PDVAC 2017: A year in review

WHO Headquarters
Geneva, 21-22 June 2017

Birgitte Giersing, PhD
Initiative for Vaccine Research
Department of Immunization, Vaccines and Biologicals
The mission of WHO’s vaccine research

‘...is the attainment of a world in which all individuals and communities enjoy the lives free from vaccine preventable diseases’

Priority areas of research:

- Research to promote and accelerate development of vaccines in early development
- Research to accelerate licensure of vaccines in earlier clinical phase of development
- Research to generate evidence to inform policy for candidate vaccines at advanced stages of development
How does WHO’s Initiative for Vaccine Research engage in product development?

- In 2014, the *Product Development for Vaccines Advisory Committee (PDVAC)* was established to prioritize WHO activities across pipeline vaccines according to three fundamental criteria:
  - Unmet public health need for a vaccine from an LMIC perspective
  - Probability of technical and regulatory success, i.e. preclinical POC established
  - Clear role for IVR/WHO to facilitate vaccine development

- To date, PDVAC has evaluated 35 pathogens

[http://www.sciencedirect.com/science/journal/0264410X/34/26]
So what are the challenges of product development for LMICs?

- Poorly defined disease burden in LMICs
- Vaccine investment is driven by market potential in high income countries
- Products for LMICs likely have different product attributes than those for HICs
- Different detection methods, case definitions, clinical endpoints in high and low income contexts
- Unclear regulatory pathway, and lack of clarity regarding data needs for policy recommendations
- Unclear product development cost and risks
- Unclear value proposition for vaccines in LMICs
- Multiple stakeholders with very different perspectives on public health priorities
What are the types of activities that PDVAC has engaged in, to date?

- Commissioning and review of pathogen landscape analyses
- Development of preferred product characteristics for new vaccines
- Development of technical roadmaps for new vaccines
- Consultations to build consensus, for example, on clinical and regulatory pathways
What are the types of activities that PDVAC has engaged in, to date?

- Commissioning and review of pathogen landscape analyses
- Development of preferred product characteristics for new vaccines
- Development of technical roadmaps for new vaccines
- Consultations to build consensus, for example, on clinical and regulatory pathways
What are WHO PPCs, and why are they valuable?

- PPCs provide strategic guidance as to WHO’s preferences for **new** vaccines – from a LMIC perspective
- Pathogen-specific (not product-specific)
- Typically developed prior to phase III clinical studies
- Aim is to optimize the global public health impact of vaccines in development
- PPCs inform product-specific target product profiles (TPPs)
- PPCs are valued because of the broad consultative process undertaken to develop consensus
Process for developing PPCs for new vaccines

1. Baseline analysis to establish priority public health goals
2. PDVAC PPC Working Group
3. Public Consultation
4. PDVAC, Finalise, Update
5. Publish on WHO website
WHO PPCs and TPPs are guidance documents that inform vaccine product development

http://www.who.int/immunization/research/ppc-tpp/en/
Pathogens that have previously been identified as areas of focus

Respiratory Syncytial Virus (RSV)
Group B streptococcus (GBS)
Group A streptococcus (GAS)
Enterotoxigenic E.coli (ETEC)
Shigella
Herpes Simplex Virus (HSV) as part of Sexually Transmitted Infections Roadmap

Tuberculosis
2nd generation Malaria
Human Immunodeficiency Virus (HIV)
Improved influenza vaccines
Progress in pathogen areas that have been previously prioritized, and activities for the next 12 months

- **Respiratory Syncytial Virus (RSV)**
  - PPC and Roadmap finalized.
  - Future activities: - vaccine standardization working group
    - establish a technical advisory group
    - review burden of disease data

- **Group B streptococcus (GBS)**
  - PPC and Roadmap finalized.
  - Future activities: - assay standardization initiative
    - consensus building on clinical endpoint case definition
    - consultation on correlates of protection and regulatory pathway
    - feasibility assessment for GBS surveillance platform
    - health economic value proposition assessment

- **Group A streptococcus (GAS)**
  - Consultation on the value proposition
  - Future activities: - PPC and Roadmap ongoing
    - value proposition assessment
Progress in pathogen areas that have been previously prioritized, and activities for the next 12 months

- ETEC and Shigella
  - Burden of disease consultation
  - Future activities:  
    - review burden of disease data
    - Develop PPCs for single and combination vaccines
    - assay standardization initiative

- Herpes Simplex Virus (HSV)
  - PPC consultation
  - Future activities:  
    - Develop PPCs for prophylactic and therapeutic vaccines
    - consensus building on clinical endpoints and regulatory pathway
    - development of the value proposition
Progress in pathogen areas that have been previously prioritized, and activities for the next 12 months

- **Tuberculosis:**
  - ✓ Working group consultation on the public health needs
  - Future activities:  - PPC development
    - Collaboration with several TB vaccine working groups

- **HIV:**
  - Future activities:  - consultation on late stage pathway from proof of concept to availability and use

- **Malaria second generation:**
  - Future activities:  - consultation and update of WHO recommendations on new malaria vaccines
Progress in pathogen areas that have been previously prioritized, and activities for the next 12 months

- Vaccines against anti-microbial resistance (AMR):
  - Consultation on the value of vaccines against AMR
  Future activities: - prioritization exercise in collaboration with other stakeholders

- New delivery technologies:
  Future activities: - development of clinical and regulatory pathways for microarray patches

- Development of the total systems effectiveness concept:
  - Consultations with global stakeholders on vision, components and use case scenarios
  Future activities: - concept development and grant writing for assessment of a test case by TSE
New directions for PDVAC since the last meeting

- Improved consideration of and focus on cross-cutting issues
- Diversification to assess novel delivery platforms and technologies
- Increased focus on the need for product and delivery innovation
- Greater contribution to some of the strategic thinking in product development decision making
- Increased consideration of the need to define the value proposition for new products
- Greater collaboration with internal and external stakeholders
Overall objective is to understand the considerations for PQ and policy recommendation EARLY.

- Licensing
- Policy recommendations & prequalification
- Introduction

- Safety
- Efficacy
- Quality

- Initial Licensure

- Product development

- WHO SAGE policy review
  - Cost effectiveness
  - Vaccine impact

- WHO PQ
  - Programmatic suitability

- Vaccine procurement
- Country interest

World Health Organization
Three committees that work together to guide product development at WHO

PDVAC: Product development for Vaccines AC
IPAC: Immunizations Practices AC
IVIRAC: Immunization and vaccine related implementation research AC
The WHO pathway from vaccine development to policy

Preclinical development
- Public health goal setting
- Guidance on clinical evaluation
- Programmatic suitability

Early stage clinical development
- Implementation Research
- Evidence review
- Dedicated safety review
- Vaccine Position Paper
- NRA joint reviews

Late stage clinical development
- Positive regulatory assessment
- SAGE recommendation

Registration
- Overarching guidance / technical support / implementation research / expert input
- Generic guidelines, NRA capacity building, ad hoc consultations

Policy
- Advisory Oversight (including associated Working Groups)

PD-VAC, IPAC, IVIR-AC
GACVS, ECBS, SAGE
http://www.who.int/immunization/policy/WHO_vaccine_development_policy.pdf?ua=1
Overview of the 2017 PDVAC meeting

- Update from the other committees that interact with PDVAC
- Update of activities and progress in areas previously prioritized by PDVAC
- Hear about 4 new pathogens, not previously reviewed at PDVAC
- Review of cross-cutting issues that need to be addressed to facilitate platform product development
Objectives of the 2017 PDVAC meeting

- Review the state of progress and challenges for vaccine and antibody candidates in the clinical pipeline,
- Consider recommendations for future activities where it will be valuable to develop consensus, for example clinical and regulatory development pathways,
- Provide advice to WHO on its current activities, and its role in the facilitation of vaccine development in specific product development areas.
Housekeeping

- Sessions are being run by Webex and will be recorded
- 2 days of ‘open’ session, followed by a closed session on Friday
- Please use microphones when speaking
- Lunch can be procured in the WHO cafeterias
- PLEASE keep to time – a very full agenda
- Executive summary will be posted next week; full meeting report will be drafted and slides will be posted during July
- Cocktail reception tonight until 7.30pm