WHO Preferred Product Characteristics for Next-Generation Influenza Vaccines

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PDVAC
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WHO vaccine policy recommendations aim primarily at protecting high risk groups against severe influenza disease and death.

Annual vaccination for high risk groups: children aged 6–59 months, pregnant women, elderly, individuals with chronic conditions, and healthcare workers

99% of paediatric influenza deaths are estimated to be in LMICs (Nair Lancet 2011)

There is a compelling unmet public health need to focus our attention on preventing severe seasonal influenza in LMICS
Prioritization of Pregnant Women Relates Burden, VE, and Feasibility of Delivery in LMICs

- High Burden
  - elderly
  - underlying conditions
- <2 years
- pregnant women
- HCW
- Feasibility
- High VE

Wkly Epidemiol Rec. 2015 May 29;90(22):261-78 (SAGE report April 2015)
The Need for Innovation

- With current evidence, the investment case for seasonal influenza vaccines in LMICs has been difficult to make.
- Product innovation and more relevant data for vaccine decision making are needed.
- Research must be mindful of:
  - Unmet public health need
  - Numerous new and under-utilized vaccines against other diseases competing for introduction
  - Programmatic limitations for vaccine delivery
“Safe and well-tolerated influenza vaccines that are effective in preventing severe influenza illness, provide protection beyond a single year, and are suitable for programmatic use, are needed for low and middle income countries.”
5 Year Strategic Objective

By 2022, documentation available for seasonal influenza vaccines that can feasibly

- Either
  - provide greater protection against vaccine-matched influenza strains, or
  - against drifted influenza strains than currently prequalified non-adjuvanted non-replicating influenza vaccines

- And that protect against severe influenza illness through at least one year after a primary series,

- And that are suitable for high-risk groups in low and middle income countries.
10 Year Strategic Objective

By 2027, influenza vaccines in advanced clinical development that have:

- the potential to provide protection against severe influenza A virus illness for at least five years after a primary vaccination series, and

- that are suitable for high-risk groups in low and middle income countries.
Policy makers from LMICs are expected to place higher value on vaccines indicated for prevention of severe illness;

Resource-poor countries have **substantial delivery platform limitations:** mostly able to immunize <2 years and pregnant women;

Resource-poor countries have called for innovation related to **programmatic suitability** (thermostability, needle free administration, expanded expiration dates, simplification of timing of vaccination, de-escalation to EPI ages);

Much can be done with current technologies, and given rate of progress of next-generation technologies, we strongly advocate efforts to make the most with what we have;

The R&D trajectory towards universal type vaccines needs to build on novel vaccine technologies and different regulatory considerations.
Thanks!

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PPC Process to Date

- March 2016 – Convening of Working Group
- August 2016 – Publication of draft PPC document for public comment
- August – September 2016 – Public consultations on draft PPC document
- November 2016 – End of public comment period
- December 2016 – Adaptation of PPC document
- January – March 2017 – PDVAC review and finalization
Working group composition

- Joseph Bresee (Centers for Disease Control and Prevention, Atlanta, USA)
- Fernando de la Hoz (Colombia National Health Institute, Bogotá, Colombia)
- Kari Johansen (European Centre for Disease Prevention and Control, Stockholm, Sweden)
- Ruth A. Karron (Johns Hopkins University, Baltimore, USA)
- Anand Krishnan (Centre for Community Medicine, All India Institute of Medical Sciences, New Delhi, India)
- Shabir A. Madhi (University of the Witwatersrand, Faculty of Health Sciences, Parktown, South Africa)
- Punam Mangtani (London School of Hygiene and Tropical Medicine, London, United Kingdom)
- Kathy Neuzil (University of Maryland Center for Vaccine Development, Baltimore, USA)
- David Spiro (National Institutes of Health, Bethesda, USA)