PANDEMIC INFLUENZA VACCINE STOCKPILE

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ASPR: Saving Lives... Protecting America
Program Overview

1. Disease outbreak/surveillance
2. WHO/ERL CVV development
3. Vaccine Seed Development
4. ERL Potency Reagents
5. Vaccine Bulk Production
6. Vaccine/Adjuvant stockpile and Stability
7. Clinical Trial
8. Pre-EUA
9. 20 M First Responders

PANDEMIC

REGULATIONS
Making Decisions about Pre-pandemic Influenza Vaccines

Interagency Decision-making body

Surveillance-Epi data

Decisions use a metered approach response

Implementation
H7N9 Risk Mitigation

- **Seed Development**
- **Potency Assay Reagents Preparation and Calibration (FDA)**
- **Bulk Production**
- **Formulation/Fill/Finish**

**Vaccine Procurement and Manufacturing (BARDA)**

- **CVV development (CDC)**
- **Recombinant vaccine manufacturing and clinical study (BARDA)**

**Current Status**

- **DMID Clinical Studies**
Acquire and store pre-pandemic vaccines and adjuvants in bulk
- Achieved stockpile requirements for clades of H5N1 and H7N9
- Long term stable pre-pandemic vaccines
- Multiple vaccine platforms

Preparedness and Response
- Prepare and respond to pre-pandemic vaccine outbreaks
- Prepare pre-EUA packages for pre-pandemic vaccine use in pandemic situation

Pioneering clinical studies
- Immunological naïve population for pre-pandemic H5N1 clinical studies needs 2 doses of adjuvanted vaccine to induce immunological response
- BRITE study: Long term stored bulk antigen
- HPB study
1\textsuperscript{st} BARDA sponsored clinical study: A randomized, double-blinded, Phase 2 clinical trial to assess safety and immunogenicity of long-term stored A/Vietnam/1203/2004 (H5N1) vaccine administered with and without adjuvant

Results:

- Data collection and analyses are on-going.
- No serious adverse event related to vaccination was observed.
- Preliminary immunogenicity results indicate that the vaccine remains safe and immunogenic.
Heterologous Prime-Boost clinical study supporting stockpile strategy and implementation

Vaccination strategy for induction of cross-protective immunity using stockpiled influenza H5 vaccines

Figure courtesy of Derek Smith (U. Cambridge)

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Peng et al, 2017. Scientific Reports
Stockpile Strategy

Multiple Vaccines

- H5N1
- H7N9
- H5Nx
- H1N1pdm
- H5N8

Outbreak Response

Vaccine, Adjuvant Stockpile/Stability

Mix and Match Studies

- Vaccine A–B–C

Adjuvants

- Egg based
- Cell based
- Live attenuated
- Recombinant