

Vaccines

Operationalization of Pandemic Plans – from Plan to Action

Influenza A (H1N1): Lessons Learned and Preparedness

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Topics to be covered

- **Types of vaccines potentially available**
- **Critical Scientific Questions to be Answered**
- **Global Needs**
- **Possible Vaccine Supply**
- **Logistics**
- **Need for Equity**
- **Financing**

Potentially Available Vaccines

- **Split Virus – manufactured in eggs similarly to present seasonal vaccines**
- **Split Virus – manufactured in cells**
- **Whole Virus, inactivated**
- **Live attenuated vaccines**
- **Products not yet licensed**
 - **Viral-like particles (VLPs)**
 - **Recombinant**
- **Stretching the vaccine supply**
 - **Adjuvants**
 - **Oil-in Water**
 - **Other**

Scientific Questions to Be Resolved Which Will Impact Vaccine Supply I

- **What are the target populations for vaccination?**
 - Critical Infrastructure – health care, other
 - Traditional groups at high risk of complications for influenza
 - Children and/or young adults
 - General population or sub-groups within the general population
- **How many doses will be needed?**
- **How much antigen will be needed per dose?**
- **Will adjuvanted vaccine be acceptable?**

Examples if the potential impact of an oil in water adjuvant on immunogenicity of H5N1 split virus Influenza vaccine

Percentage \geq 32 HI titer [†]

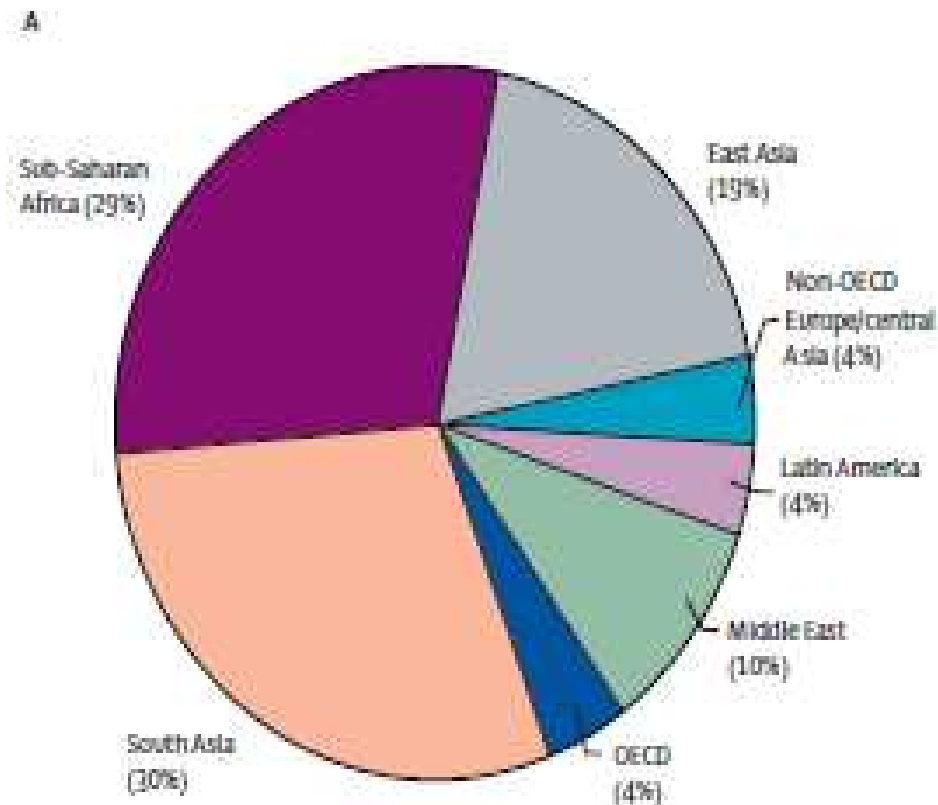
	1.9 mcg adjuvant	3.8 mcg adjuvant	7.5 mcg adjuvant	15 mcg adjuvant	7.5 mcg
Dose 1	24	29	40	32	30
Dose 2	72	81	89	86	34
% cross reacting antibody	4	9	17	23	0

[†] Levie K et al, J Infect Dis 2008; 198: 642-9.

Scientific Questions to Be Resolved Which Will Impact Vaccine Supply II

- **What will be the yields using current reference H1N1 strains?**
- **What will be the virulence of the next wave?**
- **What are the goals of a vaccination program?**
 - Prevention of deaths and severe disease?
 - Prevention of morbidity and economic disruption
 - Maintaining critical infrastructure
- **Will seasonal vaccine at normal quantities still be needed?**

Projected Global Impact of Severe a Pandemic

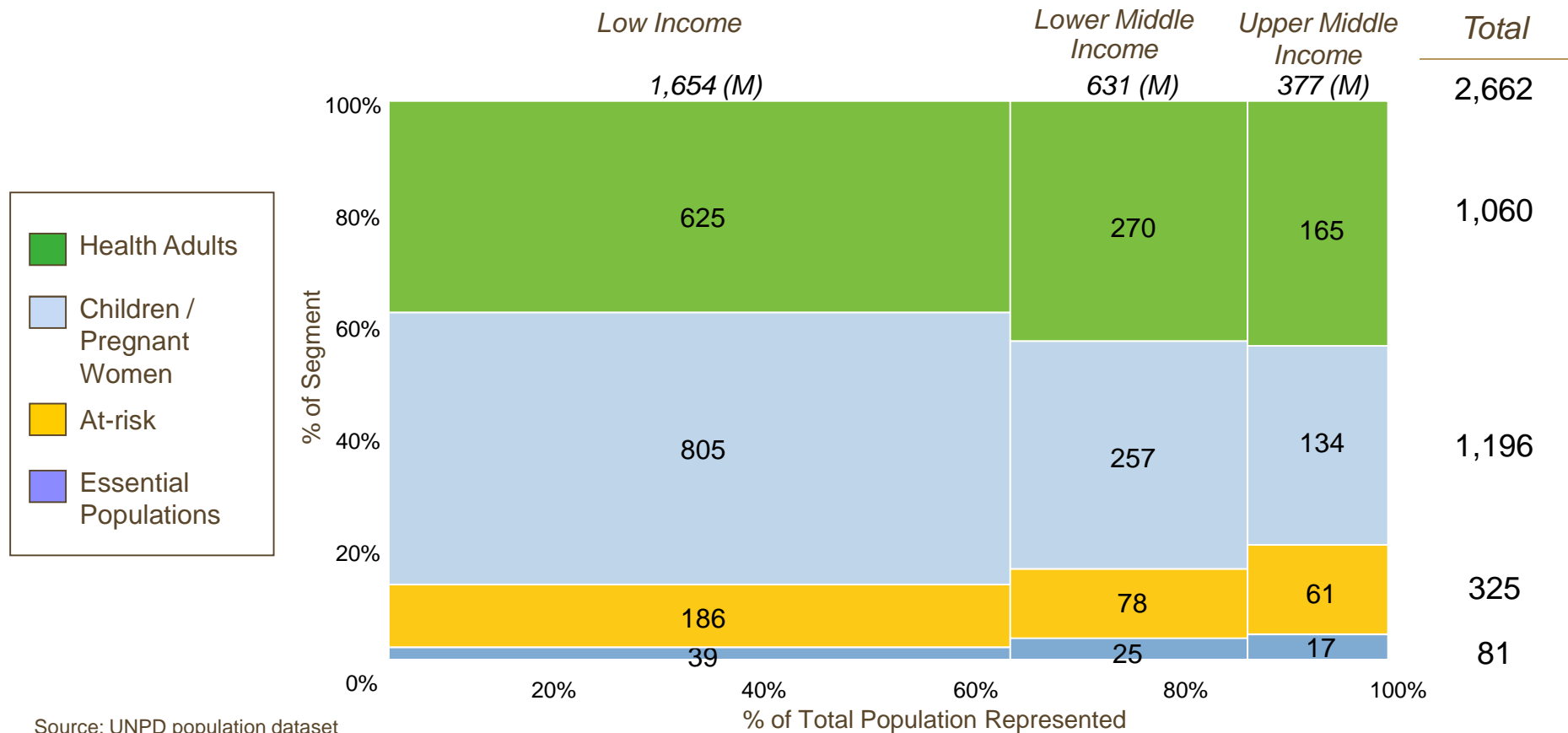


An estimated 96% of deaths during a severe influenza pandemic will occur in developing world

Murray CJ et al. Lancet 2006;368:2211-18

Developing country doses will depend on the countries and populations targeted

Country Population Segmentation, Non-Self Producing (millions)



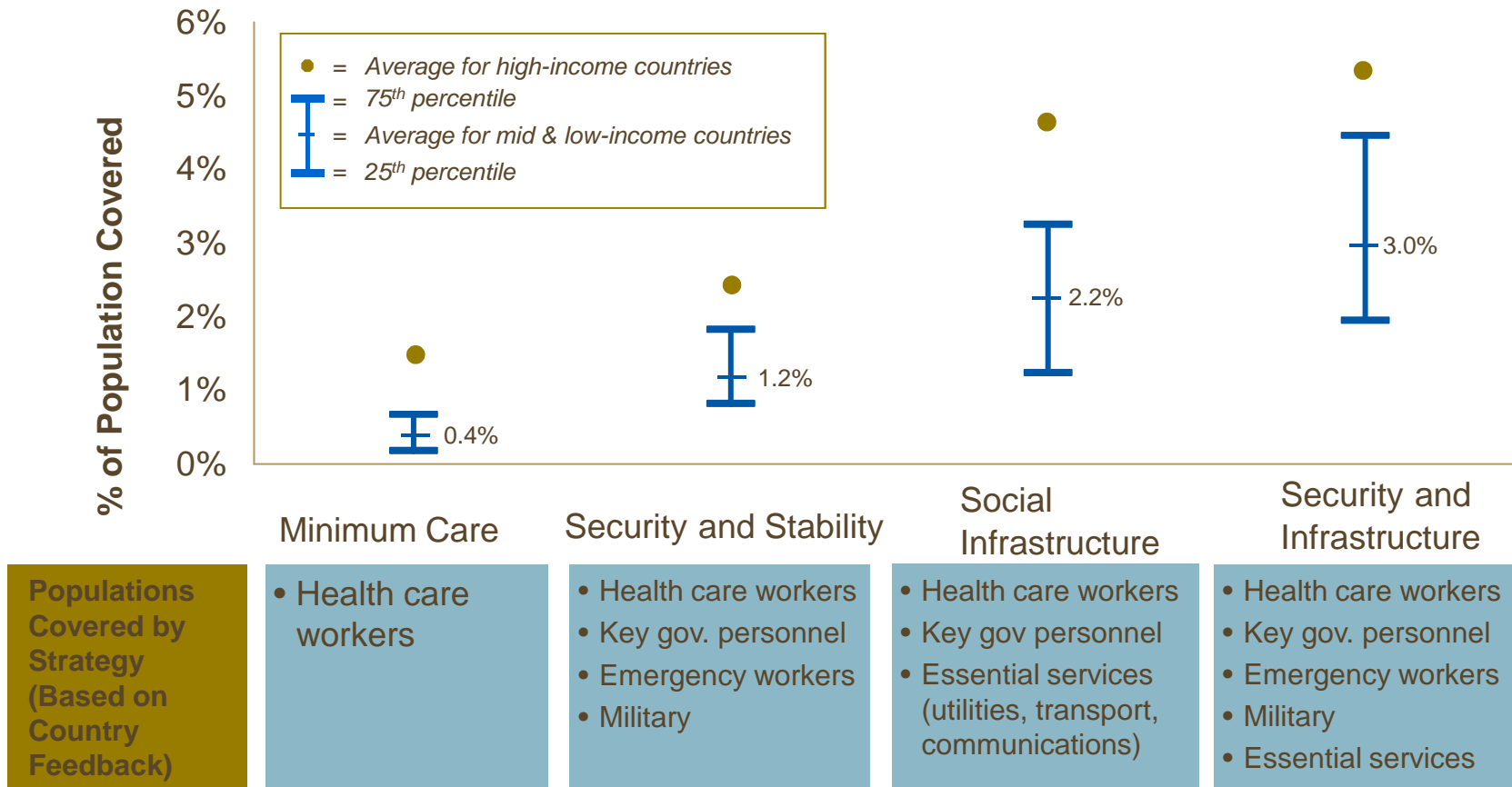
Source: UNPD population dataset
Source: Oliver Wyman, 2008

Coverage requirement

Depending upon the definition of essential populations, 0.4 – 3% of low and middle-income countries' populations would required coverage with H1N1 vaccine.

H1N1 vaccine “essential populations” strategies

(Includes 153 low and middle-income countries without current access to H1N1 vaccine)



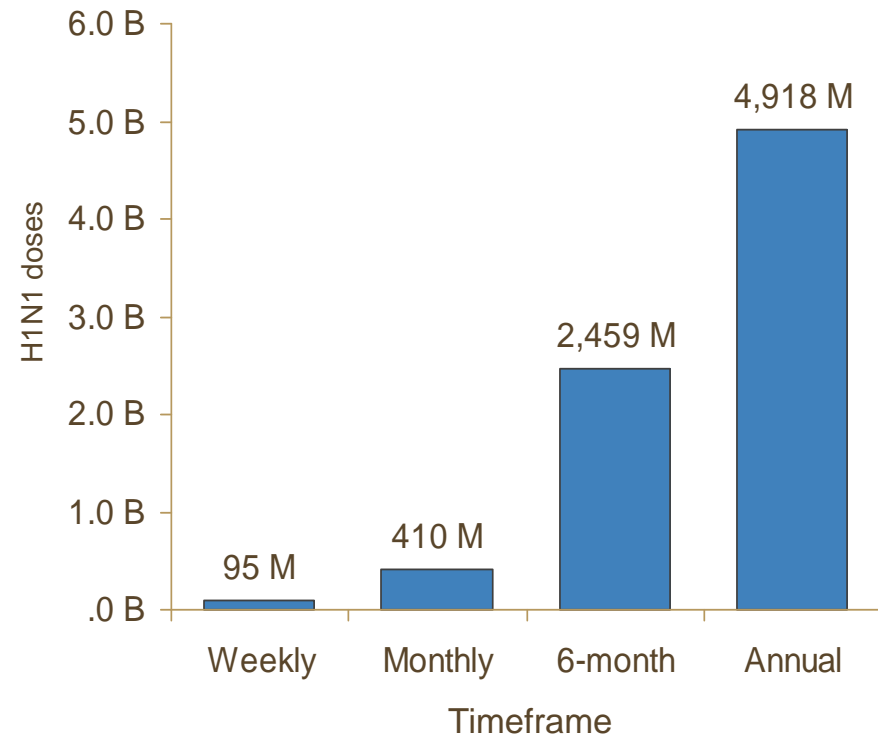
Source: Oliver Wyman, 2008

Pandemic vaccine baseline capacity was estimated at 94.5M doses per week

Assumptions / Methodology

- Survey sent to 36 potential influenza vaccine manufacturers
 - 100% response rate
 - All 21 current influenza vaccine producers responded
 - 26 manufacturers that intend to produce pandemic vaccines
 - Includes LAIV and one recombinant vaccine capacity
- Survey assumes
 - 1:1 H1N1 to seasonal yields
 - Most dose sparing formulation for each manufacturer
 - Use of full production capacity

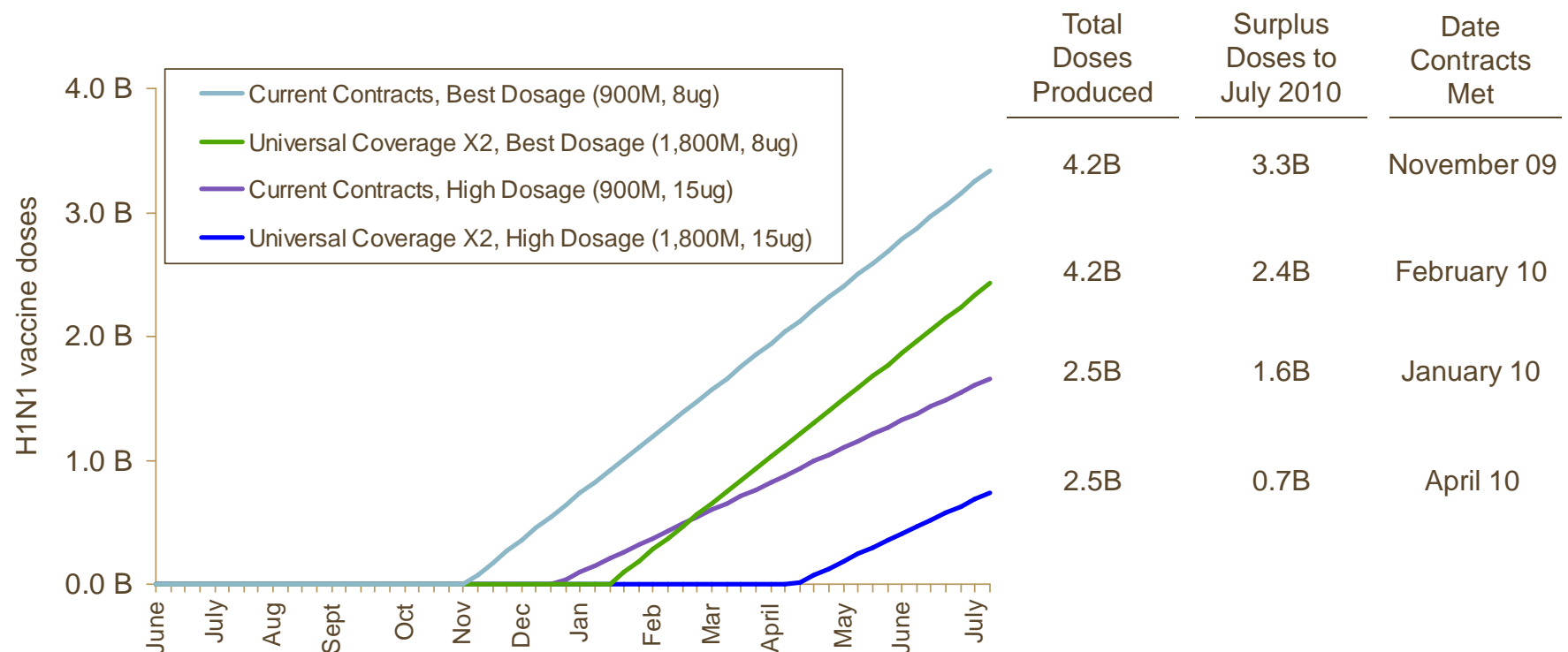
Estimated H1N1 Vaccine Capacity
At 1:1 yields, most dose-sparing formulation, full capacity



Source: Marie-Paule Kieny, WHO, presentation titled “Assessment of global production capacity for A (H1N1) pandemic vaccine”

Capacity may become available November in the best case, but may not materialize before April 2010

Surplus H1N1 Capacity Available from High-Income Country Facilities¹
 - Assuming 1:1 yields and no 2010-11 seasonal production



Source: WHO survey

¹ Assumes all facilities switch to H1N1 production at end of July (however, in reality, some facilities are converting earlier)

Source: Marie-Paule Kieny, WHO, presentation titled "Assessment of global production capacity for A (H1N1) pandemic vaccine"

Proposed Principles for Consideration I

- **The global community should take steps to protect all populations, including those without resources to protect themselves.**
- **Vaccination should be considered in the context of comprehensive pandemic preparedness and response efforts in all nations.**
- **Developed countries and vaccine manufacturers should urgently establish a priori agreement on a mechanism to ensure access to vaccine by developing countries.**
- **Influenza vaccine manufacturers should identify strategies such as tiered pricing and/or donations to make pandemic vaccine more accessible to developing nations.**

“Principles discussed at a meeting hosted by the Bill & Melinda Gates Foundation on June 18, 2009. Participants included representatives of the WHO, developed and developing countries, vaccine manufacturers and regulatory authorities.”

Proposed Principles to Consider II

- **Pandemic vaccines allocated to developing nations should become available in the same timeframe as vaccine for developed nations.**
- **The global community should seek to establish a consensus on the safety and efficacy of adjuvants, and efforts should be made to ensure the fullest use of this and other dose sparing strategies.**
- **All countries obtaining pandemic vaccine should ensure that mechanisms are in place to provide this vaccine to their populations and to ensure that this scarce resource is not wasted.**
- **The World Health Organization is uniquely positioned to lead the global response to a pandemic virus.**

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