

# **Progress in the “Decade of Vaccines”:**

## **The Role of the GVIRF in Facilitating and Enhancing the R&D Component of the Global Vaccine Action Plan**

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**GVIRF  
20-22 March 2018**



National Institute of  
Allergy and  
Infectious Diseases

# Overview

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- **Background & Context:**
  - *From “Decade of Vaccines” Collaboration to the Global Vaccine Action Plan (GVAP)*
- **GVAP Assessment**
- **R&D Parameters & Reporting**
- **GVIRF 2018: Thematic Overview**

# Why a “Decade of Vaccines”?

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## ■ Significant impact of immunization in the past decades

- *Progress with disease elimination or eradication*
- *Millions of deaths averted*

## ■ Ability to deliver immunization with high coverage

- *Already reaching >80% children globally*
- *Higher than any other intervention across the continuum of care*

## ■ Increasing number of diseases now vaccine preventable

- *Robust vaccine pipeline*
- *Progress with adding vaccines into national programs*

## ■ Despite many successes, opportunities to do much better

# Mission of the Decade of Vaccines

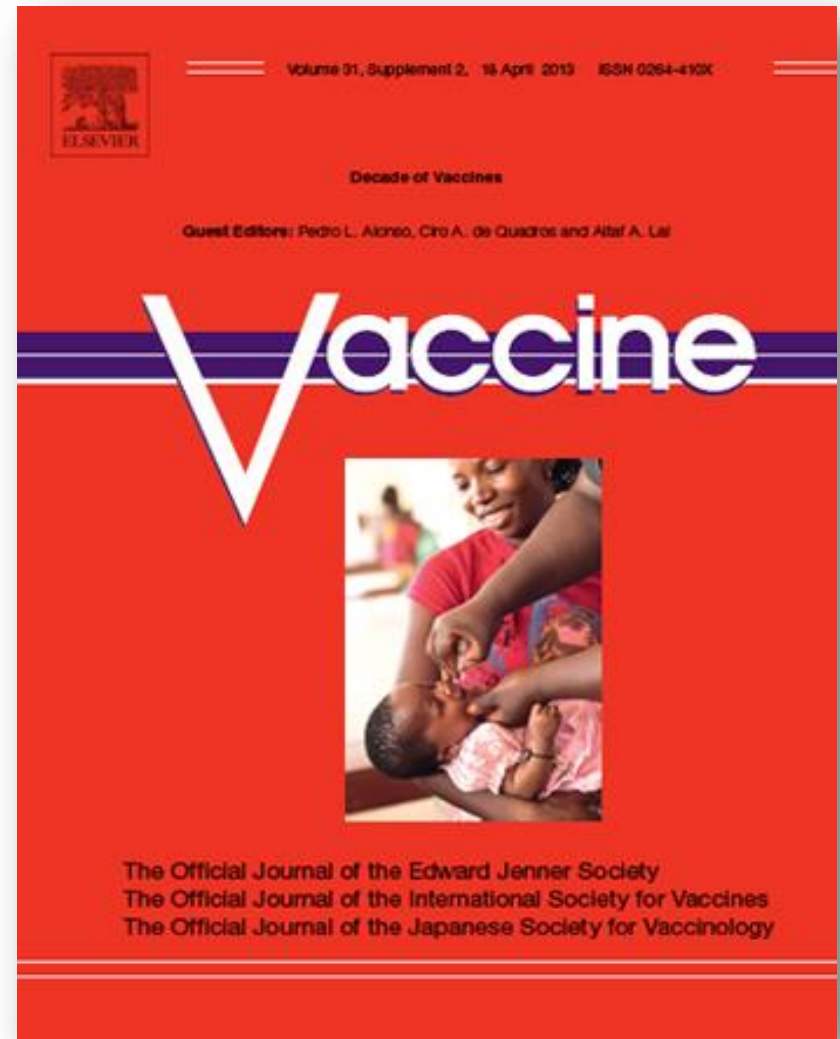
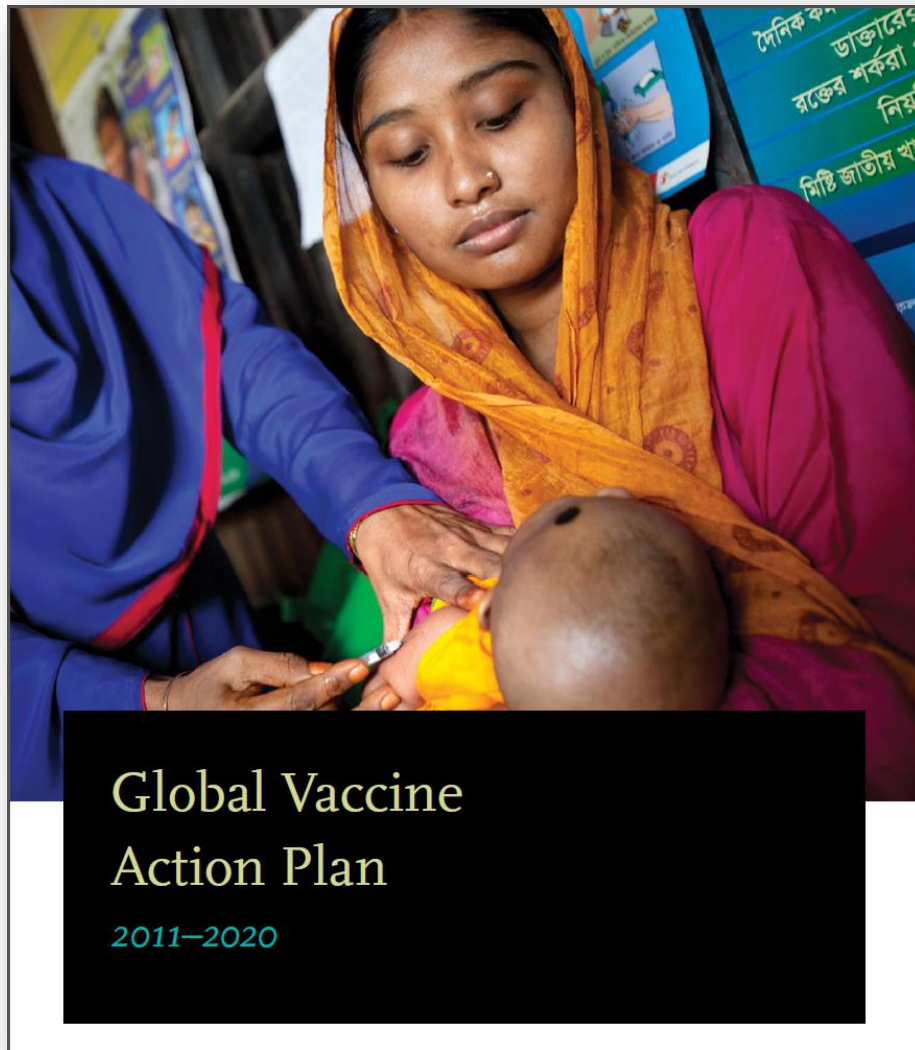


**"ATTAINMENT OF A WORLD IN  
WHICH ALL PEOPLE AT RISK ARE  
PROTECTED AGAINST VACCINE-  
PREVENTABLE DISEASES"**



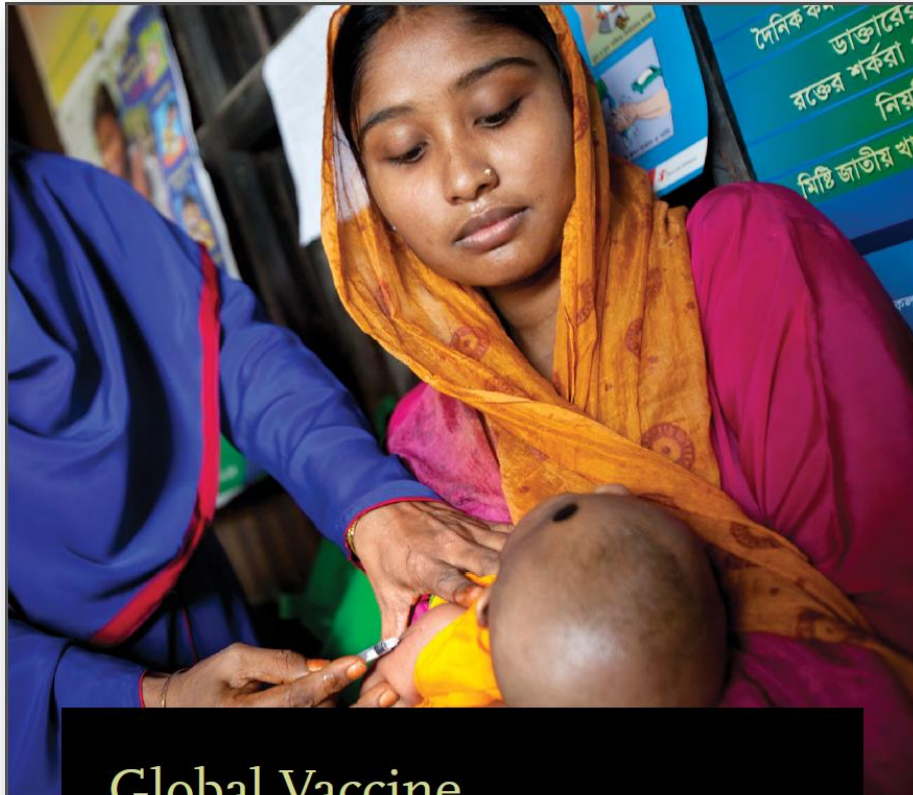
***In 2010 a Decade of Vaccines Collaboration (DoVC) was established to coordinate the development of a Global Vaccine Action Plan to provide a framework for accomplishing the mission.***

# Outputs of the Decade of Vaccines Collaboration



# Decade of Vaccines: Vision & Mission

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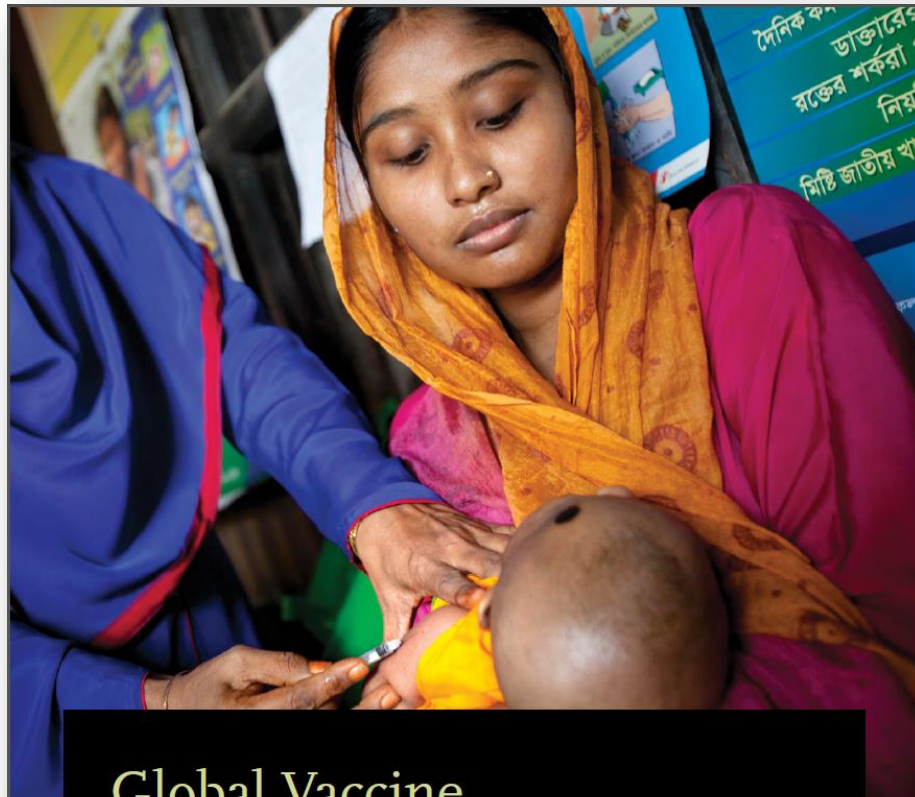
Global Vaccine  
Action Plan

2011–2020

*“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.”*

# The GVAP Differs Significantly from Prior Vaccine Initiatives



Global Vaccine  
Action Plan

2011–2020

- **Explicitly includes an R&D component**
  - *Basic & Translational*
  - *Implementation*
  - *Operational*
- **Explicitly includes an M&E/ Accountability component and framework**

# World Health Assembly Actions

- **Endorsed the GVAP in May 2012 and urged 194 member states to:**
  - ***Apply***
  - ***Commit***
  - ***Report***
    - **Annually to WHO regional and global governing bodies**
      - ***Regional Committees (Q3-Q4)***
      - ***WHO Executive Board (January)***
      - ***WHA (May)***
- **Supported the M&E/ Accountability Framework in May 2013**





# R&D Reporting

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- **Key areas relate to Strategic Objective 6 and Goal 4 of the GVAP:**
  - *Expanding capabilities and engagement with end-users;*
  - *Enabling development of new vaccines;*
  - *Accelerating development, licensing and uptake of vaccines; and*
  - *Improving programme efficiencies and increasing coverage.*
  
- **“Enhanced Collaboration on Research Matters Related to the Global Vaccine Action Plan”**
  - *Memorandum of Understanding signed in 2013 by BMGF, NIAID and WHO*
  - *Provides framework for enhanced collaboration on R&D related to the GVAP*

# R&D Reporting

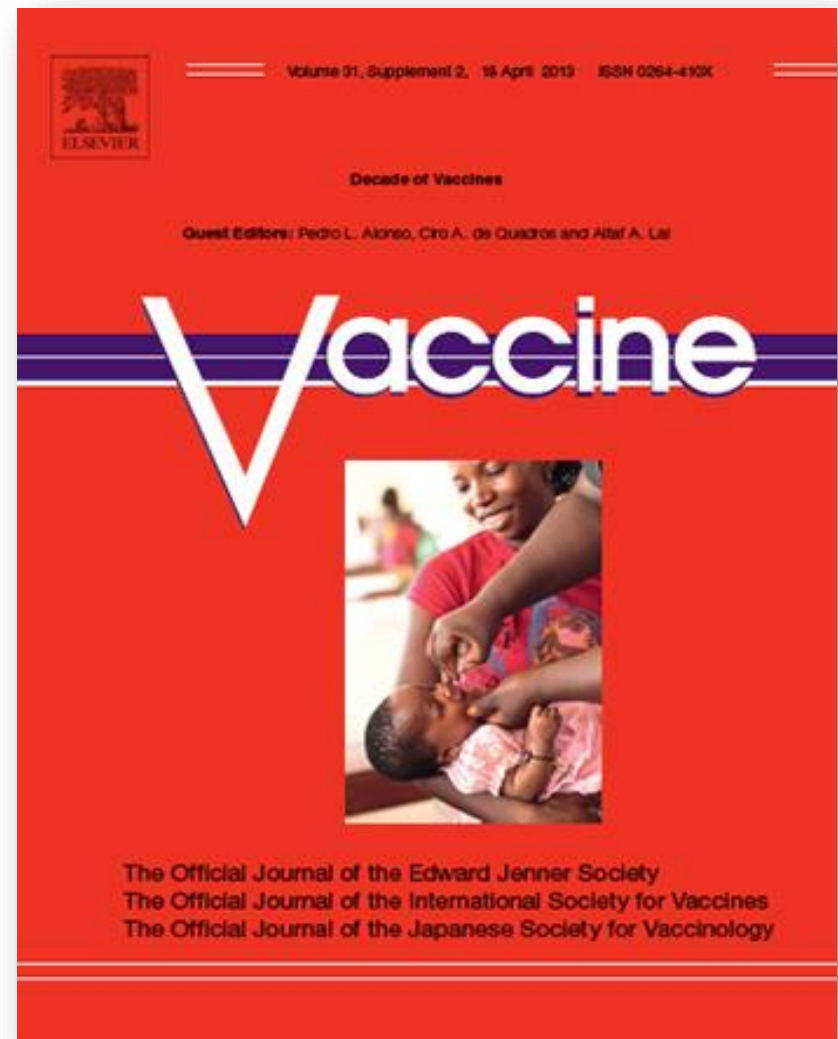
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- **Scheduled to take place every 2 years**
- **Global Vaccine & Immunization Research Forum**
  - *4 - 6 March 2014, Bethesda MD, USA*
  - *15-17 March 2016, Johannesburg, South Africa*
  - *20-22 March 2018, Bangkok, Thailand*

# “Decade of Vaccines” Supplement

*(Vaccine 31, Suppl. 2, 18 April 2013)*

- 27 Articles, 210 Authors, 90 Reviewers
- Addresses GVAP Goals and Strategic Objectives
- 9 Case Studies, including:
  - Epstein-Barr Virus,*
  - Cytomegalovirus, HIV,*
  - Respiratory Syncytial Virus, Group A Streptococci,*
  - Tuberculosis, Hookworm,*
  - Malaria, Leishmaniasis*





[www.sciencedirect.com/science/journal/0264410X/31/supp/S2](http://www.sciencedirect.com/science/journal/0264410X/31/supp/S2) (open source)

# R&D Reporting

## ■ GVIRF 2014

Contents lists available at [ScienceDirect](#)

 **Vaccine** 

journal homepage: [www.elsevier.com/locate/vaccine](http://www.elsevier.com/locate/vaccine)

Conference report

**Global Vaccine and Immunization Research Forum: Opportunities and challenges in vaccine discovery, development, and delivery**

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**ABSTRACT**

The World Health Organization, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, and the Bill & Melinda Gates Foundation convened the first Global Vaccine and Immunization Research Forum (GVIRF) in March 2014. This first GVIRF aimed to track recent progress of the Global Vaccine Action Plan research and development agenda, identify opportunities and challenges, promote partnerships in vaccine research, and facilitate the inclusion of all stakeholders in vaccine research and development. Leading scientists, vaccine developers, and public health officials from around the world discussed scientific and technical challenges in vaccine development, research to improve the impact of immunization, and regulatory issues. This report summarizes the discussions and conclusions from the forum participants.

## ■ GVIRF 2016

Contents lists available at [ScienceDirect](#)

 **Vaccine** 

journal homepage: [www.elsevier.com/locate/vaccine](http://www.elsevier.com/locate/vaccine)

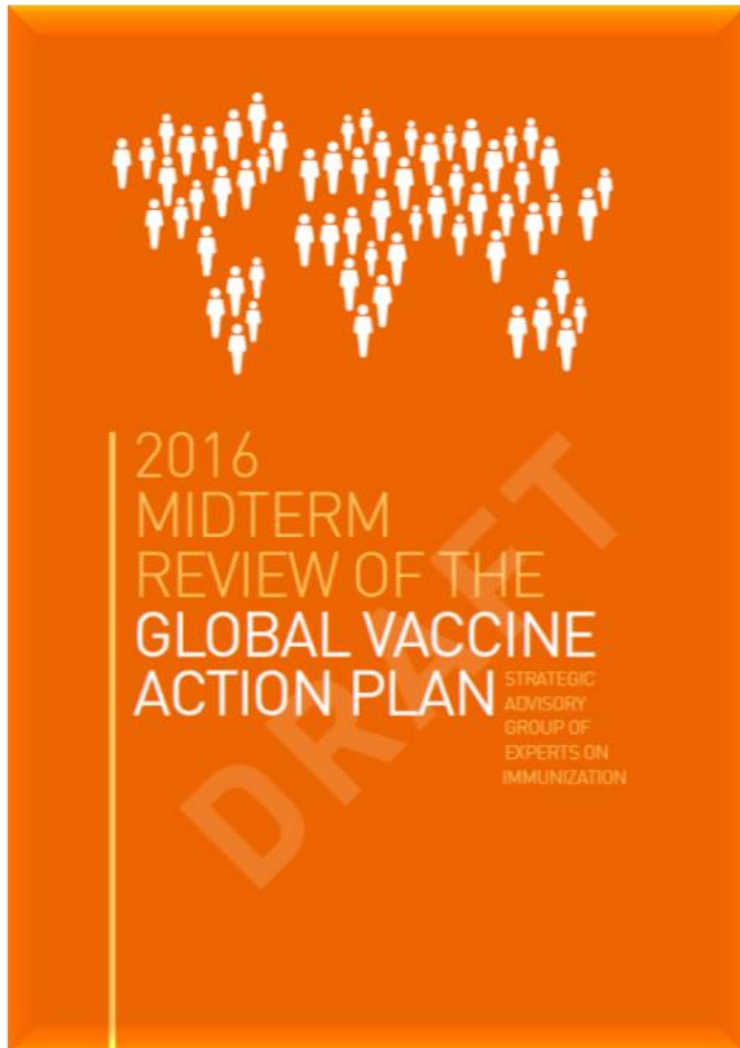
Meeting report: Global vaccine and immunization research forum

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# GVAP Mid-Term Assessment

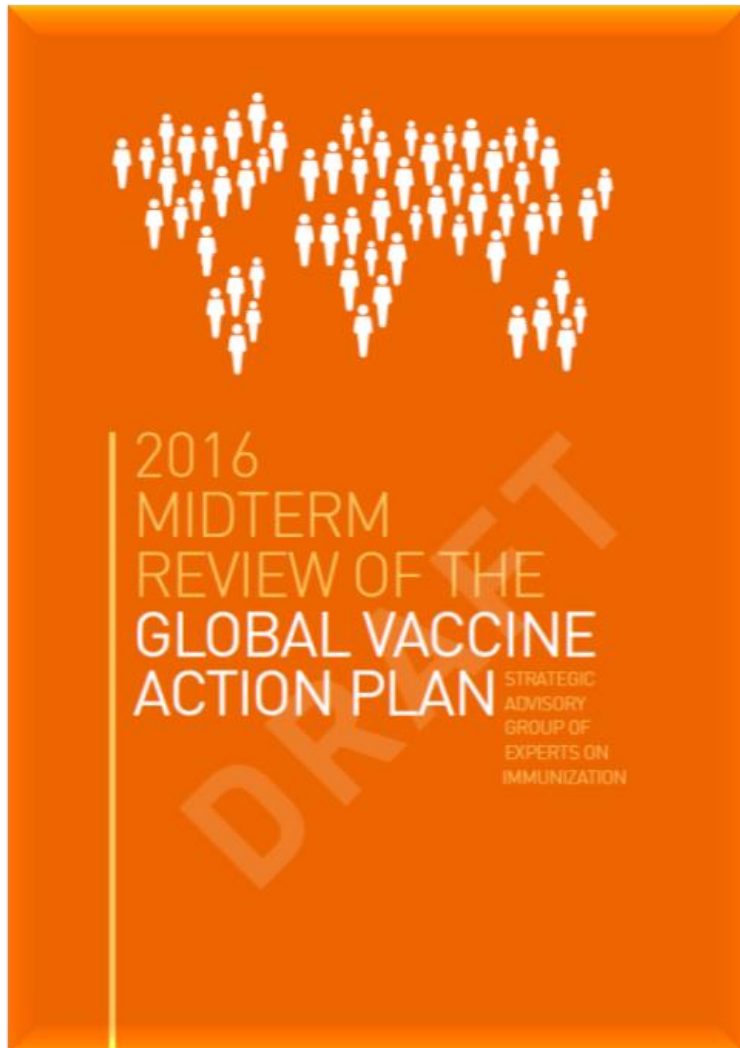
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- **SAGE “...concerned that progress toward the goals to eradicate polio, eliminate measles and rubella, eliminate maternal and neonatal tetanus, and increase equitable access to lifesaving vaccines is too slow.”**
- **“Vaccine research and development is progressing rapidly, and an expanding pipeline of new vaccines underscores the need to build health systems that can reliably reach new target age groups.”**

# GVAP Mid-Term Assessment

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- ***“Progress in vaccine R&D underscores the urgent need to expand clinical trial capacity, strengthen NRAs, and begin implementation research earlier.”***

## **Selected Recommendations:**

- **Support vaccine R&D capacity in low and middle income countries**
- **Accelerate the development and introduction of new vaccines and technologies**

# Leadership Commentary on 2016 GVAP Midterm Review

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## THE LANCET

Volume 385 - Number 10071 - Pages 763-880 - February 25-March 3, 2017

www.thelancet.com

### Reaching everyone, everywhere with life-saving vaccines

*Margaret Chan, Chris Elias, Anthony  
Fauci, Anthony Lake, Seth Berkley*

- **Significant progress** to date (e.g., highest level of routine coverage in history, increase in number of vaccines in the clinical development pipeline)
- **Challenges remain** (e.g., GVAP targets for disease elimination are behind schedule, data deficiencies at national and local levels)
- **Need to recommit** to advancing the goals and objectives of the GVAP and call on the global health community to do more

# The GVAP 'Leadership Council' Meeting Washington DC, 21 April 2017

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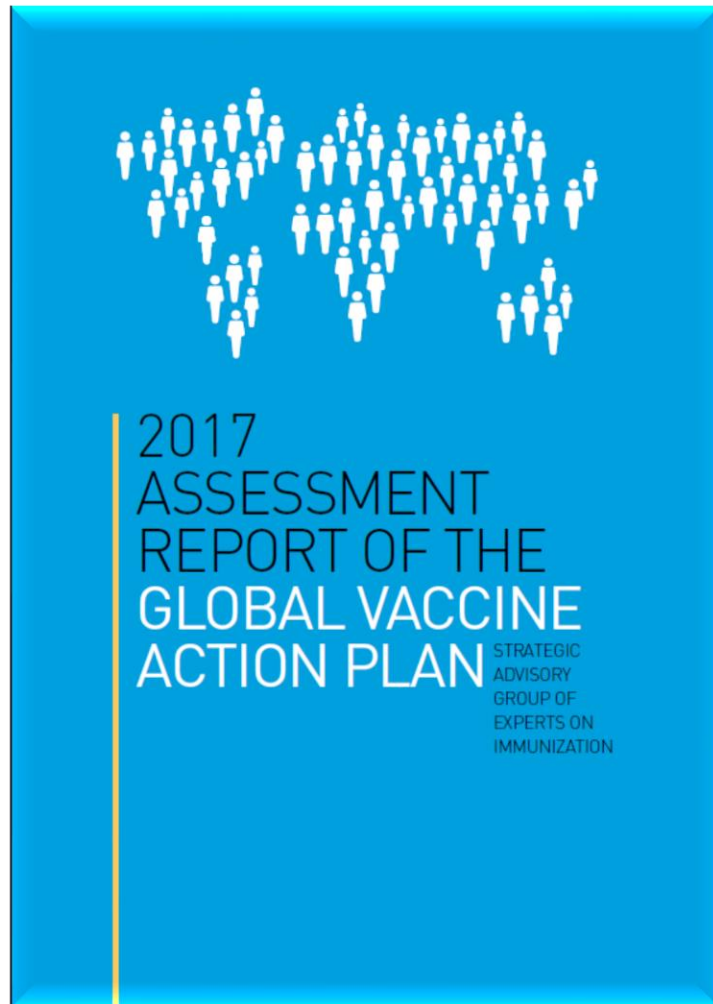


- Pleased with progress in some areas; concerned with challenges in coverage and equity
- Sense of urgency in tackling GVAP shortcomings
- Identified **multiple key needs**, including developing an **innovation agenda to support equity**



# GVAP in 2017

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## Key Messages:

- ***Progress still remains too slow for most goals to be reached by 2020.***
- ***Multiple global, regional and national issues threaten further progress.***
- ***Phase-out of funding for polio eradication is a concern.***
- ***Required action: intensify global efforts to promote immunization and to address the systemic weaknesses that are limiting equitable access***

# 6

**COUNTRY, REGIONAL AND GLOBAL RESEARCH AND DEVELOPMENT INNOVATIONS MAXIMIZE THE BENEFITS OF IMMUNIZATION.**

## INDICATORS



**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)**

## OPERATIONAL DEFINITION

Number of HIV, TB, and malaria vaccine clinical trials assessing clinical efficacy completed and with results reported

Number of influenza clinical trials assessing clinically the breadth of protection completed and reported

**6.3. Progress towards institutional and technical capacity 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**

Number of countries per WHO region having reported conduct of a vaccine clinical trials that meet quality standards (to be specified)

As defined in indicator

Four categories of equipment would be tracked:

- Refrigerators and freezers
- Cold boxes and vaccine carriers
- Coolant packs
- Temperature monitoring devices

# R&D Goals and Indicators of the GVAP



## Strategic Objective 6: Country, Regional and Global R&D Innovations Maximize the Benefits of Immunization

Indicator	Target	GVIRF 2018 Sessions
(6.1) Progress towards the development of HIV, TB and malaria vaccines	Proof of concept for a vaccine that shows >75% efficacy	<i>Plenary 1</i>
(6.2) Progress towards a universal influenza vaccine	At least one vaccine providing broad spectrum protection against Influenza A is licensed.	<i>Workshop 5</i>
(6.3) Progress towards institutional and technical capacity to carry out vaccine clinical trials	Every region has a solid base of competent countries	<i>Multiple sessions</i>



#### 4. DEVELOP AND INTRODUCE NEW AND IMPROVED VACCINES AND TECHNOLOGIES

## INDICATORS

### 4.1. Licensure and launch of vaccine or vaccines against one or more major currently non-vaccine preventable diseases

Licensure relates to registration by a functional National Regulatory Authority (NRA)

Launch is defined as addition of the vaccine to the national immunization schedule in one or more low or middle income countries (WB definition) and sustained for a period of at least 12 months. Excludes use only in the private sector. Includes vaccines in national schedule that may be selectively used in "at risk" populations

### 4.2. Licensure and launch of at least one platform delivery technology

Licensure relates to registration by a functional NRA

New platform delivery technology is defined as a new mechanism for delivering vaccines to individual recipients that facilitates coverage, improves performance, or reduces cost of vaccine or delivery, e.g. jet injectors, microneedles, aerosol etc.

Launch as defined for new vaccine introduction (see above indicator)

### 4.3. Number of low-income and middle-income countries that have introduced one or more new or underutilized vaccines

Low- and middle-income countries= world bank classification 2012

Vaccine is added in national immunization schedule and used for a sustained period of at least 12 months (excluding those used only in the private sector and not in national immunization schedule; includes vaccines included in national schedule but for selective use at risk populations, e.g. seasonal influenza)

New and underutilized vaccines refers to all vaccines that were not previously in national immunization schedule

# R&D Goals and Indicators of the GVAP



## Goal 4: Develop and Introduce New and Improved Vaccines and Technologies

Indicator	Target	GVIRF 2018 Sessions
(4.1) Licensure and launch of vaccine(s) against one or more major, currently non-vaccine preventable disease	One or more vaccines licensed and launched by a functional NRA	<b><i>Plenaries 3, 4, 5</i></b> <b><i>Workshops 1, 2, 3, 4, 7</i></b>
(4.2) Licensure and launch of at least one platform delivery technology	One or more delivery technology licensed and launched by a functional NRA	<b><i>Plenaries 3, 4, 5</i></b>

# Themes for GVIRF 2018

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■ ***Discovery***

■ ***Development***

■ ***Decision Making***

■ ***Delivery***

■ ***End-to-End  
Integration***

■ ***Equity***

# Acknowledgements

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## Scientific Organizing Committee

- *Jean-Pierre Amorij*
- *Narendra Arora*
- *Norman Baylor*
- *David Durrheim*
- *Gagandeep Kang*
- *Odile Leroy*
- *Kathleen Neuzil*
- *Bernhards Ragama Ogutu*
- *Alexander Precioso*
- *Helen Rees*
- *Lucky Slamet*
- *Gerd Zettlmeissl*

# GVIRF 2018

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- ***Welcome to GVIRF 2018!***
- ***Have an enjoyable and productive meeting!***
- ***Take this opportunity to meet and work with your colleagues to fulfill the promise of the Decade of Vaccines!***