Brookings presentation

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Smallpox Virus Stores

- Known or Probable
  - Russia: Novosibirsk, Sergiyev Posad
  - USA: Atlanta
- Possible
  - Russia: Kirov, St. Petersburg, Sverdlovsk, Pokrov
  - North Korea
  - Iraq
  - Iran
- Possible use by
  - Nation-state
  - State-sponsored terrorist group
  - Other terrorist group

Issues of Liability and Medical Care

- Smallpox vaccine is more reactogenic than any other vaccine
- Implications of no special provisions being made
- Who should be responsible for medical care and liability costs for those who are vaccinated?
  - ? Special legislative provisions (à la swine flu vaccine)
  - ? Vaccination only by Federal employees
  - ? Coverage by Workers' Compensation

Critical Smallpox Vaccine Policy Issues

Factors to consider in decision-making process:

- Level of threat – risk of infection with smallpox
- Vaccine supply
- Expected adverse reactions
- Vaccinia immune globulin (VIG) supply
- Liability issues
- State and local smallpox operational planning status

Recent Events That Have Changed Threat Perceptions

1992-1995 – Ken Alibek reveals extent of Soviet bioweapons program that involved some 60,000 staff in more than 50 laboratories and produced ton quantities of smallpox, plague, and anthrax.

- Ministry of Defense production centers intact
- Lab staff is poorly paid and leaving for unknown sites
- Biopreparat, which weaponized smallpox, continues to work on smallpox, Ebola, and Marburg

National Pharmaceutical Stockpile Smallpox Vaccine Readiness Targets

■ Wyeth Dryvax (1:5)	77M doses
■ Aventis Pasteur	85M doses
■ Acambis-Baxter	209M doses
▪ ACAM1000	54M doses
▪ ACAM2000	155M doses
■ **TOTAL**	**371M doses**

NOTE: Currently, all vaccines are Investigational New Drugs and require IRB approval and informed consent

Vaccinia Immune Globulin (VIG)

- For treatment of cutaneous complications
- 100 treatment doses needed for 1 million vaccinees
- Production requires post-vaccination human plasma

Pre-Exposure Smallpox Vaccination Policy: Major Considerations

- Post-exposure vaccination is a proven effective strategy for controlling smallpox
- DHHS investments in state and local terrorism preparedness planning will ensure the capacity to immunize the entire US population within 5 days of a smallpox outbreak
  - Vaccine supplies from the National Pharmaceutical Stockpile will reach any point in the US within 24 hours
  - Local vaccination program implementation planning, training, and exercising are already in progress

Eczema Vaccinatum in Contacts

U.S. National Surveys – 1963 and 1968

11.8 Million Primary Vaccinations

Age	Cases	Deaths
<1	12	0
1-4	71	3
5-19	14	0
>20	17	0
Total	114*	3

*Approximately 10 cases per 1 million vaccinated

The Role of Special Measures

- Isolation of patients – important. Kept in home
  Supportive care
- Isolation of contacts – only after symptoms developed
- Compulsory vaccination – No
- Quarantine – NO
  - Area or county-wide
  - Restrictions of travel

Smallpox Control Strategies

Lessons Learned from the WHO Eradication Program

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Smallpox Control Strategies:
Lessons from the WHO Eradication Program

- Abbreviated historical overview
- Vaccines and vaccination technique
- Epidemiology of smallpox
- Surveillance and containment
- Role of special measures
  - Compulsory vaccination
  - Isolation
  - Quarantine

Historical Overview of Smallpox Eradication

- 1967 – WHO Eradication Program began with a 10 year goal
- Strategy:
  - Immunity of 80%
  - Surveillance-containment
- Traditional beliefs:
  - Smallpox spreads rapidly and widely
  - Airborne spread from hospitals
- October 26th 1977 – Last naturally occurring case, Somalia
- May 8th 1980 – World Health Assembly proclaims eradication, vaccination stops and vaccine production ceases

Vaccines and Vaccination Techniques

- Vaccines:
  - Freeze-dried
  - International standards
  - Strains – Lister and New York City Board of Health
- Vaccination Technique
  - Lancet scarification
  - Multiple pressure
  - Jet injector
  - Bifurcated needle

Epidemiology of Smallpox
Relevant Attributes

- Age distribution – similar to distribution of susceptibles
- Transmission
  - Usually by droplets
  - Occasionally spread through contaminated bedding/laundry
  - No animal reservoir
  - After recovery, patient is immune: no carrier state

Epidemiology of Smallpox
Transmission Patterns in Europe: 1958-1973

- Outbreaks: 34
- Cases: 573
  - Due to transmission in hospital: 277 (48%)
  - Due to transmission in home: 143 (25%)
- Hemorrhagic and malignant cases – a threat to hospitals
  - Bradford, UK (1961) Hemorrhagic smallpox 10 cases
  - Germany (1970) Malignant smallpox 16 cases
  - Yugoslavia (1972) Hemorrhagic smallpox 38 cases
- Seasonal variation
  - Dec to May 24 importations average=45.6 additional cases
  - Jun to Nov 10 importations average=0.5 additional cases

Epidemiology of Smallpox
Spread and Virulence

- Spread of disease is comparatively slow
  - Secondary household attack rates (approx.)

Measles	76%
Chickenpox	74%
Smallpox	58%

  - Note slower community spread of smallpox than either measles or chickenpox, both of which can be transmitted before symptoms appear
- Virulence of variola major strains
  - South Asia strain most virulent (30% case-fatality rate)
  - African strains less virulent (10-15% case fatality rates)
  - No differences in strains from hemorrhagic or fatal cases

Surveillance and Containment

Contagious Period of a Typical Case

Days	Patient Status	Contagiousness
0	Patient infected	
1-12	No symptoms	Not contagious
13-14	Very sick, high fever	Not contagious
15-21	Rash – vesicles to pustules	Contagious
28-35+	Scabs over all lesions	Not contagious

Surveillance and Containment

Steps in Containment

- Vaccinate and isolate patient in designated hospital or ward
- Identify and vaccinate all persons who had been in a room with the patient since he became febrile (primary contacts)
- Place primary contacts under surveillance with temperature taken twice daily
  - If a primary contact develops fever, isolate at home or special facility until diagnosis is known
- Vaccinate all household contacts of primary contacts (secondary contacts)

The Role of Special Measures

- Isolation of patients
- Isolation of contacts
- Compulsory vaccination
- Quarantine
  - Area or county-wide
  - Restrictions of travel