

Global report including key updates and challenges from regions

Philippe Duclos
SAGE Meeting
21-23 October 2014



World Health
Organization



世界卫生组织



Organisation
mondiale de la Santé



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الصحة العالمية



Всемирная организация
здравоохранения



Organización
Mundial de la Salud

Outline

1. WHO's contribution to the GVAP – process to update the vision and mission and prioritize immunization work
2. Review of regional achievements, challenges and priorities
3. Feed-back on selected work streams of importance to SAGE
 - Integration
 - Data quality
 - Typhoid conjugate vaccine
 - Maternal immunization
 - World Immunization Week
4. SAGE working processes and topics on the horizon



1. WHO's contribution to the GVAP – process to update the vision and mission and prioritize immunization work



WHO's Vision and Mission for Vaccines and Immunization, 2015 - 2025

- A **unified** vision
- **WHO's contributions to GVAP**
 - Will describe the organizational roles of WHO's vaccines and immunization work
- WHO's vision **beyond 2020**
- Development will draw heavily on existing strategic and visionary documents
- **Inclusive** – include polio, regulatory/safety and other areas including immunization in emergency situations
- Formal endorsement by WHO of the final document
- **All regions** have committed to be **actively involved** in the development

WHO's Vision and Mission for Vaccines and Immunization, 2015 – 2025: process and timelines

WHAT	HOW	WHO	WHEN
1. Take stock of where we are	Review WHO's work in immunization/vaccines, including contributions against the GVAP; Assess WHO's strengths and weaknesses through internal assessment and expectations & Survey to partners, EPI managers and National Immunization Technical Advisory Groups, SAGE	WHO HQ & regions, Partners, SAGE	Nov 15 th
2. Project future needs	Through trends and country analysis, project what immunization will need in 10-15 years.	WHO, external support	Dec 15 th
3. Identify gaps	Map WHO's immunization and vaccines capacities, strengths and weaknesses against its future role.	WHO	Feb 15 th
4. Define future role	Analysis of which future needs WHO should fill, based on current work and its core competencies; solicit feedback.	WHO	Feb 15 th
5. Vision/mission developed	Final document outlining the vision, mission and role for WHO in immunization and vaccines.	WHO	March 31st

WHO's Contribution to the GVAP

Cross-cutting critical/core functions - all levels

- Norms & standards, policy recommendations, best practices setting
- Strategy, tools & guidelines development
- Partner coordination
- Global & regional monitoring/surveillance and feedback
- Advocacy and resource mobilization (eg. *World Immunization Week*)
- Capacity building (eg. *training material & methods*)
- Direct technical support to countries

Strategic Objective (SO) 1: All countries commit to immunization as a priority

- Support country development of and ownership of unified immunization plan (*eg. comprehensive multi year plans*)
- Generate evidence on the value of immunization
- Support creation and strengthening of National Immunization Technical Advisory Groups
- Support establishment and strengthening of Interagency Coordinating Committees & Health Systems Coordinating Committees

SO2: All understand the value of vaccines and demand immunization as right and responsibility

- Provide summaries of the evidence base for the safety and efficacy of vaccines
- Track and respond to global vaccines safety threats
- Facilitate addressing of vaccine hesitancy and demand creation
- Facilitate linkages with professional and academic networks

WHO's Contribution to the GVAP

SO3: Benefits of immunization equitably extended to all people

- Development of tools and technical support to reaching every community and understanding the causes of un- or under-immunization (include research to minimize barriers and improve coverage of vaccines currently in use)
- Support introduction of new vaccines across the life-course
- Coordinate and support supplementary immunization activities for accelerated disease control (*MenA, MR,...*)
- Respond to outbreaks in humanitarian crises and in conflict zones

WHO's Contribution to the GVAP

SO4: Immunization systems integral part of well-functioning health system

- Improve administrative data quality, analysis and use & promote state of the art immunization information systems (*eg. immunization registries and national identification systems*)
- Strengthen disease surveillance systems and laboratory capacity (including developing improved diagnostic tools)
- Ensure global capacity for vaccine safety
- Facilitate the independent assessment of all programme components (delivery, supply chain, surveillance,...) and support the development of a strong supply chain

SO 5: Sustainable access to predictable funding, quality supply and innovative technologies

- Support pooled procurement mechanisms
- Promote vaccine affordability and transparent pricing
- Facilitate demand forecasting and assessment of supply for vaccines & technologies
- Support strengthening of National Regulatory Authorities
- Prequalification of vaccines and devices
- Establish and maintain vaccines stockpiles

WHO's Contribution to the GVAP

SO6: Research and development innovations

- Prioritization of vaccines and innovations (*eg. Product Development for Vaccine Advisory committees*)
- Accelerate development of vaccines
 - In early development (*eg. preferred product characteristics*)
 - Accelerate licensure of vaccines in earlier phases of clinical development (*eg. consensus-based trial design*)
 - Generate evidence to inform policy recommendations for candidate vaccines
- Impact evaluation of vaccines in use
- Stimulate research on optimizing delivery schedules and policy recommendations
- Promote access to technology, expertise and intellectual property for relevant technologies
- Develop a global regulatory science research agenda

2. Review of regional achievements, challenges and priorities



Development of Regional Vaccine Action Plans (RVAP) (1)

AFRO

Draft RVAP to be discussed at the 64th RC, 3-7 November 2014 (Regional strategic plan for immunization 2014–2020)



AFR/RC64/5
11 June 2014

REGIONAL COMMITTEE FOR AFRICA

ORIGINAL: ENGLISH

Sixty-fourth session
Cotonou, Republic of Benin, 1–5 September 2014

Provisional agenda item 10

REGIONAL STRATEGIC PLAN FOR IMMUNIZATION 2014–2020

Report of the Secretariat

EXECUTIVE SUMMARY

1. Immunization is considered as one of the most cost-effective public health interventions. Regional coverage with three doses of Diphtheria-Tetanus-Pertussis containing vaccine and the first dose of Measles Containing Vaccine were maintained around 70% during the last three years. There has been an estimated 88% reduction in measles mortality since 2000 and only one country in the Region remains endemic for wild poliovirus.
2. External evaluation of the 2009–2013 Regional Immunization Strategic Plan revealed challenges that hinder access and utilization of immunization services. These include gaps in organization, coordination and management of immunization activities, inadequacy of vaccines and cold storage capacity, limited service delivery points, and inappropriate communication strategies resulting in low community awareness and participation.
3. One of the significant developments in the field of immunization is the Global Vaccine Action Plan that needs implementation in the Region. The Regional Immunization Strategic Plan 2014–2020 is intended to address the identified challenges by providing policy and programmatic guidance to Member States within a strong national health system and also during humanitarian emergencies.
4. The key approaches include integrating immunization into national health policy and plan and during emergencies, strengthening financing, enhancing partnerships, building national capacity, improving monitoring and data quality, improving vaccine management, safety and regulation and promoting implementation, research and innovations.
5. The Regional Committee is invited to review the Regional Immunization Strategic Plan 2014–2020 and endorse the actions proposed and the related resolution.

EURO

European Vaccine Action Plan (EVAP) adopted by the 64th RC



European
Vaccine
Action Plan
2015–2020

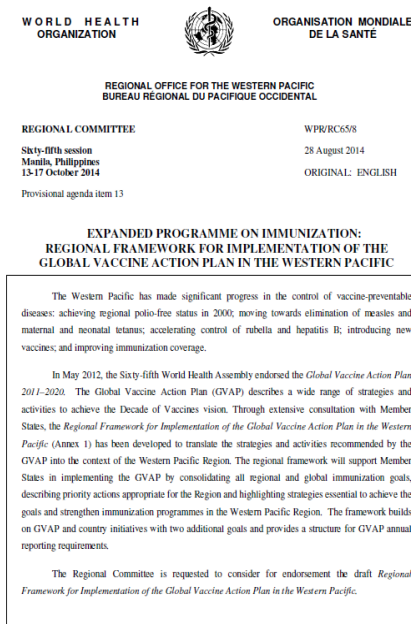


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Development of Regional Vaccine Action Plans (RVAP) (2)

WPRO

RVAP validated by RTAG
and adopted at the 65th RC,
13 -17 October 2014



PAHO

Regional Immunization Vision and Strategy 2007-2015 will finish next year. In Sept 2015, the regional adaptation of GVAP will be presented to PAHO's Directing Council

EMRO

RVAP based on CMYPs (bottom-up approach) will be submitted to the RC in Oct 2015

SEARO

Development of RVAP ongoing

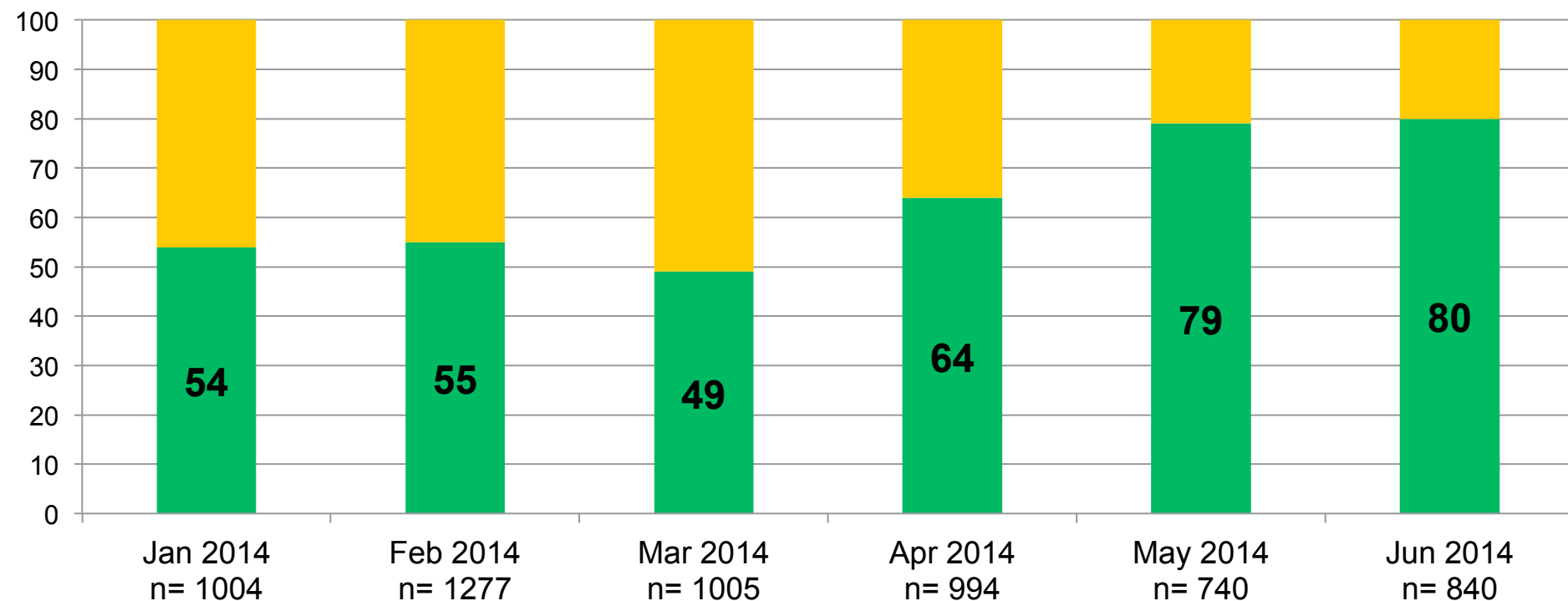
Immunization Performance in the AFR

Action to address challenges and accelerate the performance

- **Ensure easy access** to essential interventions and services
- Move from the Reach Every District to Reach Every Child approach with the **full involvement of communities**
- **Improve data quality**
- **Improve logistics** and cold chain systems
- **Strengthen** disease **surveillance** and **reporting** systems
- Ensure **adequate resources** for child health
- Ensure **improved access** to mobile and e-health technology to improve access to child health care
- Establishment/ strengthening of **NITAGs**
- **Ensure coordination, alignment and harmonisation** of existing initiatives.

Nigeria's Real Time Tracking of Routine Immunization Supervision Impact of the Supportive Supervision

% sessions supervised with all antigens present

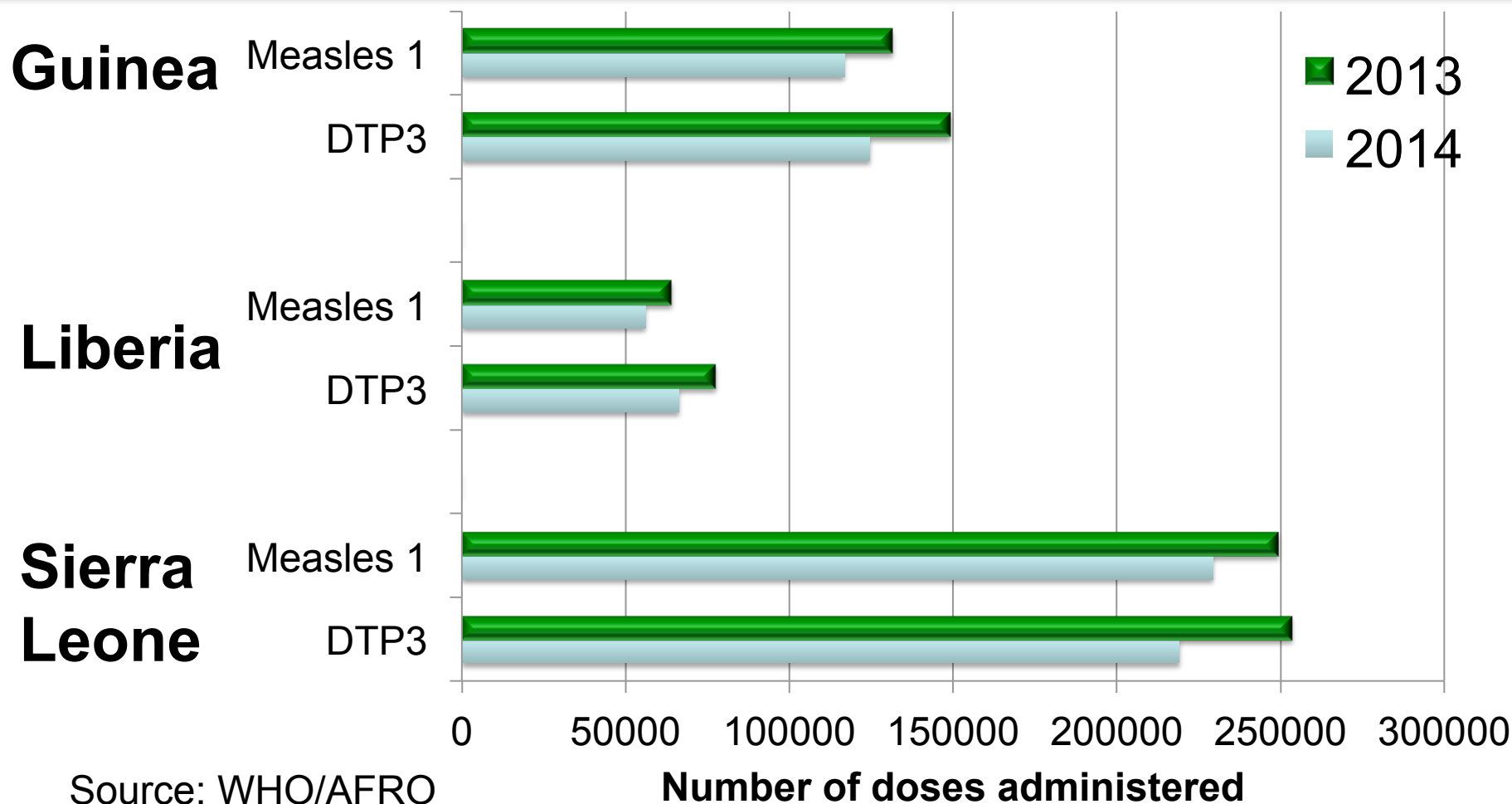


■ Some antigens not available at session site

■ All antigens available at session site

Availability of all antigens at the session site improved from 54% to 80 % demonstrating better vaccine management

Number of Doses Administered in Guinea, Liberia and Sierra Leone (Jan-Jul 2013-2014)



TAG XXII

“Vaccination: Your best shot!”

1-2 July, 2014

Washington DC

Participants:

- TAG members
- PAHO Secretariat

Topics: [*decisions]

- Polio endgame update
- Update on HPV uptake and schedules*
- Influenza vaccination
- Cholera vaccination
- Conclusions from IEC measles, rubella and CRS elimination
- Pertussis vaccines*
- PAHO Revolving Fund
- Immunization data quality
- PCV13 vaccination in adults*
- Operational research
- PAHO TAG ToRs and SOP



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53rd PAHO Directing Council 2014

“Immunization on the top agenda in the Americas”

- **Resolution:**

- CD53R14: Strategy for Universal Access to Health and Universal Health Coverage

- **For information:**

- CD53/23: PAHO Revolving Fund for Vaccine Procurement: Challenges and Opportunities
- CD53/INF/6: Plan of Action for Maintaining Measles, Rubella, and Congenital Rubella Syndrome Elimination in the Region of the Americas



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EUR: the challenges ahead

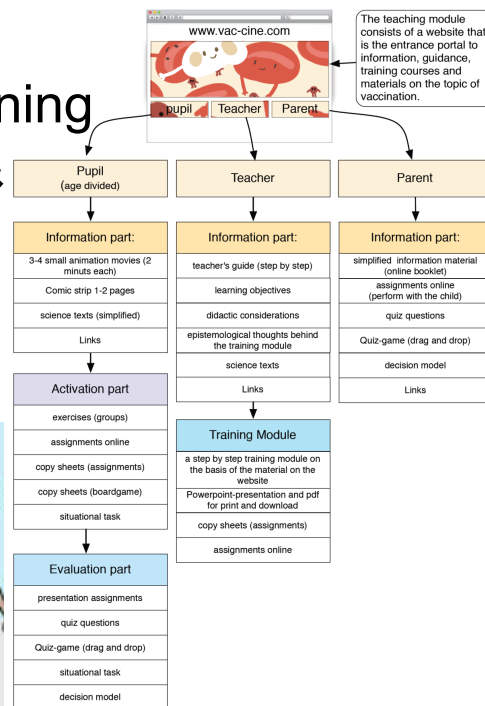
- Political commitment
- Addressing the immunity gaps
- Understand and responding to vaccine hesitancy and refusals
- Integration with other health interventions
- Alignment with health system changes
- Sustainable access to vaccines and predictable funding



ETAGE recommended the development of generic training materials on immunization for schools and for continuous medical education

Education in vaccination

- Flipped learning
- 10 -11 years
- Multi-language
- Parent & Child learning
- Anchoring beliefs & understanding

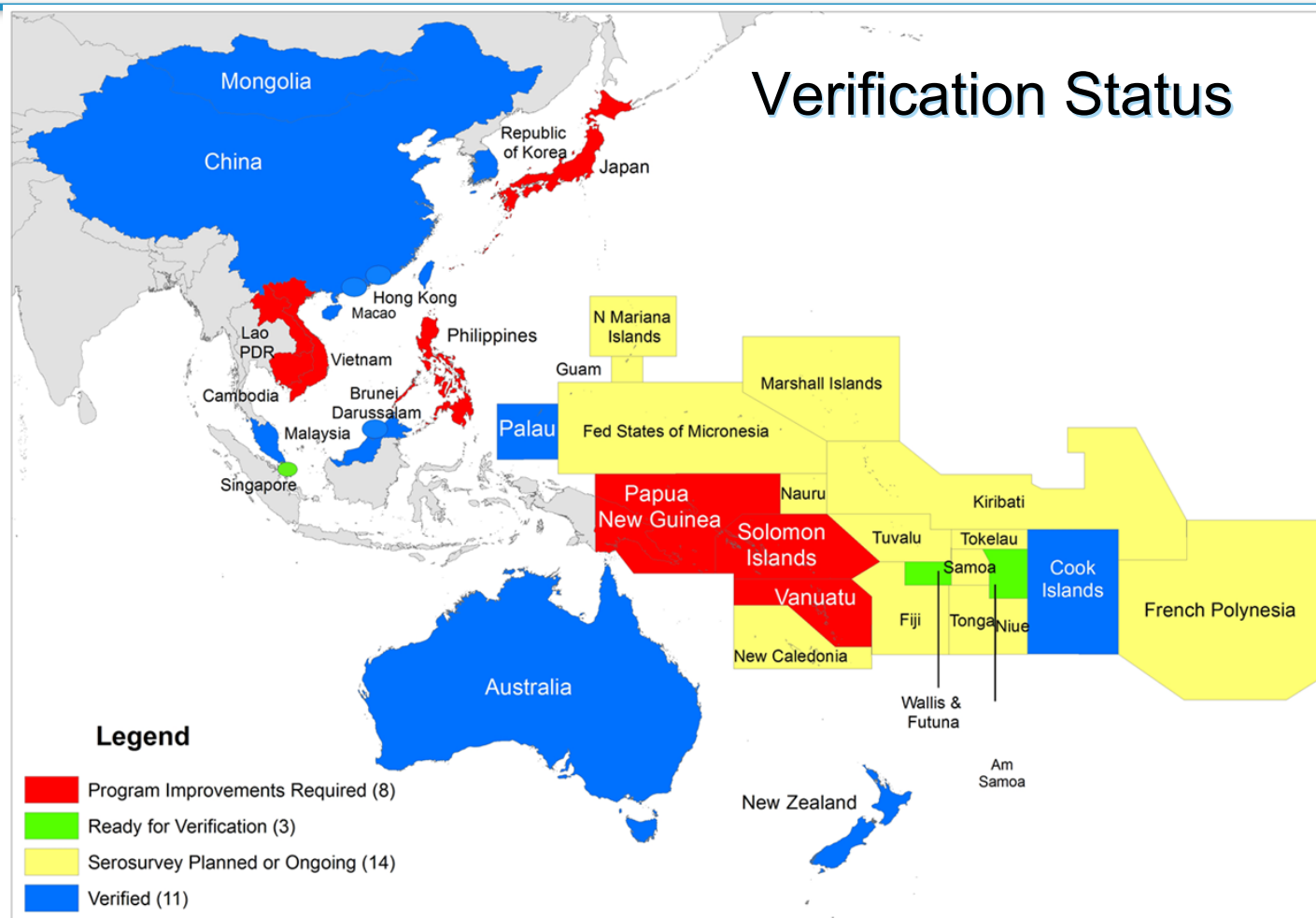


- Initial discussions
- Plan to develop CME
- Funding identified
- Face to face meeting with ESPID – Nov 2014

Hepatitis B Control: WPR

Achievements:

- **64th RCM adopted regional goal of reducing hepatitis B infection rates in children to less than 1% by 2017**
- **11 countries have been verified to have achieved the Regional goal**
- **14 countries conducting serosurveys in 2013 - 2015**



Immunization Safety and Regulation: WPR

- **Strengthening national capacity for surveillance of adverse event following immunization (AEFI)**
 - Drafted Immunization safety communication guideline in 2014
 - Responded to vaccine safety incidents in six countries in 2013/14
 - Conducted national AEFI training workshop in five countries in 2013/14
 - Conducted regional training on AEFI causality assessment and communication capacity building (9 countries participation) in 2014
- **Strengthening national regulatory capacity**
 - Validated NRA self-assessment in vaccine-procuring countries including Cambodia, Mongolia, Malaysia & Philippines in 2013-14
 - NRA assessment in vaccine producing countries: Viet Nam & China in 2014
 - Established regional NRA alliance as regulatory forum

5th meeting of the SEAR-ITAG

August 2014

- Quality of Immunization Data
- Polio and IPV Introduction
- Measles and rubella surveillance and immunization
 - Assessing population immunity and defining susceptible populations
 - CRS Sentinel Surveillance
- **Maternal and Neonatal Tetanus Elimination**
- Influenza prevention and control
- Effective vaccine management
- Adverse events following immunization
- Pooled procurement mechanisms
- Japanese Encephalitis

Japanese Encephalitis

Accelerated Control: SEAR & WPR

Requires:

- Sustain vaccination and expansion to additional risk areas
- Improved surveillance to further define risk areas in a few countries, and to monitor the impact of vaccination

SEAR:

- Sri Lanka, Thailand, India, and Nepal conducted catch-up campaigns and have introduced JEV into routine immunization
- Bangladesh recently conducted a national consultation on JE and is preparing to apply for GAVI support for JEV introduction in selected districts
- Myanmar has planned a national consultation on JE at end of Oct 2014

WPR:

- Four of 12 endemic countries vaccinate in all risk areas and five vaccinate in some risk areas
- TAG endorsed development of a regional goal for accelerated control of JE adopted by the Regional committee in Oct 2014

SEAR and WPR: bi-regional meeting in May 2014 to support surveillance and vaccine introduction.

Regional challenges for introduction of new vaccines

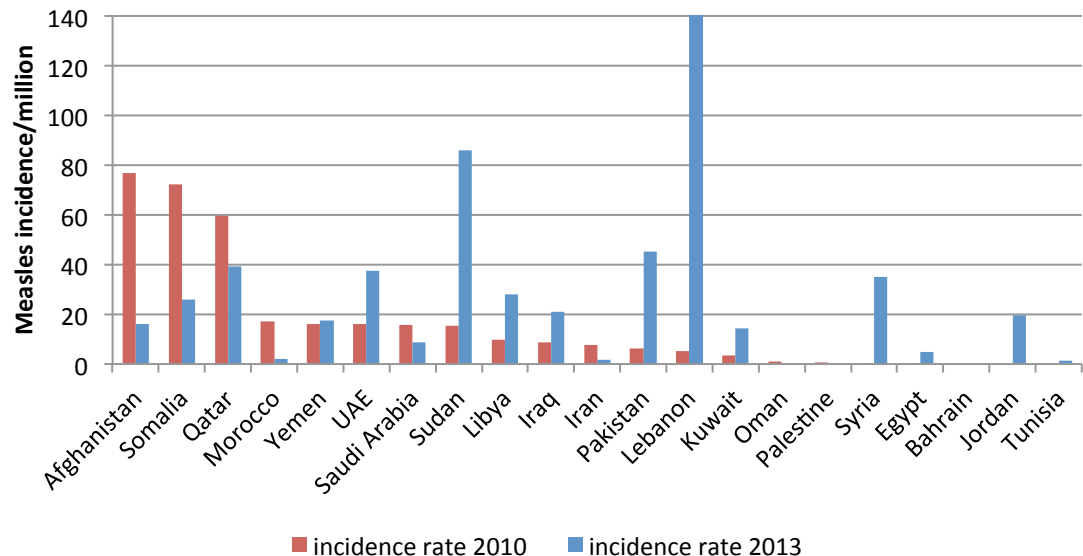
- High costs of new vaccines for non Gavi-countries and issue of Gavi-graduating countries
- Capacity building needed to support evidence-based decision-making
- Measurement of vaccine impact increasingly important to sustain policy decisions
- Communications with communities and other stakeholders, especially for HPV vaccine introduction
- New vaccines often require new or special delivery systems
- IPV introduction, competing priorities and scheduling issues

Main Challenges Countries are Facing: EMR

Emergency and security situation in increasing number of countries:

- Decreasing routine vaccination coverage
- Increasing measles incidence:
 - Elimination target is not on track
- Inability to implement planned activities
 - Important activities are cancelled or postponed to indefinite date

Measles incidence in the EMR, 2010 and 2013



Regional average of DTP coverage dropped from 86% in 2010 to 82% in 2013

94% of the children who have not received their third dose of DTP3 are living in countries facing internal difficulties

Programmatic Challenges for Measles Elimination in AFR

- Routine immunisation MCV1 coverage remaining stagnant
- Inadequate preparations and resource mobilisation for measles SIAs
 - Gaps in coverage/quality
- Multiple and competing concurrent or overlapping program priorities at national level
 - eg., Men A / YF campaigns, NUVI launch, polio outbreak response campaigns, Ebola outbreak response, political elections
- Planning for scheduled measles SIAs in countries affected by Ebola outbreak, given the risk of measles outbreaks in the next peak transmission season starting Nov/Dec 2014

Measles in the WHO European Region, 1993, and 2007-2013

341982

Bulgaria 21 664
France 14 966
Ukraine 12 744
Georgia 7830

98% REDUCTION

1993

7073

9168

7892

30529

35088

27132

31685

2007

2008

2009

2010

2011

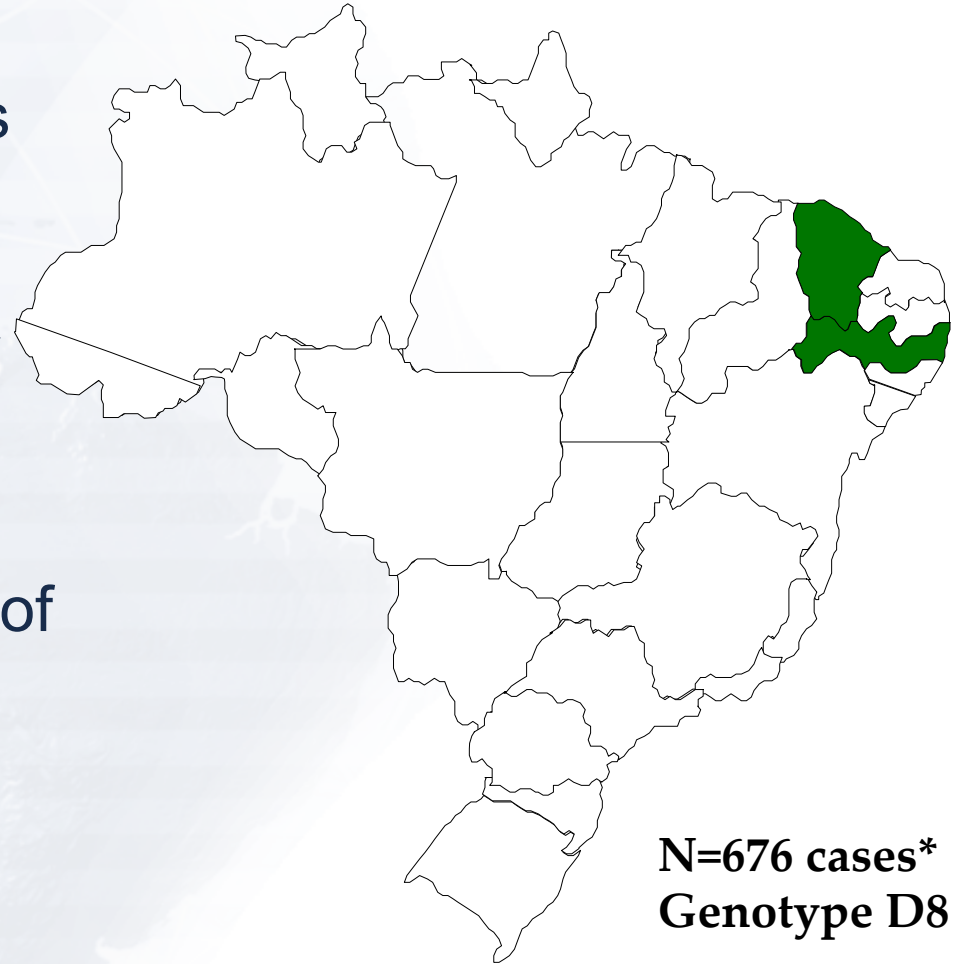
2012

2013

53rd PAHO Directing Council 2014

Progress on measles and rubella elimination

- The most recent epidemiological data indicates **reintroduction of measles virus in two states of Brazil**, which has been circulating for more than 1 year (2013-14).
- The International Expert Committee awaits the control of this outbreak, to declare the elimination of measles in the Americas.
- Rubella and CRS elimination has been sustained in the Americas.



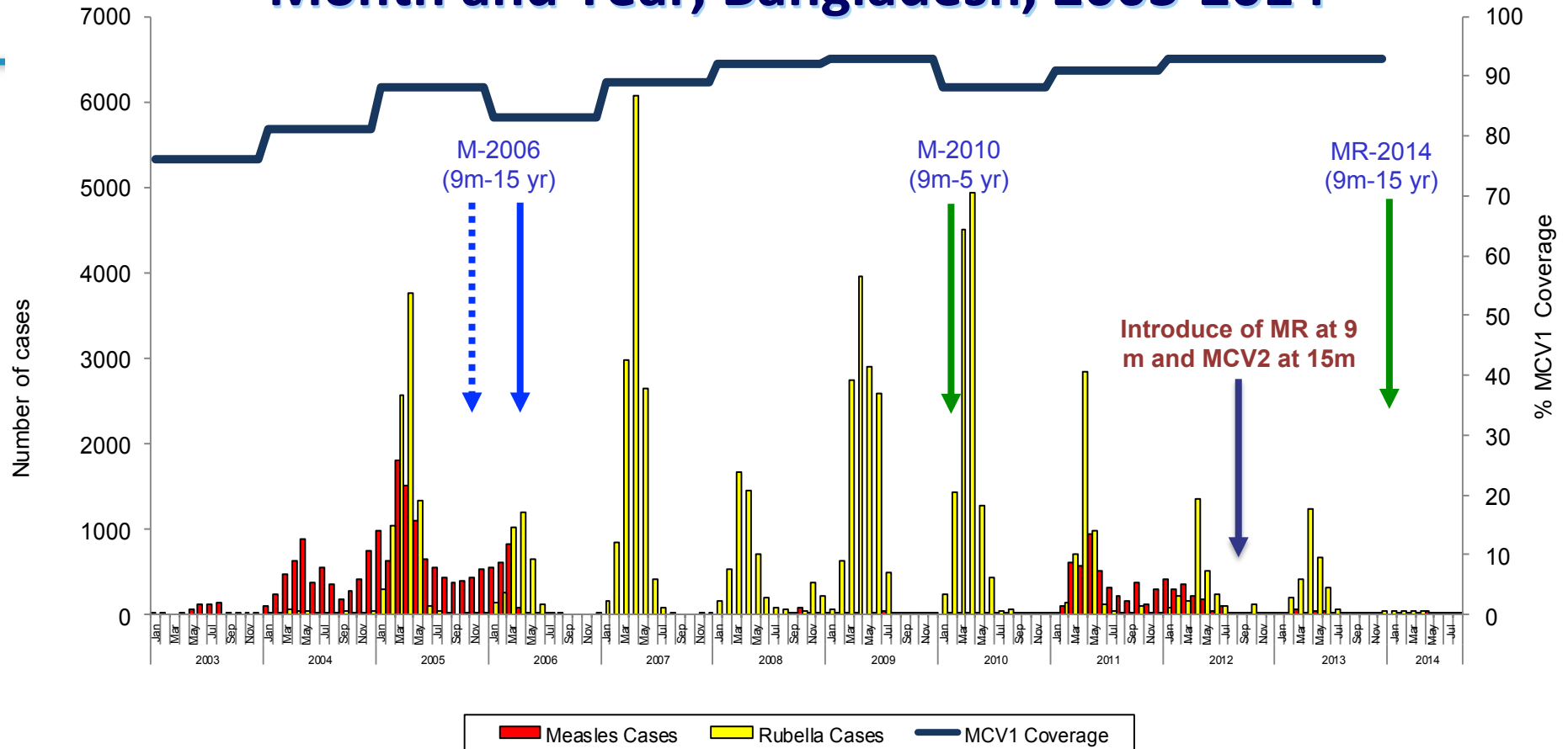
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Data as of EW 40 – source: Ministry of Health, Brazil

Immunization Strategies and Measles & Rubella Cases by Month and Year, Bangladesh, 2003-2014



Note: Serologically confirmed and epi linked cases are included

Cases from outbreaks from 2003 onwards

Cases from outbreaks and health facilities 2009 onwards

2 districts +
1 City Corporation

62 districts +
5 City Corporations

National Level



3. Feed-back on selected work streams

- Integration
- Data quality
- Typhoid conjugate vaccine
- Maternal immunization
- World Immunization Week



Integration Progress

- Still working to break down silos (even within immunization) – hard work!
- GVAP WG discussed integration and selected indicators!
- **Inter-Agency Supply Chain Group – Joint vision**
- Main opportunity with new vaccine introduction – HPV, PCV, and Rota
 - Global Action Plan for Pneumonia and Diarrheal diseases (GAPPD)
 - Cervical Cancer & Adolescent Health



Utilizing new vaccine introduction to promote integration and strengthen systems

Updated guidelines on new vaccine introduction

- Special section on use of opportunity for **integrated approaches**
- Annex with examples of ways to **strengthen the building blocks of health systems**

GAPPD

- **Planning workshops** in 4 regions, targeting high mortality countries
- **Pilot projects** planned in Bangladesh, India, and Zambia
- Interest from Armenia, Burundi, Togo
- GAVI Strategy discussions

Cervical Cancer & Adolescent Health

- UNICEF/WHO/UNFPA Adolescent Health Assessment -Toolkit (used in 6 countries)
- WHO Guidance: Options for Linking Adolescent Health Interventions with HPV Vaccination

Principles and considerations for adding a vaccine to a national immunization programme

FROM DECISION TO IMPLEMENTATION AND MONITORING



Missed Opportunities

- When receiving a different vaccine or when health facility contact
- C. Sanderson, LSHTM, work in progress unpublished
 - Analysis of Demographic Health Surveys data
 - Only 4% of children overdue for MCV1 and treated in a health facility were vaccinated (7% for DTP)
 - DRC could move from 73% to 80% MCV1; Ethiopia from 62% to 73% --- gains sufficient in some countries to move to > 90% (eg. Burkina Faso, Ghana, Malawi).
- Causes: Lack of integration - poor planning, false age restrictions/lack of funding, false contraindications

Current Efforts at Improving Quality of Immunization Coverage Data (1)

Work led by WHO in close collaboration with other partner agencies (UNICEF, BMGF and GAVI secretariat)

Data of sufficient quality if “fit” for

- guiding policies and strategies
- making operational decisions

1. Enhancing the design and use of home-based records

- Currently overlooked /neglected
- Opportunity to re-energize with IPV introduction
- Development of home-based records guide

2. Improving estimates of target populations

- Updated guidance for national programme managers to better understand and improve estimates
- Facilitate engagement with national statistics units and improves reporting

Current Efforts at Improving Quality of Immunization Coverage Data (2)

- 3. Information technologies to improve recording, reporting and use of immunization data**
 - Development of guidance on the use of information and communications technologies to improve data systems
 - Support countries in strengthening district level systems for data analysis and use
- 4. Strengthen survey approach to validate administrative coverage**
 - Updated guidelines for cluster surveys under development
- 5. Support countries for meeting GAVI Data Quality responsibilities**
 - Annual desk review of data quality
 - Periodic in-depth data quality assessments
 - Periodic household surveys

However, human resources and capacity strengthening is critical for data quality to improve

Typhoid Conjugate Vaccines

- Based on 2010 population, 11.9 million cases of typhoid fever and 129 000 deaths estimated in LMICs with 73% occurring in Asia
- 2 products licensed by Indian NRA (Vi-TT, Vi-DT) and 1 product under review by Chinese NRA (Vi-rEPA) on immunogenicity data (ECBS guidance)
- July 2014 WHO Expert Consultation reviewed adequacy of clinical data to support public health recommendations for use and concluded:
 - **Additional data** need to be generated for SAGE policy review
 - more robust immunogenicity data eg. on duration of protection; all age groups
 - clinical efficacy data desirable; particularly in children <2 years
 - **Standardization of assays** for evaluation of immune response critical
 - **Additional epidemiological data to inform country decisions**
- Tentative review by SAGE in 2017 with SAGE Working Group to be established in 2016 - Keep a watching brief on developments

Maternal Influenza Immunization at WHO

- Numerous activities coordinated and involving multiple WHO departments and collaboration with partner institutions (BMGF, Brighton Collaboration, CDC, PATH, and many others)
- Designed to address implementation obstacles to maternal influenza immunization program implementation
 - Burden of disease
 - Vaccine safety
 - Vaccine performance
 - Impact and economics
 - Implementation
 - Regulatory
 - Manufacturing
 - Data review and synthesis

Maternal Influenza Immunization: Major Activities Since Last SAGE Meeting

Vaccine Safety

- Investigating how to use data transparency initiatives by EMA and FDA to conduct reviews of unpublished trial and surveillance data
- Harmonizing/developing maternal immunization AEFI definitions and guidance (with Brighton Collaboration)

Implementation

- Conducting country case studies to identify best practices for routine maternal immunization (Malawi, El Salvador, ...)
- Developing a global guidance document for implementation

Regulatory

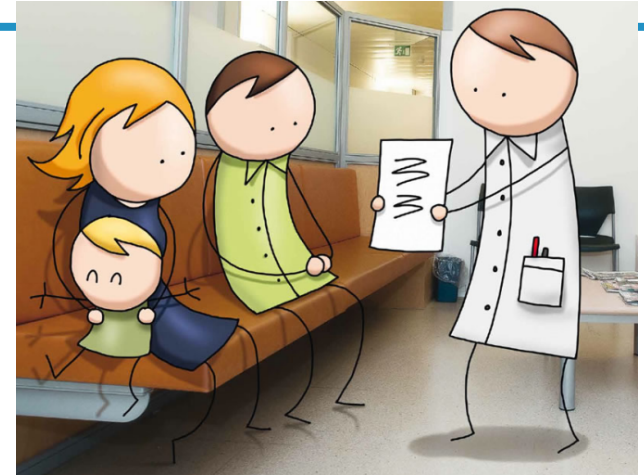
- Evaluating data needs for product labels and identifying tools to promote more permissive pregnancy & lactation sections in labels
- Consensus building on testing and licensure pathways for RSV vaccines including maternal immunization
- Meeting on all-year availability of vaccines

World Immunization Week 2014

“Are you up-to-date?”

Campaign **focused on the general public**, asking:

Do you and your family have all the vaccines you need?



Through:

- country activities
- website
- social media platforms
- media outreach



This year

- Participation from over 180 countries
- Vaccinations and outreach to health workers
- Multilingual poster toolbox with 83 000 page views
- Introduction in Europe of smartphone app with vaccination reminders
- SMS messaging: Cameroon, Sudan and Tajikistan reported dispatch of messages
- Good level of media interest, particularly given no "hard news" announcements
- Marking an important milestone!!
 - Various products launched in April & May 2014 to commemorate **40 years of EPI**

IMMUNIZE FOR A HEALTHY FUTURE

Create, print and share your own World Immunization Week poster

Select your language

عربي

中文

English

Français

Русский

Español

IMMUNIZE FOR A HEALTHY FUTURE



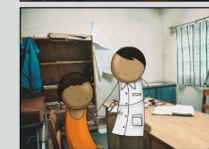
KNOW

Vaccines help keep you and your family healthy. Ask at your health clinic to know which vaccines you need.



CHECK

At home and before travelling, check whether you and your family have all the vaccines you need.



PROTECT

Protect yourself: get the vaccines you need, when you need them.

Beyond expectations: 40 years of EPI

The Expanded Programme on Immunization (EPI) was established by the World Health Assembly in 1974 at a time of great optimism for public health. The imminent certification for the eradication of smallpox was taken as proof of the power of vaccines, delivered in well-managed programmes, to permanently improve the world.¹

When EPI was established, only about 5% of the world's children were protected from six diseases (polio, diphtheria, tuberculosis, pertussis, measles, and tetanus) targeted by four vaccines. Today, that figure is 83%, with some low-income countries reaching 99% immunisation coverage.¹ The number of public health vaccines being used for universal protection has more than doubled since 1974. Almost all countries include vaccines against hepatitis B and *Haemophilus influenzae* type b in addition to the original six diseases, and quality-assured vaccines are used in 97% of all countries.² Today, WHO estimates that immunisation programmes save the lives of 2.5 million people each year and protect many millions more from illness and disability.³ With the certification of WHO's South-East Asia Region as polio-free, 80% of the world's population now lives in a country where polio has been eradicated.⁴

What accounts for this success? Does EPI offer lessons of broader relevance as the world prepares for the post-2015 era? EPI had some advantages from the outset. The prevention of childhood deaths has great public and political appeal, and that helped create momentum within individual countries and the international community to support immunisation programmes. Vaccines are scheduled interventions that can be delivered even in the absence of well functioning health systems, and even in places where capacities are weak and skilled health workers are scarce. The costs of the initial six EPI antigens against polio, diphtheria, tuberculosis, pertussis, measles, and tetanus were low.

But EPI's success must be attributed to more than these advantages. During the past four decades, EPI has encouraged new models of international cooperation, found new sources of funding, and stimulated innovation in technology and the operational performance of national immunisation programmes.² EPI has also pioneered improvements in surveillance and monitoring as a contribution to accountability for results.² Fundamental public health capacities have also been strengthened; as just one example, there are nearly 700 laboratories, in 164 countries, accredited by WHO to undertake laboratory-based surveillance for measles and other vaccine-preventable epidemic-prone diseases.⁵

The establishment of the GAVI Alliance in 2000 helped launch the most innovative EPI decade to date.⁶ Since the start of this century, WHO, UNICEF, and the GAVI Alliance have worked to change the dynamics of the market for public health vaccines, making supplies more plentiful, predictable, and affordable.⁶





4. SAGE working processes and topics on the horizon



Measles and Rubella Working Group

Emerging Policy Questions

Issues:

- Measles outbreaks with an increasing proportion of cases aged <9 months
- Measles and rubella outbreaks with a high proportion of cases aged >15 years
- No special recommendation for measles vaccination in HIV-infected children on Highly Active Retroviral Therapy (HAART)

Policy questions:

- “Should the recommended age for MCV1 in endemic settings be lowered to <9 months?”
- “Under what epidemiological circumstances should adolescents and/or young adults be vaccinated in order to stop measles or rubella transmission?” eg. immunity thresholds
- “Should an additional dose of MCV be recommended for HIV-infected children on HAART?”

Pertussis Working Group: Discussions on the Optimization of DPT and TT Immunization schedules

- Met 26-27 August 2014
 - "not enough data to support a change in the recommendation for the use of a different schedule for DTP in infants, children, adolescents and adults at this stage. In particular, there is not enough evidence to support a change from a 3-doses to a 2-doses primary immunization."
- DPT session postponed to April 2015 in view of Ebola pressure and lack of urgency of session in view of the above conclusion
- As a result updating of pertussis position paper will be delayed to Q3 2015

What is the status of the RTS,S malaria vaccine trial and of the WHO policy process?

- RTS,S/AS01 has completed a Phase 3 trial in 15,460 infants and children in 2 age groups:
 - infants aged 6-12 weeks
 - children aged 5-17 months
 - 3 monthly doses followed by a booster dose after 18 months
- JTEG reviewed the final Phase 3 data including booster dose on 25-26 Sep 2014
 - EMA Art. 58 Scientific Opinion Expected July to September 2015
 - SAGE/Malaria Policy Advisory Committee JOINT SESSION - FOR DECISION October 2015
 - ?Possible prequalification November-December 2015
 - ?GAVI Board decision during 2016

Results from first phase III trials of a dengue vaccine

- Vaccine efficacy (VE) against dengue of any serotype:
 - 56.5% (95% CI: 43.8-66.4) in Asia¹
 - 60.2% (95% CI: 52.0-68.0) in Latin America²
- VE against hospitalized dengue cases
 - 67.2% (95% CI: 50.3-78.6) in Asia
 - 80.3% (95% CI: 64.7-89.5) in Latin America
- Variable VE by serotype, age at vaccination, serostatus at baseline
- No safety signals in 12 months of follow up post-dose 3
- Expected submission to regulatory authorities Q1 2015
- Planned SAGE session on dengue in April 2016

¹Capeding MR et al. Lancet, 2014.

²http://en.sanofi.com/Images/37154_20140903_DENGUE_en.pdf

WHO Statement on Public Disclosure of Clinical Trials Results

Existing WHO Position that **All Interventional Clinical Trials** should appear on a public **Clinical Trial Registry Site**

A draft WHO Statement on Public Disclosure of Clinical Trials Results is **now open for public consultation**

→ 15 Nov Deadline for comments

<http://who.int/ictrp/results/en/>

Includes an expected timeframe for publication in a preferably open access journal

In addition to reporting in journals, use of the results component of registries is encouraged

SAGE 2015-2016 meetings

Selected topics on the horizons

Cross-cutting

- GVAP monitoring of implementation
- Use of vaccines in immunocompromised populations
- *Pain reduction*
- *Vaccines co-administration*
- *Sustainable access to vaccines in MICs*
- Strategies to reach older age groups
- *Immunization platform in 2nd year*
- Involvement of the private sector
- Strengthening NITAGs
- Maternal vaccination

Vaccine specific

- *Polio eradication*
- Measles and rubella elimination
- *Optimizing immunization schedules (hepatitis B, DPT-TT)*
- Impact monitoring
- Malaria
- Dengue
- Typhoid
- TB
- HPV
- *Ebola?*

[illegible]