EPI @ 40

Global progress in immunization, challenges, opportunities and looking forward

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World Health Organization
UNICEF 2014 Vaccine Manufacturer Consultation
8 October 2014
Smallpox eradication and creation of EPI

- Smallpox eradication certified in Dec 1979 -- proof of the power of vaccines.
- EPI set up in 1974 at a time of great optimism for public health.
- When EPI was established, only about 5% of the world children were protected from 6 diseases.
- Today, that figure is 83% with some low-income countries reaching very high immunization coverage.
EPI: one of the world’s most successful public health programmes

- Vaccines are scheduled interventions that can be delivered even in the absence of well-functioning health systems.

- EPI encouraged new models of funding and stimulated innovation in technology.

- Pioneered improvements in surveillance and monitoring as contribution to accountability for results e.g. GVAP.

- Strengthened public health capacities e.g. over 700 laboratories in 164 countries accredited by WHO to undertake lab-based surveillance for measles and other vaccine preventable diseases.

- Intensified collaboration with pharmaceutical industry led to new vaccines and new product designs and formulations for use in low resource settings.
A "Decade of Vaccines"

- Significant progress in the past decades
  - Progress with disease eradication or elimination
  - Millions of deaths averted

- Ability to deliver immunization with high coverage
  - Already reaching over 80% children globally
  - Higher than any other intervention across continuum of care

- Increasing number of diseases now vaccine preventable
  - Robust vaccine pipeline
  - Progress with adding vaccines in national programmes
  - From childhood to life-course vaccination

- Set-up of a DoV collaboration to develop a comprehensive roadmap to realize the full potential of vaccines and immunization
"We envision a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases".

"The mission of the Decade of Vaccines is to extend, 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."
Six Guiding Principles

1. COUNTRY OWNERSHIP
   Countries have primary ownership and responsibility for establishing good governance and for providing effective and quality immunization services for all.

2. SHARED RESPONSIBILITY AND PARTNERSHIP
   Immunization against vaccine-preventable diseases is an individual, community and governmental responsibility that transcends borders and sectors.

3. EQUITY
   Equitable access to immunization is a core component of the right to health.

4. INTEGRATION
   Strong immunization systems, as part of broader health systems and closely coordinated with other primary health care delivery programmes, are essential for achieving immunization goals.

5. SUSTAINABILITY
   Informed decisions and implementation strategies, appropriate levels of financial investment, and improved financial management and oversight are critical to ensuring the sustainability of immunization programmes.

6. INNOVATION
   The full potential of immunization can only be realized through learning, continuous improvement and innovation in research and development, as well as innovation and quality improvement across all aspects of immunization.
Goals of the Global Vaccine Action Plan

- Achieve a world free of poliomyelitis
- Meet global and regional elimination targets
- Meet vaccination coverage targets in every region, country and community
- Develop and introduce new and improved vaccines and technologies
- Exceed the Millennium Development Goal 4 target for reducing child mortality
Strategies towards attainment of the DoV Goals

1. All countries commit to immunization as a priority

2. Individuals and communities understand and demand immunization

3. Benefits equitably extended to all people

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

5. Sustainable access to long-term funding and quality supply

6. Country, regional and global R&D efforts maximize the benefits of immunization

- Currently available and underutilized vaccines are scaled-up

- New or improved vaccines and technologies further enhance the benefits of immunization

- Certification of polio eradication
- Elimination of neonatal tetanus
- Elimination of measles in at least 5 regions
- Elimination of rubella in at least 2 regions
- Under 5 mortality rate declines significantly
- Hundreds of millions of cases and millions of future deaths averted
The World Health Assembly endorsed the Global Vaccine Action Plan – May 2012

Urged Member States to:

- Apply
- Commit
- Report

Annually to regional and global governing bodies (RC & WHA)
Assessment of progress
ARE WE ON TRACK TO REACH OUR COVERAGE GOALS?

Immunization Vaccines and Biologicals, (IVB), World Health Organization.
194 WHO Member States. Date of slide: 17 July 2013.
Only 59 (30%) countries have ≥ 80% DTP3 in all districts


Date of slide: 16 July 2013
Polio eradication: the end in sight?

- No WPV3 cases
- WPV in endemic countries
  - Afghanistan: 40% reduction
  - Nigeria: 88% reduction; only six in 2014
  - Pakistan: ~5 fold increase
- Spread to previously polio-free countries
- Insecurity and attacks of health workers
- 2014 goal at "extreme risk" (IMB May 2014)

In 2014 (until Sep 30)
209 cases
3 endemic countries
9 re-infected countries

World Health Organization
Reduction in estimated measles deaths, 1985 - 2011

86% drop from 1985-2011

71% drop from 2000-2011

Source: WER 2013; 88(3):29-36
Progress towards measles elimination

- Measles incidence per million population (log scale)

- GOAL
- GLOBAL
- AFR
- EMR
- EUR
- SEAR
- WPR
- AMR

- 2015 Goal
- Trend to reach goal
- Projected 10-yr trend

- Trend to reach goal

- World Health Organization
Control of Epidemic Meningitis

- **Meningitis Vaccine Project**
  - Collaboration between PATH & WHO

- **Technology transfer to SII, India**
  - PS production (Synco Biopartners, Netherlands)
  - Conjugation (CBER/USFDA)
  - Lyophilization (Aera, France)

- **Product development**
  - SII, India

- **Product for African Menigitis belt at final price < $ 0.50**
MenAfriVac rollout 2010–2016

Inducing strong herd immunity

single dose mass vaccinations in 1-29 year-olds, with high coverage in 26 meningitis belt countries
Introducing new vaccines: turning a Vicious Cycle into a “Virtuous Cycle”

- Uncertain demand
- Higher prices
- Limited supply

- Increased production capacity
- Predictable demand
- Lower prices

- Establishing value
- Communicating value
- Delivering value
Progress with introduction of Hib vaccine: 1997 to 2014

1997
- 29 countries introduced
- 2 countries partially introduced

2014
- Introduced* to date (191 countries or 98.5%)
- Planned introductions in 2014 (1 countries or .5%)

Map production: Immunization Vaccines and Biologicals (IVB), World Health Organization.
194 WHO Member States.
Introduction of pneumococcal and rotavirus vaccines as of 29 Sept 2014

Pneumococcal vaccine

- Introduced* to date (111 countries or 57%)
- Planned introductions in 2014 (9 countries or 8%)
- Not Available, Not Introduced / No Plans (74 countries or 38%)

Rotavirus vaccine

- Introduced* to date (69 countries or 36%)
- Planned introductions in 2014 (3 countries or 2%)
- Not Available, Not Introduced / No Plans (122 countries or 65%)

[World map showing vaccine introductions and plans]
New vaccines target important, **but not all**, pathogens of diseases that are major causes of morbidity and mortality.

Non-vaccine interventions of proven effectiveness exist but need to be scaled up.

Better coordination between programmes can lead to synergies and efficiencies that will maximize benefits.

Immunization contacts can be used to deliver a package of interventions, or improve care seeking and health utilization.

- Birth dose of Hep B vaccine
## R&D priorities

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<th>Short-term</th>
<th>Medium-term</th>
<th>Long-term</th>
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| • Improve programme efficiencies  
• Epidemiological and operational research  
• Health information technologies | • Support development, licensing and uptake of vaccines  
• Improved vaccine thermostability  
• Simplified vaccine delivery and product packaging  
• Regulatory science | • Enable the development of new vaccines  
• Immunological research on adaptive and innate systems  
• Research into pathogens and their evolution |

Develop and introduce new and improved vaccines and technologies
NITAGs status report 2013

- 57% of countries with a NITAG with an administrative/legislative basis
- 75 (39% of countries) NITAG complying with the 6 basic process indicators** (74% increase compared with 2010) including 40 developing countries
- Mandatory DoI for members still a big limiting factor
- Still some confusion with ICCs
- AMP-HPID designated as collaborating centre for supporting evidence-based decision making

% of countries with a NITAG that meets all 6 basic process indicators* (blue 2013 – red 2010)

*Based on the JRF
**Formal ToRs, legislative or administrative basis, at least 5 areas of expertise, at least one meeting a year, agenda distributed >= 1 week ahead of meetings, mandatory declaration of interests

Global AFR AMR EMR EUR SEAR WPR

0 10 20 30 40 50 60 70 80
Two meetings a year critical input on:

- Vaccine-disease specific
  - polio eradication and endgame strategy, pandemic and pre-pandemic influenza vaccines, measles and rubella elimination, smallpox vaccines for outbreak response, and varicella, Hib, pertussis, yellow fever, and HPV vaccines

- Cross cutting
  - GVAP implementation monitoring, immunization supply chains, surveillance networks, non-specific effects of vaccines, maternal immunization, integration of immunization and child health services, framework on vaccination in humanitarian emergencies.

- In October 2014 → polio eradication, GVAP report, Japanese encephalitis, conjugate men A routine infant schedule, hepatitis E, vaccine hesitancy and DTP schedules

- Continuous enhancement of operating processes
- Calling CSOs to play a more active role
SAGE 2015-2016 meetings
Selected topics on the horizons

Cross-cutting and strategic
- DOV GVAP monitoring of implementation
- Use of vaccines in immunocompromised populations
- Strategies to reach older age groups
- Immune senescence
- Pain reduction
- Involvement of the private sector
- Strengthening of NITAGs
- Vaccine supply and accessibility to affordable vaccines

Vaccine specific
- Polio eradication
- Measles elimination
- Optimizing immunization schedules (hepatitis B, DPT-TT)
- Impact monitoring
- Preferred Product Characteristics
- HPV
- Malaria
- Dengue
WHO Vaccine Position Papers

- Build on recommendations by SAGE
- Over the last 2 years papers/updated papers published on influenza, *Haemophilus influenzae* type b, polio, rotavirus, varicella & herpes-zoster, and yellow fever vaccines.
- Revised guidance on the choice of pertussis vaccine.
- Updated position paper on use of HPV pending publication.

Selected recommendations:
- no need for YF booster
- moving from 3 to 2 HPV doses,
- introduction of at least one IPV in all countries

Summary tables on policy recommendations/schedules including on health workers and interrupted schedules
Pathways for WHO Recommendations on Vaccine Use

**Industry** and other partners

- Global Advisory Committee on Vaccine Safety
- Expert committee on Biological Standardization
- Product Development for Vaccines Advisory Committee
- Immunization and Vaccines related Implementation Research Advisory Committee
- Immunization Practices Advisory Committee

**Background Paper**
- Relevant existing technical advisory committee
- Secretariat

**SAGE**

- Input
- Request for review of evidence

**WHO Secretariat**
- WHO DG
- WHO Position Paper
- Country Decision making

**Region**
- Regional TAGS
- Regional consultations

**Other relevant non immunization related WHO policy recommendation making body**

Peer review including by industry
Product Development for Vaccines Advisory Committee (PDVAC): terms of reference

- “scanning the horizon” to identify new diseases where there is sufficient priority for WHO to initiate activities
- Consensus building for vaccine trial endpoints for policy decision making
- Initiating roadmap development
- Prioritizing & advising on development of preferred product characteristics
- Reviewing other WHO products, including methods, protocols, tools and approaches for accelerating product development
- Stimulating research by partners in line with WHO priorities
- Advising WHO on ways to improve public access to information about products in development.
The following 19 pathogen specific areas were requested as pipeline analyses:

- HIV, Tuberculosis, Malaria
- Universal influenza, RSV
- Group A Streptococcus, S. pneumoniae
- Upstream rotavirus, E. coli, Shigella, Paratyphoid, Non-typhoidal salmonella, campylobacter, norovirus
- HSV, Chagas, Leishmaniasis, Schistosomiasis, Human Hookworm
Preferred Product Characteristics: What they are & what they are not!

What they are

- Guidance from WHO for vaccine developers to take into account when designing vaccines and trials at early stage of vaccine R&D
- Will need to change in line with the scientific state-of-the-art and needs of country programmes (with ongoing review process)

What they are not

- They are not static exit criteria. Innovation is encouraged and harnessed to meet public health needs
- They do not replace standard policy or PQ processes

Addressing five priority problems will help bring the Global Vaccine Action Plan back on track.

- Weak GVAP implementation
- Poor data quality and use
- Vaccine affordability and supply
- Failures of basic integration
- Situations disrupting immunisation

**Stagnant vaccination coverage**

**Eradication and elimination goals repeatedly missed**
VACCINE AFFORDABILITY AND SUPPLY

The affordability and supply of vaccines need to be urgently examined. Each may be causing a significant problem for a large number of countries, and the current lack of proper information hinders understanding and corrective action.

SAGE recommends that:

- Technical agencies conduct urgent assessments of (i) the extent to which reported national-level stock-outs are affecting local vaccine supply and delivery, and (ii) the root causes of these stock-outs.

- Countries lead an effort to change the rules of the game on vaccine affordability, to create the transparency that is in their interest. They can do this by making pricing information publicly available, and by collaborating to develop solutions.

- Technical partners support countries to improve the transparency of vaccine pricing. Agencies themselves should do everything possible to share pricing data.
TOGETHER WE CAN MAKE IT HAPPEN!

http://www.who.int/immunization/global_vaccine_action_plan/en/