

The process for prioritising upstream vaccines for WHO activities

David Kaslow

PDVAC Chair

Global Vaccine Action Plan

2011–2020

Goals of the Decade of Vaccines (2011–2020)



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





The vaccine pipeline

THE JORDAN REPORT

ACCELERATED DEVELOPMENT OF VACCINES 2012

**577 candidate
vaccine
approaches**

110 pathogens

Jordan report every 5 years:

www.niaid.nih.gov/topics/vaccines/pages/Jordan2012.aspx

Where can WHO contribute ?

Vaccines/products
licensed and currently
in use

Implementation research overseen by
IVIR-AC

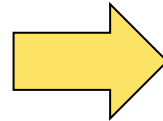
Candidate vaccines/
products under
development

No equivalent body to advise WHO on
product development issues

PDVAC terms of reference

- NOTE terms of reference **do not include** engaging in any Sponsor or Investigator-like role for Product Development
- The role is to assess the pipeline and consider WHO's role – **NOT to directly develop vaccines**

110 pathogens



**577 candidate
vaccine
approaches**

**Pre-screened to
manageable size for
detailed pipeline analyses
based on expert advice
and on understanding
that additional pathogens
will be added as
necessary each year for
further pipeline analyses**



20 pathogens

Pipeline analyses

● MODEL:

- Identify partner often from Product Development Partnership
- Provide template
- Submitted pipeline analysis is reviewed by WHO
- Then submitted to committee members
- All will be published on PDVAC website after each meeting
- Core diseases will be reviewed each year including HIV, TB, malaria, universal influenza
- Certain diseases will be reviewed less often than annually eg, some pathogen areas with either small disease burden or little activity.

- HIV, Tuberculosis, Malaria,
- Universal influenza, RSV
- Group A & B Streptococcus, S. pneumoniae
- Upstream rotavirus, E.coli, Shigella, Paratyphoid, Non-typhoidal salmonella, campylobacter, norovirus
- HSV, Chagas, Leishmaniasis, Schistosomiasis, Human Hookworm

Background documents

- ↓ Status of vaccine research and development for Campylobacter
pdf, 172kb
- ↓ Status of vaccine research and development of vaccines for Chagas disease
pdf, 165kb
- ↓ Status of vaccine research and development of vaccines for Enterotoxigenic Escherichia coli
pdf, 195kb
- ↓ Status of vaccine research and development of vaccines for Streptococcus pyogenes
pdf, 213kb
- ↓ Status of vaccine research and development of vaccines for HIV-1
pdf, 163kb
- ↓ Status of vaccine research and development of vaccines for Herpes Simplex Virus
pdf, 191kb
- ↓ Status of vaccine research and development of vaccines for Human Hookworm infection
pdf, 2.52Mb
- ↓ Status of vaccine research and development of vaccines for Leishmaniasis
pdf, 223kb
- ↓ Status of vaccine research and development of vaccines for Malaria
pdf, 206kb
- ↓ Status of vaccine research and development for Nontyphoidal Salmonellosis
pdf, 248kb
- ↓ Status of vaccine research and development for Norovirus
pdf, 255kb
- ↓ Status of vaccine research and development for Paratyphoid fever
pdf, 230kb
- ↓ Status of vaccine research and development of next-generation Rotavirus vaccines
pdf, 230kb
- ↓ Status of vaccine research and development of vaccines for Schistosomiasis
pdf, 194kb
- ↓ Status of vaccine research and development of vaccines for Shigella
pdf, 194kb
- ↓ Status of vaccine research and development of vaccines for pediatric vaccines for Streptococcus pneumoniae
pdf, 184kb
- ↓ Status of vaccine research and development of vaccines for Tuberculosis
pdf, 205kb
- ↓ Status of vaccine research and development of vaccines for Universal Influenza vaccine

How did PDVAC assess pathogen areas

- Pipeline analyses were reviewed as read-aheads
 - There is a Vaccine supplement publishing over 20 pipeline analyses to be published during 2015. This itself is a unique resource for the vaccine research community not available elsewhere
- The committee were asked to grade using 3 simple criteria:
 - Unmet public health need
 - Activity in a given area, together with the probability of technical and regulatory success, yielding the chances of a new product emerging
 - Added value for engagement from WHO eg for LMIC indications

Major existing pipeline vaccine activities in WHO

- Sexually Transmitted Infection Roadmap
 - HSV identified from this roadmap framework as most advanced STI vaccine.
- HIV, tuberculosis, malaria, universal influenza remain ongoing priorities in GVAP framework
 - Malaria vaccine funders group
 - HIV, coordination with vaccine enterprise
 - Tuberculosis, coordination with stakeholder framework

WHOs work in various upstream pathogen areas in 2015:

- RSV highlighted as most likely “big new vaccine” area, with a North America-South America-Africa Phase 3 trial due to start in Q4 2015, and 4 large manufacturers highly engaged, over 30 other RSV vaccine projects in the pipeline

WHOs work in various upstream pathogen areas in 2015:

- Group B Strep highlighted as a pathogen area with substantial disease burden, part of a maternal immunization agenda, likely technical feasibility to development a vaccine, but only one manufacturer engaged, and now on hold due to GSK-Novartis merger
- Group A Strep highlighted as a pathogen area with substantial disease burden, likely technical feasibility to develop a vaccine, but little industry interest

WHOs work in various upstream pathogen areas in 2015:

- ETEC, Shigella and Norovirus highlighted as potentially promising areas for vaccine development, with interest from the Gates foundation for ETEC and Shigella, and an advanced industry candidate for Norovirus
- Other areas will continue to be tracked
- PDVAC will have a 2015 agenda item on a framework for emergency vaccine development

Summary

- With PDVAC we now have a mechanism to assess the vast early stage vaccine pipeline every year, and advise WHO
- SAGE's input to PDVAC is very welcome: eg recommendations to include specific pathogens for pipeline analyses
- PDVAC will not directly engage in product development – this is not its role.