## Table of contents

1. Introduction

6. Monitoring progress towards GVAP goals and strategic objectives

- **GOAL 1**: achieve a world free of poliomyelitis
- **GOAL 2**: meet global and regional elimination targets
- **GOAL 3**: meet vaccination coverage targets in every region, country and community
- **GOAL 4**: develop and introduce new and improved vaccines and technologies
- **GOAL 5**: exceed the millenium development goal 4 target for reducing child mortality

38. **STRATEGIC OBJECTIVE 1**: all member states commit to immunization as a priority

48. **STRATEGIC OBJECTIVE 2**: individuals and communities understand the values of vaccines and demand immunization both as a right and a responsibility

58. **STRATEGIC OBJECTIVE 3**: the benefits of immunization are equitably extended to all people

64. **STRATEGIC OBJECTIVE 4**: strong immunization systems are an integral part of a well-functioning health system

80. **STRATEGIC OBJECTIVE 5**: immunization programmes have sustainable access to predictable funding, quality supply and innovative technologies

85. **STRATEGIC OBJECTIVE 6**: vaccine pricing report

100. **STRATEGIC OBJECTIVE 7**: country, regional and global research and development innovations maximize the benefits of immunization
2. Tracking resources invested in immunization

3. Documenting and monitoring commitments for immunization

4. Independent submissions from other stakeholders

5. Annexes

ANNEX 1

ANNEX 2

ANNEX 3

ANNEX 4
List of figures

10  Figure 1: Wild Poliovirus cases worldwide in 2012
14  Figure 2: Member States with validated elimination of neonatal tetanus (as of 31 December, 2012)
27  Figure 3: Member States that have and have not achieved national coverage of ≥ 90%
for all vaccines included in the national infant immunization schedule in 2012
31  Figure 4: Introduction of Hib and pneumococcal conjugate vaccines in high- and low-income countries (as of 31 December, 2012)
33  Figure 5: Member States with Hib-containing vaccine in their national immunization programme
(as of 31 December, 2012)
33  Figure 6: Member States with pneumococcal conjugate vaccine in their national immunization programme (as of 31 December, 2012)
34  Figure 7: Member States with Rotavirus vaccine in their national immunization programme
(as of 31 December 2012)
34  Figure 8: Member States with HPV vaccine in the national immunization programme
(as of 31 December 2012)
52  Figure 9: Estimated or measured percent of persons un- and under-vaccinated in whom lack of confidence in vaccination was a factor
60  Figure 10: Member States by the percent of districts with DTP3 coverage of ≥ 80% for 2012
63  Figure 11: DTP3 coverage rates for lowest and highest wealth quintiles from
DHS and MICS conducted from 2008 to 2011 in 25 Member States
65  Figure 12: DTP1-DTP3 dropout rates by country, 2012
66  Figure 13: Member States with DTP1-DTP3 dropout rates of ≥ 10% for the last three years (2010-2012)
68  Figure 14: Member States that have and have not sustained national
DTP3 coverage of ≥ 90% for the last three years, 2010-2012
69  Figure 15: Member States that have and have not sustained national
DTP3 coverage of ≥ 80% for the last three years, 2010-2012
Figure 16: Member states that reported data to the WHO-Coordinated Invasive Bacterial Vaccine Preventable Diseases (IB-VPD) Surveillance Network for 2012

Figure 17: Member states that reported data to the WHO-Coordinated Global Rotavirus Surveillance Network for 2012

Figure 18: Number and percent of Member States (vaccine producing and non-producing) by the functionality of their NRAs in 2012

Figure 19: Proportion of the global population living in countries with functional regulatory oversight for vaccines

Figure 20: Percentage of assured (dark blue) vs. non-assured (light blue) quality vaccines used worldwide, 1997-2012

Figure 21: UNICEF and PAHO prices for IPV, 2010-2013

Figure 22: UNICEF and PAHO prices for DTwP-HepB-Hib pentavalent vaccines from 2001 to 2013

Figure 23: Comparison of prices for pentavalent vaccines at different points in time and for different presentations

Figure 24: UNICEF and PAHO prices for pneumococcal conjugate vaccine, by type of vaccine, 2006-2013

Figure 25: PAHO and UNICEF Prices for HPV vaccines

Figure 26: PAHO and UNICEF/GAVI prices (per dose)

Figure 27: Number of prequalified products at the end of each year, from 2008 to 11 July, 2013

Figure 28: Commitments related to the median coverage of essential RMNCH interventions in Countdown to 2015

Figure 29: The Joint Reporting Form for Immunization Process

Figure 30: DTP3 national coverage by wealth quintile for all the Member States with data available between 2007-2011 (surveys conducted in 2008-2012)
List of tables

1. Table 1: The GVAP Monitoring and Evaluation/Accountability Framework: goals, strategic objectives and indicators to evaluate progress
2. Table 2: AFP/polio case count for 2012 by WHO region
3. Table 3: Case breakdown of confirmed wild poliovirus (WPV) cases by country in 2012
4. Table 4: Number of measles cases and incidence rates reported by WHO region
5. Table 5: Number of rubella cases and incidence rates reported by Member States per WHO region
6. Table 6: Number of CRS cases reported by Member States per WHO region
7. Table 7: Distribution of all 194 Member States by level of national DTP3 coverage rate and region, based on WUENIC estimates for 2012
8. Table 8: Distribution of Member States by national and district-level DTP3 coverage achievements and by region, 2012
9. Table 9: Number of Member States that achieved ≥ 90% national coverage for all the vaccines included in their national immunization schedule by region, 2010 - 2012
10. Table 10: Breakdown of 44 Member States with sustained vaccine introductions between January 2010 and December 2011, by income level and vaccine
11. Table 11: Number of Member States that have added one or more new vaccines to their national immunization schedule between January 2010 and December 2011, by WHO region
12. Table 12: Number of low- and middle-income Member States that introduced Hib-containing, pneumococcal, rotavirus or HPV vaccines between January 2010 and 31 December, 2012, by vaccine, GAVI-eligibility and income classification
13. Table 13: Member States for which total expenditures for routine immunization have been steadily increasing over the past three years (2010-2012) (n=19)
14. Table 14: Member States for which expenditures for routine immunization have been steadily declining from 2010 to 2012
15. Table 15: Analysis of the NITAG 2012 JRF data at global level and by WHO region
16. Table 16: Number of Member States with NITAGs by various criteria, income status, GAVI eligibility and population size, 2012 JRF data
17. Table 17: Number of Member States that responded to Question 1 about assessing the level of confidence in vaccination at the sub-national level
18. Table 18: Types of assessments on vaccination confidence of the population reported by countries responding to confidence-related questions on the JRF or self-administered questionnaire
19. Table 19: Number and percent of Member States that provided a measured or estimated percentage of un- or under-vaccinated in whom a lack of confidence in vaccination was a factor
20. Table 20: Distribution of Member States by the percent of districts achieving ≥ 80% coverage for DTP3 in 2012, by WHO region
<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>Member States that have sustained national DTP3 coverage of ≥ 90% for the last two years (2011 and 2012)</td>
</tr>
<tr>
<td>22</td>
<td>Member States that have sustained national DTP3 coverage of ≥ 90% for 2010 and 2011 but not in 2012</td>
</tr>
<tr>
<td>23</td>
<td>Member States that have sustained national DTP3 coverage of ≥ 80% but &lt; 90% for the last three years (2010-2012)</td>
</tr>
<tr>
<td>24</td>
<td>Number and percent of Member States by Grade of Confidence (GoC) for DTP3 coverage estimates for 2010-2012</td>
</tr>
<tr>
<td>25</td>
<td>Number and percent of Member States achieving above and below National DTP3 coverage of 90% in 2012 (from WUENIC) by Grade of Confidence (GoC)</td>
</tr>
<tr>
<td>26</td>
<td>Number of Member States that reported rotavirus diarrhoea and IB-VPD surveillance data to WHO in 2012, by WHO region.</td>
</tr>
<tr>
<td>27</td>
<td>Member States reporting on the JRF that they conduct sentinel site surveillance for rotavirus diarrhoea and IB-VPD, by WHO region</td>
</tr>
<tr>
<td>28</td>
<td>Member States in each income category reporting that they conduct sentinel site surveillance for rotavirus diarrhoea and IB-VPD</td>
</tr>
<tr>
<td>29</td>
<td>Number and percent of Members States (vaccine producing and non-producing) by the functionality of their NRAs in 2012</td>
</tr>
<tr>
<td>30</td>
<td>Proposed country matrix of vaccine price data and current data availability</td>
</tr>
<tr>
<td>31</td>
<td>Published vaccine pricing commitments from suppliers for GAVI-graduating countries, as of July 2013</td>
</tr>
<tr>
<td>32</td>
<td>Vaccine Price Table (Data Provided by UNICEF and PAHO) in US$*</td>
</tr>
<tr>
<td>33</td>
<td>Number of prequalified products at the end of each year, 2008 to 2013</td>
</tr>
<tr>
<td>34</td>
<td>Number of products newly prequalified during 2012</td>
</tr>
<tr>
<td>35</td>
<td>Time trends in DTP3 coverage in Member States with DTP3 coverage of &lt; 70% in 2012</td>
</tr>
<tr>
<td>36</td>
<td>Member States with DTP1-DTP3 dropout rates of ≥ 10% for 2012 and showing an increasing trend in dropouts for the years 2010-2012</td>
</tr>
<tr>
<td>37</td>
<td>Member States with DTP1-DTP3 dropout rates of ≥ 10% for 2012 showing a decreasing trend for the years 2010-2012</td>
</tr>
<tr>
<td>38</td>
<td>Member States with DTP1-DTP3 dropout rates of ≥ 10% for 2012 and showing a stable trend for the years 2010-2012</td>
</tr>
<tr>
<td>39</td>
<td>Member States with DTP1-DTP3 dropout rates or ≥ 10% for 2012 and showing an inconsistent trend for the years 2010-2012</td>
</tr>
</tbody>
</table>
Acronyms

AFP  Acute Flaccid Paralysis
AFRO  WHO Regional Office for Africa
AMC  Advance Market Commitment
AMP  Agence de Medecine Preventive
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
IPFMA  International Federation of Pharmaceutical Manufacturers & Associations
IMB  Independent Monitoring Board
IPV  Inactivated Polio Vaccine
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 Country
LMIC  Lower Middle Income Country
LQA-CS  Lot Quality Assurance – Cluster Sampling
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>M&amp;E/A</td>
<td>Monitoring &amp; Evaluation/Accountability Framework</td>
</tr>
<tr>
<td>M&amp;RI</td>
<td>Measles &amp; Rubella Initiative</td>
</tr>
<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
</tr>
<tr>
<td>MIC</td>
<td>Middle Income Countries</td>
</tr>
<tr>
<td>MICS</td>
<td>Multiple Indicators Cluster Survey</td>
</tr>
<tr>
<td>MMR</td>
<td>Measles, Mumps and Rubella</td>
</tr>
<tr>
<td>MNTE</td>
<td>Maternal and Neonatal Tetanus Elimination</td>
</tr>
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<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MR</td>
<td>Measles-Rubella</td>
</tr>
<tr>
<td>MSF</td>
<td>Médecins Sans Frontières/Doctors Without Borders</td>
</tr>
<tr>
<td>MVI</td>
<td>Malaria Vaccine Initiative</td>
</tr>
<tr>
<td>MVP</td>
<td>Meningitis Vaccine Project</td>
</tr>
<tr>
<td>NGOs</td>
<td>nongovernmental organizations</td>
</tr>
<tr>
<td>NIDs</td>
<td>National Immunization Days</td>
</tr>
<tr>
<td>NIP</td>
<td>National Immunization Programme</td>
</tr>
<tr>
<td>NITAG</td>
<td>National Immunization Technical Advisory Groups</td>
</tr>
<tr>
<td>NRA</td>
<td>National Regulatory Authority</td>
</tr>
<tr>
<td>NTMR</td>
<td>Neonatal Tetanus Mortality Rate</td>
</tr>
<tr>
<td>OCCGE</td>
<td>Organisation pour la Coordination et la Coopération pour la lutte contre les Grandes Endémies</td>
</tr>
<tr>
<td>OECD</td>
<td>Organization for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OPV</td>
<td>Oral Polio Vaccine</td>
</tr>
<tr>
<td>PAHO</td>
<td>WHO Regional Office for the Americas/Pan American Health Organization</td>
</tr>
<tr>
<td>PCV</td>
<td>Pneumococcal Conjugate Vaccine</td>
</tr>
<tr>
<td>PMNCH</td>
<td>Partnership for Maternal, Neonatal and Child Health</td>
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<tr>
<td>PQS</td>
<td>WHO Performance, Quality and Safety</td>
</tr>
<tr>
<td>RMNCH</td>
<td>Reproductive, maternal, newborn and child health</td>
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<tr>
<td>RO</td>
<td>Regional Office</td>
</tr>
<tr>
<td>RV</td>
<td>Rotavirus Vaccine</td>
</tr>
<tr>
<td>SAGE</td>
<td>Strategic Advisory Group of Experts on Immunization.</td>
</tr>
<tr>
<td>SEARO</td>
<td>WHO Regional Office for South-East Asia</td>
</tr>
<tr>
<td>SHA</td>
<td>System of Health Accounts</td>
</tr>
<tr>
<td>SIAs</td>
<td>Supplementary Immunization Activities</td>
</tr>
<tr>
<td>SO</td>
<td>GVAP Strategic Objective</td>
</tr>
<tr>
<td>TAG</td>
<td>Technical Advisory Group</td>
</tr>
<tr>
<td>TIP</td>
<td>Tailoring Immunization Programmes</td>
</tr>
<tr>
<td>TT</td>
<td>Tetanus Toxoid</td>
</tr>
<tr>
<td>UMIC</td>
<td>Upper Middle Income Country</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children's Fund</td>
</tr>
<tr>
<td>UNSG</td>
<td>UN Secretary-General</td>
</tr>
<tr>
<td>V3P</td>
<td>Vaccine Product Price and Procurement</td>
</tr>
<tr>
<td>VENICE</td>
<td>Vaccine European New Integrated Collaboration Effort</td>
</tr>
<tr>
<td>VIMS</td>
<td>Vaccine Information Management System</td>
</tr>
<tr>
<td>VPD</td>
<td>vaccine-preventable diseases</td>
</tr>
<tr>
<td>WAHO</td>
<td>West African Health Organization</td>
</tr>
<tr>
<td>WAP</td>
<td>Weighted Average Prices</td>
</tr>
<tr>
<td>WB</td>
<td>World Bank in the list</td>
</tr>
<tr>
<td>WG</td>
<td>Working Group</td>
</tr>
<tr>
<td>WHA</td>
<td>World Health Assembly</td>
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<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WHO CC</td>
<td>World Health Organization Collaborating Centre</td>
</tr>
<tr>
<td>WIW</td>
<td>World Immunization Week (last week of April)</td>
</tr>
<tr>
<td>WPRO</td>
<td>WHO Regional Office for the Western Pacific</td>
</tr>
<tr>
<td>WPV</td>
<td>Wild Poliovirus</td>
</tr>
<tr>
<td>WUENIC</td>
<td>WHO-UNICEF Estimates of National Immunization Coverage</td>
</tr>
</tbody>
</table>
Introduction

The Global Action Plan and process for monitoring progress

The Global Vaccine Action Plan (GVAP) is a framework adopted at the 65th World Health Assembly in 2012 to achieve the vision of the Decade of Vaccines 2011-2020 (DoV) of “a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases.” The GVAP’s mission is to “improve health by extending by 2020 and beyond the full benefits of immunization to all people, regardless of where they are born, who they are, or where they live.”

The GVAP has articulated five goals and six Strategic Objectives to achieve this mission, as shown in Table 1.

The 65th World Health Assembly (WHA) in May 2012 requested the WHO Director General to monitor progress and report annually, using an accountability framework, to in order to guide immunization discussions and future actions. In response, the DoV partners developed a Monitoring & Evaluation/Accountability (M&E/A) Framework that identifies specific indicators to measure progress for each Goal and Strategic Objective, as well as data sources (see Table 1). The DoV partners also agreed to a process for an annual independent review of progress, which was presented to the 66th World Health Assembly in May 2013.

Table 1: The GVAP Monitoring and Evaluation/Accountability Framework: goals, strategic objectives and indicators to evaluate progress

<table>
<thead>
<tr>
<th>Goal/Strategic Objective</th>
<th>Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goals:</td>
<td></td>
</tr>
<tr>
<td>1. Achieve a world free of poliomyelitis</td>
<td>1.1 Interrupt wild poliovirus transmission globally</td>
</tr>
<tr>
<td></td>
<td>1.2 Certification of poliomyelitis eradication</td>
</tr>
<tr>
<td>2. Meet global and regional elimination targets</td>
<td>2.1 Neonatal tetanus elimination</td>
</tr>
<tr>
<td></td>
<td>2.2 Measles elimination</td>
</tr>
<tr>
<td></td>
<td>2.3 Rubella/Congenital rubella syndrome (CRS) elimination</td>
</tr>
<tr>
<td>3. Meet vaccination coverage targets in every region, country and community</td>
<td>3.1 Reach 90% national coverage and 80% in every district or equivalent administrative unit with three doses of diphtheria-tetanus-pertussis-containing vaccines</td>
</tr>
<tr>
<td></td>
<td>3.2 Reach 90% national coverage and 80% in every district or equivalent administrative unit for all vaccines in national programmes, unless otherwise recommended</td>
</tr>
<tr>
<td>4. Develop and introduce new and improved vaccines and technologies</td>
<td>4.1 Licensure and launch of vaccine or vaccines against one or more major currently non-vaccine preventable diseases</td>
</tr>
<tr>
<td></td>
<td>4.2 Licensure and launch of at least one platform delivery technology</td>
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<tr>
<td></td>
<td>4.3 Number of low-income and middle-income countries that have introduced one or more new or under-utilized vaccines</td>
</tr>
<tr>
<td>5. Exceed the Millennium Development Goal 4 target for reducing child mortality</td>
<td>5.1 Reduce under-five mortality rate</td>
</tr>
</tbody>
</table>

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1. The GVAP can be found at: [www.who.int/immunization/global_vaccine_action_plan/en/](http://www.who.int/immunization/global_vaccine_action_plan/en/)
2. WHA resolution 65.17 (found at: [http://apps.who.int/gb/or/e/a_whaf65r1.html](http://apps.who.int/gb/or/e/a_whaf65r1.html))
## Strategic Objectives (SOs)

### 1. All countries commit to immunization as a priority

1.1 Domestic expenditures for immunization per person targeted

1.2 Presence of an independent technical advisory group that meets defined criteria

### 2. Individuals and communities understand the value of vaccines and demand immunization both as a right and a responsibility

2.1 Percentage of countries that have assessed (or measured) the level of confidence in vaccination at the sub-national level

2.2 Percentage of un- and under-vaccinated in whom lack of confidence was a factor that influenced their decision

### 3. The benefits of immunization are equitably extended to all people

3.1 Percentage of districts with 80% or greater coverage with three doses of diphtheria-tetanus-pertussis-containing vaccine

3.2 Reduction in coverage gaps between wealth quintiles and other appropriate equity indicator(s)

### 4. Strong immunization systems are an integral part of a well-functioning health system

4.1 Dropout rates between first dose (DTP) and third dose (DPT) of diphtheria-tetanus-pertussis-containing vaccines

4.2 Sustained coverage of diphtheria-tetanus-pertussis-containing vaccines 90% or greater for three or more years

4.3 Immunization coverage data assessed as high quality by WHO and UNICEF

4.4 Number of Member States with case-based surveillance for vaccine-preventable diseases

### 5. Immunization programmes have sustainable access to predictable funding, quality supply and innovative technologies

5.1 Percentage of doses of vaccine used worldwide that are of assured quality

### 6. Country, regional and global research and development innovations maximize the benefits of immunization

6.1 Progress towards development of HIV, TB and malaria vaccines

6.2 Progress towards a universal influenza vaccine (protecting against drift and shift variants)

6.3 Progress towards institutional and technical capacity to carry out vaccine clinical trials

6.4 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

6.5 Number of vaccine delivery technologies (devices and equipment) that have received WHO pre-qualification against the 2010 baseline

The annual review process consists of:

a. an in-depth report of progress against each indicator, prepared by the DoV Secretariat (“DoV GVAP Secretariat Report”), which follows; and

b. an assessment report presented to the WHO Strategic Advisory Group of Experts (SAGE) on Immunization each year by a DoV Working Group that assesses progress against the GVAP and makes recommendations for improvements.

The DoV GVAP Secretariat report gathers each year all available information on progress and activities related to the indicators of the GVAP Monitoring & Evaluation/Accountability Framework. The DoV Working Group uses this report and other sources of information to prepare the assessment report to the SAGE. The 2013 assessment report was presented to the SAGE in November 2013. The assessment report, along with input from the SAGE, forms the basis of reports on GVAP progress to be presented to the WHO Executive Board and the 2014 World Health Assembly.

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The DoV GVAP Secretariat report

The report consists of four sections. The first three sections were prepared by the DoV Secretariat, which is made up of the Bill & Melinda Gates Foundation, GAVI Alliance secretariat, UNICEF, US National Institute of Allergy and Infectious Diseases and WHO. These sections are:

1. Monitoring Progress towards GVAP Goals and Strategic Objectives, which includes a narrative report on vaccine price trends (under SO5)
2. Monitoring Resources Invested in Immunization, and
3. Documenting and Monitoring Immunization Commitments

In addition, there is a Section IV consisting of Independent Submissions from other DoV Stakeholders.

Below are additional information and comments about each major section of this report:

1: Monitoring Progress towards GVAP Goals and Strategic Objectives

This section reports on progress against the indicators for each of the GVAP goals and strategic objectives, using the operational definitions proposed in the M&E/A Framework. Data sources include the WHO-UNICEF Joint Reporting Form (JRF) database, other databases (e.g., Demographic and Health Surveys (DHS), Multiple Indicators Cluster Survey (MICS), pre-qualification database), and other WHO reports, such as reports from the Polio Eradication Programme and the Measles and Rubella Elimination Programme, surveillance reports, and neonatal tetanus elimination validation reports.

Data presented in this report are for 2012, except for some indicators for which additional validated data for 2013 are available. Please note that 2010 is the baseline for the majority of the indicators. For some indicators, such as those related to Goal 1 to eradicate polio and Goal 5 to reduce child mortality, the section mainly summarized reports and recommendations that have already been developed and disseminated by existing independent advisory committees that focus on these topics.

The structure for this report follows the GVAP outline, as adopted by the World Health Assembly. As a result, vaccination coverage data are presented in several different sections, including under Goal 3 (meeting vaccination coverage targets), Strategic Objective 3 (extending immunization equitably to all people) and Strategic Objective 4 (indicators of strong immunization systems, i.e., dropout rates and sustained coverage).

As requested by the SAGE in November 2012, a separate narrative report under Strategic Objective 5 was developed to report on progress with vaccine pricing, in lieu of an indicator. The vaccine pricing report – prepared by representatives from the Bill & Melinda Gates Foundation (BMGF), Médecins Sans Frontières (MSF), GAVI Alliance Secretariat, the Pan American Health Organization (PAHO), UNICEF and WHO – provides an overview of the importance of vaccine pricing in the global context for both low- and middle-income countries. It summarizes some of the complexities of pricing and price comparisons, the gaps in available information, and possible improvements and further actions required in this area.

For Strategic Objective 2 concerning the level of country populations’ confidence in vaccination, questions on the JRF to obtain this information from countries are still being piloted and thus the quantitative data collected were sparse. Consequently, we have included in this report several case studies and reports that examine causes of populations’ lack of confidence in vaccination or describe efforts to engage communities to stimulate demand for immunization and consequently increase coverage.

Data quality

The WHO-UNICEF Joint Reporting Forms (JRF) and the WHO-UNICEF Estimates of National Immunization Coverage (WUENIC) are the main data sources for many of the indicators, including all those related to immunization coverage. While immunization data are considered to be among the more reliable data in public health, especially for low- and middle-income countries, the DoV Secretariat recognizes that there are some limitations on the availability and quality of these data. Details on the JRF and WUENIC data and their limitations are presented in Annex 1. In addition, under each indicator in this report, there is a discussion of the data sources, methods of data collection and analysis, and quality of the data used to track the indicator.
2: Monitoring Resources Invested in Immunization

Data from National Health Accounts, using the 2011 System of Health Accounts (SHA) framework, will be used to monitor resources invested in immunization from both domestic and international sources in each country. This year, the report describes how resources for immunization will be monitored and the types of data that will be presented in future reports.

3: Documenting and Monitoring Immunization Commitments

It was agreed that the DoV will use the framework of the UN Secretary-General’s Global Strategy for Women’s and Children’s Health to monitor financial commitments from governments and donors for immunization. A process has been put in place to collect immunization-specific commitments through this mechanism, coordinated by the Partnership for Maternal, Neonatal and Child Health (PMNCH). The 2013 PMNCH report was published in September 2013.5

4: Independent Submissions from other Stakeholders

DoV stakeholders were requested to provide independent reports that describe their activities related to meeting the goals and strategic objectives of GVAP, highlighting success stories, as well as challenges and opportunities. Six organizations – Agence de Medecine Preventive (AMP), Barcelona Institute for Global Health, John Hopkins University, PATH, Sabin Vaccine Institute, and Save the Children—submitted reports. These reports are presented in this document without any modifications by the Secretariat.

Monitoring progress towards GVAP goals and strategic objectives
Below are details on the progress achieved in 2012 against each of the GVAP five goals and six strategic objectives, by indicator. Two major sources of data for this report are:

a. The WHO-UNICEF Joint Reporting Form on Immunization (JRF), which collects national-level data from countries 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; and

b. The WHO-UNICEF estimates of national infant immunization coverage (WUENIC), which are derived from various data sources, including coverage data from the JRFs.

Annex 1 explains these data sources and their limitations in detail.
GOAL 1
achieve a world free of poliomyelitis

INDICATOR 1.1: interrupt wild poliovirus transmission globally

<table>
<thead>
<tr>
<th>TARGET</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>No wild poliovirus isolated globally for at least one year in the presence of certification quality AFP surveillance. Certification quality AFP surveillance defined as annual non-polio AFP rate of at least 1/100,000 population &lt; 15 years at national and sub-national level, with adequate stool specimens collected from at least 80% of AFP cases.</td>
</tr>
<tr>
<td>DATA SOURCES</td>
<td>National AFP surveillance systems plus supplementary surveillance data were available (environment surveillance or enterovirus surveillance through national lab networks)</td>
</tr>
</tbody>
</table>

INDICATOR 1.2: certification of poliomyelitis eradication

<table>
<thead>
<tr>
<th>TARGET</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>No wild poliovirus isolated globally for at least three years in the presence of certification quality AFP surveillance (defined under 1.1 above)</td>
</tr>
<tr>
<td>DATA SOURCES</td>
<td>Final national documentation on polio-free status submitted by national certification committees and regional certification commissions</td>
</tr>
</tbody>
</table>

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. The IMB reports are publicly available.6

Below are excerpts from key documents to provide context on the Polio Eradication and End Game Strategy Plan 2013-2018 and information on progress against this goal and recommendations for corrective action. Up-to-date polio surveillance data, which is updated weekly, can be found at: www.polioeradication.org/Dataandmonitoring.aspx.
Advances against polio in 2012 (from the Executive Summary of the Global Polio Eradication Initiative’s Polio Eradication and End Game Strategy Plan 2013-2018)\(^7\)

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.

By the end of 2012, the total number of polio cases worldwide plunged 66% over the previous year to 223 [see Tables 2 and 3 below]. 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 circulating vaccine-derived polio viruses (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 programmes in all Member States, facilitated by the introduction of at least one dose of IPV.

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.

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 [for coverage] of 95% increased from 59% in January 2012 to a peak of 74% in October 2012.

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.

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.

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.

### Table 2: AFP/polio case count for 2012 by WHO region

<table>
<thead>
<tr>
<th>Region</th>
<th>Number of AFP cases reported</th>
<th>Non-polio AFP rate (per 100,000 children &lt; 15)</th>
<th>Percent (%) of AFP cases with adequate specimens</th>
<th>Total confirmed polio cases</th>
<th>Confirmed wild polio virus cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFR</td>
<td>18,075</td>
<td>4.8</td>
<td>90</td>
<td>168</td>
<td>128*</td>
</tr>
<tr>
<td>AMR</td>
<td>2,110</td>
<td>1.2</td>
<td>80</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EMR</td>
<td>11,119</td>
<td>5.2</td>
<td>91</td>
<td>123</td>
<td>95*</td>
</tr>
<tr>
<td>EUR</td>
<td>1,512</td>
<td>1.3</td>
<td>89</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>SEA</td>
<td>66,045</td>
<td>12.2</td>
<td>87</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>WPR</td>
<td>7,596</td>
<td>2.2</td>
<td>91</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Global Total</td>
<td>106,457</td>
<td>6.0</td>
<td>88</td>
<td>293</td>
<td>223*</td>
</tr>
</tbody>
</table>

* The difference between total confirmed polio cases and wild polio virus confirmed cases is due to circulating vaccine-derived polio virus.

\(^7\) The full report can be found at: www.polioeradication.org/Portals0/Document/Resources/StrategyWork/PEESP_EN-US.pdf
Table 3: Case breakdown of confirmed wild poliovirus (WPV) cases by country in 2012

<table>
<thead>
<tr>
<th>Countries</th>
<th>WPV1</th>
<th>WPV3</th>
<th>W1W3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nigeria</td>
<td>103</td>
<td>19</td>
<td></td>
<td>122</td>
</tr>
<tr>
<td>Pakistan</td>
<td>55</td>
<td>2</td>
<td>1</td>
<td>58</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>37</td>
<td></td>
<td></td>
<td>37</td>
</tr>
<tr>
<td>Niger*</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Chad*</td>
<td>5</td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>201</td>
<td>21</td>
<td>1</td>
<td>223</td>
</tr>
</tbody>
</table>

* Outbreak cases in non-endemic countries

Figure 1: Wild Poliovirus cases worldwide in 2012

01 January - 31 December

Data in HQ as of 16 April 2013

Excludes viruses detected from environmental surveillance and vaccine derived polioviruses. 1 WPV1 case in Gilgit Baltistan, date of onset 11 August, does not appear on the map.
Recommendations of the Independent Monitoring Board of the GPEI from its May 2013 report

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.

Additional references

GOAL 2
meet global and regional elimination targets

**INDICATOR 2.1: NEONATAL TETANUS ELIMINATION**

<table>
<thead>
<tr>
<th>TARGET</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>An incidence of &lt; 1 case of neonatal tetanus per 1,000 live births per year in all districts or similar administrative units of a country and maintenance of elimination. Neonatal tetanus indicator acts as proxy for maternal tetanus</td>
</tr>
</tbody>
</table>
| DATA SOURCES | WHO-UNICEF joint reporting forms (JRFs)  
Country health management information system (HMIS) reports  
Country disease surveillance reports  
Immunization coverage survey reports  
Multiple Indicator Cluster Sampling (MICS) survey reports, demographic and health survey (DHS) reports and any other reports of immunization and reproductive health programme reviews |
| MILESTONES | (from baseline of 2010 with 40 countries still to achieve elimination):  
10 countries eliminated neonatal tetanus (NT) by 2012  
22 countries eliminated NT by 2013  
36 countries eliminated NT by 2014  
40 countries eliminated NT by 2015 |

**Introduction and background**

Maternal and neonatal tetanus (MNT) 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. Due to the nature of the disease, tetanus cannot be eradicated. In order to eliminate tetanus as a public health problem, the 42nd World Health Assembly in 1989 established a goal to eliminate neonatal tetanus. This goal was later endorsed by the World Summit for Children in 1990.

In 1999, the Maternal and Neonatal Tetanus Elimination (MNTE) Initiative was launched by UNICEF, WHO and UNFPA, adding the elimination of maternal tetanus to the goal. The Initiative has focused on the 59 priority Member States that were assessed to have more than one case of neonatal tetanus per 1,000 live births in 1999.9

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Description of the validation process for neonatal tetanus 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 the provision of tetanus toxoid (TT) containing vaccines through supplemental immunization activities (vaccination campaigns) to fill immunity gaps, have been completed, or when a country’s own review of district-level data indicates that there is no need for additional activities and that neonatal tetanus rates in all districts are less than 1/1,000 live births. This is followed by a pre-validation assessment, which is an intensive review of core and surrogate indicators for MNT, complemented by field visits to some of the 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 status of MNT risk in the poorest-performing districts is assessed to be low, plans are then put in place to implement a Lot Quality Assurance-Cluster Sampling (LQA-CS) survey. It has to be noted that some Member States (e.g. Gabon, some states in India) do not conduct pre-validation assessments.

The neonatal tetanus LQA-CS survey is a neonatal mortality survey that takes place only in high-risk districts, in which neonatal deaths are investigated by verbal autopsy to determine if the death was caused by tetanus. Because the neonatal tetanus case fatality rate is very high (>80%), especially in high-risk populations that lack intensive medical care facilities, the mortality rate is assumed to approximate the incidence of the disease. The primary sample consists of live births delivered during a 12-month eligibility period that ends at least four weeks before the start of the survey.

The LQA-CS survey assesses whether or not the neonatal tetanus mortality rate (NTMR) in the survey areas probably exceeds 1/1,000 live births during the 12-month eligibility period – the pre-determined maximum accepted number of NT deaths that defines whether the district “passes” or “fails”. The survey is not designed to provide a point estimate of the NTMR for the surveyed area. An official notification of the survey findings and the survey report are then sent by WHO/ Geneva to the country’s Minister of Health.

Data availability and quality

The quality of routine administrative data by district is often questionable for many Member States, and WHO often relies more on survey data, if available. However, data from several different sources, including HMIS or routine administrative data, immunization coverage surveys and health programme review reports, are used to assess whether the country claims of having eliminated MNT is valid and whether an LQA-CS survey is needed. The difficulty to correctly identify all births and neonatal deaths and correctly assess whether or not a death may be due to neonatal tetanus are some of the limitations of the LQA-CS.

Results

In 2012, six Member States (Burkina Faso, Cameroon, China, Guinea Bissau, Tanzania and Timor Leste) were validated as having eliminated MNT. With four Member States validated in 2011 (Ghana, Liberia, Senegal and Uganda), the milestone for achieving elimination in ten additional countries between 2010 and 2012 was thus met. A total of 29 out of the 59 priority Member States (54%) had achieved MNT elimination as of December 2012 (see Figure 2). An additional three countries – Côte d’Ivoire, Iraq and Sierra Leone – achieved MNT elimination by June of 2013, increasing the total to 32 Member States among the 59 priority states (see Update box).

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10 LQA-CS survey protocol was revised in 2012 but has not been published yet.
Member states failing to achieve MNT elimination target (as of 31 December 2012) are: Afghanistan, Angola, Cambodia, Central African Republic, Chad, DR Congo, Côte 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.

Figure 2: Member States with validated elimination of neonatal tetanus (as of 31 December, 2012)

29 Countries eliminated MNT - 2000 to 2012

*(Plus 15 States out of 35 in India, Ethiopia part and 29 provinces out of 33 in Indonesia) leaving 30 countries yet to eliminate MNT

China’s achievement of 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 supplemental TT vaccination campaigns.

In 2012, upon completing planned vaccination campaigns (SIAs) and/or improvement in clean delivery practices, pre-validation assessments were conducted in eight Member States (Cambodia, Cameroon, China, Côte d’Ivoire, India, Indonesia, Mauritania and Sierra Leone). In addition, TT vaccination 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 during its Mother and Child Health Weeks. In all 10 countries that conducted SIAs in 2012, nearly 3.7 million women of reproductive age received at least two doses of TT vaccine.

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11 Member states failing to achieve MNT elimination target (as of 31 December 2012) are: Afghanistan, Angola, Cambodia, Central African Republic, Chad, DR Congo, Côte 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.
Update as of 31, June 2013

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

Discussion

Efforts to sustain MNT elimination in Member States that have achieved it

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 umbilical cord care. At the global and regional levels, efforts are being made to provide guidance to Member States on sustaining their achievements. The MNTE Initiative is also following up with Member States on the need for periodic data reviews and implementation of corrective measures based on the data review to ensure that their elimination status is maintained.

Efforts to sustain MNT elimination also include:

- A focus on school-based delivery of TT or Td vaccine as part of school health programmes.
- 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 that includes neonatal tetanus.

Member States that have failed to achieve the elimination target: reasons why and required actions

The major reasons for countries not achieving MNT elimination include:

- Limited resources, including the lack of timely financial resources for TT supplemental immunization activities, as well as for health education to improve clean delivery and cord care practices;
- Poor access to immunization and reproductive health services, including antenatal care and clean delivery services, especially in under-served areas;
- Socio-cultural barriers and practices, such as the continued practice of applying harmful substances on umbilical cord stumps;
- 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) that limit opportunities to conduct TT campaigns, as well as missed opportunities to integrate TT vaccination with that of other antigens. These issues are especially significant in the remaining polio-endemic Member States (Afghanistan, Nigeria and Pakistan), but are also true in other Member States as well.
• NT surveillance in most of the 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.

Thus, some 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 government support, and changes in health infrastructure (such as decentralization or devolution). Inadequate human resources for health care also further complicate the situation. Lack of domestic resources from national budgets has also impacted activities in some Member States.

To improve this situation, partnerships must be strengthened to sustain financing and to increase advocacy national governments and other stakeholders to keep MNTE high on the agenda. In addition, innovative strategies should be employed to reach the most disadvantaged with packages of high-impact interventions through integrated approaches (such as Mother and Child Days and Immunization Weeks) and using simple appropriate technologies, such as TT Uniject™ devices.

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**Highlights**

• The milestone for 10 additional Member States being validated as having eliminated neonatal tetanus from 2010 to 2012 was met. These include six Member States that achieved MNT elimination in 2012.

• Three Member States (Côte d’Ivoire, Iraq and Sierra Leone), as well as three Indian states have been validated for MNT elimination during the first half of 2013, increasing the total number of priority Member States that have eliminated the disease to 32.

• Four Member States conducted pre-validation assessments and were found to have made adequate progress to enable them to proceed to with validation surveys.

• An additional 3.7 million women of reproductive age received two protective doses of TT vaccine in 10 Member States in 2012, making a total of over 118 million women who have benefitted from the Initiative since 1999.

• The availability of funds to support MNTE activities was delayed, especially in high-risk districts where cases are still being reported.

• Five Member States with persistent security and access issues – Afghanistan, Angola, Haiti, Mali and South Sudan – developed MNTE national action plans and started activities.

• The TT Uniject™ – the most appropriate technology for reaching the most remote areas of Member States, such as Afghanistan, Chad, Mali, Pakistan, parts of South Sudan and Yemen – is not easily accessible to these countries due to its relatively high costs and limited availability. This device would enable immunization programmes to use lay health workers who can be trained to safely administer the vaccine in their villages.
Introduction and background

As of June 2013, 5 of the 6 WHO regions, AFR, AMR, EMR, EUR and WPR, had established measles elimination goals. Of these, AMR has already achieved measles elimination. The target years for elimination are 2015 or earlier in EMR, EUR, and WPR, and 2020 in AFR.

At the 63rd World Health Assembly in 2010, the following global measles interim milestones for 2015 were proposed towards the eventual global eradication of measles. These milestones include achieving the Global Immunization Vision and Strategy’s goal to increase measles vaccination coverage, as well as targets for reduction of incidence and mortality, as follows:

- Exceed 90% coverage with the first dose of measles-containing vaccine nationally and 80% vaccination coverage in every district or equivalent administrative unit;
- Reduce annual measles incidence to < 5 cases per million and maintain that level;
- Reduce measles mortality by 95% or more in comparison with 2000 estimates.
Data availability and quality

- Reports from regional verification commissions were produced in 2012 or 2013 for only two regions: the Western Pacific (WPR) and the Americas (AMR). The Western Pacific commission produced the report: “Progress towards measles elimination in the Western Pacific Region, 2009–2012”.
- The Americas region prepared two reports which have not yet been published: 1) the Experts Meeting of Measles and Rubella Laboratory Network, May 7th, 2013, Washington, DC, USA; and 2) International Expert Committee (IEC) for documenting and verifying the measles, rubella and CRS elimination, May 7-8, Washington, DC, USA.
- There were, therefore, no progress reports on measles elimination from verification commissions in EURO, AFRO, SEARO or EMRO. The limitations with JRF and WUENIC coverage data are discussed in Annex 1 under the title “Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC”.

Results

The year 2012 saw important gains in measles control (Table 4). 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 that Southern African Member States brought their outbreaks under control through national vaccination campaigns. Cambodia used measles SIAs to identify children who were missed during routine immunization. It was also the year that India, building on lessons and experience to stop polio transmission, continued their drive to immunize 134 million children against measles through a phased campaign in states with low routine immunization coverage, accompanied by the introduction of a second measles dose in the routine immunization schedule in better-performing states.

Table 4: Number of measles cases and incidence rates reported by WHO region

<table>
<thead>
<tr>
<th>WHO Region</th>
<th>Number of Member States reporting</th>
<th>Number of cases</th>
<th>Incidence per million population</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFR</td>
<td>46</td>
<td>199,174</td>
<td>235.1</td>
</tr>
<tr>
<td>AMR</td>
<td>35</td>
<td>10,072</td>
<td>17.1</td>
</tr>
<tr>
<td>EMR</td>
<td>20</td>
<td>30,625</td>
<td>34.1</td>
</tr>
<tr>
<td>EUR</td>
<td>52</td>
<td>49,460</td>
<td>34.1</td>
</tr>
<tr>
<td>SEAR</td>
<td>11</td>
<td>52,529</td>
<td>29.3</td>
</tr>
<tr>
<td>WPR</td>
<td>25</td>
<td>342,107</td>
<td>52.6</td>
</tr>
<tr>
<td>Total</td>
<td>189</td>
<td>354,882</td>
<td>53.9</td>
</tr>
</tbody>
</table>

Source: M&RI Annual report 2012

Critically, 2012 was also the year that 194 Member States – through the adoption of the GVAP at the World Health Assembly – committed to eliminating measles and rubella in five of the six WHO Regions by 2020. The Measles & Rubella Initiative provided a roadmap to achieve this goal, and released a new global strategic plan (2012-2020), building on SAGE recommendations for rubella vaccination and surveillance. The GAVI Alliance pledged to help fund the plan, offering support to introduce rubella-containing vaccine in 49 Member States, funds for measles campaigns in six of the most challenging Member States, and funds to mount a response to measles outbreaks with immunization.
With progress came challenges. More than 20 million infants did not receive a routine dose of measles-containing vaccine in 2012. 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 per 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 into 2012. Ukraine had the highest reported measles incidence in the world in 2012. This is one of several European Member States that had outbreaks in 2011 and 2012, which 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 supplemental immunization campaigns—a strategic investment of time and money—failed to reach the goal of 95% of children vaccinated against measles in every district in these countries.

**Highlights**

- Measles morbidity and mortality has been reduced by >90% since the introduction of measles vaccine globally.
- Measles control and elimination efforts are a major contributor to the reduction in childhood mortality and the achievement of Millennium Development Goal (MDG) 4 (approximately 20% of overall reduction in child mortality is attributable to improved control and elimination of measles).
- All Member States in the Americas have achieved measles elimination but remain at constant risk for importations and outbreaks until other regions also 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 is noted that in September 2013 the Southeast Asian Regional Committee endorsed a regional measles elimination goal with 2020 as the target year.
- Measles outbreaks reveal gaps in immunization programmes and highlight inequities in access to services.

**References**

- Additional documents can be found at: www.measlesinitiative.org/vgn-ext-templating/v/index.jsp/vgnextoid/815c081a7a593210YgnVCM10000089f0870aRCRD.html.
Sources: 2012 Measles & Rubella Initiative annual report and Status Report submitted to SAGE in November 2012 (see References).

### Data availability and quality

Limitations with the JRF and WUENIC coverage data are explained in detail in Annex 1. Both rubella and CRS surveillance data are under-reported and incomplete at the global level. The Americas is the only region with reliable rubella and CRS surveillance data. Rubella surveillance is improving in the other regions through linkage with measles surveillance.

### Results\(^7\)

The Americas region has achieved its elimination goals and a significant decline in rubella incidence has been observed in the European region. However, two of the other WHO regions have only recently established a goal to accelerate control of the disease (SEAR and WPR) and two others (EMR and AFR) have not yet set a goal to control the disease. Meanwhile, congenital rubella syndrome continues to be an important cause of preventable morbidity. In 2012, while only around 300 CRS cases were reported to WHO (Table 6), an estimated 103,000 children were actually born with CRS, leaving many deaf and blind and with heart and other conditions that poor families simply cannot afford to treat. This points to the fact that the disease continues to be grossly under-reported, due to the lack of CRS surveillance outside of the Americas and selected Member States in other regions.

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\(^7\) Sources: 2012 Measles & Rubella Initiative annual report and Status Report submitted to SAGE in November 2012 (see References).
Table 5: Number of rubella cases and incidence rates reported by Member States per WHO region

<table>
<thead>
<tr>
<th>WHO Region</th>
<th>Number of Member States reporting rubella</th>
<th>Number of rubella cases</th>
<th>Rubella incidence per million population</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFRO</td>
<td>37</td>
<td>40</td>
<td>39</td>
</tr>
<tr>
<td>AMR</td>
<td>35</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>EMR</td>
<td>17</td>
<td>17</td>
<td>20</td>
</tr>
<tr>
<td>EUR</td>
<td>49</td>
<td>47</td>
<td>44</td>
</tr>
<tr>
<td>SEAR</td>
<td>9</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>WPR</td>
<td>23</td>
<td>24</td>
<td>22</td>
</tr>
<tr>
<td>Total</td>
<td>170</td>
<td>173</td>
<td>171</td>
</tr>
</tbody>
</table>

Table 6: Number of CRS cases reported by Member States per WHO region

<table>
<thead>
<tr>
<th>WHO Region</th>
<th>Number of member states reporting CRS</th>
<th>Number of CRS cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFR</td>
<td>15</td>
<td>16</td>
</tr>
<tr>
<td>AMR</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>EMR</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>EUR</td>
<td>44</td>
<td>47</td>
</tr>
<tr>
<td>SEAR</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>WPR</td>
<td>19</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>127</td>
<td>129</td>
</tr>
</tbody>
</table>

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 four WHO Regions:
  - Two (WPR and SEAR) have established goals to control rubella (by 2015 and 2020, respectively);
  - AFR and EMR do not yet have rubella control or elimination goals.
- The pace of introduction of rubella-containing vaccine (RCV) is increasing as a result of GAVI Alliance support. As of end of 2012, 134 Members States 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

• Additional documents can be found at: www.measlesinitiative.org/vgn-ext-templating/v/index.jsp/vgnextoid/815c081a7a593210VgnVCM10000089f0870aRCRD.html.
GOAL 3
meet vaccination coverage targets in every region, country and community

Data availability and quality

WUENIC are available for all the 194 Member States. For Member States that did not report coverage for 2012, the WUENIC was extrapolated from previously reported data.

Though WUENIC 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 in national DTP₃ coverage is limited by the availability of valid district-level coverage data.

In this assessment, district-level coverage data were considered valid if WUENIC estimates are the same as the administrative coverage data reported by national authorities on the JRF, or if the WUENIC estimates of national coverage are 90% or greater. Using this definition, 114 Members States (58.8%) have valid DTP₃ district-level coverage estimates in 2012 (Table 8). Of the remaining 80 Member States, 36 have WUENIC estimates that differ from the JRF administrative data and have national coverage < 90%, and are therefore not considered valid, and 44 did not report district level coverage.

However, the fact that WUENIC estimates are the same as administrative coverage data from the Member States is not by itself a sufficient indicator of the quality of coverage data. This is because administrative reports may be the only source of data for 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 should be validated by conducting a survey in at least a sample of districts.

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. Member States must therefore improve the quality of their administrative data collection and reporting at the district level, and/or use surveys, where appropriate, to validate the district level coverage. Coverage surveys are especially needed in cases where uncertainties remain about the size of the target population by district. The timely availability of high-quality data is essential for their national programmes to continuously monitor programme performance at all levels and take corrective actions, when indicated.
Results

National DTP₃ immunization coverage

Of the 194 member States, 131 (68%) had achieved a national DTP₃ coverage rate of ≥ 90%. However, the distribution was uneven between regions (Table 7). In the African region, only 39% of Member States achieved this threshold of coverage. While the proportion of countries reaching 90% DTP₃ coverage 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) have yet to achieve this threshold. Among the 63 Member States with coverage of < 90%, six (3.1%) had coverage of < 50%, ten (5.2%) had coverage between 50% and 69%, and 47 (24.2%) had coverage of 70-89%.

Table 7: Distribution of all 194 Member States by level of national DTP₃ coverage rate and region, based on WUENIC estimates for 2012

<table>
<thead>
<tr>
<th>WHO region</th>
<th>DTP₃ ≥ 90%</th>
<th>DTP₃ of 70-89%</th>
<th>DTP₃ of 50-69%</th>
<th>DTP₃ &lt; 50%</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n</td>
</tr>
<tr>
<td>AFR</td>
<td>18 (39.1)</td>
<td>21 (45.7)</td>
<td>3 (6.5)</td>
<td>4 (8.7)</td>
<td>46</td>
</tr>
<tr>
<td>AMR</td>
<td>26 (74.3)</td>
<td>8 (22.9)</td>
<td>1 (2.9)</td>
<td>0</td>
<td>35</td>
</tr>
<tr>
<td>EMR</td>
<td>13 (59.1)</td>
<td>5 (22.7)</td>
<td>2 (9.1)</td>
<td>2 (9.1)</td>
<td>22</td>
</tr>
<tr>
<td>EUR</td>
<td>48 (90.6)</td>
<td>5 (9.4)</td>
<td>0</td>
<td>0</td>
<td>53</td>
</tr>
<tr>
<td>SEAR</td>
<td>7 (63.6)</td>
<td>2 (18.2)</td>
<td>2 (18.2)</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>WPR</td>
<td>19 (70.4)</td>
<td>6 (22.2)</td>
<td>2 (7.4)</td>
<td>0</td>
<td>27</td>
</tr>
<tr>
<td>Global</td>
<td>131 (67.5)</td>
<td>47 (24.2)</td>
<td>10 (5.2)</td>
<td>6 (3.1)</td>
<td>194</td>
</tr>
</tbody>
</table>

For Member States with DTP₃ coverage of < 70%, time trends in coverage are shown in the Annex (Table 36). Coverage has stagnated in most of these poor-performing States. A recent decline in coverage is noted in Nigeria and in the Syrian Arab Republic, where the recent conflict has no doubt contributed to the decline. DTP₃ coverage was over 90% in Iraq prior to 1988, but has fallen since then. An increase in coverage has been noted in Chad and Ethiopia. The newest Member State, South Sudan, is reporting increased coverage in the past few years based on administrative data. However, since WUENIC estimates are only available for 2011 and 2012, an assessment of this trend cannot be made.

District-level DTP₃ coverage

Among the 114 Member States with valid district level coverage estimates in 2012, only 59 had achieved national level coverage of ≥ 90% and coverage of ≥ 80% in every district (or equivalent administrative level) (Table 8). As mentioned above, 80 countries (41.2%) did not have district coverage data that were considered valid.
Table 8: Distribution of Member States by national and district-level DTP₃ coverage achievements and by region, 2012

<table>
<thead>
<tr>
<th>WHO region</th>
<th>Countries with DTP₃, district coverage data available and valid</th>
<th></th>
<th></th>
<th>DTP₃ District coverage data not available</th>
<th>DTP₃ District coverage data available but not valid</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DTP₃ coverage national ≥ 90% &amp; all districts ≥ 80% voluntary</td>
<td>DTP₃ coverage national ≥ 90% but not all districts ≥ 80% voluntary</td>
<td>DTP₃ national coverage &lt; 90%</td>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFR</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>AMR</td>
<td>5 (11)</td>
<td>9 (20)</td>
<td>7 (15)</td>
<td>21 (46)</td>
<td>5 (11)</td>
<td>20 (43)</td>
</tr>
<tr>
<td>EMR</td>
<td>7 (32)</td>
<td>3 (14)</td>
<td>2 (9)</td>
<td>12 (35)</td>
<td>6 (17)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>EUR</td>
<td>26 (49)</td>
<td>6 (11)</td>
<td>0</td>
<td>32 (60)</td>
<td>19 (36)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>SEAR</td>
<td>3 (27)</td>
<td>3 (27)</td>
<td>1 (9)</td>
<td>7 (64)</td>
<td>2 (18)</td>
<td>2 (18)</td>
</tr>
<tr>
<td>WPR</td>
<td>8 (30)</td>
<td>4 (15)</td>
<td>3 (11)</td>
<td>15 (56)</td>
<td>8 (30)</td>
<td>4 (15)</td>
</tr>
<tr>
<td>Global</td>
<td>59 (30)</td>
<td>37 (19)</td>
<td>18 (9)</td>
<td>114 (59)</td>
<td>44 (23)</td>
<td>36 (19)</td>
</tr>
</tbody>
</table>

Highlights

- One hundred thirty-one (68%) of the Member States have reached national DTP₃ coverage of ≥ 90%; but only 13 of them are low-income countries.
- The percent of Member States that did not reach the 90% target for national DTP₃ coverage was 60.9% in AFR, 40.9% in EMR, 36.4% in SEAR and 29.6% in WPR.
- Only 59 Member States (30%) have reached national DTP₃ coverage of ≥ 90% as well as coverage in all districts of 80% or above.
- In the AMR region, 12 (34.3%) Member States reached national DTP₃ coverage of ≥ 90%, but not the target of 80% coverage in all districts.
- In EUR, 6 (11%) Member States achieving national DTP₃ coverage ≥ 90% did not achieve DTP₃ coverage ≥ 80% in all districts.

---

 voluntary

 voluntary

 voluntary
Data availability and quality

We are only able to measure progress against the target for national-level coverage at this point, since district-level administrative data are currently available only for DTP3 and measles-containing (MCV1) vaccines. The SAGE DoV Working Group should consider the need for collecting district-level coverage data for all vaccines, or instead use DTP3 coverage as a proxy for geographic equity in coverage, 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 should be taken into consideration in making this decision.

Results

Countries achieving national coverage of 90% or greater for all vaccines in their immunization schedule in 2012 are shown in Figure 3. Ninety-three countries (48%) reached this target for all vaccines, while 101 (52%) did not. These results have not changed much over the past three years (Table 9).

Among the 61 Member States with both DTP3 and PCV3 national coverage data in 2012 (i.e., PCV3 had been used for at least one year), national DTP3 coverage was ≥ 5% higher than PCV3 coverage in 23 of the countries and ≥ 10% higher than PCV3 coverage in 13 other countries. For two Member States, PCV3 coverage was higher than DTP3 by more than 5%.

Among the 27 Member States with national coverage data for both DTP3 and rotavirus, 16 had national coverage rates for DTP3 that were ≥ 5% higher than the rates for the last dose of rotavirus vaccine, and in ten countries, the difference was ≥ 10%. In two Member States, coverage rates for the last dose of rotavirus vaccine were higher than DTP3 coverage by ≥ 5%. The causes for the differences in coverage need to be further examined at the country level, as they are not apparent from the data reported through the JRF.

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23 For more information about the JRF and WUENIC coverage data, please refer to Annex 1 on "Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC".
### Table 9: Number of Member States that achieved ≥ 90% national coverage for all the vaccines included in their national immunization schedule by region, 2010 - 2012

<table>
<thead>
<tr>
<th>WHO region</th>
<th>2010 n (%)</th>
<th>2011 n (%)</th>
<th>2012 n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFR</td>
<td>15 (32.6)</td>
<td>13 (28.3)</td>
<td>12 (26.1)</td>
</tr>
<tr>
<td>AMRO</td>
<td>18 (51.4)</td>
<td>14 (40)</td>
<td>16 (45.7)</td>
</tr>
<tr>
<td>EMR</td>
<td>10 (47.6)</td>
<td>10 (45.5)</td>
<td>10 (45.5)</td>
</tr>
<tr>
<td>EUR</td>
<td>30 (56.6)</td>
<td>32 (60.4)</td>
<td>33 (62.3)</td>
</tr>
<tr>
<td>SEAR</td>
<td>6 (54.5)</td>
<td>6 (54.5)</td>
<td>6 (54.5)</td>
</tr>
<tr>
<td>WPR</td>
<td>13 (48.1)</td>
<td>15 (55.6)</td>
<td>16 (59.3)</td>
</tr>
<tr>
<td>Global</td>
<td>92 (47.7)</td>
<td>90 (46.4)</td>
<td>93 (47.9)</td>
</tr>
</tbody>
</table>

### Figure 3: Member States that have and have not achieved national coverage of ≥ 90% for all vaccines included in the national infant immunization schedule in 2012

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. © WHO 2013. All rights reserved.

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
GOAL 4
develop and introduce new and improved vaccines and technologies

Any new vaccine that is considered by the SAGE DoV Working Group to have significant public health value would be viewed as contributing to this target. However, the DoV will focus on actively tracking on a bi-annual basis progress towards the development of the following seven target vaccines: dengue, hepatitis C, cytomegalovirus, respiratory syncytial virus (RSV), leishmania, helminth infections, and Group A streptococcus (GAS). These vaccines were selected to represent viral, bacterial and parasitic diseases that can potentially be prevented through vaccination.

Incremental progress on the development of vaccines against these seven targeted diseases will be summarized in a report to be prepared by the DoV Secretariat for discussion at the Global Vaccine and Immunization Research Forum (GVIRF) in March 2014, and, then included in the secretariat report to the SAGE DoV Working Group.

### INDICATOR 4.1: LICENSURE AND LAUNCH OF VACCINE OR VACCINES AGAINST ONE OR MORE MAJOR CURRENTLY NON-VACCINE PREVENTABLE DISEASES

<table>
<thead>
<tr>
<th>TARGET</th>
<th>2020: One or more vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>Licensure of the vaccine by a functional National Regulatory Authority (NRA)</td>
</tr>
<tr>
<td></td>
<td>A launch is defined as an addition of a vaccine to the national immunization schedule in one or more low- or middle-income countries (as defined by the World Bank)</td>
</tr>
<tr>
<td></td>
<td>2nd generation products with significant benefits (e.g., 2nd generation influenza or rotavirus vaccines) will be considered “new vaccines”, as advised by the SAGE</td>
</tr>
<tr>
<td>DATA SOURCES</td>
<td>Annual surveys conducted by WHO with national regulatory authorities (NRAs) with results updated on the WHO website twice a year</td>
</tr>
<tr>
<td></td>
<td>WHO-UNICEF joint reporting forms (JRFs)</td>
</tr>
</tbody>
</table>

### INDICATOR 4.2: LICENSURE AND LAUNCH OF AT LEAST ONE PLATFORM DELIVERY TECHNOLOGY

<table>
<thead>
<tr>
<th>TARGET</th>
<th>2020: One or more vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>New platform delivery technology is defined as a new mechanism for delivering vaccines to individuals that facilitates coverage, improves performance, or reduces the cost of vaccine or delivery (e.g., jet injectors, micro-needles, aerosols)</td>
</tr>
<tr>
<td></td>
<td>Licensure relates to registration by a functional NRA</td>
</tr>
<tr>
<td></td>
<td>A launch is defined as the use of the technology in the national immunization programme of one or more low- or middle-income countries</td>
</tr>
<tr>
<td>DATA SOURCES</td>
<td>Annual surveys conducted by WHO with national regulatory authorities (NRAs) with results updated on the WHO website twice a year</td>
</tr>
<tr>
<td></td>
<td>WHO-UNICEF joint reporting forms (JRFs)</td>
</tr>
</tbody>
</table>
The process for measuring progress against this indicator will begin in 2014. A qualitative report on the incremental progress towards the development of vaccine delivery platform technologies will be commissioned and discussed at the 2014 Global Vaccine and Immunization Research Forum (GVIRF) and, then included in the secretariat report to the SAGE DoV Working Group.

### INDICATOR 4.3: NUMBER OF LOW-INCOME AND MIDDLE-INCOME COUNTRIES THAT HAVE INTRODUCED ONE OR MORE UNDER-UTILIZED VACCINES

**TARGET**
- 2015: At least 90 Member States
- 2020: All low- and middle-income Member States

**DEFINITION OF INDICATOR**
- A vaccine is added to the national immunization schedule and used for a sustained period of at least 12 months
- New and under-utilized vaccines are all vaccines that were not previously in the national immunization schedule

**DATA SOURCES**
- WHO-UNICEF joint reporting forms (JRFs)
- The Vaccine Information Management System (VIMS) report, June 2013. The report, which displays data and figures on the introduction status of Hib, pneumococcal conjugate and rotavirus vaccines, was generated by the VIMS database that is 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.

**Data availability and quality**

The limitations with JRF and WUENIC coverage data are discussed in Annex 1.

**Results**

In the first two years of the Decade of Vaccines – from January 2010 to December 2011 – 44 low- and middle-income countries added at least one new vaccine to their national immunization programme and sustained these vaccines for at least 12 months, i.e. till December 2012 (Table 10). These vaccines include: Hib-containing vaccine, pneumococcal conjugate vaccine (PCV), rotavirus, HPV, meningococcal (C conjugate or tetravalent polysaccharide vaccine), and yellow fever vaccines. These 44 countries represent about one-third (32%) of all of the world’s low- and middle-income countries (Table 11). Thirty-eight of these Member States introduced one vaccine during this two-year period, while six countries introduced more than one vaccine. A total of 50 vaccine introductions took place in these 44 countries during this two-year period.

Progress in adding vaccines to national immunization programmes has taken place in all regions, though it has been particularly slow in the Southeast Asia region, where only one of the 11 low- or middle-income countries introduced a new vaccine into their national programme in 2010 or 2011 (Table 11).

In addition, six Member States in Africa (four of which are not among the 44 Member States listed above) conducted campaigns for Meningococcal A conjugate vaccination during 2010-2011. These campaigns are not included among the 50 vaccine introductions that took place in 2010 and 2011, since they were not part of the routine immunization programme.

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Table 10: Breakdown of 44 Member States with sustained vaccine introductions between January 2010 and December 2011, by income level and vaccine

<table>
<thead>
<tr>
<th>Country income level</th>
<th>Hib</th>
<th>Pneumococcal</th>
<th>Rotavirus</th>
<th>HPV</th>
<th>Meningococcal (C or tetravalent)</th>
<th>Yellow fever</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>1</td>
<td>8</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Low-middle</td>
<td>5</td>
<td>7</td>
<td>3 (+2)</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Upper-middle</td>
<td>8</td>
<td>5 (+1)</td>
<td>0</td>
<td>2 (+1)</td>
<td>1 (+2)</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>14</td>
<td>20 (+1)</td>
<td>3 (+2)</td>
<td>5 (+1)</td>
<td>1 (+2)</td>
<td>1</td>
</tr>
</tbody>
</table>

Note: 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 31 December 2012, the cumulative number of Member States that introduced a new vaccine since the start of the DoV in 2010 climbed to 63 – with 80 introductions – and it is expected that the use of these vaccines will be sustained (Table 12). Several Member States added more than one vaccine during this three-year period.

Although there have been concerns about the ability of non-GAVI eligible countries to add vaccines to their programmes, the data show that two-thirds of lower middle-income countries that have never received GAVI support added a vaccine to their schedule in the past three years (Table 12). However, with newer, more expensive vaccines coming in the future, this is an 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 lower middle-income countries.

Table 11: Number of Member States that have added one or more new vaccines to their national immunization schedule between January 2010 and December 2011, by WHO region

<table>
<thead>
<tr>
<th>WHO region</th>
<th>No. of Low, lower-middle and upper-middle income Member States/Total Member States in region</th>
<th>No. (%) of Low, lower-middle and upper-middle income Member States that have introduced one vaccine</th>
<th>No. (%) of Low, lower-middle and upper-middle income Member States that have introduced more than one vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFR</td>
<td>45/46</td>
<td>11 (24%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>AMR</td>
<td>26/35</td>
<td>11 (42%)</td>
<td>4 (15%)</td>
</tr>
<tr>
<td>EMR</td>
<td>16/22</td>
<td>3 (19%)</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>EUR</td>
<td>20/53</td>
<td>6 (30%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>SEAR</td>
<td>11/11</td>
<td>1 (9.1%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>WPR</td>
<td>19*/27</td>
<td>6 (32%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total</td>
<td>137/194</td>
<td>38 (28%)</td>
<td>6 (4%)</td>
</tr>
</tbody>
</table>

* Cook Islands was not classified by the World Bank 2012 Report. However, it was included as an Upper Middle Income Country for this report.
Table 12: Number of low- and middle-income Member States that introduced Hib-containing, pneumococcal, rotavirus or HPV vaccines between January 2010 and 31 December, 2012, by vaccine, GAVI-eligibility and income classification

<table>
<thead>
<tr>
<th>Country classification</th>
<th>No. countries</th>
<th>Hib</th>
<th>Pneumococcal</th>
<th>Rotavirus</th>
<th>HPV</th>
<th>No. of introductions</th>
<th>Any of the four vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>GAVI-eligible countries</td>
<td>56</td>
<td>6</td>
<td>17</td>
<td>5</td>
<td>2</td>
<td>30</td>
<td>26 (46%)</td>
</tr>
<tr>
<td>GAVI-graduating countries</td>
<td>16</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>9</td>
<td>8 (50%)</td>
</tr>
<tr>
<td>Non-GAVI lower-middle income countries</td>
<td>12</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>12</td>
<td>8 (67%)</td>
</tr>
<tr>
<td>Non-GAVI upper middle-income countries</td>
<td>52</td>
<td>8</td>
<td>11</td>
<td>4</td>
<td>6</td>
<td>29</td>
<td>21 (40%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>136</strong></td>
<td><strong>20</strong></td>
<td><strong>35</strong></td>
<td><strong>16</strong></td>
<td><strong>9</strong></td>
<td><strong>80</strong></td>
<td><strong>63 (46%)</strong></td>
</tr>
</tbody>
</table>

Data presented in the VIMS report shows that the time lag between the introduction of vaccines in high-income and low-income countries was reduced. The time period from when 50% of high-income countries added Hib vaccine to their national programme to when 50% of low-income countries did so was approximately 10 years. In contrast, for pneumococcal conjugate vaccines, it is projected that this time lag will be just over three years. Financial support through the GAVI Alliance for vaccine procurement, as well as other measures taken to establish and communicate the value of new vaccines, have undoubtedly contributed to this outcome.
Figure 4: Introduction of Hib and pneumococcal conjugate vaccines in high- and low-income countries (from VIMS 2013 report)²⁵

Continued efforts will be required for the long-term sustainability of vaccines in national immunization programmes in low- and middle-income countries. This will require increased investments in surveillance and in conducting impact assessments to justify the continued investments required to sustain the use of these vaccines.

The maps in Figure 5 through Figure 8 show the status of the use of Hib, PCV, rotavirus and HPV vaccines in national immunization programmes world-wide.

Figure 5: Member States with Hib-containing vaccine in their national immunization programme (as of 31 December, 2012)

- **Introduced (180 Member States or 93%)**
- **Introduced in some parts of the countries (4 Member States or 2%)**
- **Not Introduced (10 Member States or 5%)**

Not available

Not applicable

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Figure 6: Member States with pneumococcal conjugate vaccine in their national immunization programme (as of 31 December, 2012)

- **Introduced (87 Member States or 52%)**
- **Introduced in some parts of the countries (1 Member States or 1%)**
- **Not Introduced (101 Member States or 52%)**

Not applicable

Introduced for risk groups only (5 Member States or 3%)

Not applicable

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**Figure 7:** Member States with Rotavirus vaccine in their national immunization programme (as of 31 December 2012)

- **Introduced** (40 Member States or 21%)
- **Introduced in some parts of the countries** (1 Member States or 1%)
- **Not Introduced** (153 Member States or 79%)

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**Figure 8:** Member States with HPV vaccine in the national immunization programme (as of 31 December 2012)

- **Introduced** (180 Member States or 93%)
- **Introduced in some parts of the countries** (4 Member States or 2%)
- **Not Introduced** (10 Member States or 5%)

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. © WHO 2013. All rights reserved.
Monitoring progress towards GVAP goals and strategic objectives

Highlights

- Eighty new vaccine introductions took place from January 2010 to 31 December, 2012 in 63 low- and middle-income Member States and their use has been sustained.
- Of the 80 vaccine introductions, 41 were in 29 lower-middle or upper-middle income countries not receiving GAVI support.
- Eight of the countries that introduced new vaccines during this period have since graduated from GAVI support and efforts are needed to sustain the use of the new vaccines in these countries.
- While access to affordable vaccines is provided through the UNICEF Supply Division procurement mechanism for GAVI-eligible countries, an 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 expected to delay the planned introduction of these vaccines in the coming two to three years.
GOAL 5  
exceed the millenium development goal 4 target for reducing child mortality

Excerpt 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.

Measles

Despite the significant decline in measles deaths during the past decade, measles still accounts for over 100,000 child deaths annually. These 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 mortality. 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 is preventable by vaccination (e.g. rotavirus and cholera). Similarly pathogens, such as *Haemophilus influenzae* type b, *Streptococcus pneumoniae*, and influenza virus, for which safe and effective vaccines are available against the major pathogens causing these disease syndromes, making a large proportion of them preventable.

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).

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 that cause neonatal sepsis and meningitis, notably group B streptococcal vaccines, can potentially have a large impact on newborn survival, though the magnitude of the effect needs to be quantified to allow prioritization for the introduction and use of this vaccine.

References

- A Promised Renewed (found at: www.apromiserenewed.org/Dashboard.html).

STRAIGHT OBJECTIVE 1
all member states commit to immunization as a priority

INDICATOR SO 1.1: DOMESTIC EXPENDITURES FOR IMMUNIZATION PER PERSON TARGETED

<table>
<thead>
<tr>
<th>TARGET</th>
<th>Increasing trend in country allocation to national immunization programmes</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>Domestic expenditures for immunization are all expenditures financed by domestic resources (from national and sub-national government budgets) for immunization-specific activities carried out within the routine immunization programme for both vaccine procurement and immunization delivery. Supplemental immunization activities (SIAs) are excluded, as are extra-budgetary expenditures from development partners, and out-of-pocket and private expenditures. For persons targeted, the number of live births from UN population data(^{29}) was used as a standard denominator that was available for all countries.</td>
</tr>
<tr>
<td>DATA SOURCES</td>
<td>WHO-UNICEF joint reporting forms (JRFs) (questions concerning immunization financing – see explanation below)</td>
</tr>
</tbody>
</table>

Data availability and quality

The JRF template includes the six following immunization financing related 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.

Questions 2 and 5 concerning total expenditures (in absolute terms) for vaccines and routine immunization were added to the JRF in 2010, along with revised instructions to ensure harmonization of Member States’ responses.

The quality and completeness of financing data reported through the JRF mechanism is a major concern. For instance, 60 Member States (31%) did not provide information on absolute expenditure amounts (Questions 2 and 5) in the past three years (2010-2012). Several of these countries provided instead the estimated percentage of government funding (Questions 3 and 6 above), indicating that total amounts were not available.

The JRF is generally completed by national immunization programme managers or their designees, who appear to have difficulty in securing and reporting reliable immunization expenditure data. Consequently, there are many inconsistencies and missing data. Possible explanations include 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; the lack of expertise in financial monitoring within national immunization programmes; difficulties in clearly identifying the “borders” of immunization programs and what input costs to include; and a lack of interest among some Member States’ in reporting financing information.

\(^{30}\) This includes all recurrent, immunization-specific expenditures for routine immunization, including 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.
WHO has a process in place to identify and correct data problems and gaps. It cross-checks the data from the JFRs each year to identify missing data and potential inconsistencies, using two main methods:

1. analyzing the data over time (time series analysis) to, for instance, identify extremely divergent values reported from one year to the next for the same country; and
2. assessing the consistency between reported expenditures for the routine immunization and expenditures for vaccines (the first one should include and be higher than the second one).

The time series analysis is used to fill in missing values by assuming the continuation of financing trends over time or by averaging available values. For Member States with available comprehensive Multi-Year Plans (cMYPs), data from the cMYP costing and financing tools are used as an additional source to cross-check and fill in missing data or correct inconsistent data.

Records of inconsistencies and missing values are shared with Member States through the WHO Regional Offices. However, feedback from the countries to revise the data is often lacking. The process of checking and correcting data inconsistencies for 2012, reported in the 2013 JRF, is yet to be completed.

Care should be taken in interpreting these financing data, as several inconsistencies remain in the data set. These include Member States reporting high fluctuations in expenditures between years or extremely high values compared to Member States in the same income range.

The rate of reporting financing data on the JFRs also needs to be improved. Only 60 Member States (31%) provided immunization financing data for each of the past three years, 43 Member States (22%) provided data for two of the three years, and 31 (16%) provided data for only one year. Another 60 Member States (31%) – mainly high-income countries – did not provide any immunization financing data between 2010 and 2012.

Starting in 2013, the System of Health Accounts (SHA) will be used to estimate immunization-specific expenditures (see to Chapter II). By 2015, 75 low- and middle-income countries are expected to use this methodology, which should strengthen the quality of immunization financing data reported on the JRFs.

Results

As would be expected, the reported domestic expenditures for immunization per person targeted vary considerably between Member States in different income categories. In general, domestic expenditures on immunization per live birth are greater with increased country income.

Of the 60 Member States that have expenditure data for each of the years between 2010 and 2012, 19 – mostly low and lower-middle income countries – report a consistent increase in expenditures during this three-year period (Table 13). One country – DR Congo – started financing its immunization programme for the first time in 2011.

In 10 Member States, the trend seems to be downward (Table 14). In some instances, the decrease may be explained by declining prices for some of the new vaccines. However, in some instances (e.g. Sri Lanka and Sudan) the drop seems implausible, as the amounts reported in 2012 are extremely low. This may reflect incorrect data reported in the JRF, or 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 31 Member States, no specific trend could be determined over this three-year period.
Table 13: Member States for which total expenditures for routine immunization have been steadily increasing over the past three years (2010-2012) (n=19)

<table>
<thead>
<tr>
<th>Member State</th>
<th>GNI per capita (US$, 2012)</th>
<th>WB Income classification</th>
<th>Total expenditures (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>2010</td>
</tr>
<tr>
<td>Cambodia</td>
<td>$880</td>
<td>LIC</td>
<td>$0.9</td>
</tr>
<tr>
<td>Congo DR</td>
<td>$220</td>
<td>LIC</td>
<td>$0.0</td>
</tr>
<tr>
<td>Eritrea</td>
<td>$450</td>
<td>LIC</td>
<td>$0.5</td>
</tr>
<tr>
<td>Madagascar</td>
<td>$430</td>
<td>LIC</td>
<td>$0.6</td>
</tr>
<tr>
<td>Mozambique</td>
<td>$510</td>
<td>LIC</td>
<td>$4.2</td>
</tr>
<tr>
<td>Togo</td>
<td>$500</td>
<td>LIC</td>
<td>$22.5</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>$680</td>
<td>LIC</td>
<td>$2.7</td>
</tr>
<tr>
<td>Congo</td>
<td>$2,550</td>
<td>LMIC</td>
<td>$1.2</td>
</tr>
<tr>
<td>Guatemala</td>
<td>$3,120</td>
<td>LMIC</td>
<td>$27.8</td>
</tr>
<tr>
<td>India</td>
<td>$1,530</td>
<td>LMIC</td>
<td>$3.6</td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td>$1,790</td>
<td>LMIC</td>
<td>$5.3</td>
</tr>
<tr>
<td>Paraguay</td>
<td>$3,290</td>
<td>LMIC</td>
<td>$51.9</td>
</tr>
<tr>
<td>Tonga</td>
<td>$4,240</td>
<td>LMIC</td>
<td>$14.9</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>$1,400</td>
<td>LMIC</td>
<td>$5.9</td>
</tr>
<tr>
<td>Colombia</td>
<td>$6,990</td>
<td>UMIC</td>
<td>$64.4</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>$5,470</td>
<td>UMIC</td>
<td>$14.3</td>
</tr>
<tr>
<td>Iran</td>
<td>NA</td>
<td>UMIC</td>
<td>$13.4</td>
</tr>
<tr>
<td>Venezuela</td>
<td>$12,470</td>
<td>UMIC</td>
<td>$51.8</td>
</tr>
<tr>
<td>Netherlands</td>
<td>$48,250</td>
<td>HIC</td>
<td>$181.7</td>
</tr>
</tbody>
</table>

NA = Data not available on World Bank database.
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 routine immunization have been steadily declining from 2010 to 2012

<table>
<thead>
<tr>
<th>Country</th>
<th>GNI per capita (US$, 2012)</th>
<th>WB Income classification</th>
<th>Total expenditures (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>2010</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>$840</td>
<td>LIC</td>
<td>$8.3</td>
</tr>
<tr>
<td>Benin</td>
<td>$750</td>
<td>LIC</td>
<td>$6.7</td>
</tr>
<tr>
<td>Chad</td>
<td>$740</td>
<td>LIC</td>
<td>$7.8</td>
</tr>
<tr>
<td>Tanzania</td>
<td>$570</td>
<td>LIC</td>
<td>$3.7</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>$2,920</td>
<td>LMIC</td>
<td>$32.7</td>
</tr>
<tr>
<td>Sudan</td>
<td>$1,450</td>
<td>LMIC</td>
<td>$2.8</td>
</tr>
<tr>
<td>Vanuatu</td>
<td>$3,080</td>
<td>LMIC</td>
<td>$17.5</td>
</tr>
<tr>
<td>Yemen</td>
<td>$1,070</td>
<td>LMIC</td>
<td>$1.4</td>
</tr>
<tr>
<td>Argentina</td>
<td>NA</td>
<td>UMIC</td>
<td>$80.7</td>
</tr>
<tr>
<td>Cuba</td>
<td>NA</td>
<td>UMIC</td>
<td>$199.9</td>
</tr>
</tbody>
</table>

NA = Data not available on World Bank database. LIC: low-income country; LMIC: lower-middle-income country; UMIC: upper-middle-income country; HIC: high-income country

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

Highlights

• Among the 60 Member States for which data on domestic immunization expenditures are available for each year from 2010 to 2012, 19 have seen a steady increase in domestic expenditures during this period.
• Domestic spending on immunization in 10 other Member States declined over this three-year period, while in the remaining 31 countries no trend is discernible as the data are inconsistent.
• Data quality is variable and several inconsistencies and missing data are noted. Further data validation at country level is recommended.
• Thirty-one Member States (16%) provided immunization financing data for only one year, and 60 Member States (31%), mainly high-income countries, did not provide any data at all for this indicator.
• The System of Health Accounts (SHA) will be used starting in 2013 to estimate immunization-specific expenditures and improve the reporting of financing data on the JRFs.
Data availability and quality

Data availability

Process indicators related to the establishment of NITAGs have been included in the WHO-UNICEF JRF since 2011 (with data collected for 2010). In this summary, information from Member States regarding NITAGs come from the 2013 JRF and is compared with JRF data from 2012 and 2011. For Member States that did not yet complete the JRF for 2013, information from the previous year's JRF was used instead. 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.31

Additional information was obtained from a February 2013 survey of NITAGs in the 27 European Union Member states plus Norway and Iceland, as part of the Vaccine European New Integrated Collaboration Effort (VENICE) project (see Reference 2).

As of 11 July, 2013, 182 Member States (94%) completed the 2013 JRF for 2012 and provided a response to at least one of the NITAG-related questions. Nine Member States had reported NITAG data the previous year. Therefore, data for 191 Member States were available for the analysis.

31 See Blau et al, Reference 1 in the REFERENCE section.
Data quality

There are several limitations to the NITAG data from the JRFs. First, some Member States did not provide answers to the NITAG-related questions in the most recent JRF, and for others, some of the responses between 2012 and 2013 are inconsistent. Second, because the analysis focuses on data officially reported by the Member States, without a systematic process for validating the data with national counterparts (although this is done in some regions), there may be some inaccuracies for certain Member States. Since the introduction of the NITAG-related questions in the JRF is relatively recent, it is possible that some questions may not have been well understood. 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 immunization funding, planning, implementation and advocacy. In the 2013 and 2012 JRFs, seven African Member States explicitly stated that they had reported in prior years having a NITAG when in fact, these were actually ICCs. Consequently, data for 2012 are likely to be more reliable than those from previous years.

Data from the Member States that reported the existence of a NITAG with formal terms of reference and/or a formal administrative or legislative basis should be less susceptible to reporting bias, and therefore closest to the actual number of countries that have a NITAG. The number of Member States reporting the existence of a NITAG that complies with all six criteria (i.e., is fully functional) is also less susceptible to reporting bias.

Results

Notable progress was made between 2010 and 2012 concerning the establishment and functioning of NITAGs. Ninety-nine Member States (52%) reported the existence of a NITAG with a formal legislative or administrative basis, among Member States reporting NITAG data on their JRF (Table 16). In 2012, 63 Member States reported having a NITAG that met all six criteria, including 38 low- and middle-income Member States. This is a 47% increase over 2010, when only 43 countries reported having a fully-functional NITAG. Thus, despite the short period of time and considering that establishing and strengthening NITAGs is a long-term process, there seems to be constant progress in the establishment of NITAGs over the last few years. Overall, 52% of the world’s population now live in a country with a NITAG that meets all six criteria.

The Eastern Mediterranean region (EMR) had the highest proportion of Member States reporting the existence of a fully-functional NITAG (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, as compared to 22% in AFR, 41% in WPR, 43% in AMR, 70% in EUR, and 82% in SEAR. According to the 2013 survey, 85% of the 27 European Member States surveyed reported having established a NITAG.

Examining NITAG status by country income (Table 17), 11% of low-income countries, 29% of middle-income countries, and 57% of high-income countries reported having a NITAG in 2012 that met all six process criteria.
Table 15: Analysis of the NITAG 2012 JRF data at global level and by WHO region

<table>
<thead>
<tr>
<th>Process indicator/ criterion</th>
<th>Data point</th>
<th>Region</th>
<th>All regions</th>
<th>AFR</th>
<th>AMR</th>
<th>EMR</th>
<th>EUR</th>
<th>SEAR</th>
<th>WPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responding Member States out of all WHO Member States (%)</td>
<td>191/194 (98)</td>
<td>46/46 (100)</td>
<td>35/35 (100)</td>
<td>22/22 (100)</td>
<td>50/53 (94)</td>
<td>11/11 (100)</td>
<td>27/27 (100)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Existence of a NITAG</td>
<td>No. (%) of Member States responding</td>
<td>116 (61)</td>
<td>13 (28)</td>
<td>19 (54)</td>
<td>21 (95)</td>
<td>38 (76)</td>
<td>10 (91)</td>
<td>15 (56)</td>
<td></td>
</tr>
<tr>
<td>% of population covered</td>
<td>89</td>
<td>57</td>
<td>91</td>
<td>98</td>
<td>67</td>
<td>99</td>
<td>99</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NITAG with formal terms of reference</td>
<td>No. (% of those reporting)</td>
<td>104 (90)</td>
<td>12 (92)</td>
<td>15 (79)</td>
<td>20 (95)</td>
<td>35 (92)</td>
<td>10 (100)</td>
<td>12 (80)</td>
<td></td>
</tr>
<tr>
<td>% of responding Member States</td>
<td>54</td>
<td>26</td>
<td>43</td>
<td>91</td>
<td>70</td>
<td>91</td>
<td>44</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NITAG with a legislative or administrative basis</td>
<td>No. (% of those reporting)</td>
<td>99 (85)</td>
<td>10 (77)</td>
<td>15 (79)</td>
<td>19 (90)</td>
<td>35 (92)</td>
<td>9 (90)</td>
<td>11 (73)</td>
<td></td>
</tr>
<tr>
<td>% of responding Member States</td>
<td>52</td>
<td>22</td>
<td>43</td>
<td>86</td>
<td>70</td>
<td>82</td>
<td>41</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of population covered</td>
<td>85</td>
<td>43</td>
<td>90</td>
<td>96</td>
<td>65</td>
<td>97</td>
<td>98</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NITAG with ≥ 5 areas of expertise represented</td>
<td>No. (% of those reporting)</td>
<td>106 (91)</td>
<td>10 (77)</td>
<td>17 (89)</td>
<td>20 (95)</td>
<td>36 (95)</td>
<td>10 (100)</td>
<td>13 (87)</td>
<td></td>
</tr>
<tr>
<td>NITAG which met at least once in 2012</td>
<td>No. (% of those reporting)</td>
<td>103 (89)</td>
<td>12 (92)</td>
<td>16 (84)</td>
<td>18 (86)</td>
<td>38 (100)</td>
<td>8 (80)</td>
<td>11 (73)</td>
<td></td>
</tr>
<tr>
<td>NITAG agenda and background docs distributed ≥ 1 week before meeting</td>
<td>No. (% of those reporting)</td>
<td>104 (90)</td>
<td>10 (77)</td>
<td>18 (95)</td>
<td>19 (90)</td>
<td>36 (95)</td>
<td>10 (100)</td>
<td>11 (73)</td>
<td></td>
</tr>
<tr>
<td>NITAG members required to disclose conflict of interest</td>
<td>No. (% of those reporting)</td>
<td>76 (66)</td>
<td>6 (46)</td>
<td>13 (68)</td>
<td>15 (71)</td>
<td>24 (63)</td>
<td>7 (70)</td>
<td>11 (73)</td>
<td></td>
</tr>
<tr>
<td>NITAG meeting all six criteria above</td>
<td>No. (% of those reporting)</td>
<td>63 (54)</td>
<td>3 (23)</td>
<td>13 (68)</td>
<td>13 (62)</td>
<td>22 (58)</td>
<td>5 (50)</td>
<td>7 (47)</td>
<td></td>
</tr>
<tr>
<td>% of responding Member States</td>
<td>33</td>
<td>7</td>
<td>37</td>
<td>59</td>
<td>44</td>
<td>45</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of the entire population covered</td>
<td>52</td>
<td>7</td>
<td>88</td>
<td>83</td>
<td>41</td>
<td>20</td>
<td>81</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 16: Number of Member States with NITAGs by various criteria, income status, GAVI eligibility and population size, 2012 JRF data

<table>
<thead>
<tr>
<th>Process indicator/ criterion</th>
<th>WB income status*</th>
<th>GAVI- eligible countries (n=57)</th>
<th>Population size**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low (n=36)</td>
<td>Middle (n=100)</td>
<td>High (n=55)</td>
</tr>
<tr>
<td>Reporting Member States (% of total)</td>
<td>36 (100)</td>
<td>99 (99)</td>
<td>53 (96)</td>
</tr>
<tr>
<td>Has a NITAG No. (% of those reporting)</td>
<td>13 (36)</td>
<td>62 (63)</td>
<td>41 (77)</td>
</tr>
<tr>
<td>NITAG has formal terms of reference No. (% of those reporting)</td>
<td>13 (36)</td>
<td>53 (54)</td>
<td>38 (72)</td>
</tr>
<tr>
<td>Legislative or administrative basis for NITAG No. (% of those reporting)</td>
<td>10 (28)</td>
<td>50 (51)</td>
<td>39 (74)</td>
</tr>
<tr>
<td>≥ 5 areas of expertise represented No. (% of those reporting)</td>
<td>9 (25)</td>
<td>59 (60)</td>
<td>38 (72)</td>
</tr>
<tr>
<td>Met at least once in 2012 No. (% of those reporting)</td>
<td>10 (28)</td>
<td>53 (54)</td>
<td>40 (75)</td>
</tr>
<tr>
<td>Agenda/background docs distributed ≥ 1 week before meetings No. (% of those reporting)</td>
<td>11 (31)</td>
<td>53 (54)</td>
<td>40 (75)</td>
</tr>
<tr>
<td>Members required to disclose conflict of interest No. (% of those reporting)</td>
<td>7 (19)</td>
<td>36 (36)</td>
<td>33 (62)</td>
</tr>
<tr>
<td>Meet all six criteria above No. (% of those reporting)</td>
<td>4 (11)</td>
<td>29 (29)</td>
<td>30 (57)</td>
</tr>
</tbody>
</table>

* The denominator is 191 Member States for which the World Bank provided information, as of July 2013. Information on income status is missing for the Cook Islands, Nauru, and Niue.

** Small: < 7,789,876; Large: ≥ 7,789,876. This number is the median of the total population for the 194 Member States.
Discussion

Because the proportion of Member States with a NITAG is greater in the more populous Member States (85% in terms of those with a legal basis) than in the less populous ones (52%), the overall proportion of the population supported by a NITAG is substantially greater than the proportion of countries with a NITAG. In areas where regional engagement has been strong and there have been strong statements from regional Technical Advisory Group (TAG) regarding the need to strengthen NITAGs, such as in AMR, EMR, EUR and SEAR, rapid progress is being achieved. The participation of NITAG Chairs at immunization and regional TAG meetings in most regions and the fostering of exchange between NITAGs have been received very positively by all and can contribute to capacity strengthening.

Beyond progress in increasing the number of NITAGs, there has been substantial improvement in the quality 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 this progress is the need for concerted advocacy from all partners on the need to establish or strengthen NITAGs and to clearly communicate the different roles and responsibilities between NITAGs and ICCS. It should also be made clear that the introduction of new vaccines in a country does not in any way diminish the need for to establish or strengthen a NITAG; in fact, just the opposite is true.

It is recommended that the existence of a NITAG be a requirement for applying for GAVI support and that GAVI encourages countries to access Health System Strengthening (HSS) funds to establish or strengthen NITAGs. Communication at the global and national levels should also make it clear that the purpose of a NITAG is not only to facilitate new vaccine introductions, but rather, to serve as a technical resource to the government and to immunization programme managers to review strategies and recommendations for use of vaccines in the current vaccination programs, as well as to review and synthesize evidence for making decisions regarding new vaccine introductions. NITAGs could also play an important role in monitoring and holding accountable immunization programmes at the national level, by providing an independent review of progress.

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 criteria is the first step, and committees that meet these criteria should continue to be strengthened. Fostering exchange between NITAGs is an important way to facilitate support and progress. This exchange should extend to making evidence available to other groups, such as public posting of systematic reviews of disease burden and vaccine effectiveness. 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 the Strengthening Independent Immunization and Vaccine Advisory Committees (SIVAC) and ProVac. Efforts to establish NITAGs through professional organizations such as national paediatric associations, need to be well-coordinated with the government, to ensure that there parallel groups are not established. In addition, countries can explore the possibility of transforming existing technical advisory groups set up for polio or other specific vaccine-preventable diseases into NITAGs.
Highlights

- By the end of 2012, 63 Member States, including 33 low- and middle-income countries, reported having a NITAG that met all six established criteria, representing a 47% increase from the 43 reported in 2010.
- 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 from the government, progress in establishing and strengthening NITAGs can be rapid.
- Progress needs to be accelerated to reach the GVAP NITAG target all of Member States having a functional NITAG.
- 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.

References

- Duclos P, et al., “Progress in the establishment and strengthening of national immunization technical advisory groups: analysis from the 2013 WHO-UNICEF JRF, data for 2012”, paper submitted to Vaccine (to be provided by the Secretariat).
STRATEGIC OBJECTIVE 2
individuals and communities understand the values of vaccines and demand immunization both as a right and a responsibility

INDICATOR SO 2.1: PERCENTAGE OF COUNTRIES THAT HAVE ASSESSED (OR MEASURED) THE LEVEL OF CONFIDENCE IN VACCINATION AT THE SUB-NATIONAL LEVEL

<table>
<thead>
<tr>
<th>TARGET</th>
<th>Increasing trends in the percent of member states that have assessed the population's level of confidence in vaccination at the sub-national level</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>Vaccine confidence: trust in the usefulness and safety of vaccines and in the system that delivers them. Vaccination confidence exists on a continuum and is one of the factors that influence behavior ranging from acceptance of vaccination to refusal</td>
</tr>
<tr>
<td>DATA SOURCES</td>
<td>WHO-UNICEF joint reporting forms (JRFs) (new questions concerning population confidence or hesitancy in accepting vaccines, pilot tested in 83 Member States in two WHO regions – see explanation below)</td>
</tr>
<tr>
<td></td>
<td>Questionnaire concerning population confidence or hesitancy regarding vaccines, self-administered by 11 immunization programme managers during regional meeting in AFR (see below)</td>
</tr>
</tbody>
</table>

Data sources and quality

In response to a recommendation by the SAGE Working Group on Vaccine Hesitancy, two WHO regions – the Americas and the European region – volunteered to pilot test questions related to this Strategic Objective that were added to the 2012 Joint Report Form (JRF). The JRFs with these new questions were sent to the Member States in AMR and EUR in December 2012 and January 2013. The two questions on the JRF related to this indicator were:

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

In addition, immunization managers from the Southern, Eastern and Central African regions were asked to complete a self-administered questionnaire (containing the same questions as on the JRF) during regional EPI meetings held in the first quarter of 2013.

Of the 83 Member States in AMR and EUR who submitted the JRF, one third did not respond to the first question about whether or not an assessment of confidence in vaccination among the population had ever been conducted (Table 17). Several of those that responded affirmatively did not specify what kind of assessment was done (Question 2). Eleven of the 14 immunization managers who were given the self-administered questionnaires provided responses to all the questions.
Results

Of the 67 Member States that responded to question 1, only 18 indicated that they had conducted an assessment of population confidence in vaccination at the sub-national level, including seven Member States in AMR, eight in EUR and three in AFR (Table 17). Of these 18 Member States, one was a low-income country, 11 were middle-income and six were high-income. Among those not providing responses, it was impossible to determine whether no assessment was done or if the immunization manager filling out the JRF or questionnaire simply could not provide an answer.

Table 17: Number of Member States that responded to Question 1 about assessing the level of confidence in vaccination at the sub-national level

<table>
<thead>
<tr>
<th>Responses</th>
<th>Countries participating in the piloting of JRF questions concerning vaccine confidence</th>
<th>AFR (self-administered questionnaire)</th>
<th>Total n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EUR n (%)</td>
<td>AMR n (%)</td>
<td>Total EUR and AMR n (%)</td>
</tr>
<tr>
<td>Conducted an assessment</td>
<td>8 (17%)</td>
<td>7 (20%)</td>
<td>15 (18%)</td>
</tr>
<tr>
<td>Didn’t conduct an assessment</td>
<td>17 (35%)</td>
<td>24 (69%)</td>
<td>41 (49%)</td>
</tr>
<tr>
<td>Total responding to Question 1</td>
<td>25 (52%)</td>
<td>31 (89%)</td>
<td>56 (67%)</td>
</tr>
<tr>
<td>Didn’t complete Question 1</td>
<td>23 (48%)</td>
<td>4 (11%)</td>
<td>27 (33%)</td>
</tr>
<tr>
<td>Total</td>
<td>48 (100%)</td>
<td>35 (100%)</td>
<td>83 (100%)</td>
</tr>
</tbody>
</table>

The types of assessments on vaccination confidence that were reported ranged from specific surveys on this topic, to questions added as part of immunization programme reviews or immunization coverage surveys, to questions included in large national health surveys (see Table 18).
### Table 18: Types of assessments on vaccination confidence of the population reported by countries responding to confidence-related questions on the JRF or self-administered questionnaire

<table>
<thead>
<tr>
<th>Member State</th>
<th>Type of assessment</th>
<th>Year assessment conducted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>Rapid monitoring of vaccination provided information to explain the reasons for non-vaccination or for abandoning the recommended vaccination schedule.</td>
<td>No year indicated</td>
</tr>
<tr>
<td>Chile</td>
<td>Conducted a small study, requested by the MINISTRY of Finance in 2012, which focused on people's perception of the National Immunization Program.</td>
<td>2012</td>
</tr>
<tr>
<td>Cuba</td>
<td>Not specified</td>
<td>2012</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>Not specified</td>
<td>2012</td>
</tr>
<tr>
<td>Guatemala</td>
<td>Random survey (1164 mothers / guardians) house to house. May 2011</td>
<td>2011</td>
</tr>
<tr>
<td>Jamaica</td>
<td>User survey as part of an evaluation of the Immunization Program in 2003</td>
<td>2003</td>
</tr>
<tr>
<td>Mexico</td>
<td>National Survey of Health and Nutrition</td>
<td>2006</td>
</tr>
<tr>
<td>Armenia</td>
<td>Not specified</td>
<td>No year indicated</td>
</tr>
<tr>
<td>Belgium</td>
<td>Vaccination coverage study of infants (18-24 months of age) and adolescents in Flanders</td>
<td>2012</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Administrative data</td>
<td>2011</td>
</tr>
<tr>
<td>Germany</td>
<td>Representative survey targeting parents of children aged 0-13 years</td>
<td>2010</td>
</tr>
<tr>
<td>Iceland</td>
<td>Survey among parents</td>
<td>2010</td>
</tr>
<tr>
<td>Italy</td>
<td>1. Survey on communication and organizational aspects of the HPV vaccination campaign and acceptance of the vaccination in the regions of Italy and proposal for a technical document for future campaigns (VALORE) (report not yet available); and 2. Survey on Social Determinants of Vaccine Refusal in the Veneto Region. Report available at <a href="http://prevenzione.ulss20.verona.it/indagine_scelta_vaccinale.html">http://prevenzione.ulss20.verona.it/indagine_scelta_vaccinale.html</a></td>
<td>2011-2012 2009-2011</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Prevalence study</td>
<td>2011</td>
</tr>
<tr>
<td>Russian Federation</td>
<td>Questioning during European Immunization Week</td>
<td>2012</td>
</tr>
<tr>
<td>Democratic Republic of Congo</td>
<td>National immunization coverage survey</td>
<td>2012</td>
</tr>
<tr>
<td>Eritrea</td>
<td>EPI program review were carried out at national, subnational &amp; district level &amp; caregivers with technical support from AFRO/IST</td>
<td>2011</td>
</tr>
<tr>
<td>Uganda</td>
<td>Several studies: social survey on evidence-based communication, independent surveys conducted during SIA and NID vaccination campaigns, social mobilization survey in 35 districts</td>
<td>2012</td>
</tr>
</tbody>
</table>
Monitoring progress towards GVAP goals and strategic objectives

Highlights

• The first attempt to obtain information from Member States about their efforts to assess their population's confidence in vaccination at the national or sub-national levels took place in 2013 through pilot testing of new questions on the JRF in two WHO regions (AMR and EUR) and through a self-administered questionnaire given to immunization programme managers at regional meetings in Africa.

• Only 67 Member States out of 94 responded to the survey, and of these, 18 (27%) indicated that they had conducted an assessment of their population's confidence in vaccination, while 49 (73%) reported that no assessment on this topic had taken place. Few countries provided any details on the nature of the assessments.

• The response rate for these questions when administered through the JRF was suboptimal, but improved when the questions were included on a self-administered questionnaire given during regional immunization managers’ meetings.

• The responses received from countries about vaccination confidence assessments were difficult to interpret. Hence, it is felt that the current questions and the methods of administering them require further consideration.

Data sources and quality

As with indicator SO1.1, data for this indicator came from new questions added to the JRF that was pilot tested in the AMR and EUR regions, as well as on a self-administered questionnaire given to immunization programme managers during regional meetings in the African region. Three questions related to this indicator were added to the 2012 pilot JRF:

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)?
2. Was this percentage measured or estimated?
3. Any comments or specific issues?

Of the 94 Member States participating in piloting these questions (see Indicator 2.1 above), only 13 (14%) provided a measure or estimate of the percent of un- and under-vaccinated in whom lack of confidence in vaccination was a factor which influenced their decision to not get vaccinated (Table 19). However, it is unclear whether no response means that no assessment of vaccine confidence had ever been carried out or if the programme managers didn't know how to respond.

<table>
<thead>
<tr>
<th>INDICATOR SO 2.2: PERCENTAGE OF UN- AND UNDER-VACCINATED IN WHOM LACK OF CONFIDENCE WAS A FACTOR THAT INFLUENCED THEIR DECISION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TARGET</strong></td>
</tr>
<tr>
<td><strong>DEFINITION OF INDICATOR</strong></td>
</tr>
<tr>
<td><strong>DATA SOURCES</strong></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Table 19: Number and percent of Member States that provided a measured or estimated percentage of un- or under-vaccinated in whom a lack of confidence in vaccination was a factor

<table>
<thead>
<tr>
<th>Data provided?</th>
<th>EUR</th>
<th>AMR</th>
<th>Total EUR and AMR</th>
<th>AFR</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>3 (6)</td>
<td>5 (14)</td>
<td>8 (10)</td>
<td>5 (45)</td>
<td>13 (14)</td>
</tr>
<tr>
<td>No</td>
<td>45 (94)</td>
<td>30 (86)</td>
<td>75 (90)</td>
<td>6 (55)</td>
<td>81 (86)</td>
</tr>
<tr>
<td>Total</td>
<td>48 (100)</td>
<td>35 (100)</td>
<td>83 (100)</td>
<td>11 (100)</td>
<td>94 (100)</td>
</tr>
</tbody>
</table>

Results

Of the 13 Member States that provided a percent of un- or under-vaccinated in which the lack of confidence in vaccination played a role, the percent was a measurement based on an assessment in four countries (Germany, Guatemala, DR Congo and the Czech Republic), while the remaining nine countries provided an estimate. The responses ranged from 0% in four countries (Cuba, Dominica, Sao Tome de Principe and Botswana) to 19% in Uganda (Figure 9). Czech Republic provided a range of 9.6-27%, depending on the vaccine. The percent of un-vaccinated who lacked confidence in vaccination was 8% overall in the DR Congo, but varied from 3.9 to 15.3% in different provinces. These results suggest that a lack of confidence in vaccination may play an important role in children not being vaccinated in several countries. However, it is unclear how these estimates were derived, making it difficult to compare the responses from Member States. The responses also revealed a variety of determinants in vaccination hesitancy, from religious factors to concerns about the safety of vaccines.

Figure 9: Estimated or measured percent of persons un- and under-vaccinated in whom lack of confidence in vaccination was a factor
Monitoring progress towards GVAP goals and strategic objectives

Highlights

• The pilot test revealed that several Member States had assessed the population’s confidence or hesitancy in vaccination in the past, with 13 of the 94 Member States in AMR, EUR and AFR providing estimates of the percent of un- or under-vaccinated for whom a lack of confidence was a factor.

• The percentages estimated at the national level ranged from 0% to 19%, but were as high as 27% (in the Czech Republic), depending on the vaccine.

• There is a need to continue pilot testing to evaluate the feasibility of collecting data on the role of hesitancy (lack of confidence) in vaccination in people not being vaccinated using the JRF or other methods.

• This research could identify populations that have issues with vaccination that had previously not been viewed as lacking confidence, such as in Uganda.

• A variety of determinants of vaccination hesitancy, from religious factors to concerns about the safety of vaccines, were identified by Member States.
Case studies on efforts to improve population confidence in vaccination

Because of the paucity of data from the JRFs and questionnaires, WHO compiled several case studies on country efforts to improve population’s confidence in vaccination and reduce vaccination “hesitancy.” These included one published report (from Nigeria) and two that were prepared specifically for this review (from the European Region and Nepal). These three case studies are summarized below.


The Northern Nigerian states of Jigawa, Katsina, Yobe and Zamfara, with a 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, creating a vicious cycle of distrust in and underuse of health services. The immunization programme 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.

The PRRINN-MNCH Community Engagement Approach

The PRRINN-MNCH programme, funded by the UK Department for International Development (DFID) and the Government of Norway and managed by a consortium led by Health Partners International, Save the Children and Grid Consulting, developed and implemented a community engagement strategy centered on community volunteerism and social approval. The whole community is involved, including religious and traditional leaders, husbands, grandmothers, and young women, in order to generate wide social approval for behavior change. Community volunteers 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 in turning new awareness into action. The community is mobilized to take individual and collective responsibility for the immunization of their children. For example:

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

Results

Community Volunteers document their activities monthly to monitor and review progress. A mid-term household survey in focus areas shows that between 2009 and 2011, OPV3 coverage increased from 26% to 66%; knowledge about the vaccination schedule increased from 8% to 52%; standing permission from husbands for vaccination increased from 40% to 80%; and the rate of fully immunized children increased from 2% to 23%.

Key lessons learned

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

95 For further details visit www.prrinn-mnch.org.
CASE STUDY 2: Development and Pilot Testing of the Guide to Tailoring Immunization Programmes (TIP) in the WHO European Region

In 2010, the SAGE stated that if the WHO European Region (EURO) cannot improve coverage of immunization among susceptible populations, achieving the goal of measles eradication will not be possible. In response, the EURO Vaccine Preventable Diseases and Immunization Programme (VPI) developed the Guide for Tailoring Immunization Programmes (TIP) to boost national and sub-national infant and child 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, 2) diagnose supply- and demand-side barriers and motivators to vaccination, and 3) design evidence-based responses to sustain vaccination and reach the remaining susceptible populations in EURO. This allows Member States to tailor immunization services to boost vaccination coverage rates, which in turn will assist the Region in meeting disease elimination and eradication goals.

TIP in Bulgaria

In February 2012, EURO requested permission to work alongside Bulgaria’s National Immunization Programme 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. This activity 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 parents.

TIP Pilot in Sweden

In early 2013, EURO applied lessons learned from its experience in Bulgaria to 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 order to provide input into the Swedish Immunization Programme’s Strategy to Reach Hard-to-Reach Groups. Three communities were identified:

1. An anthroposophic community, in Jarna (a philosophical movement);
2. The Somali community, particularly in Rinkeby and Tensta in northern Stockholm; and
3. Migrant communities in the suburbs of Göteborg.

The workshop was attended by representatives from SMI, ECDC Health Communications Unit, as well as staff and graduate students from several universities and schools of public health in Sweden (Karolinska University, Lund School of Public Health, Nordic School of Public Health NHV, Göteborg University). The use of the TIP diagnostic framework received positive feedback and TIP in general was viewed as effective in providing guidance on key questions to address to each targeted 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 to inform the design of strategies to close the gaps in measles and rubella immunization coverage in these communities. These strategies will be tested in the latter part of 2013.
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 emerge from the three day workshop, inspired, driven and restless with a mission to accomplish. They are responsible for the health and development of all citizens of their district, but had been lulled into complacency due to uninspiring supervision and challenges of terrain, vaccine supply, staff shortage, and ‘inconvenient’ priorities of migrant and ethnic minorities in a landlocked country with a turbulent political history. Now, they had committed to declare their Village Development Committee or VDC – the smallest development unit in the Nepal administrative system – as fully immunized – and soon.

The Morang workshop was the latest in a series of workshops conducted by Nepal’s National Immunization Program, together with WHO and UNICEF country offices. 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 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.

Appreciative Inquiry is a positive, vision-oriented, inspirational approach that enables people to construct ‘dreams’ by revisiting past moments of excellence and life-giving experiences, and then be driven by the attainment of the goals. The approach generates powerful shifts within individuals where they begin to see themselves as catalysts for change, and not as passive recipients. This induces them to take responsibility, which in turn, generates 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. It is a practical approach that is rooted in people past achievements and builds grounded goals. Because the shift is internal and fundamental, it generates sustainable change.

Applying this approach to routine immunization 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 to go the extra mile (which in Nepal could be a couple of days’ walk) to list every child; record full immunization status by ward, vaccine and 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 mobilize funding to fill vacant health worker positions. It also implied demonstrating to senior policymakers that new approaches bring new results.
After the workshop, the VDC teams (and therefore the districts) are tasked with: 1) line listing every child, tracing all dropouts in each ward of every VDC and ensuring immunization is completed; 2) mobilizing schools, community leaders, mothers groups, community-based organizations and private hospitals in identifying and reaching every child with vaccination; 3) inviting community leaders to monitor vaccination; 4) recruiting people for vacant vaccinator posts with local resources; and 5) declaring VDC as 'fully immunized'. The district teams are expected to certify the fully-immunized status with independent monitoring. A Declaration event is encouraged as a strategic opportunity for advocacy at multiple levels.

As of June 2012, 18 workshops had been conducted and as many as 50 VCDs in nine districts had declared themselves fully-immunized. The National Immunization program has since decided to extend the program to 42 districts by 2014.
STRATEGIC OBJECTIVE 3
the benefits of immunization are equitably extended to all people

INDICATOR SO 3.1: PERCENTAGE OF DISTRICTS (OR EQUIVALENT ADMINISTRATIVE UNITS) WITH 80% OR GREATER COVERAGE WITH THREE DOSES OF DIPHTHERIA-TETANUS-PERTUSSIS-CONTAINING VACCINE

<table>
<thead>
<tr>
<th>TARGET</th>
<th>All Member States achieve DTP3 coverage of ≥ 80% in all districts by 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>Same as for Goal 3: District-level DTP3 coverage data are considered valid only if the WUENIC and administrative data from the JFR are the same or if the WUENIC for national DTP3 coverage is ≥ 90%</td>
</tr>
<tr>
<td>DATA SOURCES</td>
<td>WUENIC Administrative data on vaccination coverage from country JRFs (to compare with WUENIC estimates as a check of validity)</td>
</tr>
</tbody>
</table>

Data availability and quality

The same data used to measure progress of Goal 3 (Meet vaccination coverage targets in every region, country and community) were used for this indicator (see the chapter on Goal 3). The same methods of determining the validity of district-level coverage data (i.e., only countries where WUENIC and administrative coverage data are the same or the WUENIC for national coverage is ≥ 90%) were also used. (For further information about JRF and WUENIC data, see Annex 1).

District-level coverage data for 2012 were available and considered valid (per the above definition) for 114 of the 194 Member States; while 80 countries either reported no district-level coverage data or the WUENIC and administrative data did not match, making them invalid (Table 20).

Results

Among the 114 Member States with valid district-level DPT3 coverage data in 2012, coverage was ≥ 80% in all districts in 59 Member States (representing 30% of all countries), and in 80-99% of districts in another 28 Member States (Table 20 and Figure 12). Ten countries reported that < 50% of districts achieved DTP3 coverage of ≥ 80% (Bolivia, Chile, Djibouti, Dominican Republic, Eritrea, Gabon, Lao PDR, Peru, Swaziland and Uganda).

It should be noted that many Member States with low coverage and uncertain data quality are excluded from this analysis and, therefore, it does not provide a complete picture of geographical equity in vaccination coverage. In addition, since the number of Member States with valid district level data varies each year, it is difficult to comment on trends over time.

The lack of valid district-level data in several Member States in sub-Saharan Africa and in Asia (notably in EMR) is an impediment to tracking this indicator, especially in Member States where equity in coverage is an important issue. The main reason for the lack of data validity is that uncertainty concerning the size of the target population (denominator) increases at the district level. Therefore, district-level coverage estimates are often a crude (and sometimes misleading) tool to manage immunization programmes and monitor equity of vaccination coverage.
Monitoring progress towards GVAP goals and strategic objectives

Table 20: Distribution of Member States by the percent of districts achieving ≥ 80% coverage for DTP₃ in 2012, by WHO region

<table>
<thead>
<tr>
<th>WHO region</th>
<th>Countries with DTP₃, district coverage data available and valid</th>
<th>DTP₃ District coverage data not available</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100% districts with DTP₃ ≥ 80%</td>
<td>80-99% districts with DTP₃ ≥ 80%</td>
<td>50-79% districts with DTP₃ ≥ 80%</td>
</tr>
<tr>
<td>AFR</td>
<td>5 11</td>
<td>5 11</td>
<td>7 15</td>
</tr>
<tr>
<td>AMR</td>
<td>10 29</td>
<td>10 29</td>
<td>3 9</td>
</tr>
<tr>
<td>EMR</td>
<td>7 32</td>
<td>3 14</td>
<td>1 5</td>
</tr>
<tr>
<td>EUR</td>
<td>26 49</td>
<td>5 9</td>
<td>1 2</td>
</tr>
<tr>
<td>SEAR</td>
<td>3 27</td>
<td>2 18</td>
<td>2 18</td>
</tr>
<tr>
<td>WPR</td>
<td>8 30</td>
<td>3 11</td>
<td>1 4</td>
</tr>
<tr>
<td>Total</td>
<td>59 30</td>
<td>28 14</td>
<td>17 8</td>
</tr>
</tbody>
</table>

On way to remedy this would be to conduct assessments of district-level vaccination coverage through surveys. Such studies may also serve to identify and address factors that may be contributing to low coverage at the local level. In addition, a few countries have established electronic nominal registries with unique identifiers for each person and the ability to accurately document immunization status by geography.³⁹ However, such registries take time to establish and scale up and can still be ineffective in large countries with decentralized health systems.

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**Highlights**

- Fifty-nine Member States (30%) had validated rates of DTP₃ coverage of ≥ 80% in all districts in 2012.
- Seventeen Member States with validated district-level coverage rates had between 50% and 79% of their districts achieving DTP₃ coverage of ≥ 80% in 2012, while 10 countries had < 50% of districts achieving coverage of ≥ 80%.
- District-level coverage data were not available or was not considered valid (due to conflicting WUENIC and JRF administrative data) in a total of 80 (41%) Member States. These include 54% of Member States in AFR, 45% of those in EMR, 44% of countries in WRP and 40% of those in EUR.

³⁹ See Annex 1 for a description of nominal registries.
Figure 10: Member States by the percent of districts with DTP3 coverage of ≥ 80% for 2012

Source: WHO-UNICEF coverage estimates 2013 revision and JRF as at 11 July 2013.

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Data availability and quality

Data for this analysis are derived from a 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 and UNICEF documents. Health inequality data must be interpreted with caution due to several limitations. Since estimates of household wealth and immunization coverage are only available through DHS and MICS surveys, which are conducted periodically, these data cannot be generated for each country on an annual basis. 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.

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 of some indicators. Detailed information about the indicator criteria is available in the WHO Indicator and Measurement Registry (www.who.int/gho/indicator_registry/en/).

To measure trends, at least two measures are required. Baseline data were originally defined as data from DHSs or MICSs that took place in 2009 or later, but only 14 Member States were found to have conducted surveys during this timeframe. The starting period for surveys to use for baseline data was consequently pushed back to 2008 (which includes the 2007 birth cohort). This expanded the number of Member States with DTP3 coverage data by wealth quintile to 25 (for the years 2007-2010). These baseline data will then be compared with data from subsequent surveys in future analyses to monitor trends in closing the equity gap in coverage.

For those Member States that have not conducted a survey since 2008, the baseline will need to be established once a survey takes place. 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.

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40 The database can be found at: http://apps.who.int/gho/data/node.main.HE-1540?lang=en.
41 See 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).

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Results

Baseline data on DTP₃ coverage rates for the highest and lowest wealth quintile from DHS and MICS conducted from 2008-2011 in 25 Member States are shown in Figure 11. In only five countries (Ethiopia, Madagascar, Mozambique, Nigeria and Philippines) was the difference in coverage between the highest and lowest quintile ≥ 20 percentage points. This means that 20 of the 25 (75%) of countries with recent survey data have already reduced the difference in immunization coverage between the highest and lowest wealth quintiles to < 20%. However, the difference in DTP₃ coverage between the highest and lowest wealth quintiles in 14 of these 25 Member States was more than 10 percentage points. In contrast, coverage in the poorest quintile was slightly higher than that in the richest quintile in Albania and the Maldives.

The coverage by wealth quintile for each of the 25 countries with data is shown in the country graphs in Figure 31 in Annex. These graphs show that the highest and lowest coverage is not necessarily in the richest and poorest quintile, respectively. In a few Member States (e.g., Nigeria and Madagascar), household wealth appears to be a strong determinant of coverage, with a clear linear progression in vaccination coverage as household wealth increases. However, in most other Member States, there is less of a clear progression in coverage by household wealth.

In general, Member States with high national coverage are likely to have smaller differences in coverage between wealth quintiles. Member States with national DTP₃ coverage rates of < 90% that do not have baseline data from a recent survey are encouraged to conduct a survey to establish a baseline. Countries 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

- Baseline data from DHS or MICS surveys conducted between 2008 and 2011 on national DTP₃ national coverage rates by wealth quintiles are available for only 25 Member States.
- 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.
- Twenty of the 25 (75%) of countries with recent survey data have already reduced immunization coverage differences between the highest and lowest wealth quintiles to < 20%, which is the target for 2020.
- In 14 Member States, the difference in DTP₃ coverage between the wealthiest and poorest quintile was greater than 10%, and in five of these countries, the difference was more than 20%.
- In Nigeria and Madagascar, a progressive increase in coverage with increasing household wealth was observed, while in the remaining Member States, there was not such a clear trend.
Figure 11: DTPi coverage rates for lowest and highest wealth quintiles from DHS and MICS conducted from 2008 to 2011 in 25 Member States
STRATEGIC OBJECTIVE 4

Strong immunization systems are an integral part of a well-functioning health system

INDICATOR SO 4.1: DROPOUT RATE BETWEEN FIRST DOSE (DTP₁) AND THIRD DOSE (DTP₃) OF DIPHTHERIA-TETANUS-PERTUSSIS-CONTAINING VACCINES

<table>
<thead>
<tr>
<th>Target</th>
<th>Decreasing trend in dropout rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition of Indicator</td>
<td>The indicator is calculated using the formula:</td>
</tr>
<tr>
<td>Data availability and quality</td>
<td>(DTP₁-DTP₃)/DTP₁ x 100</td>
</tr>
<tr>
<td>Data Source</td>
<td>WUENIC (coverage estimates)</td>
</tr>
</tbody>
</table>

Data availability and quality

Data for this indicator cover the three year period of 2010 to 2012, except for South Sudan, for which data are available only for 2011 and 2012. A description of the WUENIC and their quality can be found in Annex 1.

Results

In 2012, over 80% of Member States had dropout rates from DTP₁ to DTP₃ of less than 10% (Figure 14). The dropout rates were ≥ 10% in 36 (18.6%) Member States; they were 11-19% in 25 Member States, and ≥ 20% in 11 Member States.⁴³

Among the 36 Member States with a DTP₁-DTP₃ dropout rates of ≥ 10% in 2012, 17 (47.2%) achieved national coverage for DTP₃ of ≥ 90%, indicating that they could achieve high national coverage for all three doses if the reasons for the high dropout rates were identified and addressed.

The number of Member States with dropout rates of ≥ 10% has remained relatively static over the past three years (Figure 15). Given the imprecision of coverage data, however, changes in the dropout rates from one year to the next in a country need to be interpreted with caution (Table 39 to Table 42 in Annex). Nonetheless, notable increases in dropout rates were observed in the Syrian Arab Republic and Iraq, both countries facing civil strife and insecurity (see Table 39 in Annex). Significant increases were also observed in the Federated States of Micronesia, Marshall Islands and Nauru, while dropout rates decreased significantly in Palau. However, these are small countries or territories with small birth cohorts, which can result in large swings in rates from one year to the next.

The Member States with the highest dropout rates were also those with DTP₃ coverage rates of less than 70%. This indicates that the target populations have not been able to access services consistently, resulting in low coverage for the full complement of child health services. The fact that in many of these Member States the dropout rates seem to be increasing or stagnating suggests that active measures are not being taken to identify causes of vaccination dropout and address them. Identifying these causes and taking corrective measures could result in increases in coverage that will put these Member States on track to achieving coverage for DTP₃ of ≥ 90%.

⁴³ Central African Republic, Chad, Equatorial Guinea, Ethiopia, Guinea, Haiti, Indonesia, Iraq, Papua New Guinea, South Sudan, Syrian Arab Republic.
Monitoring progress towards GVAP goals and strategic objectives

Figure 12: DTP<sub>1</sub>-DTP<sub>3</sub> dropout rates by country, 2012

- < 10% (158 Member States or 81%)
- 10% - < 20% (25 Member States or 13%)
- ≥ 20% (11 Member States or 6%)
- 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

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**Highlights for 2012**

- Thirty-six Member States (18.6%) had DTP<sub>1</sub>-DTP<sub>3</sub> dropout rates of ≥ 10%.
- Of the 36 Member States with a DTP<sub>1</sub>-DTP<sub>3</sub> dropout rates of ≥ 10% in 2012, 17 (47.2%) achieved national coverage for DTP<sub>1</sub> of ≥ 90%, indicating that they could achieve high national coverage for all three doses if the reasons for the high dropout rates were identified and addressed.
- 11 Member States had DTP<sub>1</sub>-DTP<sub>3</sub> dropout rates of ≥ 20.
- Six Member States saw their DTP<sub>1</sub>-DTP<sub>3</sub> dropout rates rise to ≥ 10%, where as they had been < 10% the previous year.
- Member States with the highest dropout rates tended to be those with DTP<sub>3</sub> of < 70%.
Figure 13: Member States with DTP1-DTP3 dropout rates of ≥ 10% for the last three years (2010-2012)
Data availability and quality

Data for this indicator are from the WHO-UNICEF estimates of national infant immunization coverage (WUENIC) (see Annex 1 for more information). In Member States where the WUENIC is based primarily on estimates from periodic coverage surveys, which may be conducted only every three years or less, this is a difficult indicator to reliably measure since year-to-year changes in coverage cannot be captured. It should also be noted that South Sudan is not included in the analysis for this indicator since it only became a WHO Member State in 2011.

Results

One hundred sixteen Member States (60%) have achieved and sustained national DTP$_3$ coverage of ≥ 90% for the past three years (Figure 16) and 155 countries (80%) sustained coverage of ≥ 80% (Figure 17). There is the possibility of six additional Member States meeting this indicator in 2013, since they increased their coverage to ≥ 90% in 2011 and sustained this level in 2012 (Table 21). Unfortunately, in four Member States that had achieved DTP$_3$ coverage of ≥ 90% in 2010 and sustained it in 2011, coverage dropped to below 90% in 2012 (Table 23).

<table>
<thead>
<tr>
<th>Country</th>
<th>WHO region</th>
<th>GAVI country</th>
<th>Income group</th>
<th>National DTP$_3$ coverage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nepal</td>
<td>SEAR</td>
<td>Yes</td>
<td>low</td>
<td>82  92  90</td>
</tr>
<tr>
<td>Samoa</td>
<td>WPR</td>
<td>Low-middle</td>
<td>87</td>
<td>91  92</td>
</tr>
<tr>
<td>Senegal</td>
<td>AFR</td>
<td>Yes</td>
<td>Low-middle</td>
<td>89  92</td>
</tr>
<tr>
<td>Swaziland</td>
<td>AFR</td>
<td>Low-middle</td>
<td>89</td>
<td>91  95</td>
</tr>
<tr>
<td>Tuvalu</td>
<td>WPR</td>
<td>upper-middle</td>
<td>89</td>
<td>96  97</td>
</tr>
<tr>
<td>Malta</td>
<td>EUR</td>
<td>high</td>
<td>76</td>
<td>96  99</td>
</tr>
</tbody>
</table>

Note: Member States are sorted by increasing DTP$_3$ coverage rate for 2012.

Eighteen Member States that had achieved DTP$_3$ coverage rates of ≥ 80% in 2010 failed to reach the desired threshold of ≥ 90% by 2012 (Table 24). This indicates the need for careful examination of the causes for un- or under-immunization and for innovative approaches to making the leap from coverage in the 80s to the 90s over the next few years. In addition, DTP$_3$ coverage rates showed a decreasing trend from 2010 to 2012 in a total of 30 Member States.
**Figure 14:** Member States that have and have not sustained national DTP₃ coverage of ≥ 90% for the last three years, 2010-2012

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

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Figure 15: Member States that have and have not sustained national DTP₃ coverage of ≥ 80% for the last three years, 2010-2012

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
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Table 22: Member States that have sustained national DTP₃ coverage of ≥ 90% for 2010 and 2011 but not in 2012

<table>
<thead>
<tr>
<th>Country</th>
<th>National DTP₃ coverage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2010</td>
</tr>
<tr>
<td>Nauru</td>
<td>99</td>
</tr>
<tr>
<td>Republic of Congo</td>
<td>90</td>
</tr>
<tr>
<td>Honduras</td>
<td>95</td>
</tr>
<tr>
<td>Iceland</td>
<td>96</td>
</tr>
</tbody>
</table>

Note: Member States are sorted by increasing DTP₃ coverage rate for 2012.
Table 23: Member States that have sustained national DTP₃ coverage of ≥ 80% but < 90% for the last three years (2010-2012)

<table>
<thead>
<tr>
<th>Country</th>
<th>WHO Region</th>
<th>GAVI country</th>
<th>Income Group</th>
<th>National DTP₃ coverage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2010</td>
</tr>
<tr>
<td>Bolivia</td>
<td>AMR</td>
<td>Yes</td>
<td>LMIC</td>
<td>80</td>
</tr>
<tr>
<td>Guinea-Bissau</td>
<td>AFR</td>
<td>Yes</td>
<td>LIC</td>
<td>80</td>
</tr>
<tr>
<td>Djibouti</td>
<td>EMR</td>
<td>Yes</td>
<td>LMIC</td>
<td>88</td>
</tr>
<tr>
<td>Micronesia</td>
<td>WPR</td>
<td>Yes</td>
<td>LMIC</td>
<td>85</td>
</tr>
<tr>
<td>Pakistan</td>
<td>EMR</td>
<td>Yes</td>
<td>LMIC</td>
<td>86</td>
</tr>
<tr>
<td>Lebanon</td>
<td>EMR</td>
<td>Yes</td>
<td>UMIC</td>
<td>81</td>
</tr>
<tr>
<td>Yemen</td>
<td>EMR</td>
<td>Yes</td>
<td>LMIC</td>
<td>87</td>
</tr>
<tr>
<td>Austria</td>
<td>EUR</td>
<td>Yes</td>
<td>HIC</td>
<td>83</td>
</tr>
<tr>
<td>Kenya</td>
<td>AFR</td>
<td>Yes</td>
<td>LIC</td>
<td>83</td>
</tr>
<tr>
<td>Lesotho</td>
<td>AFR</td>
<td>Yes</td>
<td>LMIC</td>
<td>83</td>
</tr>
<tr>
<td>Namibia</td>
<td>AFR</td>
<td>Yes</td>
<td>UMIC</td>
<td>83</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>AFR</td>
<td>Yes</td>
<td>LIC</td>
<td>84</td>
</tr>
<tr>
<td>Benin</td>
<td>AFR</td>
<td>Yes</td>
<td>LIC</td>
<td>83</td>
</tr>
<tr>
<td>Cameroon</td>
<td>AFR</td>
<td>Yes</td>
<td>LMIC</td>
<td>84</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>AMR</td>
<td>Yes</td>
<td>UMIC</td>
<td>88</td>
</tr>
<tr>
<td>Madagascar</td>
<td>AFR</td>
<td>Yes</td>
<td>LIC</td>
<td>85</td>
</tr>
<tr>
<td>Paraguay</td>
<td>AMR</td>
<td>Yes</td>
<td>LMIC</td>
<td>89</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>AFR</td>
<td>Yes</td>
<td>LIC</td>
<td>89</td>
</tr>
</tbody>
</table>

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

In Member States where the WUENIC is based on coverage surveys, the observed stagnation in coverage rates can be because the data are based on the same survey and not because of a lack of action. This is true for some of the large Member States with large numbers of unimmunized children, including India, Indonesia and Nigeria.

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**Highlights**

- Sixty percent (116) of Member States achieved and sustained a national DTP₃ coverage rate of ≥ 90% for the last three years (2010-2012).
- Six additional Member States sustained DTP₃ coverage of ≥ 90% for the past two years.
- Fifty-one Member States did not achieve coverage of ≥ 90% in any of the last three years.
Data availability and quality

The WUENIC coverage estimates are based on data that are of varying, and, in some instances, unknown quality. Since 2011, WHO and UNICEF have provided a measure of their confidence in the WUENIC for each country for the following vaccinations: BCG, the first and third doses of DPT, polio (third dose), measles containing vaccines, hepatitis B (third dose), Hib (third dose), the last dose of rotavirus (second or third, depending on the vaccine) and PCV (third dose). In the absence of other sources of information to make a judgment on the quality of these data, the WUENIC Grade of Confidence (GoC) for DTP3 coverage is used as a proxy for the quality of coverage data.

As there is no underlying probability model upon which the WUENIC are based, WHO and UNICEF are unable to present classical measures of uncertainty, such as confidence intervals. Moreover, they have chosen not to make subjective estimates of plausibility/certainty ranges around the coverage. Thus, it is important to understand that the GoC is not an indicator of the quality of data from national authorities per se, but instead reflects only the level of confidence that WHO and UNICEF have in the WUENIC estimates.

The Grades of Confidence consist of three grades given for each vaccination for each country: high, medium and low. A high GoC is assigned when the WUENIC estimate is supported by coverage data reported by the country (e.g., on JRF) (R+), coverage that has been recalculated with an independent denominator from the World Population Prospects(D+), and at least one supporting survey within the last two years (S+). When the GoC is high, we can consider that the data are of good quality, since the coverage estimates from more than one source are consistent with each other. However, the estimate still carries a risk of being incorrect.

A medium GoC is given when the coverage estimate is supported by at least one data source (R+, S+ or D+) and there are no data sources that are inconsistent with the estimate. A low GoC is assigned when there are no directly supporting data, or data from at least one source is not consistent with the estimate.

It should be noted that the quality of the coverage data 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 it may receive a low GoC if the country did not report its data to WHO, or a medium GoC if its data are not supported by data from a recent survey.

Results

In 2012, WUENIC for DPT, were given a low Grade of Confidence score for 110 (57%) Member States. Only seven countries (3.6%) received a high GoC score, while 40% received a medium GoC (Table 24). Fewer countries received high GoCs for DPT, in 2012 than in prior years, perhaps due to the increasing number of coverage surveys that countries have recently conducted.
Table 24: Number and percent of Member States by Grade of Confidence (GoC) for DTP3 coverage estimates for 2010-2012

<table>
<thead>
<tr>
<th>Grade of confidence</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Low</td>
<td>95 (49.2)</td>
<td>104 (53.6)</td>
<td>110 (56.7)</td>
</tr>
<tr>
<td>Medium</td>
<td>85 (40.0)</td>
<td>75 (38.7)</td>
<td>77 (39.7)</td>
</tr>
<tr>
<td>High</td>
<td>13 (6.7)</td>
<td>15 (7.7)</td>
<td>7 (3.6)</td>
</tr>
<tr>
<td>Total</td>
<td>194 (100.0)</td>
<td>194 (100.0)</td>
<td>194 (100.0)</td>
</tr>
</tbody>
</table>

A large proportion of Member States with WUENIC estimates of ≥ 90% were assigned a medium GoC, possibly because fewer of these Member States conduct surveys, in addition to administrative reports, to estimate immunization coverage (Table 25).

Table 25: Number and percent of Member States achieving above and below National DTP3 coverage of 90% in 2012 (from WUENIC) by Grade of Confidence (GoC)

<table>
<thead>
<tr>
<th>Grade of confidence</th>
<th>DTP3 ≥ 90%</th>
<th>DTP3 &lt; 90%</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>68 (51.9)</td>
<td>42 (66.7)</td>
<td>110 (56.7)</td>
</tr>
<tr>
<td>Medium</td>
<td>59 (45.0)</td>
<td>18 (28.6)</td>
<td>77 (39.7)</td>
</tr>
<tr>
<td>High</td>
<td>4 (3.1)</td>
<td>3 (4.8)</td>
<td>7 (3.6)</td>
</tr>
<tr>
<td>Total</td>
<td>131 (100.0)</td>
<td>63 (100.0)</td>
<td>194 (100.0)</td>
</tr>
</tbody>
</table>

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

Highlights

- The Grade of Confidence (GoC) used for the WHO-UNICEF immunization coverage estimates (WUENIC) is a suboptimal measure, but the only currently available indicator to assess the quality of immunization coverage data from all Member States.
- Only 3.6% of the Member States were assigned a high GoC for DTP3 coverage data in 2012, while more than half (57%) had a low GoC.
- Seventy-seven (43%) Member States in 2012 had additional data supporting reported coverage estimates, with no contradictory estimates from any other source (i.e., medium or high GoCs).
1. Measles and rubella

Data availability and quality

Though 182/194 Member States conduct cases based surveillance and 149/194 reported laboratory-based surveillance data; reporting of data to regional and global levels varies. Some regions receive only aggregate data from Member States and furthermore Regions report only aggregate data to WHO HQ. Reporting is weekly in some regions and monthly in others, with monthly transmission to WHO HQ. Currently regions should send their case-based data to WHO HQ on a yearly basis. The goal, however, is to have weekly transmission of case-based data from Member States to the Regional Offices and on to WHO/HQ. With the adoption of a measles elimination goal in the SEAR, two large countries (total population approximately 1.5 billion) with inadequate surveillance systems are making plans to reach regional and international standards. India is planning to transition from outbreak-based to case-based surveillance with laboratory confirmation nationwide by 2015 and Indonesia is planning to extend laboratory testing to all suspected cases nationwide.

Data quality is difficult to assess with data currently reported to global level in aggregate format. Epidemiological and laboratory data are reported separately and often difficult to consolidate for the number of laboratory-confirmed cases and number of specimens tested. Without individual case reporting no direct linkage between cases and specimens is possible. At regional level, limited verification of case-based data revealed some inconsistencies or out-of-range data. Discussions with regional and country staff suggest that staff is not adequate in number or training to review and correct these issues at country or regional levels. More careful data quality checks and feedback to regions will be possible when they begin sending their case-based data to WHO HQ.
Results

The standard for epidemiological surveillance for measles and rubella is to conduct 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 have complete national coverage and have adequate sensitivity to detect any ongoing transmission. These surveillance data should be used to track and improve overall immunization programme performance. WHO and the SAGE Measles-Rubella working group have published descriptions of indicators and targets for tracking surveillance performance. (WER 8549 and 8809)

Surveillance for measles and rubella is steadily improving globally. Global surveillance has shown a reduction in measles cases, even as surveillance has become more sensitive in more Member States with an increase in laboratory confirmation through the WHO Measles and Rubella Laboratory Network. Between 2000 and 2011, the number of Member States reporting measles surveillance data to WHO annually increased from 169 (88%) to 188 (97%). Between 2004 and 2011, the number of Member States that conduct case-based surveillance, including laboratory confirmation, increased from 120 (62%) to 183 (94%), leaving 11 Member States still to implement laboratory-confirmed measles surveillance nation-wide. From 2000 to 2011, the number of countries with access to standardized quality-controlled measles testing by the WHO Measles and Rubella Laboratory Network increased from 71 (37%) to 191 (98%).

The WHO Global Measles and Rubella Laboratory Network includes 698 laboratories organized in a tiered structure that provides diagnostic and virus 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-based surveillance needs to be scaled up in some large Member States (e.g., India and Indonesia), which have recently adopted a measles elimination goal. 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 in the European region with elimination goals are not reporting measles and rubella case-based data to WHO. In 2013, only 42 of the 53 countries in EUR (79%) are reporting case-based data for measles to WHO and 34 (64%) are reporting such data for rubella. Guidelines are being developed for establishing sentinel CRS surveillance, and the capacity for technical assistance is being expanded through training for regional and country WHO focal points and for 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 for a greater focus on this critical component of the programme. There is a need for updated guidance and standard procedures for conducting reviews of integrated vaccine-preventable disease surveillance. In addition, there is the opportunity and expectation that measles-rubella surveillance will assume some of the costs of maintaining the AFP surveillance network (e.g. surveillance officer salaries).

Financial and human resources to conduct country-wide, case-based surveillance with laboratory confirmation of cases remain inadequate. Filling the resource gaps will require stronger commitments and contributions from the Member States, without which the verification of measles elimination may be in jeopardy due to the inability of Member States to meet the surveillance quality indicators.

Highlights

- Of the 194 Member States, 188 (97%) have established measles case-based surveillance and 191 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, which may put verification of measles and rubella elimination in jeopardy.

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43 This summary is taken from the 2012 Measles & Rubella Initiative (M&RI) annual report (see in Reference list at the end of this section. Tables summarizing the reported cases and incidence rates for measles, rubella and CRS are shown in the chapter on Goal 2, Indicators 2.2 and 2.3.)
References


2. Invasive bacterial vaccine-preventable diseases and rotavirus

Data availability and quality

Information on case-based surveillance for IB-VPDs and rotavirus come from two sources: 1) data reported annually through the WHO-UNICEF JRF; and 2) data reported by sentinel sites participating in a WHO-coordinated surveillance network.

The WHO-UNICEF Joint Reporting Form

The current JRF requests information on the presence of surveillance systems for rotavirus and IB-VPD 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
2. “Is there a surveillance system for rotavirus diarrhoea, in which cases are confirmed by laboratory, and surveillance data can provide information to allow evaluation of the impact of vaccination against rotavirus?”

Responses to these questions provide information on 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 a WHO-coordinated surveillance network currently do not report surveillance data to WHO.

Several high- or middle-income countries have not reported on this indicator in the JRF. These include the USA and Canada, which publish reports on incidence of rotavirus and invasive bacterial diseases prior to and after the introduction of vaccines targeting these diseases. 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 on the JRF that they did not conduct surveillance (as described in the Results section below). In countries that do not participate in the WHO-coordinated surveillance, it is difficult to verify their responses on the JRF.

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. The surveillance focuses primarily on children < 5 years of 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 and laboratory methods and report data to the respective WHO regional offices monthly or quarterly. The regional data are consolidated every six months into a global database and global surveillance bulletins are published every six months. Member states participating in this network are mainly low- and middle-income countries that receive direct technical assistance from WHO. GAVI-eligible countries also receive financial support for establishing case-based surveillance for these diseases.
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 the quality of their surveillance.

**Results**

According to data from the joint reporting forms (JRFs), 129 Member States (67%) reported having a case-based surveillance system, including laboratory confirmation of cases, in place in 2012 for invasive bacterial diseases. Forty-three countries (22%) reported not having a surveillance system for these diseases, while 22 countries (11%) did not respond to this question or said that it wasn’t applicable. Of the 129 countries that reported having case-based surveillance for IB-VPDs, 66 provided the data to WHO in 2012 (Figure 16 and Table 26). However, seven of these countries did not respond affirmatively to this question on the JRF.

**Figure 16: Member states that reported data to the WHO-Coordinated Invasive Bacterial Vaccine Preventable Diseases (IB-VPD) Surveillance Network for 2012**

Data from the JRF show that 101 countries (52%) reported having a surveillance system for rotavirus diarrhoea with suspect cases confirmed by laboratory testing. Seventy-one Member States (37%) reported that they did not have rotavirus surveillance and 22 (11%) did not respond or said the question wasn’t applicable. Of the 101 Member States that reported having rotavirus surveillance in place, 60 – all low- and middle-income – provided their surveillance data to WHO in 2012 (Figure 17 and Table 26). However, among these 60, seven did not report having surveillance on the JRF or didn’t respond the question.
Figure 17: Member states that reported data to the WHO-Coordinated Global Rotavirus Surveillance Network for 2012

A breakdown of Member States reporting having sentinel site surveillance for IB-VPDs and rotavirus on the JRF is shown by WHO region and by income level in Table 27 and Table 28, respectively. Among low-income countries, 20 (56%) reported conducting rotavirus surveillance and 26 (72%) reported conducting IB-VPD surveillance (Table 28). The figures were highest for GAVI-eligible countries, which receive financial support to set up disease surveillance. Overall, of the world’s 137 low- and middle-income countries, 91 (66%) reported conducting IB-VPD surveillance and 77 (56%) reported conducting rotavirus surveillance. In light of the incomplete and inconsistent reporting through the JRF, these data are difficult to interpret and comparisons between regions may not be appropriate.
**Table 27:** Member States reporting on the JRF that they conduct sentinel site surveillance for rotavirus diarrhoea and IB-VPD, by WHO region

<table>
<thead>
<tr>
<th>WHO Region</th>
<th>Total no. of Member States</th>
<th>No. (%) of Member States with rotavirus surveillance</th>
<th>No. (%) of Member States with IB-VPD surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFR</td>
<td>46</td>
<td>28 (61%)</td>
<td>35 (77%)</td>
</tr>
<tr>
<td>AMR</td>
<td>35</td>
<td>23 (66%)</td>
<td>25 (71%)</td>
</tr>
<tr>
<td>EMR</td>
<td>22</td>
<td>14 (64%)</td>
<td>15 (68%)</td>
</tr>
<tr>
<td>EUR</td>
<td>53</td>
<td>23 (43%)</td>
<td>35 (66%)</td>
</tr>
<tr>
<td>SEAR</td>
<td>11</td>
<td>3 (27%)</td>
<td>5 (45%)</td>
</tr>
<tr>
<td>WPR</td>
<td>27</td>
<td>10 (37%)</td>
<td>14 (52%)</td>
</tr>
<tr>
<td>Total</td>
<td>194</td>
<td>101 (52%)</td>
<td>129 (66%)</td>
</tr>
</tbody>
</table>

**Table 28:** Member States in each income category reporting that they conduct sentinel site surveillance for rotavirus diarrhoea and IB-VPD

<table>
<thead>
<tr>
<th>Income category</th>
<th>Total no. of Member States</th>
<th>No. (%) with rotavirus surveillance</th>
<th>No. (%) with IB-VPD surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-income</td>
<td>36</td>
<td>20 (56%)</td>
<td>26 (72%)</td>
</tr>
<tr>
<td>Middle-income</td>
<td>101</td>
<td>57 (56%)</td>
<td>65 (64%)</td>
</tr>
<tr>
<td>GAVI-eligible*</td>
<td>73</td>
<td>47 (64%)</td>
<td>52 (71%)</td>
</tr>
</tbody>
</table>

* Includes the GAVI countries that are graduating from GAVI support.

While these data indicate that there is ongoing surveillance for diseases targeted by new vaccines in many countries, the nature and quality of the surveillance in a large number of low- and middle-income countries that do not participate in the WHO-coordinated surveillance network is unknown. While resources exist to support GAVI-eligible countries to assess and improve surveillance quality, existing resources will not allow support for and quality assessment of surveillance in the remaining middle-income countries.

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 quality assurance procedures have only been recently fully established. At the same time, with an increasing number of low- and middle-income 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 suitable to meet the evolving needs and to inform measures that may be taken to further improve the two sentinel surveillance networks, WHO launched a strategic review of the two sentinel hospital surveillance networks under the guidance of a technical advisory group. The objectives of this review are to:

1) assess whether and to what extent the original objectives of the surveillance network have been met,
2) critically assess whether the current surveillance strategy is suitable to meet the evolving surveillance objectives and specifically, to determine whether and how the surveillance may be used to document the impact of vaccination. The review is being conducted by an independent group of experts and the results will be presented to the SAGE in November 2013.
Highlights

• Globally, 129 (67%) Member States – including 91 low- and middle-income countries – reported having an IB-VPD case-based surveillance system in place, using laboratory confirmation of cases, on the most recent JRF, and 66 countries provided IB-VPD surveillance data to WHO in 2012.

• For rotavirus, 101 (52%) of countries, 77 of them low- and middle-income, have such a system in place, with 60 providing data to WHO in 2012.

• The wording of this indicator does not include 'laboratory-confirmation' of cases. Including this phrase in SO Indicator 4.4 would be important to ensure that reliable high-quality data are produced and to strengthen global laboratory capacity to conduct 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 the quality of disease surveillance in the remaining countries.

• The combined technical and logistical advances in immunization 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

A note on defining vaccines of “assured quality”

WHO defines a vaccine of assured quality as one that consistently meets appropriate levels of purity, potency, safety and efficacy, as judged through an independent review system competent to make an evidence-based decision on the product for a specific 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. This definition therefore depends on the existence of a competent and functional regulatory authority (NRA) to regulate the product, as assessed by an external expert team using widely-agreed indicators. This definition also indicates clear pathways to improve vaccine quality by strengthening national regulatory authorities, which WHO is actively engaged in doing. Only vaccines of assured quality should be considered for use in national immunization programmes.

At the end of 2012 there were 44 vaccine-producing Member States. Manufacturers in these Member States, through exports, supply all other 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 assess whether a vaccine already approved by a functional NRA is suitable for procurement by the UN for use in target populations (typically in high disease burden settings) outside of the producing country. The list of prequalified vaccines, published on the WHO Website, is also used by a third group of Member States – self-procuring countries – to find sources of vaccines of assured quality.

The indicator for this Strategic Objective is thus defined as the proportion of vaccine doses used worldwide that are either directly regulated by a functional NRA or are prequalified by WHO. Therefore, in reporting progress against this indicator, we look at the number of prequalified vaccines that are suitable for use, through UN procurement, in high disease burden Member States, the number of vaccine-producing countries with fully-functional NRAs, as well as the proportion of the global population that is directly provided with regulatory oversight by a functional NRA, as assessed by WHO.
Data sources, availability and quality

Information on the number of prequalified vaccines comes from a database maintained by the WHO Vaccine Prequalification Secretariat, which publishes the list of prequalified vaccines on its website. Information on the percentage of doses of assured quality comes from the WHO-UNICEF JRF, and is correlated with national immunization coverage data for each country, as well as data from routine NRA assessments conducted by WHO in Member States.

WHO conducts a systematic review and analysis twice a year of the number of doses of assured quality. To assess the quality of the data, WHO gathers additional information from manufacturers, NRAs and national control laboratories (NCLs), and national immunization programmes on: 1) vaccines produced by manufacturers; 2) vaccines released by the NRA/NCL; 3) vaccines procured; 4) vaccines distributed to the programme; 5) vaccines used (including wastage rate); and 6) vaccines administered (doses effectively used to vaccinate each targeted population).

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

Results

As of the end of 2012, there were a total of 125 vaccine products prequalified by WHO (Table 29). This is a 13% increase since 2010, when 111 vaccines were prequalified. There were several quality issues identified in 2012 both with bulk and finished products that affected the global supply of prequalified pentavalent vaccines. In addition, future security of the supply of MMR vaccines will be affected by the decision of one manufacturer to stop making the mumps component. Supply of this MMR vaccine will continue until 2015 when the supply of already produced bulk vaccine is likely to be exhausted.

As of July 2013, 35 of the 44 Member States that produce vaccines (80%) had fully functional NRAs, as assessed by WHO (Figure 18). Twenty-three of these Member States were producing one or more WHO prequalified vaccines by the end of 2012. In terms of global population, 68% (4.7 billion people) live in the 60 countries – both vaccine-producing and non-producing – where there is direct oversight by a functional NRA (Figure 19). However, even in the remaining countries without functional NRAs where 32% of the world’s population lives, they have access to WHO prequalified vaccines.

### Table 29: Number of vaccines prequalified by WHO in 2010 and 2012

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>2010</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>DTwP</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Measles</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>MR</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>MMR</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>DTwP-Hepatitis B-Hib*</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>DTwP-Hepatitis B+Hib**</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Pneumococcal conjugate</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>HPV</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Other vaccines</td>
<td>83</td>
<td>94</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>111</td>
<td>125</td>
</tr>
</tbody>
</table>

* Fully liquid vaccine
** Lyophilized Hib vaccine reconstituted with liquid DTP-HepB vaccine

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48 www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/
Figure 18: Number and percent of Members States (vaccine producing and non-producing) by the functionality of their NRAs in 2012

![Bar chart showing the number and percent of Members States (vaccine producing and non-producing) by the functionality of their NRAs in 2012.]

Figure 19: Proportion of the global population living in countries with functional regulatory oversight for vaccines

![Bar chart showing the proportion of the global population living in countries with functional regulatory oversight for vaccines.]

Overall, 97% of the global doses of vaccines used in national immunization programmes are of assured quality (Figure 20). This is well on the way to meeting the target of 100% of vaccine doses used by national immunization programmes are of assured quality by 2020.
Monitoring progress towards GVAP goals and strategic objectives

Figure 20: Percentage of assured (dark blue) vs. non-assured (light blue) quality vaccines used worldwide, 1997-2012

Since 2009, India and China – two Member States with large populations and large capacity to produce different types of vaccines – have accelerated their efforts to strengthen their regulatory oversight for vaccines. India – one of the world’s major suppliers of prequalified vaccines – already had a functional NRA by this time. China’s NRA became functional in early 2011. This country thus now has a great potential to become another major supplier of prequalified vaccines. Continuous efforts by these two Member States to meet the highest quality standards have been documented and reflect major commitments by their respective governments. This commitment has involved a massive recruitment of regulatory staff and substantially increased budgets (totaling US$ 500 million to US$ 1 billion in each country) between 2008 and 2012. Moreover, each of these governments has committed additional support for their NRAs in their national five-year strategic plans.

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.

Given the permanent changes in the vaccine market profile, and increased investments from major pharmaceutical companies to build vaccine plants in developing emerging markets, there is a risk of investments in vaccine production taking place in Member States where there is no, or a poorly functional, regulatory system. In order to reduce that risk, WHO has classified Member States into three categories by risk of vaccine quality:

a. high-risk countries that produce prequalified vaccines, 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 countries where continuous monitoring is expected every 2-5 years, although they do not produce prequalified vaccines, and
c. low-risk countries, which are countries that do not produce prequalified vaccines and are not major vaccine suppliers to national immunization programmes, and where regulatory oversight should be monitored every five to seven years.
Highlights

- Ninety-seven percent of the total vaccine doses used globally as of December 2012 is of assured quality.
- The number of prequalified vaccines has grown by 13% from the GVAP baseline in 2010.
- Continuity of the supply of key prequalified vaccines (e.g. DTP-hepB-Hib pentavalent vaccines) has been problematic, leading to vaccine shortages in some Member States.
- All vaccines used by national immunization programmes are produced in 44 Member States, of which 35 have a functional regulatory system, as monitored by WHO.
- Major vaccine suppliers, China and India, have maintained their regulatory oversight for vaccines at a functional level to ensure vaccine quality.
Vaccine pricing report

Executive summary

The price of vaccines, especially for the new and under-utilized vaccines, is an important determinant of their introduction and sustained use in low- and middle-income countries. However, prices for the same vaccine can vary significantly between countries, despite substantial price reductions for several vaccines in recent years. There are currently limited sources of data available to monitor vaccine prices, particularly outside of the pooled procurement mechanisms for vaccines run by PAHO and UNICEF.

Given the importance of vaccine price on their uptake, it was recommended that the annual report to the World Health Assembly on GVAP progress include a "Vaccine price indicator". The purpose of this indicator is to facilitate global dialogue with partners and countries on the issue of vaccine pricing and to promote improved availability and quality of information on vaccine prices. Monitoring vaccine prices and developing activities to optimise and facilitate vaccine affordability, supply security and sustainability in all countries will provide a measure of success of the GVAP.

To develop this indicator, a Working Group was formed, which held discussions with partners and other stakeholders to reach a consensus on a methodology for monitoring vaccine prices and on the contents of this and future vaccine pricing reports as part of the overall GVAP annual progress report. Because of the complexities of the vaccine market, it was decided to initially monitor the prices of several vaccines and report the results in a narrative report, instead of developing a single vaccine price indicator. The Working Group decided to monitor vaccine prices over time for five key vaccines – inactivated polio vaccine (IPV), DTwP-HebB-Hib pentavalent vaccine, pneumococcal conjugate vaccine (PCV), rotavirus vaccine and human papillomavirus (HPV) vaccine – for all low- and middle-income countries, using a matrix that groups countries by procurement method (e.g., UNICEF, PAHO, self-procuring) and GAVI-eligibility. Prices for measles-containing vaccines may also be added to the matrix.

This report notes that vaccine pricing is dependent on the market conditions (e.g., supply costs and demand dynamics), as well as on stakeholder and supplier strategies and practices (e.g., procurement mechanisms, funding mechanisms and product characteristics and preferences). However, there has been substantive progress in the availability and transparency of pricing data from both PAHO and UNICEF in recent years, with the publication of historical and current prices. The PAHO Revolving Fund publishes weighted average prices (WAP) for its Member States each year and actual prices for some sole-source vaccines. The UNICEF Supply Division publishes awarded prices under established Long Term Arrangements (LTA), which largely cover low-income and some middle-income countries. In the future, UNICEF will also publish awarded prices following a tender, albeit outside of the LTA framework, including for middle-income countries.

The biggest gap in data on vaccine prices remains for non-GAVI, non-UNICEF and non-PAHO middle-income countries. More than 45 middle-income countries are currently self-procuring some vaccines and are not eligible for GAVI support or pricing. Considerable inconsistencies and ambiguities in pricing policies and practices remain for different groups of countries (e.g. GAVI-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.

As more comparable data are collected and collated over the decade, greater transparency will be possible. This should improve future reporting on vaccine prices and allow more discernible trends and impacts to be evaluated.
1. The importance of vaccine prices

Vaccine prices are one of the main drivers of immunization costs. They have been roughly estimated to comprise up to 50% of the total cost of implementing the GVAP, and are becoming the largest proportion of costs for national immunization programmes. The price of vaccines, especially for the new or underutilized vaccines, is an important determinant of whether or not they are introduced and their use sustained in low- and middle-income countries. Vaccine prices are therefore one of the key obstacles to the introduction of new vaccines by middle-income countries that are not supported by donors. The sustainability of providing new vaccines in countries graduating from GAVI support has been identified as a major concern as more countries move into this category and may have to pay considerably higher prices through government procurement. The GAVI Alliance has secured a certain level of commitment from some suppliers to allow graduating countries to access GAVI prices through the UNICEF Supply Division for certain periods of time (see Table 30).

2. Context and purpose of this report

Establishment of a Working Group to monitor vaccine price trends

Given the importance of vaccine price on their uptake, the 66th World Health Assembly (WHA) in May 2013 recommended that the annual GVAP progress report to the World Health Assembly include a “Vaccine price indicator”. To quote the WHA report: “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.” The purpose of this indicator was to facilitate global dialogue with partners and countries on the issue of vaccine pricing and to promote improved availability and quality of information on vaccine prices. Monitoring vaccine prices 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.

As a result of this recommendation, a Working Group on the GVAP Price Indicator was established to determine the scope and contents of the annual report on vaccine pricing and to propose possible indicators that may be used to track vaccine prices. The Working Group included representatives from WHO, UNICEF, GAVI Secretariat, PAHO, Médecins Sans Frontières (MSF) 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 that WHO has been implementing since 2011.

The Working Group on the GVAP Price Indicator was specifically asked to provide advice on:

- An approach and methodology for monitoring and reporting on vaccine prices, including which vaccines, countries and data sources should be included;
- A list of specific priority areas to be addressed in annual reports;
- How to strengthen and improve the availability of vaccine price data; and
- Potential dissemination and use of the vaccine price data in these reports to facilitate global and country-level dialogue on vaccine development and access.

The Working Group and partners concluded that because of the complexities of the vaccine market – where the price of the same vaccine may vary considerably between countries, depending on market conditions (production costs, demand) and purchasing and procurement strategies (such as pooled procurement mechanisms, funding and contracting conditions) – coupled with a paucity of data, it would be difficult to find a single indicator at this point in time to reflect pricing trends. Instead, the group decided to start by preparing a narrative report on vaccine pricing trends. From this first narrative report, one or more indicators that would facilitate tracking of vaccine prices could be identified and considered for future reports.
Working Group recommendations

All partners in the Working Group agreed on the importance of including a price indicator in the GVAP monitoring, evaluation and accountability framework. The group also concluded that:

- A country matrix of vaccine prices that includes all low- and middle-income countries – sub-grouped by GAVI eligibility and procurement method – should be developed and included in the GVAP annual report;
- The selection of the vaccines to include in the matrix should take into account their reflection of GVAP’s goals and both the current and proposed priorities throughout the GVAP time period;
- Current sources of vaccine price data are: a) UNICEF actual prices for low-income and GAVI-eligible countries, and b) PAHO’s weighted average prices (WAP) for Member States participating in the PAHO Revolving Fund;
- Possible sources of price data for Member States that do not procure vaccines through UNICEF/GAVI or PAHO – including the 45 or more partially or fully self-procuring middle-income countries – could include initiatives such as the WHO V3P project, the WHO-UNICEF joint reporting forms (JRF) and partners such as MSF;
- The price data points for the matrix should include manufacturers’ prices at the point of export for each vaccine and presentation for each sub-group of countries (including lowest and highest UNICEF prices and PAHO weighted average prices), with a baseline set at 2010. Where possible, price trends should start from 2001 – the start of GAVI support;
- A discussion of the context and complexity of vaccine pricing should be included in the annual report, including vaccine market information (both supply and demand) for each vaccine and the sources and mechanisms of financing, since they all affect pricing;
- In future, when data becomes available from countries outside of the pooled procurement mechanisms, it will be important to contextualize these data to allow for greater comparability in vaccine prices between countries and to minimize misinterpretation and simplification. This could require more complex calculations and indicators.

The agreed upon structure and data sources for the country matrix of vaccine prices to be included in the annual pricing report to GVAP is shown in Table 30.

### Table 30: Proposed country matrix of vaccine price data and current data availability

<table>
<thead>
<tr>
<th>Country Groups</th>
<th>Publically available price data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-income countries</td>
<td></td>
</tr>
<tr>
<td>UNICEF/GAVI</td>
<td>Low/High* and weighted average prices (WAP)</td>
</tr>
<tr>
<td>PAHO</td>
<td>WAP or actual price for sole-source supply</td>
</tr>
<tr>
<td>Self-Procuring</td>
<td>No data or very limited and partial on country websites. No information publicly available in comparable form</td>
</tr>
<tr>
<td>Middle-income countries</td>
<td></td>
</tr>
<tr>
<td>UNICEF/GAVI Graduating/Graduated</td>
<td>Low/High and WAP</td>
</tr>
<tr>
<td>UNICEF Non-GAVI</td>
<td>Limited, details not currently published</td>
</tr>
<tr>
<td>PAHO**</td>
<td>WAP or actual price for sole-source supply</td>
</tr>
<tr>
<td>Self-Procuring</td>
<td>No data or very limited and partial on country websites. No information publicly available in comparable form</td>
</tr>
</tbody>
</table>

* Low and high refer to the lowest and highest price from individual suppliers for the vaccine.
** While the matrix separates country-income groups by World Bank Income Status, PAHO does not differentiate pricing using this method. Therefore, PAHO prices will be indicated as one price for both low- and middle-income country groups.
The Working Group also proposed that the vaccine pricing reports include a discussion of the following priority areas:

- Challenging market dynamics on the supply or demand side for specific vaccines;
- Prices paid in middle-income countries, especially self-procuring, non-GAVI eligible countries;
- Financing impacts: the role of development partners in affecting prices, such as GAVI market shaping activities and strategic goals in reducing PAHO weighted average prices (WAP);
- The role of pooled procurement on vaccine supply and on price changes;
- The impact on vaccine prices of initiatives, such as Advanced Market Commitments (AMC) for pneumococcal conjugate vaccine, UNICEF’s efforts to issue tenders for middle-income countries and WHO’s V3P project;
- The impact of vaccine manufacturers from developing countries (“emerging producers”) on vaccine supply and pricing;
- The impact on vaccine access and prices of new supply strategies for low- and middle-income countries developed by some multi-national pharmaceutical companies, including increased price transparency;
- Ability of the purchaser to influence prices through new contracting and financing strategies.

Vaccines to be included in the annual report of vaccine price trends

The Working Group on the GVAP Price Indicator selected the following five vaccines to include in the first narrative report, in consideration of their public health impact, especially on mortality in children under five, and on their contribution to the GVAP goals and strategic objectives:

1. Inactivated polio vaccine (IPV) (contributing to Goal 1 to achieve a world free of poliomyelitis and recognizing the potential changes in the polio vaccine market during the course of the decade);
2. Pentavalent vaccine (DTP-HepB-Hib) (contributing to Goal 5 to reduce child mortality);
3. Pneumococcal conjugate vaccine (PCV) (contributing to Goal 4 to introduce new vaccines and Goal 5 to reduce child mortality);
4. Rotavirus vaccine (contributing to both Goals 4 and 5);
5. Human Papillomavirus (HPV) vaccine (contributing to Goals 4 and 5, as well as to Strategic Objective 3, which includes expanding the traditional target population for immunization).

The Working Group also discussed whether or not to include measles or measles-containing vaccines (e.g., measles-rubella (MR) and measles-mumps-rubella (MMR)) in the GVAP price tracking efforts. While not included in this initial report, there was discussion of possibly including them in future reports for following reasons:

- Measles and rubella are targeted for elimination in five of the 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 the single-antigen measles vaccine to MR vaccine (in GAVI-eligible countries) and to MMR vaccine in all other countries (e.g., PAHO countries);
- Currently the MR and MMR vaccine supply situation is tenuous, due to the small number of prequalified MR/MMR vaccines at present. There is only one prequalified MR vaccine (made by Serum Institute of India (SII)) and only four prequalified MMR vaccines (made by SII, Sanofi, GSK and MSD); however only SII and Sanofi provide the vaccine in 10 dose vials;
- With limited competition in the medium term, there is potential for significant price increases for MR and MMR vaccines, which will increase the cost of reaching the GVAP goals of eliminating measles and rubella;
- Tracking MR and MMR vaccine prices may be a good way to prevent and manage any significant price increases.

Vaccines of regional importance, such as yellow fever, Japanese encephalitis (JE) and typhoid, were also proposed, but the group felt that inclusion of these vaccines in future reports should be discussed with the DoV-GVAP Working Group that reports to the SAGE.

This first annual report on vaccine pricing provides an overview of the importance of vaccine pricing in the global context for both low- and middle-income countries. It summarises some of the complexities of pricing and price comparisons, the gaps in currently-available information, and possible improvements and further actions required in this area through the DoV and GVAP. The report also includes short reports on the current situation regarding PAHO and UNICEF pricing and supply for each of the five focus vaccines.
3. The complexity of the vaccine market and pricing

The vaccine market is quite unique, with distinct features that increase the complexity of assessing and understanding vaccine pricing and its context. The vaccine market is made up of individual markets (for each vaccine), each with their own specific characteristics, particularly on the supply side. Key features of the overall vaccine market include the following:

- Vaccines are biological products, manufactured in a highly-regulated environment to ensure quality, and are vulnerable to supply failure, such as production failures or breaks in the cold chain;
- Vaccine manufacturing is a high-risk business characterized by high production costs and large capital investment requirements, long production cycles, and extreme vulnerability to demand fluctuations. These risks contribute to the overall price of a vaccine;
- Vaccines are administered to otherwise healthy individuals. Therefore, quality and safety are of utmost importance and risk aversion is, appropriately, very high;
- 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 (with few producers) either by product or presentation. “Parallel monopoly” markets – in which two different products that are not directly interchangeable are competing for the same market (e.g., the two-dose and three-dose rotavirus vaccines) – are a particular feature of many of the new vaccines;
- Vaccines are predominantly funded by governments and development partners rather than by individuals, especially for the majority of populations living in low- and middle-income countries;
- The vaccine market is relatively small when compared to total pharmaceutical sales – making up between 2% and 3% of the global pharmaceutical market – but it has a rapid annual growth. The vaccine market has increased nearly five times 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 approximately 80% of the global market. Vaccine production is thus becoming a profitable and promising niche for the pharmaceutical industry, attracting an increasing number of large multi-national manufacturers;
- Traditional vaccines are often provided to different countries in different presentations. There are significant distinctions (market divergence) between the vaccines provided to high-income countries and those provided to countries supported by development partners (e.g., GAVI), as well as those used in most middle-income countries. However, some of the new vaccines (i.e., same products) are being introduced in GAVI-supported countries at almost the same time as they are being introduced in high-income countries – a sign of market convergence;
- There are two large pooled purchasers of vaccines, with the UNICEF Supply Division procuring some or all vaccines on behalf of up to 100 countries each year and the PAHO Revolving Fund procuring vaccines for around 40 Member States. Both organizations share many common strategies and features but differ in some specific principles and practices;
- Some manufacturers and development partners, such as GAVI and UNICEF, support the concept of “tiered pricing” for vaccines, in which the lowest price is provided to low-income countries and those supported by development partners;
- Emerging market vaccine manufacturers (i.e., from developing countries) play an important role in meeting the global vaccine demand, particularly for traditional and under-utilized vaccines; in lowering vaccine prices; and in increasing production capacity, including through arrangements with multi-national manufacturers. The use of pricing structures such a tiered pricing among these emerging manufacturers is somewhat limited;
- In many individual vaccine markets, there is a tenuous balance between demand and available supply, which requires constant management and communication. In some cases, self-procuring countries are essentially competing for the limited supply with the large procuring entities, such as UNICEF and PAHO.

Vaccine pricing is consequently influenced by a number of factors on both the demand and the supply side of the market. On the demand side, these factors include the burden of disease; the size of the target population and accuracy of demand forecasts; vaccine presentation and formulation preferences, sources of funding; the regulatory process; procurement mechanisms and processes; and transaction costs. On the supply side, some of the many factors influencing price – in addition to market access strategies of individual suppliers – include the production technology and capacity; product characteristics that affect the cost of production; the availability of supply; the level of competition; the predictability of demand and funding; and the influence of purchasers and global health initiatives.

A Pricing Policy Paper from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) in 2008 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.54

Vaccine pricing has become increasingly more complex for all stakeholders, making it more and more difficult to compare prices across countries. There has been a shift from annual standard transactional procurement to more complex and longer-term procurement and financial arrangements. Global examples include the Advance Market Commitment (AMC) for Pneumococcal Vaccine, GSK’s recent price-volume agreement with UNICEF for rotavirus vaccine55, and more recently the HPV price commitments with UNICEF for GAVI-eligible countries. Even for a few of the older traditional vaccines, some strategies, such as multi-year contracts, have been employed to secure supply, but at the same time, this makes the understanding of prices and contractual terms less evident. Development partners, civil society organizations, manufacturers, procurement partners and Member States are often pursuing different and sometimes conflicting objectives regarding the pricing of vaccines.

Some confidential contractual arrangements – such as bundling, discounts, rebates, assured volumes, and contracted price change triggers56 – are considered important to the industry for commercial reasons. These provisions are designed to secure better pricing and supply, but at the same time they result in complicated contracts that can further mask the actual price of the vaccines. In addition, while the published prices that UNICEF and PAHO negotiate with suppliers apply equally to eligible countries or donors (except for shipping and related costs beyond the port of export), pricing and contracting for individual countries procuring vaccines on their own can be more complex. Individual country prices can include international and domestic transport, insurance, storage, taxes, duties and other supply chain costs. Some countries may also include other goods and services in the vaccine supply contract – such as the provision of cold chain equipment, training of country staff, surveillance system support, and promotional and advocacy materials – which are then reflected in the price. Therefore, direct price comparisons between two procurement systems – such as between the UNICEF Supply Division and the PAHO Revolving Fund, between UNICEF and a self-procuring country or between PAHO and a self-procuring country – requires more in-depth knowledge of the context, procurement systems and actual practices for each reported contractual price.

The complexities of comparing vaccine pricing from different sources makes it challenging to report vaccine pricing and trends. As more comparable data are collected and collated in the coming years, greater transparency will be possible. This should improve annual reporting of vaccine pricing and allow more discernible trends and impacts to be evaluated.

4. Current and future vaccine price data and information sources

The two main sources of currently available published data on vaccine pricing are the UNICEF Supply Division and the PAHO Revolving Fund for vaccines purchased through these two pooled procurement mechanisms. There has been considerable progress made at PAHO and UNICEF in recent years in making vaccine price data publically available.

UNICEF price information

UNICEF publishes the supplier-specific awarded price per dose, product, and calendar year, based on multi-year long-term arrangements (LTAs). The country (or development partner) pays the actual contracted price for the particular product from that supplier (as opposed to WAPs that PAHO countries pay to the Revolving Fund). For specific, ad hoc requests, predominantly from middle-income countries, UNICEF issues individual tenders. To date, the organization has not published

prices awarded outside of established LTAs but is working to do so in the near future. In 2013, UNICEF issued pooled procurement tenders for three vaccines – pneumococcal, rotavirus and HPV vaccines – for middle-income countries not eligible for GAVI support, but the results of this initiative are yet to be announced.57

In addition, GAVI has secured pricing commitments from manufacturers for some vaccines for once countries graduate from GAVI support. Some of these commitments have already been realized through contracts with UNICEF, as the primary procurement agency for GAVI. Other commitments have been made outside of a formal procurement process. These commitments for GAVI-graduating countries are summarized in Table 31. In addition, Sanofi Pasteur and its affiliate, Shantha Biotech, have indicated they will offer GAVI prices for all GAVI vaccines that they supply to graduating countries through UNICEF.58

54 See: www.ifpsma.org.
55 The five-year contract with UNICEF will reduce the price of the GSK rotavirus vaccine to €3.76 per course for GAVI-supported countries.
56 For example, price reductions tied to a certain volume of purchases or to the length of the contract with the supplier.
57 Available at www.unicef.org/supply/index_67101.html.
58 www.gavialliance.org.
Some assurance has yet to be secured for certain products, such as HPV vaccine, which is currently excluded from the extension of the GAVI price to graduating countries. Since these negotiated prices do not currently include all vaccines and suppliers, GAVI graduating/graduated countries will remain a distinct group in the proposed country matrix of vaccine prices.

### Table 31: Published vaccine pricing commitments from suppliers for GAVI-graduating countries, as of July 2013

<table>
<thead>
<tr>
<th>Current GAVI Supported Vaccine</th>
<th>WHO Prequalified Suppliers</th>
<th>Published Graduating Country Price Commitment</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentavalent Vaccine (DTwPHePbHib)</td>
<td>Biological E</td>
<td>No published commitment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Crucell</td>
<td>Same price for GAVI-eligible countries if procured through UNICEF</td>
<td>Until 2020</td>
</tr>
<tr>
<td></td>
<td>GSK</td>
<td>No published commitment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LG Life Sciences</td>
<td>No published commitment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serum Institute of India</td>
<td>No published commitment</td>
<td></td>
</tr>
<tr>
<td>Pneumococcal Conjugate Vaccine (PCV)</td>
<td>Pfizer</td>
<td>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</td>
<td>Until at least 2020</td>
</tr>
<tr>
<td></td>
<td>GSK</td>
<td>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</td>
<td>Until at least 2020</td>
</tr>
<tr>
<td>Rotavirus Vaccine</td>
<td>GSK</td>
<td>Same price for all GAVI-eligible countries (€1.88) for graduated countries procuring through UNICEF that were approved for GAVI support for rotavirus prior to 2012</td>
<td>Under current contract until 2016</td>
</tr>
<tr>
<td></td>
<td>Merck</td>
<td>No published commitment</td>
<td></td>
</tr>
<tr>
<td>Human Papillomavirus Vaccine (HPV)</td>
<td>GSK</td>
<td>No published commitment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Merck</td>
<td>No published commitment</td>
<td></td>
</tr>
</tbody>
</table>

Source: GAVI Secretariat [www.gavialliance.org](http://www.gavialliance.org)

* See text for an explanation of tail price for the AMC.

### PAHO Revolving Fund price information

PAHO pricing is based on a weighted average price (WAP) for vaccines for which multiple suppliers are contracted (i.e., an average of the various prices from different suppliers). Countries pay the WAP and not the individual supplier price of the vaccine. For new vaccines, such as pneumococcal conjugate, rotavirus and HPV, with parallel monopoly markets (two distinct products competing for the same market), the price paid by PAHO Member States is the actual price for the specific vaccine/producer selected.

### Data on prices paid by self-procuring low- and middle-income countries

Outside of these two pooled procurement systems, there is limited comparable data available on prices paid by the approximately 45 self-procuring middle-income countries. Due to the complexity of comparing prices noted above, it is not sufficient to use any published data at face value, since they are not likely to be directly comparable with the published UNICEF and PAHO prices. While some trends in pricing could be extrapolated from some individual country data, these data do not normally indicate contractual or delivery terms, which may have changed over time.

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* [www.gavialliance.org](http://www.gavialliance.org)
Several initiatives have been launched to improve the transparency of vaccine prices, particularly for self-procuring countries, and to publish these data in a comparable format. The WHO Vaccine Product, Price and Procurement (V3P) project is currently piloting a mechanism which will allow countries to provide vaccine price 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 the components and contractual arrangements involved in the pricing. WHO is also investigating the use of the WHO-UNICEF joint reporting form (JRF) as a possible means for countries to report vaccine prices on an annual basis. While the comparability of this information across countries and years could be limited, it could nonetheless provide information on general trends in vaccine prices.

During the period of the Decade of Vaccines, it is anticipated that there would be further discussion and efforts to improve the availability of vaccine pricing data which would lead to more effective monitoring and targeted activities. Support from global partners is required to ensure that such activities are prioritized, funded and undertaken.

5. UNICEF and PAHO pricing and supply trends for vaccines to be included in the vaccine price matrix

Below is a brief summary of the UNICEF/PAHO market and price trends for the five vaccines that will be included in the proposed matrix. UNICEF and PAHO prices for these vaccines by country classification are shown in Table 32 for selected years from 2001 to 2013. There are a number of gaps to the matrix which subsequent reports will endeavor to fill.

### Table 32: Vaccine Price Table (Data Provided by UNICEF and PAHO) in US$*

<table>
<thead>
<tr>
<th>VACCINE AND MATRIX GROUP</th>
<th>PRESENTATION</th>
<th>YEAR AND PRICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAHO Actual – Low</td>
<td></td>
<td>2.906</td>
</tr>
<tr>
<td>PAHO Actual – High</td>
<td></td>
<td>4.146</td>
</tr>
<tr>
<td>PAHO WAP</td>
<td></td>
<td>4.50 5.50 5.98</td>
</tr>
<tr>
<td>UNICEF MIC - Actual Low</td>
<td></td>
<td>3.40 3.30</td>
</tr>
<tr>
<td>UNICEF MIC - Actual High</td>
<td></td>
<td>3.80 3.30</td>
</tr>
<tr>
<td>DTwP-HepB-Hib pentavalent vaccine</td>
<td></td>
<td>2001 2006 2010 2011 2012 2013</td>
</tr>
<tr>
<td>UNICEF/GAVI – Low</td>
<td>Liquid 1 dose</td>
<td>3.63 2.70 2.25 2.50 1.95</td>
</tr>
<tr>
<td></td>
<td>Lyo 2 dose</td>
<td>3.50 3.60 2.25 2.25 2.95 1.97</td>
</tr>
<tr>
<td></td>
<td>Liquid 10 dose</td>
<td>1.75 1.601 1.191</td>
</tr>
<tr>
<td>UNICEF/GAVI – High</td>
<td>Liquid 1 dose</td>
<td>- 3.63 3.20 3.20 3.20 2.70</td>
</tr>
<tr>
<td></td>
<td>Lyo 2 dose</td>
<td>3.50 3.601 2.95 2.95 2.95 2.95</td>
</tr>
<tr>
<td></td>
<td>Liquid 10 dose</td>
<td>2.111 2.111 2.111</td>
</tr>
<tr>
<td>PAHO WAP</td>
<td>Liquid 1 dose</td>
<td>3.30 3.19 2.99 2.85</td>
</tr>
<tr>
<td></td>
<td>Lyo 1 dose</td>
<td>3.50 3.99 3.20 2.95 2.88 2.52</td>
</tr>
<tr>
<td></td>
<td>Liquid 10 dose</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.20</td>
</tr>
<tr>
<td>UNICEF MIC Actual – Low</td>
<td>Unspecified Presentation</td>
<td>2.97 2.30</td>
</tr>
<tr>
<td>UNICEF MIC Actual – High</td>
<td>Unspecified Presentation</td>
<td>5.40 5.40</td>
</tr>
</tbody>
</table>

### VACCINE AND MATRIX GROUP PRESENTATION YEAR AND PRICE

<table>
<thead>
<tr>
<th>VACCINE AND MATRIX GROUP</th>
<th>PRESENTATION</th>
<th>YEAR AND PRICE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pneumococcal Conjugate Vaccine</strong></td>
<td></td>
<td>2001 2006 2010 2011 2012 2013</td>
</tr>
<tr>
<td>PAHO</td>
<td>PCV7</td>
<td>53.00 20.00</td>
</tr>
<tr>
<td></td>
<td>PCV13</td>
<td>16.34 15.84</td>
</tr>
<tr>
<td>AMC UNICEF</td>
<td>PCV10 or 13(^{3})</td>
<td>3.50 3.50 3.50</td>
</tr>
<tr>
<td>UNICEF MIC Actual (non AMC)</td>
<td>PCV10</td>
<td>19.00 16.00</td>
</tr>
<tr>
<td><strong>Human Papilloma Vaccine</strong></td>
<td></td>
<td>2001 2006 2010 2011 2012 2013</td>
</tr>
<tr>
<td>PAHO (Actual)</td>
<td>Bivalent</td>
<td>18.95 14.00 13.48 13.08</td>
</tr>
<tr>
<td></td>
<td>Quadrivalent</td>
<td>14.25 13.79</td>
</tr>
<tr>
<td>UNICEF/GAVI (Actual)</td>
<td>Bivalent (2-dose vial)</td>
<td>4.60</td>
</tr>
<tr>
<td></td>
<td>Quadrivalent</td>
<td>4.50</td>
</tr>
<tr>
<td><strong>Rotavirus Vaccine</strong></td>
<td></td>
<td>2001 2006 2010 2011 2012 2013</td>
</tr>
<tr>
<td>PAHO (Actual)</td>
<td>2-dose course</td>
<td>7.50 7.50 6.88 6.50</td>
</tr>
<tr>
<td></td>
<td>3 Dose Course</td>
<td>5.15 5.25 5.25 5.15</td>
</tr>
<tr>
<td>UNICEF/GAVI (Actual)</td>
<td>2 Dose Course</td>
<td>2.52(^{1,3}) 2.52(^{1,3})</td>
</tr>
<tr>
<td></td>
<td>3 Dose Course</td>
<td>5.00(^{2}) 5.00</td>
</tr>
</tbody>
</table>

**MIC = Middle-income country; WAP = Weighted average price; Lyo = lyophilized formulation**

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

“High” and “low” refer to the highest and lowest prices obtained from suppliers for each vaccine and presentation.

1 Unspecified special conditions Apply.  
2 The price consists of a co-payment (the Tail Price) of a maximum of USD 3.50 funded by a country or GAVI and a subsidy of the difference between USD 7.00 and the Tail Price funded by the donors of the Advance Market Commitment (AMC) (total price USD 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 ([www.gavialliance.org/funding/pneumococcal-amc/amc-legal-agreements/](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 USD 7.00 continues to apply.  
3 Price is contracted at €1.88 (converted to USD 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 USD 5.00.  
5 Price is based on Incoterms CPT – destinations in India  
6 Price of USD 2.90 is from a manufacturer in The Netherlands, USD 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.

### 5.1 Inactivated polio vaccine (IPV)

**Pooled procurement demand**

In the PAHO region, IPV is mostly supplied for high-risk groups. PAHO is procuring IPV for 17 Member States in 2013; only one 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 Figure 21 show an increase in the WAP from 2010 to 2012. The actual prices from the two PAHO suppliers for 2013 differ by 30%.
UNICEF is currently procuring very limited quantities of IPV (approximately 200,000 - 300,000 doses per year) for two middle-income countries. No low-income or GAVI-eligible country currently procures IPV. UNICEF issues an annual tender for this demand. The two price points provided by UNICEF for 2010 and 2012 show a 3% reduction in the lowest price and a 15% reduction in the highest price during this period.

The IPV market will likely change considerably in the course of the DoV due to the SAGE recommendation in 2012 for countries to introduce at least one dose of IPV into their routine schedule, as part of the polio eradication endgame strategy. This recommendation, along with potential GAVI support to implement it, significantly increase demand for IPV. Demand may also increase for combination vaccines containing IPV (e.g., DTP-HebB-Hib-IPV, particularly in middle-income countries. It is proposed to include these newer combination vaccines in the GVAP price Indicator as they become available.

### Supply considerations

There are currently four manufacturers with pre-qualified products, and an additional manufacturer is expected to have a WHO-prequalified IPV in single- and multi-dose vial presentations by early 2014. However, one manufacturer has recently had its production suspended by WHO and there is no information on when production will start again. In 2013 PAHO has contracts with two IPV suppliers. While the total quantity requested annually has been fulfilled, delays from manufacturers have occurred. The timely supply of IPV is therefore fragile.

5.2 Pentavalent vaccine (DTeP-HepB-Hib)

#### Pooled procurement demand

PAHO predominantly procures the liquid single-dose presentation of pentavalent. In 2001 and 2006 only one supplier of this presentation was available, but since 2010 three suppliers have been under contract. A price is publicly available for the 10-dose presentation, since it was requested by only one Member State in 2013, but procurement has yet to occur. Market preference has shifted from the original lyophilized formulation to the liquid formulation and thus only a few small islands in the Caribbean are still procuring the lyophilized version through the PAHO Revolving Fund.

Pentavalent vaccine is now used in almost all GAVI-supported countries and is continuing to be introduced in middle-income countries that procure through UNICEF. UNICEF procures 1-dose, 2-dose and 10-dose presentations in both liquid and lyophilized forms. The demand is largely for fully liquid vaccine, with 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 were for nine non-GAVI-supported countries. By 2012, UNICEF procurement for pentavalent had jumped to 171 million doses for 72 countries (162 million doses for 62 GAVI-supported countries and 9 million doses for 10 non-GAVI countries). The demand for pentavalent vaccine from GAVI-supported countries through UNICEF is now stabilizing to around 200 million doses per year, while the annual demand for non-GAVI-supported countries through UNICEF
Procurement Services has fluctuated and is now approximately 10-15 million doses.

The price per dose for pentavalent vaccines is on the whole decreasing due to increased competition, especially from emerging market manufacturers, and the active support of donors (see Figure 22 and Figure 23). The 10-dose presentation has the lowest price per dose (down to a little over $1.00 for the low UNICEF/GAVI price for 10-dose liquid presentation). The differential between the highest and lowest price for non-GAVI middle-income countries procuring through UNICEF is significant. This market is likely to change in the future with the entry onto the market of a whole-cell hexavalent (DTwP-HepB-Hib-IPV) vaccine.

**Figure 22:** UNICEF and PAHO prices for DTwP-HepB-Hib pentavalent vaccines from 2001 to 2013

Figure 23: Comparison of prices for pentavalent vaccines at different points in time and for different presentations

Supply considerations
The Pentavalent market has been volatile for the last few years, with multiple suspensions and some delisting of products from WHO prequalification. After several years of a fragile supply, the situation is now stabilizing. There are currently five manufacturers with prequalified products and a robust pipeline for future products. UNICEF, together with partners, is actively pursuing a supply security policy by awarding multiple manufacturers to mitigate supply failures. PAHO anticipates a more stable supply in the coming years, but also expects a shift to the whole-cell hexavalent vaccine once this product becomes available.

5.3 Pneumococcal conjugate vaccine (PCV)
Pooled procurement demand
From 2006 to 2010, PAHO procured the PCV7 presentation of this vaccine. Seven Member States that previously used PCV7 changed to PCV10, and currently eight countries procure PCV10 from PAHO. PAHO also procures PCV13 for 13 Member States. Unlike GAVI-supported countries, non-GAVI supported countries purchasing PCV through PAHO do not have access to the prices established through the Accelerated Market Commitment (AMC) described below.
In 2010, UNICEF procured a total of 8.4 million doses of PCV vaccine for 11 Member States, ten of which were GAVI-supported countries and one was a middle-income country not supported by GAVI. By 2012, these figures had jumped to 58.8 million doses for 28 countries, of which 58.7 million doses were for 27 GAVI-supported countries.

Demand from GAVI-supported countries continues to increase with new approvals for GAVI support, and currently 51 GAVI-eligible countries have been approved for support for PCV introduction. This will reach a total annual requirement of around 150 million doses when all countries have fully introduced the vaccine. In addition, nine more Member States are expected to apply for GAVI funding and introduce the vaccine before 2016. At this point in time (mid-2013), only one country not supported by GAVI is regularly procuring PCV through UNICEF, and initial procurements are in process for two more non-GAVI-supported countries.

Supply Considerations

PCV is a parallel monopoly market, with two prequalified products – PCV10 and PCV13 – that are not easily interchangeable. New producers are expected on the market at the earliest by 2016/2017.

The PCV market (Figure 24) for GAVI-supported countries is regulated by AMC prices established through UNICEF, in line with the terms and conditions of the AMC. The AMC is available for all GAVI-supported and graduating countries. UNICEF has issued tenders and entered into supply arrangements for PCV under the AMC that last up to 12 years. Under the terms of the AMC, the initial price of the vaccine for doses contracted in 2010 is US$7.00 per dose, to be co-financed by development partners, GAVI and countries. When the AMC donor funds allocated under this agreement have been fully disbursed, the initial “tail price” of $3.50 per dose goes into effect. Countries that entered into contracts in 2010 were able to procure the first doses of PCV13 at the tail price of $3.50 in 2013. By mid-2013 the tail price has been reduced to $3.40 across all contracts and will be further reduced to $3.30 starting in 2014. For PCV10 the tail price for doses procured under the third supply agreement will fall to $3.40 per dose, while those procured under earlier contracts will stay $3.50.

Figure 24: UNICEF and PAHO prices for pneumococcal conjugate vaccine, by type of vaccine, 2006-2013

![Figure 24: UNICEF and PAHO prices for pneumococcal conjugate vaccine, by type of vaccine, 2006-2013](image)

The price for AMC UNICEF (PCV10 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 (www.gavi alliance.org/funding/pneumococcal-amc/amc-legal-agreements/). The price for PCV10 is for one Member State only.
As of the end of 2012, awards have been made to cover a demand over 10 years of 1.46 billion doses, which will reach 146 million doses annually by 2016. There is sufficient supply available for the first deliveries to 19 countries in 2013. However, due to production problems with one vaccine, availability will be limited the second half of 2013 and the first half of 2014, necessitating strict global management of doses and stocks. As a result, three to five countries will need to postpone introducing PCV until 2014 to ensure that they will have a sustainable supply.

5.4 Human Papillomavirus (HPV) vaccine

HPV is a parallel monopoly market. The two currently available WHO-prequalified products are a bivalent vaccine produced by GSK and a quadrivalent vaccine produced by Merck. Both products are available in single-dose vials, and the GSK product is also available in a 2-dose presentation, which could help to lower the price. A second generation of HPV vaccines is under development by both multinational and emerging manufacturers, but no new vaccine is expected to be on the market before 2016.

PAHO started procuring the bivalent vaccine for one Member State in 2010 and starting procuring the quadrivalent vaccine in 2012. By 2013, eight countries and territories in the Americas were procuring HPV vaccines through PAHO for universal coverage.

UNICEF procured HPV vaccine for the first time in 2013. The recent tender on behalf of GAVI-supported countries achieved a price of $4.50 per dose for the quadrivalent (Merck) vaccine and $4.60 for the bivalent (GSK) vaccine. These prices will not be available to GAVI-graduating countries nor to middle-income countries procuring through UNICEF. Further negotiations could result in price commitments for these groups of countries.

While the pooled procurement market for both HPV vaccines is currently quite small, it is expected to increase significantly during the DoV, due to the availability of GAVI funding for selected countries. In addition, a number of countries, particularly GAVI-graduating and middle-income countries, 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 vaccine and include commitments from governments to fund the vaccine after the donation period. The price offered after the donation period may not be specified.

5.5 Rotavirus vaccine

Pooled procurement demand

Rotavirus vaccine also has a parallel monopoly market with two WHO prequalified products: one with a 2-dose course (produced by GSK) and the other requiring three doses (produced by Merck). Prices should therefore be considered in relation to the number of vaccines required per course. There is a strong preference among countries for the 2-dose GSK vaccine, which has led to supply problems for this vaccine that are predicted to continue until 2015.
PAHO Member States started procuring rotavirus vaccine in 2009 and by 2013, 11 countries or territories were procuring the 2-dose vaccine, while two countries and one small Caribbean island are procuring the 3-dose vaccine. PAHO has indicated that no other Member States in the region are interested in the 3-dose vaccine.

UNICEF started procuring rotavirus vaccine in 2011 and in 2012, it procured a total of 12.3 million doses for nine GAVI-supported countries, of which six were using the 2-dose GSK vaccine and three were using the 3-dose Merck vaccine. Demand continues to increase from GAVI-supported countries, with 29 countries currently approved for GAVI support. Ten more countries are expected to apply for GAVI support and introduce the vaccine before 2016.

As of mid-2013, UNICEF has not procured rotavirus vaccine for non-GAVI eligible countries. GSK has agreed to extend the UNICEF/GAVI price to GAVI graduating countries that have already introduced the vaccine with GAVI support, but not to countries that have not yet introduced the vaccine. Special contracting and/or payment terms apply to the UNICEF listed prices for GAVI countries. No UNICEF price has been established yet for non-GAVI countries.

As shown in Figure 28, the PAHO and UNICEF prices per dose for the 3-dose (Merck) vaccine are nearly the same, whereas the PAHO price per dose for the 2-dose (GSK) vaccine is more than two and a half times the UNICEF/GAVI price for this vaccine.

**Figure 26: PAHO and UNICEF/GAVI prices (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.

**Supply Considerations**

UNICEF has issued a five-year tender for rotavirus (2012-2016) with awards to the two current manufacturers. Supply is scaling up with an anticipated 10 million courses expected to be made available in 2013, increasing to around 18 million courses in 2014, an increase of 80%.

Due to a strong preference among countries for the 2-dose vaccine and the need to scale up production capacity for this vaccine throughout the year, supply of this vaccine will continue to be constrained throughout 2013 and 2014. Additional supply remains available for the 3-dose vaccine. New producers of rotavirus vaccines are expected on the market by 2015/2016.
STRATEGIC OBJECTIVE 6
Country, regional and global research and development innovations maximize the benefits of immunization

INDICATOR SO 6.1: PROGRESS TOWARDS DEVELOPMENT OF HIV, TB AND MALARIA VACCINES

<table>
<thead>
<tr>
<th>TARGET</th>
<th>Proof of concept for a vaccine that shows ≥75% efficacy for HIV/AIDS, tuberculosis or malaria vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>Number of HIV, TB and malaria vaccine clinical trials assessing clinical efficacy completed and with results reported</td>
</tr>
<tr>
<td>DATA SOURCE</td>
<td>International Clinical Trials Registry Platform (ICTRP), maintained by WHO</td>
</tr>
</tbody>
</table>

Results
Reporting of progress against this indicator will begin in 2014, with the preparation of separate qualitative reports for HIV, TB and malaria vaccines to be discussed at the Global Vaccine and Immunization Research Forum (GVIRF) in March 2014 and included in the secretariat report to the SAGE DoV Working Group.

INDICATOR SO 6.2: PROGRESS TOWARDS A UNIVERSAL INFLUENZA VACCINE (PROTECTING AGAINST DRIFT AND SHIFT VARIANTS) VACCINES

<table>
<thead>
<tr>
<th>TARGET</th>
<th>At least one vaccine providing broad spectrum protection against influenza A virus is licensed</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>Number of influenza clinical trials assessing the breath of protection that are completed and reported</td>
</tr>
<tr>
<td>DATA SOURCE</td>
<td>International Clinical Trials Registry Platform (ICTRP), maintained by WHO</td>
</tr>
</tbody>
</table>

Results
Reporting of progress against this indicator will begin in 2014, with the preparation of a qualitative report that will be discussed at the Global Vaccine and Immunization Research Forum (GVIRF) in March 2014 and included in the secretariat report to the SAGE DoV Working Group.

INDICATOR SO 6.3: PROGRESS TOWARDS INSTITUTIONAL AND TECHNICAL CAPACITY TO CARRY OUT VACCINE CLINICAL TRIALS

<table>
<thead>
<tr>
<th>TARGET</th>
<th>Every region has a solid base of Member States competent in hosting and managing vaccine trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>Number of Member States per WHO region having reported conduct of a vaccine clinical trial that meets quality standards (including active trials and those in process of recruitment) - The assumption is that a clinical trial that is registered in the WHO vaccine clinical trial database, which requires a minimum amount of information, meets the minimum quality standards</td>
</tr>
<tr>
<td>DATA SOURCE</td>
<td>International Clinical Trials Registry Platform (ICTRP), maintained by WHO</td>
</tr>
</tbody>
</table>

Results
Reporting of progress against this indicator will begin in 2014, with the preparation of a qualitative report that will be discussed at the Global Vaccine and Immunization Research Forum (GVIRF) in March 2014 and included in the secretariat report to the SAGE DoV Working Group.

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INDICATOR SO 6.4: 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

<table>
<thead>
<tr>
<th>TARGET</th>
<th>None specified</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION OF INDICATOR</td>
<td>Controlled temperature chain (CTC) is defined as allowing vaccines to be kept and administered at ambient temperatures up to 40°C, as per the conditions specified on their label, for one limited period of time immediately preceding administration (length of time will vary by antigen and setting). Up until this point, the vaccine should continue to be kept in the traditional 2-8oC cold chain.</td>
</tr>
<tr>
<td>DATA SOURCES</td>
<td>To monitor outcomes (label change): revised vaccine product inserts allowing for use of the vaccine at ambient temperatures up to 40°C accessed from the WHO Vaccine Pre-Qualification Database, manufacturers’ websites and hard copies of product inserts. To monitor progress: Public announcements made by vaccine companies of ongoing studies to assess feasibility of using their vaccines in a CTC, including journal articles, media reports and conference presentations. Private correspondence and information disclosed to WHO under non-disclosure agreements, such as email correspondence and meeting minutes.</td>
</tr>
</tbody>
</table>

**Data availability and quality**

The information used for this report is not collected on a regular basis or through a formal process, but was gathered specifically for the DoV GV AP Secretariat annual report. Most of the data were obtained first hand by WHO staff and are therefore considered highly reliable. Once a label revision 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 change for a vaccine. Therefore, it is also important to track the incremental progress towards a label revision and not just report the final results, to ensure that we are on track to achieve this indicator. However, much of the information about progress in CTC label changes is confidential and is shared with WHO under non-disclosure agreements. While this information is highly reliable, it can only be reported on in general terms and cannot be verified since it is not in the public domain.

**Results**

On 27 October 2012, the Indian regulatory authority granted its approval for the use of the MenAfriVac® meningococcal A conjugate vaccine in a controlled temperature chain (CTC), allowing it 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 national immunization programmes to obtain such a label. WHO has also prequalified the vaccine with this label revision. Following regulatory approval, and using guidance developed through WHO’s Immunization Practices Advisory Committee (IPAC), the first use of MenAfriVac® in a CTC was in mass vaccination campaigns in Banikoara, Northern Benin in 2012, during which more than 155,000 people were vaccinated. 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 reported starting tests and/or analysis to obtain CTC labels for some of their products. These include vaccines against yellow fever, HPV and Hepatitis B.

**Discussion**

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°C cold chain is frequently extremely difficult if not impossible in settings with limited capacity in cold chain maintenance and ice pack production. 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 the existing heat stability of vaccines to enable the use of vaccines outside the standard 2-8°C range through the regulatory process, without requiring any reformulation of the vaccine. Regulatory approval will allow for `on-label’ use and is important to ensure that 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 involves four complimentary, inter-linked work streams, as follows:

- **Vaccines**: Exploring and defining regulatory pathways to license and pre-qualify specific vaccines for use at higher temperatures;
- **Operations**: 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 that proven technologies are available to support the implementation of a CTC, including peak temperature threshold indicators; and
- **Incentives**: Defining mechanisms to create incentives for the licensing of products to reflect their true heat stability, including ensuring that Member States have access to product information and the ability to select products that meet their needs.

The initial focus of this work is on vaccines used in campaigns and/or delivered through special strategies, such as HPV and the birth dose of hepatitis B vaccine.

To ensure that regulators are ready to grant revisions 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 group’s first meeting was hosted by Health Canada – a leader in this area – and co-led by the Paul Ehrlich Institute on 4-6 December, 2012. Regulators from Brazil, Canada, France, Germany, Korea, Thailand and the U.S.A. attended, along with five vaccine manufacturers from both developing and developed countries. After a follow-up meeting in June 2013 in Germany, the resulting regulatory guidance for CTC will be published as a reference article in the journal *Biologicals*, 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 label 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 during the vaccine development process to enable them to label vaccines to reflect their true heat stability. However, for this to be possible, the public sector will need to develop a mechanism to provide incentives to manufacturers that produce vaccines which, as in the case of CTC, are designed to meet country needs. This will likely require a shift in how vaccine costs are measured from cost per dose purchased to cost per dose delivered, since CTC should result in lowering the storage and delivery costs of vaccines.

**Highlights**

- The first vaccine licensed and WHO pre-qualified for use in a controlled-temperature chain (CTC) is the meningococcal A conjugate (MenAfricaVac®) vaccine, which was successfully used in vaccination campaigns in Benin in 2012 using the CTC approach.
- By the end of 2012, four manufacturers had launched CTC studies for various vaccines, including yellow fever, HPV and hepatitis B.
- The development of guidance for regulating vaccines in a CTC began in late 2012, co-led by Health Canada and the Paul Ehrlich Institute.
- The ability to incentivize manufacturers to develop vaccines to meet country constraints remains a challenge.
Data source, availability and quality

In 2006, WHO’s Quality, Safety and Standards (QSS) unit established the Performance, Quality and Safety (PQS) scheme for the prequalification of a range of cold chain equipment, injection devices and other products needed for safe and effective vaccine delivery.\(^62\) This system, which replaced the Product Information Sheet (PIS) system, went entirely online in 2010, the year of baseline data.

This system selects immunization equipment eligible for purchase by UN agencies. It requires industry to comply with criteria of performance, quality and safety for their products that are established by independent and WHO-accredited laboratories. As more Member States are now requiring PQS prequalification in their tenders for immunization equipment, the PQS system is now being applied to equipment well beyond that which is purchased by the UN.

This indicator is the number of products that have been prequalified by the PQS as of 31 December, 2012, in comparison to the number of prequalified products that existed on 31 December, 2010. It does not take into account products that might have entered the list and been withdrawn in the interim period. Therefore it is just the difference between two data points.

The numbers come from the PQS database, which consists of three registries: for companies, laboratories and products. Each time a manufacturer submit a dossier for a product, this is recorded in the database. When the product reaches the prequalification stage, its information is published on the PQS website. The PQS database can produce reports of all cold chain and vaccine delivery-related 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 recorded with a date, which allows for monitoring the time it takes for products to go through the PQS pre-qualification process.

Results

As of December 31, 2012, 216 cold chain and vaccine delivery products were prequalified by the PQS (Table 33). This compares to 163 at the end of 2010 – an increase of 53 products or 32.5% during this two-year period. The types of products that were prequalified in 2012 alone are shown in Table 34. By July 11, 2013, the number of prequalified products had risen to 234 (from 53 manufacturers) (Figure 27). Some of the more innovative products that have been prequalified or are in the process are shown in Box 1.

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\(^62\) See: [http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/](http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/)
Table 33: Number of prequalified products at the end of each year, 2008 to 2013

<table>
<thead>
<tr>
<th>Product type</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013*</th>
</tr>
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<tbody>
<tr>
<td>Cold rooms and related equipment</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Refrigerators and freezers</td>
<td>0</td>
<td>8</td>
<td>14</td>
<td>23</td>
<td>33</td>
<td>35</td>
</tr>
<tr>
<td>Cold boxes and vaccine carriers</td>
<td>0</td>
<td>2</td>
<td>31</td>
<td>32</td>
<td>34</td>
<td>36</td>
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<td>Water packs</td>
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<td>1</td>
<td>15</td>
<td>16</td>
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<td>17</td>
</tr>
<tr>
<td>Temperature monitoring devices</td>
<td>7</td>
<td>10</td>
<td>11</td>
<td>12</td>
<td>17</td>
<td>22</td>
</tr>
<tr>
<td>AD syringes for immunization</td>
<td>21</td>
<td>31</td>
<td>30</td>
<td>27</td>
<td>29</td>
<td>33</td>
</tr>
<tr>
<td>Waste management equipment</td>
<td>5</td>
<td>9</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Therapeutic injection devices</td>
<td>22</td>
<td>35</td>
<td>49</td>
<td>60</td>
<td>72</td>
<td>78</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>55</td>
<td>97</td>
<td>163</td>
<td>183</td>
<td>216</td>
<td>234</td>
</tr>
</tbody>
</table>

* Up to 11 July 2013

Figure 27: Number of prequalified products at the end of each year, from 2008 to 11 July, 2013

Table 34: Number of products newly prequalified during 2012

<table>
<thead>
<tr>
<th>Product type</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerators and freezers</td>
<td>20</td>
</tr>
<tr>
<td>Cold boxes and vaccine carriers</td>
<td>3</td>
</tr>
<tr>
<td>Coolant packs</td>
<td>3</td>
</tr>
<tr>
<td>Temperature monitoring devices</td>
<td>6</td>
</tr>
<tr>
<td>Injection devices for immunization</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>36</td>
</tr>
</tbody>
</table>
Box 1: Examples of innovative cold chain and vaccine delivery products that have been newly introduced

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°C) on an LCD screen without the need for a computer or other accessories for a period of 30 days.

20-day electronic shipping indicator (new generation): This single-use device is meant to record all temperature “excursions” during transit of international shipments. Like the device described above, data can be retrieved on an LCD screen. Both devices have options for computer download and the automatic generation of PDF reports with temperature graphs.

Centralized temperature monitoring systems: These systems are for use in large storage facilities with reliable power sources and internet or mobile phone connectivity. They allow remote temperature monitoring of several cold/freezer rooms in a centralized location with options of SMS or email alerts.

Auto-disabled (AD) jet injector: The new generation of jet injectors using single-use auto-disabled cartridges.

Solar direct drive refrigerators (without battery): This new technology has the great advantage of not requiring 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 appliance in places where electricity is not available.

Long holdover refrigerators: Refrigerators with the capacity of having a long holdover time allowing them to maintain an inside temperature between 2 to 8°C for several days without power.

Long-term passive containers: Although none of these containers are yet prequalified, it is foreseen that they will be able to keep vaccines stored 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 2013.

Discussion

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 that consists of three steps:

1. Establish and/or adopt international standards to provide a framework of reference for the design, development and production of each product;
2. For each type of product, develop and maintain technical specifications and related test procedures that adequately reflect programmatic and operational needs; and
3. Monitor products post-market in order to assess performance, quality and safety characteristics over their lifetime from the perspective of the user, and monitor their suitability for programmatic and operational needs.

The aim 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.

Specific areas of progress with the PQS system since the DoV began include the following:

- **Documentation**: During the past few 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 the UNICEF Supply Division, manufacturers and laboratories. There are now 34 sets of specification/verification documentation covering nine categories of equipment and devices that are included in the PQS system (see Box 2). These include eight sub-categories of devices added during the period 2010 to 2012, reflecting the rapid evolution of technologies in the field of vaccine cold chain maintenance.
Box 2: Categories of cold chain equipment and immunization delivery devices in the PQS

1. Cold rooms & freezer rooms (extended to large volume rooms)
2. Refrigerators and freezers – nine subcategories
3. Cold box and vaccine carrier – five subcategories
4. Coolant packs
5. Temperature monitoring devices – 13 subcategories
6. Accessories
7. Auto-disable injection devices – two subcategories
8. Waste management – two subcategories
9. Reuse prevention injection devices for therapeutic use and vaccine reconstitution

- **The PQS database**: Major progress has been made in instituting the PQS web-based database, which now contains an online catalogue that is regularly updated.63
- **Laboratories**: Clients now have a choice of 11 accredited laboratories covering all technical areas. Efforts are being made to identify other facilities in order to bring laboratories closer to the manufacturers.
- **The PQS review process**: The current process for prequalifying cold chain and immunization delivery-related products is mainly based on the documentation that manufacturers provide according to specifications and verification protocols. The evaluation of a product follows the procedures described in the relevant standard operating procedures. In addition to the prequalification of equipment and devices, PQS organizes an annual review of all dossiers to update all documentation related to manufacturers and products. This review is implemented by external experts and provides the opportunity to examine the performance of the PQS system itself.
- **Innovation**: Efforts of the PQS are now focusing on expanding to products that were not included in the past but that are necessary to adapt to a changing environment brought about by a substantial increase in the volume of vaccines that countries are storing. These products include improved technologies to monitor the temperature at which vaccines are stored. At the same time, Member States are now much more demanding in terms of justifying the quality of the vaccines they use, which puts pressure on the development of procedures and technologies that will monitor and demonstrate vaccine quality at any point in time. These two aspects – the increasing volume of vaccines that Member States are storing and the increasing demand from them to be able to demonstrate vaccine quality at all times – are considered by the PQS programme in looking at innovative technologies that will best meet countries’ needs. However, this will require more field studies and field monitoring of new products. Due to the limited resources of PQS programme, these activities have to be implemented collaboratively with partners, including IVB units, NGOs, UN organizations such as UNICEF, the industry and relevant testing laboratories.
- **Pace of product pre-qualification**: As described in the Results section above, the prequalification of equipment and devices is now running at an increased pace as more and more products are submitted for prequalification. The increased number of products submitted is putting more pressure on the PQS programme to process all dossiers in a timely fashion. The PQS has met its objective in having all prequalification applications evaluated within an eight-week timeframe, despite the significant increase of the number of these applications.

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Monitoring progress towards GVAP goals and strategic objectives
2

Tracking resources invested in immunization
Background

As per the M&E/A Framework presented to the 66th 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 (SHA 2011). The SHA 2011 is an effort to create a single platform for collecting and analyzing all of a country’s health expenditures, including those for priority programmes, such as immunization. The concept is that various health resource-tracking initiatives (see below) will add data to the SHA 2011.

Why track expenditure for immunization?

Over the last few years there has been a substantial increase in funding for national immunization programmes. However, evidence suggests that impact of increased funding on coverage rates is slow and that resources are not necessarily reaching front line providers. Immunization activities continue to be underfunded, and financial sustainability is a concern. Tracking immunization expenditures on a routine basis within the framework of the SHA 2011 will help countries to improve accountability mechanisms and practices, and to assess whether resources are sufficient and best used to improve efficiency, equity, and sustainability.

Why use a single country platform to track expenditures for immunization?

The increase in the number of global health initiatives had generated a demand for disease-specific expenditure tracking. Country program managers (e.g. for HIV, TB, malaria, immunization, tobacco) are asked to report to the various global alliances on their country’s spending for their particular programme. However, such vertical, parallel reporting often results in inconsistencies in shared costs, such as expenditures in health facilities, are treated, which 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.

Such challenges may become magnified as recently established initiatives launch their own resource tracking activities. These include Family Planning 2020 and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), which requires countries to document counterpart financing in HIV, tuberculosis and malaria. There is also the platform proposed by the Commission on Information and Accountability for Women’s and Children’s Health (COIA), which calls for countries to track and report, by 2015 at least two aggregate resource indicators: 1) total health expenditures, and 2) total reproductive, maternal, newborn and child health (RMNCH) expenditures, both by financing source, and per capita.

To address these concerns, it was proposed that the Decade of Vaccines GVAP/Global Vaccine Action Plan use the SHA 2011 to track immunization resources, instead of creating another new system. By doing so, the GVAP aims to promote coordination, improve accountability, and reduced the reporting burden on countries.

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What is the System of Health Accounts 2011 \(^{65}\) (SHA 2011)?

The SHA 2011 is a new global standard for reporting health expenditures that is being set up by WHO and its partners to synergize and unify the resource tracking work of the different initiative mentioned above. This is a single country platform for the collection, mapping and analysis of financial data, so that expenditures can be reported and used yearly with more technical rigour, while reducing the work load of national staff. The system 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. The SHA generates consistent and comprehensive data on health spending in a country, which in turn can contribute to evidence-based policy-making. It can be used as a monitoring and evaluation tool to track changes in policy priorities and to determine if the introduction of reforms and new programmes resulted in changes in health resources allocation and expenditure.

The SHA methodology collects and analyses data 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. Some of the questions that the SHA can answer are:

- What is the total envelope of health spending?
- Who are the main financiers of health spending – governments, 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?

What are the risk and challenges?

Examination of the roadmaps that have been submitted by the countries to WHO demonstrate that there is limited or zero funding going towards resource tracking activities for health. Providing financial support to countries to enable them to use the SHA 2011 methodology 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 the SHA 2011, this will benefit the countries and produce one set of numbers for reporting by all. WHO is attempting to mobilize resources by encouraging other health resource-tracking initiatives to pool their funds into one single effort in each country, which the Global Fund has now agreed to do.

One major challenge will be to obtain relevant data from all major stakeholders and health providers in a country, especially from the private sector, in order to get accurate estimates of the total extent of health expenditures.

What is WHO doing?

The SHA 2011 methodology was developed jointly by WHO, OECD and Eurostat over a period of three years, including consultations with country experts. Technical assistance in developing the tools was provided by the USAID-funded HS2020 project, implemented by Abt Associates. WHO has also been collaborating with health accounts teams in health ministries in Member States for 10 years, and has established effective collaborative relationships with most in-country experts.
What is the way forward and what are the next steps for WHO and its partners?

• Continue technical assistance to institutionalize a harmonized country platform for collecting health and immunization expenditure data, and to build capacity at the country level;
• Improve country accountability processes by having health accounts teams in the Ministry of Health partner 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 that agreements 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 SHA 2011 has been revised to better respond to the type of health expenditure data demanded by Member States. Half a dozen countries have started preparing their latest health accounts using the new methodology and set of tools with success. For example, the Democratic Republic of Congo will use results produced and analysed with the help of the new tools in June 2013 and Burkina Faso will support an ECOWAS partner country and share its experience and knowledge in using the SHA 2011 methodology and tools.
Documenting and monitoring commitments for immunization
This section aims to provide an overview of the commitments made towards DoV/GAVP, the process agreed by the SAGE to make commitments, and a summary of the process in place to monitor immunization commitments made under the UN Secretary General's Global Strategy for Women and Children's Health.

Guiding principles to make commitments towards the DoV and GVAP

During their November 2012 meeting, the SAGE reviewed the process for monitoring commitments to the DoV, and agreed to use the same framework as used to document commitments to the UN Secretary General's Global Strategy for Women's and Children's Health. However, while the framework and process for documenting commitments may remain the same, the nature of commitments earmarked for immunization needs to be fairly explicit to allow tracking of commitments that specifically address immunization. The SAGE reviewed and endorsed the guidelines used for making commitments to the Global Strategy for Women's and Children's Health and examples of the types of commitments that could be made to the DoV.

Ideally commitments should be tangible and concrete, and represent activities or actions that can be reported on. Where possible, it would be helpful if the commitments were linked to one or more of the UNSG Global Strategy's goals and/or one or more of the 11 indicators used by the Commission on Information and Accountability for Women's and Children's Health (COIA).

Preferably the commitments will 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. If possible, the source of funding should be mentioned for non-financial (in-kind) commitments to avoid double counting. It is important that commitments for immunization are registered under the UNSG Global Strategy, since it is the only framework that allows us to monitor commitments made by the private sector, academia and civil society organizations (CSOs).

Monitoring commitments made for immunization

The Independent Experts Review Group (iERG) requested that the Partnership for Maternal, Newborn and Child Health (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) and they are increasing in number. There is also recognition of the need to move the focus from analyzing the 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 on the content and estimated value of the commitments to the Global Strategy, using self-reported data. The 2012 and 2013 PMNCH reports compile and analyze all the new commitments made since the September 2010 launch of the Global Strategy, and focus increasingly 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 the Global Strategy was launched in 2010. The WHA DoV annual progress report will be shared with PMNCH so it can include progress against this commitment.
The 2012 PMNCH report shows that most commitments that focus on specific interventions address critical gaps, but some key interventions with low coverage still receive limited attention (see Figure 28 from the PMNCH report). 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 28 compares 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, post-natal 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. These include diarrhea, pneumonia and malaria, which were the target of fewer than 50% of respondents.

PMNCH support for global accountability processes and platforms includes:

- **Countdown to 2015**: PMNCH acts as secretariat and co-lead of the Communications and Events sub-committee of Countdown to 2015. It is 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.

- **Information and Accountability for Women’s and Children’s Health (COIA)**: PMNCH acts as the coordinating platform for the Commission’s Advocacy and Action group.
Figure 28: Commitments related to the median coverage of essential RMNCH interventions in Countdown to 2015
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 continues to increase.

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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 with 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.

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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 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 long-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.

GAVP 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.

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
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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.
Independent submissions from other stakeholders

**CHILD MORTALITY: A GLOBAL COMPARISON**

- 50% of child deaths occur in 8 countries
- Remaining 180 countries contribute 50%

**OVER THE NEXT DECADE, SCALING UP VACCINE COVERAGE to 90% in 8 COUNTRIES**
with the most child deaths

- Avert U.S. $99 billion in costs and economic losses

- Save over 3.8 million children

- More than the GDP of Qatar

- 952 million barrels of crude oil

- Feed 362 million poor children for an entire year

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*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 future of immunization to reach all children, to enable them to thrive, by 2030. Vaccines have saved more lives than any other public health intervention in the world. Today, 70 percent of the world's children are protected by the vaccines available today. In addition, vaccines prevent 20 million deaths each year. In 2015, 102 million lives were saved and 3.7 million lives were saved.

POTENTIAL COST OF ILLNESS Averted

- $63B
- $27B:
  - Polio
  - Pneumonia
- $24B:
  - Rotavirus
- $12B:
  - Hand-foot-mouth disease

COST OF ILLNESS BY CATEGORY

- $6.2B:
  - Lost productivity
- $1.4B:
  - Prophylactic costs
- $55B:
  - Lost wages

ILLNESS PREVENTED & LIVES SAVED

- 102M:
  - 31M: Cases prevented
  - 21M: Lives saved
- 3.7M:
  - 1.4M: Cases prevented
  - 1.5M: Lives saved
  - 0.8M: Cases prevented

VACCINES

SAVING MONEY, SAVING LIVES

#VACCINESWORK
Independent submissions from other stakeholders
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 than 118 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.
Independent submissions from other stakeholders

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](http://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/](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.

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, 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
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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
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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
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Annexes
ANNEX 1: Understanding immunization coverage data: WHO-UNICEF joint reporting form on immunization coverage (JRF) and WHO-UNICEF estimates of national infant immunization coverage (WUENIC)

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.\(^\text{73}\)

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 Excel based data-collection tool and submit the data to WHO and UNICEF during the second quarter of each year. 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.

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Figure 29: 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 from 139 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. Immunization coverage data sources for JRF

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 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. 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 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%.

1.2 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 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 records76 — 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 is also possible challenge.

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.

1.3 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.

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). 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. 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:

- State of the world's children: www.unicef.org/sowc/

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 becomes available, the relevant portion of the WUENIC time series is updated.

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.

77 www.who.int/immunization_monitoring/outline/immunization_coverage/en/index4.html
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%.

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 important, 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.
ANNEX 2: Time trends in DTP<sub>3</sub> coverage in Member States with coverage < 70% in 2012

Table 35: Time trends in DTP<sub>3</sub> coverage in Member States with DTP<sub>3</sub> coverage of < 70% in 2012

Central African Republic

Chad

Equatorial Guinea

Ethiopia

Guinea

Haiti
Indonesia

South Sudan

Nigeria

Iraq

Somalia

Papua New Guinea
Administrative coverage

Official country estimate

WUENIC

South Africa

Syrian Arab Republic (the)

Timor-Leste

Vanuatu
ANNEX 3: SO 3: DTP$_3$ coverage by wealth quintile

Figure 30: DTP$_3$ national coverage by wealth quintile for all the Member States with data available between 2007-2011 (surveys conducted in 2008-2012)
ANNEX 4: SO4.1: DTP<sub>1</sub> – DTP<sub>3</sub> drop-out rates

Table 36: Member States with DTP1-DTP3 dropout rates of ≥ 10% for 2012 and showing an increasing trend in dropouts for the years 2010-2012

<table>
<thead>
<tr>
<th>Country</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cameroon</td>
<td>9</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Suriname</td>
<td>3</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>Uganda</td>
<td>8</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Nigeria</td>
<td>10</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>Panama</td>
<td>2</td>
<td>11</td>
<td>14</td>
</tr>
<tr>
<td>DR Congo</td>
<td>15</td>
<td>13</td>
<td>16</td>
</tr>
<tr>
<td>Micronesia</td>
<td>6</td>
<td>13</td>
<td>16</td>
</tr>
<tr>
<td>Marshall Islands</td>
<td>5</td>
<td>12</td>
<td>18</td>
</tr>
<tr>
<td>Nauru</td>
<td>0</td>
<td>0</td>
<td>19</td>
</tr>
<tr>
<td>Iraq</td>
<td>14</td>
<td>12</td>
<td>21</td>
</tr>
<tr>
<td>Syrian Arab Republic</td>
<td>10</td>
<td>16</td>
<td>34</td>
</tr>
</tbody>
</table>

Note: Member States are sorted by increasing DTP<sub>1</sub>-DTP<sub>3</sub> dropout rate for 2012

Table 37: Member States with DTP1-DTP3 dropout rates of ≥ 10% for 2012 showing a decreasing trend for the years 2010-2012

<table>
<thead>
<tr>
<th>Country</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palau</td>
<td>30</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Venezuela</td>
<td>13</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>Mauritania</td>
<td>22</td>
<td>18</td>
<td>16</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>23</td>
<td>21</td>
<td>17</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>28</td>
<td>25</td>
<td>24</td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td>30</td>
<td>27</td>
<td>26</td>
</tr>
<tr>
<td>Indonesia</td>
<td>32</td>
<td>31</td>
<td>30</td>
</tr>
</tbody>
</table>

Note: Member States are sorted by increasing DTP<sub>1</sub>-DTP<sub>3</sub> dropout rate for 2012
**Table 38: Member States with DTP1-DTP3 dropouts rate of ≥ 10% for 2012 and showing a stable trend for the years 2010-2012**

<table>
<thead>
<tr>
<th>Country</th>
<th>National dropout rates (%)</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td></td>
<td>11</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Lesotho</td>
<td></td>
<td>11</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td></td>
<td>11</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Guinea-Bissau</td>
<td></td>
<td>13</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Vanuatu</td>
<td></td>
<td>13</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>India</td>
<td></td>
<td>18</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Haiti</td>
<td></td>
<td>26</td>
<td>26</td>
<td>26</td>
</tr>
<tr>
<td>Equatorial Guinea</td>
<td></td>
<td>49</td>
<td>49</td>
<td>49</td>
</tr>
</tbody>
</table>

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

**Table 39: Member States with DTP1-DTP3 dropout rates or ≥ 10% for 2012 and showing an inconsistent trend for the years 2010-2012**

<table>
<thead>
<tr>
<th>Country</th>
<th>National dropout rates (%)</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liberia</td>
<td></td>
<td>13</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Madagascar</td>
<td></td>
<td>10</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Togo</td>
<td></td>
<td>11</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>Mali</td>
<td></td>
<td>11</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>Mozambique</td>
<td></td>
<td>19</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Somalia</td>
<td></td>
<td>18</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td>Chad</td>
<td></td>
<td>29</td>
<td>40</td>
<td>30</td>
</tr>
<tr>
<td>Guinea</td>
<td></td>
<td>26</td>
<td>31</td>
<td>31</td>
</tr>
<tr>
<td>Central African Republic</td>
<td></td>
<td>33</td>
<td>32</td>
<td>32</td>
</tr>
</tbody>
</table>

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