

Pandemic Vaccine Preparedness

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Key Facts of Current Virus

- 62% under the age of 18
- 35 hospitalized, all under the age 35
- Preponderance of woman
- Contagious but not especially virulent (Compared to H5N1, which killed 62%)
- “Late” flu season in Mexico may well have been H1N1 coursing its way through population

Key Facts of Vaccine Preparation

- At tail end of seasonal vaccine production so we “caught a break” this time around (January-March; April; May-June)
- Currently working on H1N1 “seed stock”
- WHO meeting May 18th to decide whether to go forward with limited H1N1 vaccine

Vaccine Options: Egg-Based

- Proven, safe, but at times, finicky technology
- Year to year risks in manufacturing; pandemic might threaten flocks (H5N1)
- Limited capacity: Could need about 5-10X the current capacity for 300M doses @ 90ug x 2
- Sanofi, GSK, Novartis increasing capacity, but much of it is not domestic facilities
- FDA's new guidance, pandemic strains rapidly approvable as supplements to existing products

Alternative Strategies to Expand Supply

- Use of Adjuvants (two approved by EMEA)
- Cell based manufacturing (Novartis facility)
- Alternative delivery (intradermal)
- Use of a live attenuated vaccine (potential to induce immunity with single small dose)
- Peptide and DNA vaccines
- Universal vaccine (elicit a T cell response)

Selected Lessons Learned

- Panic sets in quickly, therefore we need a domestic capacity to handle surge production
- Need more real time production methods or a vaccine that doesn't need to change seasonally
- FDA needs better regulatory tools for assessing immunogenicity, potency, certifying lots
- Most significant advances have stemmed from demand for better intellectual property. Market rewarded this (BioShield, Medicare)