International Federation of Pharmaceutical Manufacturers & Associations



Reflections on Global Influenza Control

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Conflict of interest statement:

Bram Palache FluPal Consultancy B.V.

Member Core-Team IFPMA Influenza Vaccine Supply (IVS) Member Vaccine Europe:

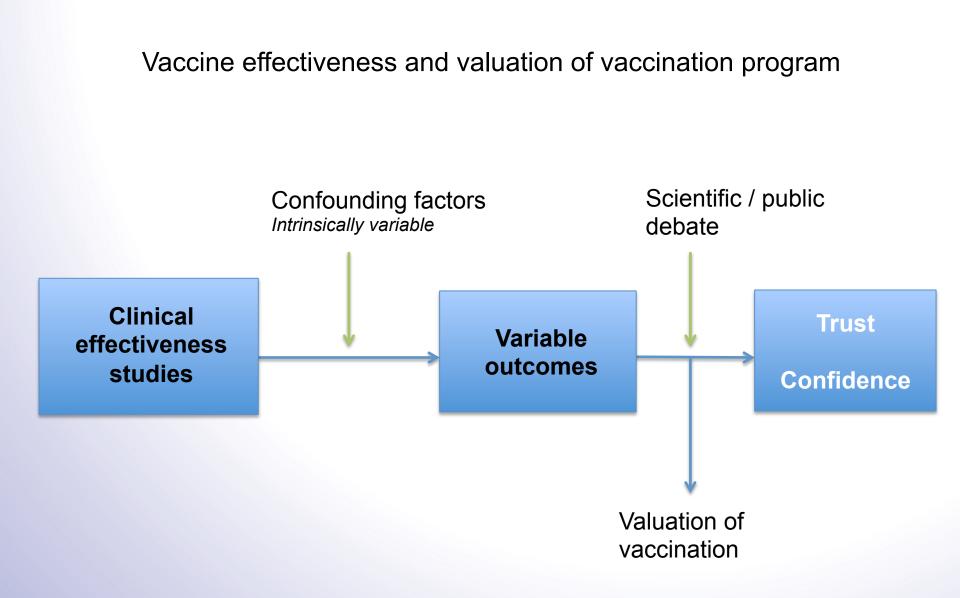
- Influenza group
- External Affairs group

Essential factors for vaccine policy development and implementation



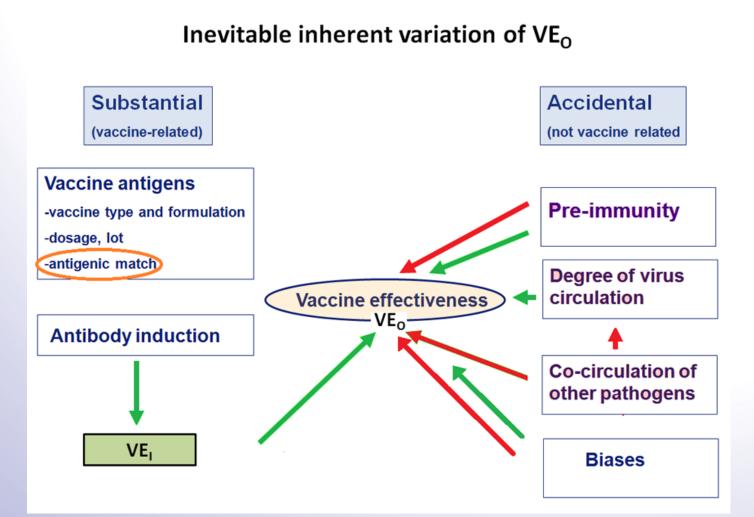
- Burden of Disease
- Vaccine Safety and Benefits
- Vaccine availability

- Communication, education, information
- Immunization infrasructure
- Vaccine coverage rate



Confounding factors affecting vaccine effectiveness





Examples of effect of confounding factors on influenza vaccine effectiveness study outcomes



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- Kristin Nichol (2006) One data set analysis with 2 flu case-definitions: different outcomes!!
 - Vaccine 2006;24:6726-6728
- Hoskins revisited (Beyer et al, 1998)
 - Repeated vaccination (Vaccine 1998;16:1929-1932

- Cochrane revisited (Beyer et al; 2013)
 - Vaccination of elderly (Vaccine 2013;31:6030-6033)



Global Basic File on influenza

- Substantial global annual burden of influenza-associated disease is well documented (many countries/regions, but not all!)
- Influenza vaccine safety is well documented and continuously monitored (pharmacovigilance programs)
- Vaccine effectiveness and benefits are well established and documented, despite seasonal variation in effect size
- Supply capacity can match the vaccine demand needed to meet the coverage rates as per WHO recommendations



Reflections on Burden of Disease

Thesis:

 Substantial global annual burden of influenza-associated disease is well documented (many countries/regions, but not all!)

Reflection:

- Is extrapolation of global BoD "reasonable" as basis for local immunization policy development?
- Preferred ethical/moral option?
 - Do not immunize before local evidence is available?
 - Immunize / protect patients based on available global evidence?

Benefits of influenza vaccination in USA (2005-2011)



Influenza Vaccine Supply

Cases averted (all ages) / season (million, 95%CI) **1.1** – **5.0** (0.6-1.7) (2.9-8.6)

Total in 6 seasons: **13 599 931** (8 001 525 – 22 806 782)

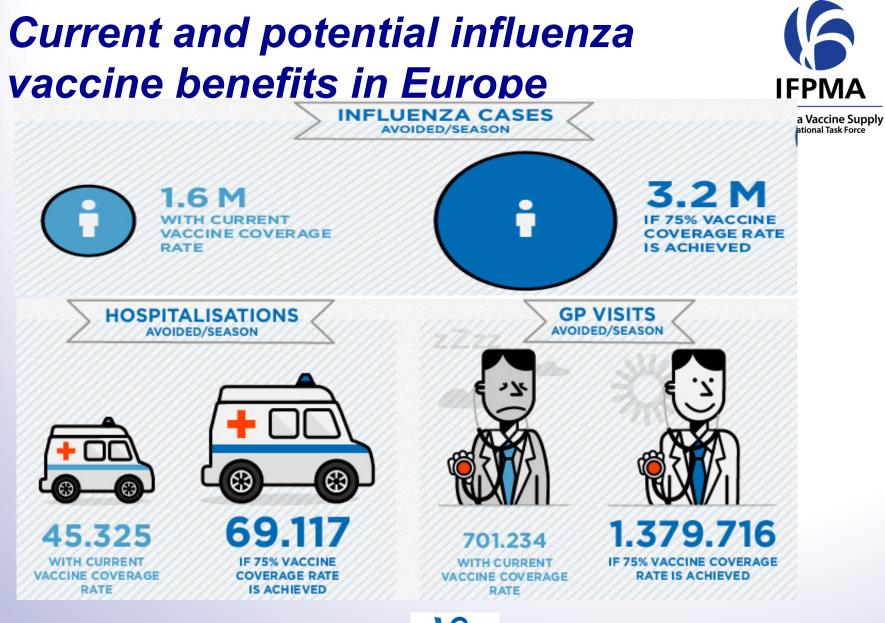
Hospitalizations averted (all ages) / season 7.700 - 40.400 (3.700 -14.100) (20.800 - 73.000)

<u>Total in 6 seasons</u>: **112 875** (65 036 – 191 540)

Medically attended cases averted (all ages)

Total in 6 seasons: 5 818 175 (3 426 742 – 10 104 621)

Source: Kostova D et al. PLoS one, June 2013







Reflections on Vaccine Benefits

- Relative vs absolute benefits:
 - Vaccine effectiveness study outcomes are "relative" and year / location-specific
 - Even with "low" effectiveness results, there is a substantial absolute number of cases, serious disease, hospitalizations and deaths prevented
 - Vaccine effectiveness data may blurr the public health value of influenza immunization programs



Global Basic File and public health

Thesis:

- "Global Basic File" justifies immunization policy and recommendations globally
 - What about the ethics of not immunizing at risk populations?

World Health Organization recommended priority groups for seasonal influenza vaccination:



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SAGE recommendations for influenza vaccination (2012)

- 5 recommended priority groups for countries using or considering introduction of seasonal influenza vaccination.
 - Pregnant women highest priority group.
 - 4 other priority groups (in no order of priority) are:
 - Health-care workers;
 - Children under 5 (particularly 6-23 months);
 - Elderly;
 - Underlying health conditions.



Vaccine Availability Global Vaccine Distribution Data



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Seasonal influenza vaccine dose distribution in 195 countries (2004–2013): Little progress in estimated global vaccination coverage

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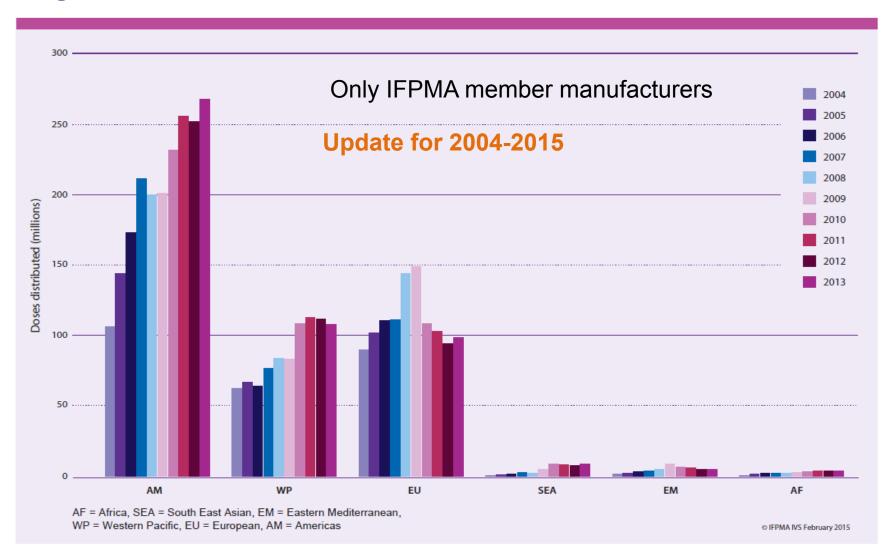
Seasonal influenza Vaccination policy Vaccine recommendations Vaccine reimbursement Vaccination coverage rates Monitoring and evaluation

ABSTRACT

Seasonal influenza is an important disease which results in 250,000-500,000 annual deaths worldwide. Global targets for vaccination coverage rates (VCRs) in high-risk groups are at least 75% in adults ≥65 years and increased coverage in other risk groups. The International Federation of Pharmaceutical Manufacturers and Associations Influenza Vaccine Supply (IFPMA IVS) International Task Force developed a survey methodology in 2008, to assess the global distribution of influenza vaccine doses as a proxy for VCRs. This paper updates the previous survey results on absolute numbers of influenza vaccine doses distributed between 2004 and 2013 inclusive, and dose distribution rates per 1000 population, and provides a gualitative assessment of the principal enablers and barriers to seasonal influenza vaccination. The two main findings from the quantitative portion of the survey are the continued negative trend for dose distribution in the EURO region and the perpetuation of appreciable differences in scale of dose distribution between WHO regions, with no observed convergence in the rates of doses distributed per 1000 population over time. The main findings from the qualitative portion of the survey were that actively managing the vaccination program in real-time and ensuring political commitment to vaccination are important enablers of vaccination, whereas insufficient access to vaccination and lack of political commitment to seasonal influenza vaccination programs are likely contributing to vaccination target failures. In all regions of the world, seasonal influenza vaccination is underutilized as a public health tool. The survey provides evidence of lost opportunity to protect populations against potentially serious influenza-associated disease. We call on the national and international public health communities to re-evaluate their political commitment to the prevention of the annual influenza disease burden and to develop a systematic approach to improve vaccine distribution equitably.

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Distribution of seasonal influenza vaccine by WHO region 2004 - 2013



Reflections on Vaccine Availability



- WHO operates Global influenza surveillance network (GISRS) 365 days/ year through 143 Laboratories around the world
- Industry operates 2 global vaccine production campaigns / year (> 500 million doses)
- Pandemic preparedness is much linked to seasonal influenza control
- Industry supports WHO (GISRS) and PIP (Pandemic Influenza Preparedness) Framework for global seasonal and pandemic influenza prevention
- Supply capacity can match the vaccine demand needed to meet the coverage rates as per WHO recommendations
- There is huge global disparity in influenza vaccine usage

