immunization data environment through technical assistance to WHO in building a web-based data repository.
- With a recent award by the Bill & Melina Gates Foundation, PATH has launched a new project focusing directly on the challenges related to data quality and use, based in the belief that better data, coupled with better decision-making, will lead to better health outcomes. PATH will partner with countries to develop an approach that focuses on information system products, data-sharing policies and practices, and the people who use them.
- PATH has helped Vietnam increase the quality, safety, and efficiency of its national immunization program through an approach that tests system improvements at a provincial level, identifies best practices, and encourages other provinces to adopt them. PATH's focus includes technical training to health managers and vaccine stock management support in an effort to ensure that 99 percent of newborns are protected through a birth dose of hepatitis B vaccine within the first three days of life.
- In partnership with global, national, and regional collaborators, PATH has strengthened and expanded disease surveillance systems for rotavirus (including intussusception), Japanese

encephalitis, and meningitis A, allowing countries to develop more accurate data on disease burden and the impact and safety of vaccine introduction.
- PATH continues our long-time work on vaccine cold chain and logistics, including projects focused on solar refrigeration technologies, a web-based version of PATH's Cold Chain Equipment Manager platform, and controlled temperature chain research.

Strategic objective 5: Immunization programs have sustainable access to long-term funding and quality supply

PATH works to ensure innovative, effective, and safe vaccines are available in sufficient supply as cost-effective options for countries to combat vaccine-preventable diseases. Examples of our work:
- PATH and our global partners developed standardized methodology for a strategic demand and supply forecast for vaccines in the current and future GAVI portfolio. Forecast outputs informed rotavirus and pneumococcal calls-for-offer, as well as partner financial planning and impact and policy assessment.
- An agreement between PATH and its manufacturing partner in China, the Chengdu Institute of Biological Products, has allowed a number of endemic countries to introduce Japanese encephalitis vaccine at an affordable public-sector price; over 150 million doses of the vaccine have been purchased or donated and delivered outside of China through this agreement.

Strategic objective 6: Country, regional, and global research and development innovations maximize the benefits of immunization

In addition to our numerous core vaccine development activities, PATH and our partners support the improvement of vaccine distribution logistics and systems, safe injection, and immunization waste management. Examples of our work:
- PATH supported India, Peru, Uganda, and Vietnam to conduct formative research and HPV vaccination demonstration projects, paving the way for Peru and Uganda to launch national immunization campaigns and influencing GAVI's guidelines on HPV demonstration projects.
- PATH has developed and sustained innovative partnership models for vaccine development with a wide variety of international manufacturers, including Bharat Biotech, the Chinese National Biotech Group, Merck & Co., Inc., Sanofi Pasteur, and Serum Institute of India. These partnerships foster adequate supplies of appropriate vaccines at a sustainable price for countries.
- Through broad-based epidemiological research and clinical studies, PATH is working with WHO headquarters and regional offices in Africa to accelerate the development of a malaria vaccine, working in collaboration with GlaxoSmithKline Vaccines and research centers across Africa.
- PATH contributed to studies in Bangladesh, Ghana, Pakistan, and other countries investigating optimal dosing schedules for vaccines, as well as the effects on immunogenicity of other factors, such as breastfeeding before or after vaccination.
- PATH worked to increase the availability of industry-quality adjuvant technologies, as well as investigating potential effective and affordable adjuvanted formulations of inactivated polio vaccine.

Conclusion

PATH has a deep and longstanding commitment to vaccines and immunization. Through our comprehensive efforts from vaccine development to sustainable implementation, PATH is committed to furthering the GVAP strategic objectives and playing an integral role in providing all people with equitable access to life-saving vaccines.

Annex: Case studies of PATH's vaccine and immunization work

Optimize: Vaccine distribution logistics and systems

Optimize is a six-year WHO-PATH collaboration with a unique mandate to think far into the future to create a vaccine supply chain and technologies that are flexible and robust enough to handle an increasingly large and costly portfolio of vaccines, and ultimately to create synergies with the delivery of other health commodities. PATH provides specific expertise and experience in technology development, vaccines and vaccine formulations, modeling, advocacy, policy, communications, and business development and commercialization. WHO contributes expertise in immunization, health economics, norms and standards, regulatory issues, vaccine management and immunization logistics, and monitoring and impact analyses.

The work of Optimize has directly contributed to GVAP Strategic objectives 5 and 6 by developing new mechanisms to ensure quality supply of vaccines and new innovations to maximize the benefits of immunization. Among numerous other activities, Optimize continued to strengthen existing mechanisms and advisory groups and worked to ensure ownership by WHO or UNICEF so established mechanisms will continue after the project closes in 2013. These mechanisms and groups include the TechNet21 website; the Vaccine Presentation and Packaging Advisory Group; WHO's Immunization Practices Advisory Committee; the Programmatic Suitability for Prequalification process; the Performance, Quality and Safety process; and the Cold Chain and Logistics Task Force.

Through Optimize's important contributions to these groups and processes, information flow and collaboration between WHO, UNICEF, manufacturers, and countries has increased. As a result of this work, vaccine manufacturers and donors are requesting target product profiles and public-sector input on products, and there is an increasing emphasis on the total system costs of new products. Cold chain equipment manufacturers can access guidelines and provide input into the development of new equipment categories for the PQS process, and they are increasingly field testing products with country partners to optimize equipment design.

Further information: www.path.org/projects/project-optimize-resources-global.php

Japanese encephalitis vaccine

The PATH Japanese encephalitis (JE) project worked with international partners and ministries of health in developing countries in Asia and the Pacific to accelerate the introduction of a safe and affordable JE vaccine, with the ultimate aim of controlling clinical JE.

PATH's JE work also addresses the GVAP Strategic Objectives of 5 and 6 by increasing access to a life-saving vaccine. PATH has supported Chinese vaccine manufacturer, Chengdu Institute of Biological Products (CDIBP), in quality manufacturing and clinical development of its SA 14-14-2 live, attenuated JE vaccine since 2005.

PATH negotiated an affordable public-sector price with CDIBP so that developing countries could procure the vaccine for poor children at highest risk of the disease. To date, more than 150 million doses of this vaccine have been purchased or donated and delivered outside of China through this agreement. PATH also helped CDIBP achieve international quality production standards, including assisting in the design of a new manufacturing facility to ensure a high-quality, adequate, stable, and affordable vaccine supply. PATH worked with CDIBP to design and support a series of clinical trials to evaluate the immunogenicity and safety of JE vaccine in Bangladesh, the Philippines, and Sri Lanka. CDIBP applied to WHO for prequalification of their JE vaccine, and as of August 1, 2013, the final inspection is complete and CDIBP is awaiting a final decision from WHO on prequalification.

Further information: www.path.org/projects/japanese_encephalitis_project.php

Rotavirus vaccine

PATH has a long and rich organizational history of leadership in rotavirus vaccine development, research, policy, and advocacy. A series of ambitious projects since 1998 have included the Rotavirus Vaccine Program, the Advancing Rotavirus Vaccine Development project, the Vaccine Implementation Technical Assistance Consortium, and the Rotavirus Vaccine Impact project, among others. These initiatives have allowed PATH to steadily accelerate the development and introduction of rotavirus vaccines in developing countries.

PATH's rotavirus projects contribute toward GVAP Strategic Objectives 3, 5, and 6 by ensuring a new vaccine is appropriate for developing country contexts, as well as available to them in an equitable manner. With PATH's support, Nicaragua introduced rotavirus vaccine in the same year it was available in the developing world—a first for any vaccine.

Additional vaccine development and delivery research is also under way with in-country partners to expand supplier, presentation, and dosing options available to low-income countries. Just this year, the results from a Phase 3 trial of an oral rotavirus vaccine developed and manufactured in India by PATH's partner, Bharat Biotech. Trial data showed ROTAVAC® to be safe and efficacious, significantly reducing severe rotavirus diarrhoea by 56 percent during the first year of life, with protection continuing into the second year of life.

PATH and its partners conduct studies and targeted advocacy to secure the successful introduction of rotavirus vaccines in developing countries. PATH helped provide the first post-licensure data on the real-world effectiveness of the Rotarix® product in a GAVI-eligible country. As of July 2013, 14 GAVI-eligible countries have introduced rotavirus vaccines, with additional introductions planned.

Further information: http://sites.path.org/rotavirusvaccine/

Human papillomavirus vaccine

PATH's work in HPV focuses primarily on vaccination, although PATH endorses a comprehensive approach that includes vaccination of young adolescents, as well as screening and pre-cancer treatment of adult women. Our HPV work addresses the GVAP Strategic Objectives 3, 4, and 5, through vaccine introduction work in coordination with other non-vaccine screening activities.

Through the HPV: Evidence for Impact project, PATH conducted extensive in-country assessment and documentation of the most effective and cost-effective strategies to protect young adolescent girls against cervical cancer using HPV vaccine. Supporting formative research and vaccination demonstration projects in India, Peru, Uganda, Vietnam, and other countries, PATH helped pave the way for Peru and Uganda to launch national immunization campaigns and has assisted nine countries in applying for GAVI support for demonstration projects or pilot introductions. Additional technical support to GAVI-eligible countries is ongoing.

Further information: www.path.org/projects/cervical_cancer_vaccine.php

Malaria vaccine

PATH is working to accelerate the development of malaria vaccine and catalyze timely access in endemic countries through its Malaria Vaccine Initiative (MVI). This work directly works towards GVAP Strategic Objective 6 and Goal 4 through the creation of new vaccine for a currently non-vaccine-preventable disease.

Continuing to work closely with WHO Headquarters and Regional Office for Africa, MVI continued to make significant progress in the development of its vaccine candidate RTS,S, working in collaboration with GlaxoSmithKline Vaccines and research centers across Africa. MVI initiated additional studies with a variety of academic, governmental, and industry partners to compare the efficacy of malaria vaccine platforms and evaluated the immunogenicity of an innovative conjugated vaccine formulation.

Further information: www.malariavaccine.org

Meningitis A vaccine: MenAfriVac™

The Meningitis Vaccine Project (MVP) is a partnership between WHO and PATH with a goal to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, introduction, and widespread use of conjugate meningococcal vaccines. MVP activities address all GVAP strategic objectives through work to ensure country commitment, the demand of the population for the vaccine, equity, a new vaccine that is affordable and available, and collaboration across the health system and public and private sectors.

A unique partnership between PATH, WHO, and vaccine manufacturer the Serum Institute of India, MVP reached a critical milestone in 2012—reaching more than 100 million people with the vaccine specifically developed to protect from meningococcal A meningitis, the strain of the disease most destructive to people living in Africa's meningitis belt.

The innovative vaccine-development model involved partners with expertise in technology, materials, and manufacturing located on four continents. As of December 2012, MenAfriVac® had been rolled out in ten countries: Benin, Burkina Faso, Cameroon, Chad, Ghana, Mali, Niger, Nigeria, North Sudan, and Senegal. Vaccination campaigns will eventually provide a contiguous block of immunized populations across the heart of the meningitis belt, with the potential to eliminate the primary cause of the disease.

Further information: www.path.org/blog/2012/12/milestones-meningitis-vaccine/

Submitted by Laurie Werner
Operations Lead, BID Initiative
Vaccine Access and Delivery
PATH
2201 Westlake Avenue, Suite 200| Seattle, WA, 98121, USA
lwerner@path.org

Sabin Vaccine Institute: A rapid survey of Global Vaccine Action Plan implementation

Please refer to attached PDF document (*to be provided by Secretariat*)

Submitted by Mariya Savchuk, Senior Program Officer*
Sustainable Immunization Financing Program
Sabin Vaccine Institute
**Corresponding author, mariya.savchuk@sabin.org*

Save the Children submission to the first Decade of Vaccines Global Vaccine Action Plan annual assessment report to be presented at SAGE, November 2013

Equity is a guiding principle of the Global Vaccine Action Plan (GVAP). The GVAP calls for universal access to the full benefits of immunization. Yet those who are left behind are the children most in need, for whom vaccines hold the most potential (see Finding the Final Fifth for further information). Without addressing these inequities, the goals of the GVAP will not be achieved.

Delivering on this promise will require prioritizing equity in the implementation of the GVAP at global, regional and country levels (see article in Vaccine). It must inform the strategies undertaken and the metrics for monitoring progress (see Immunization for All for further information). This must be at the proximate level of effecting equity of outcomes – through sufficient investments in expanding equity in coverage of immunization and strengthening the health system to seize the opportunities for integrated approaches and sustainable change. Equity must also influence research and development agendas of the pharmaceutical companies and their pricing mechanisms. It should guide the allocation of technical and financial support from development partners. And it requires the involvement of civil society in the development and implementation of plans at all levels, as a partner and also a watchdog to hold stakeholders accountable.

What has happened in the first year of implementation of the GVAP has been fairly opaque to civil society. We look forward to reading the report produced for SAGE and request that substantial emphasis is given to analyzing the extent to which equity is prioritized in both the process for and the content of implementation of the GVAP.

Submitted by Lara Brearley
Senior Health Policy & Research Adviser
Save the Children UK
1 St John's Lane, London EC1M 4AR, UK
L.Brearley@savethechildren.org.uk

ACRONYMS

AFP	Acute Flaccid Paralysis
AFRO	WHO Regional Office for Africa
AMC	Advance Market Commitment
AMP	Agence de Médecine Préventive
BMGF	Bill & Melinda Gates Foundation
BMI	Body Mass Index
CDIBP	Chengdu Institute of Biological Products
cGMP	current Good Manufacturing Practice
CIP	Carriage and Insurance Paid to (Incoterms)
CISM	Manhiça Health Research Centre, Mozambique
cMYP	Comprehensive Multiyear Plans
COIA	Commission on Information and Accountability for Women's and Children's Health
CPT	Carriage paid to (incoterms)
CRESIB	Barcelona Centre for International Health Research
CRS	Congenital Rubella Syndrome
CSO	Civil Society Organization
CTC	Controlled Temperature Chain
CV	Community volunteers
DDO	District Development Officer
DHO	District Health Officer
DHS	Demographic and Health Survey
DoV	Decade of Vaccines
DoVE	Decade of Vaccines Economics
DTP	Diphtheria, tetanus toxoid and pertussis
ECOWAS	Economic Community Of West African States
EMRO	WHO Regional Office for Europe
EPI	Expanded Programme on Immunization
EURO	WHO Regional Office for Europe
FCA	Free Carrier (Incoterms)
G	GVAP Goal
GAVP	Global Vaccine Action Plan
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GNI	Gross National Income
GoC	Grade of Confidence
GPEI	Global Polio Eradication Initiative
GVIRF	Global Vaccine and Immunization Research Forum
HIC	High Income Country
HMIS	Health Management Information System
HPV	Human Papillomavirus
HQ	Headquarters
HSS	Health System Strengthening
IB-VPD	Invasive Bacterial Vaccine Preventable Diseases
ICC	Inter-agency Coordinating Committee
ICTRP	International Clinical Trials Registry Platform
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations

IMB	Independent Monitoring Board
IPV	Inactivated Polio Vaccine
IVAC	International Vaccine Access Center
IVAC	International Vaccine Access Center, Johns Hopkins Bloomberg School of Public Health
IVB	WHO Immunization, Vaccines and Biologicals Department
JE	Japanese encephalitis
JRF	WHO-UNICEF Joint Reporting Form
LDO	Local Development Officer
LIC	Low Income Countries
LIC	Low Income Country
LMIC	Lower Middle Income Country
LQA-CS	Lot Quality Assurance – Cluster Sampling
M&E/A	Monitoring & Evaluation/Accountability Framework
M&RI	Measles & Rubella Initiative
MDG	Millennium Development Goal
MIC	Middle Income Countries
MICS	Multiple Indicators Cluster Survey
MMR	Measles, Mumps and Rubella
MNTE	Maternal and Neonatal Tetanus Elimination
MoH	Ministry of Health
MR	Measles-Rubella
MSF	Médecins Sans Frontières/Doctors Without Borders
MVI	Malaria Vaccine Initiative
MVP	Meningitis Vaccine Project
NGOs	nongovernmental organizations
NIDs	National Immunization Days
NIP	National Immunization Programme
NITAG	National Immunization Technical Advisory Groups
NRA	National Regulatory Authority
NTMR	Neonatal Tetanus Mortality Rate
OCCGE	Organisation pour la Coordination et la Coopération pour la lutte contre les Grandes Endémies
OECD	Organization for Economic Co-operation and Development
OPV	Oral Polio Vaccine
PAHO	WHO Regional Office for the Americas/Pan American Health Organization
PCV	pneumococcal conjugate vaccine
PCV	Pneumococcal Conjugate Vaccine
PMNCH	Partnership for Maternal, Neonatal and Child Health
PQS	WHO Performance, Quality and Safety
RMNCH	reproductive, maternal, newborn and child health
RO	Regional Office
RV	Rotavirus Vaccine
SAGE	Strategic Advisory Group of Experts on Immunization.
SEARO	WHO Regional Office for South-East Asia
SHA	Systems of Health Accounts
SHA	System of Health Accounts

SIAs	Supplemental Immunization Activities
SIAs	Supplementary Immunization Activities
SO	GVAP Strategic Objective
TAG	Technical Advisory Group
TIP	Tailoring Immunization Programmes
TT	Tetanus Toxoid
UMIC	Upper Middle Income Country
UN	United Nations
UNICEF	United Nations Children's Fund
UNSG	UN Secretary-General
V3P	Vaccine Product Price and Procurement
VENICE	Vaccine European New Integrated Collaboration Effort
VIMS	Vaccine Information Management System
VPD	vaccine-preventable diseases
WAHO	West African Health Organization
WAP	Weighted Average Prices
WG	Working Group
WHA	World Health Assembly
WHO	World Health Organization
WHO CC	World Health Organization Collaborating Centre
WIW	World Immunization Week (last week of April)
WPRO	WHO Regional Office for the Western Pacific
WPV	Wild Poliovirus
WUENIC	WHO-UNICEF Estimates of National Immunization Coverage

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