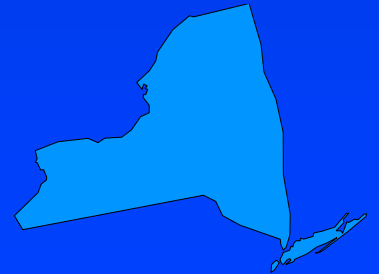


Smallpox: A Clinical and Public Health Perspective

New York State Department of Health



Smallpox, 2003

- Smallpox has had a major impact throughout human history;
- Smallpox is also closely linked with the development of medicine and public health:
 - Inoculation with cowpox to prevent smallpox in the 1790s was to first use of vaccination to prevent disease.
- Smallpox was the first disease declared eradicated by human efforts in 1979;
- Smallpox vaccination in the U.S. ceased in 1972.

**Why are we talking about smallpox
vaccination now?**

9/11 and Anthrax



Why Smallpox Vaccination Now?

- September 11: *“We are evaluating old threats in a new light.”*
- Possible risk: *“We believe that regimes hostile to the United States may possess this dangerous virus.”*
- The risk appears low. There is *“no information that a smallpox attack is imminent.”*
- Be prepared: *“it is prudent to prepare for the possibility that terrorists would... use diseases as a weapon.”*
- Response teams: *“We will make vaccinations available on a voluntary basis.”*

Why Smallpox Vaccination Now?

- *“These vaccinations are a precaution only, and not a response to any information concerning imminent danger. Given the current level of threat and the inherent health risks of the vaccine, we have decided not to initiate a broader vaccination program for all Americans at this time.”*

President Bush. Dec 13, 2002

What is the federal smallpox plan?

Federal Smallpox Pre-Event Vaccination Policy*

- Stage I – Public Health Response Teams and Health Care Response Teams at hospitals to care for suspected or confirmed smallpox patients;
 - Estimated number: up to 500,000
 - Estimated start date: January 24, 2003. Completion 30-90 days.
- Stage II – Offer to all health care workers and first responders (police, fire, EMS, etc.)
 - Estimated number: up to 10 million
 - Estimated start date: Summer 2003. Completion - ?

*December 13, 2002

**Why are health care workers
involved?**

How Smallpox Was Acquired

Smallpox Importations in Europe, 1950 – 1971^{+,++}

Mode	Cases	%Total
Hospital Transmission	359	55%
Work-related	51	8%
Family and intimate contacts	129	20%
Casual contacts	63	10%
Miscellaneous	6	1%
Unpredictable cases	44	7%

⁺ Excludes 28 importations of unknown or unreported mode of transmission.

⁺⁺J Infectious Diseases 1972; 125: 161-169.

Who Contracted Smallpox in Hospitals

Smallpox Importations in Europe, 1950 – 1971⁺

Mode	Cases	%Total
Hospital staff and family	146	41%
Hospital clientele	211	59%
– Inpatients	193	91%
– Outpatients and visitors	18	9%

⁺ J Infectious Diseases 1972; 125: 161-169.

What is smallpox?

Smallpox

- Smallpox is a disease caused by a virus.
- The last naturally occurring cases occurred in 1977.
- Smallpox usually causes a severe, pustular rash.
- In the past, smallpox had a 30% death rate.
- Smallpox is spread by:
 - Direct contact with pustules of infected persons;
 - Close contact (within 6 _ ft) with respiratory droplets;
 - Rarely airborne contact over longer distances.

Smallpox Rash



Semi-confluent Smallpox

- Pustules confluent on face but discrete elsewhere



Confluent Smallpox

- **Confluent rash on face and forearms**



Smallpox Lesions



Smallpox versus Chickenpox Rash

Smallpox

Chickenpox

Timing in a given area

**Simultaneous
(1-2 days)**

**New crops appear
every few days**

**Stage of
maturation**

**Same stage in a
given area**

**Vesicles, pustules,
scabs adjacent
areas**

**Distribution/
progression**

**Concentrated on
face, forearms
+palms/soles**

**Concentrated on
trunk
Not palms/soles**

Why is smallpox a concern?

CDC Category A Bioterrorism Agents

Agents that pose a risk to national security because they:

- can be easily disseminated or transmitted person-to-person
- cause high mortality, with potential for major public health impact
- might cause public panic and social disruption
- require special action for public health preparedness

CDC Category A Bioterrorism Agents

- Smallpox (Variola major)
- Anthrax (*Bacillus anthracis*)
- Plague (*Yersinia pestis*)
- Botulism (*Clostridium botulinum*)
- Tularemia (*Francisella tularensis*)
- Ebola and other Filoviruses

**How bad would a smallpox
outbreak be?**

Factors Tempering Smallpox Concerns

- **Incubation period 12-14 days following exposure (range 7-17 days);**
- **Contagiousness usually begins with onset of rash.**
- **Persons with smallpox are generally very ill in bed before they are contagious.**
- **Historically, outbreaks occurred in households but not schools or workplaces.**

Factors Tempering Smallpox Concerns

- **Vaccination of contacts within 3 days of exposure is 95% effective in preventing illness; vaccination may be effective up to 7 days after exposure.**
- **Smallpox is significantly less contagious than diseases like measles or influenza.**
- **Introductions into Western countries in modern era have been limited in the extend of spread.**

Factors Tempering Smallpox Concerns

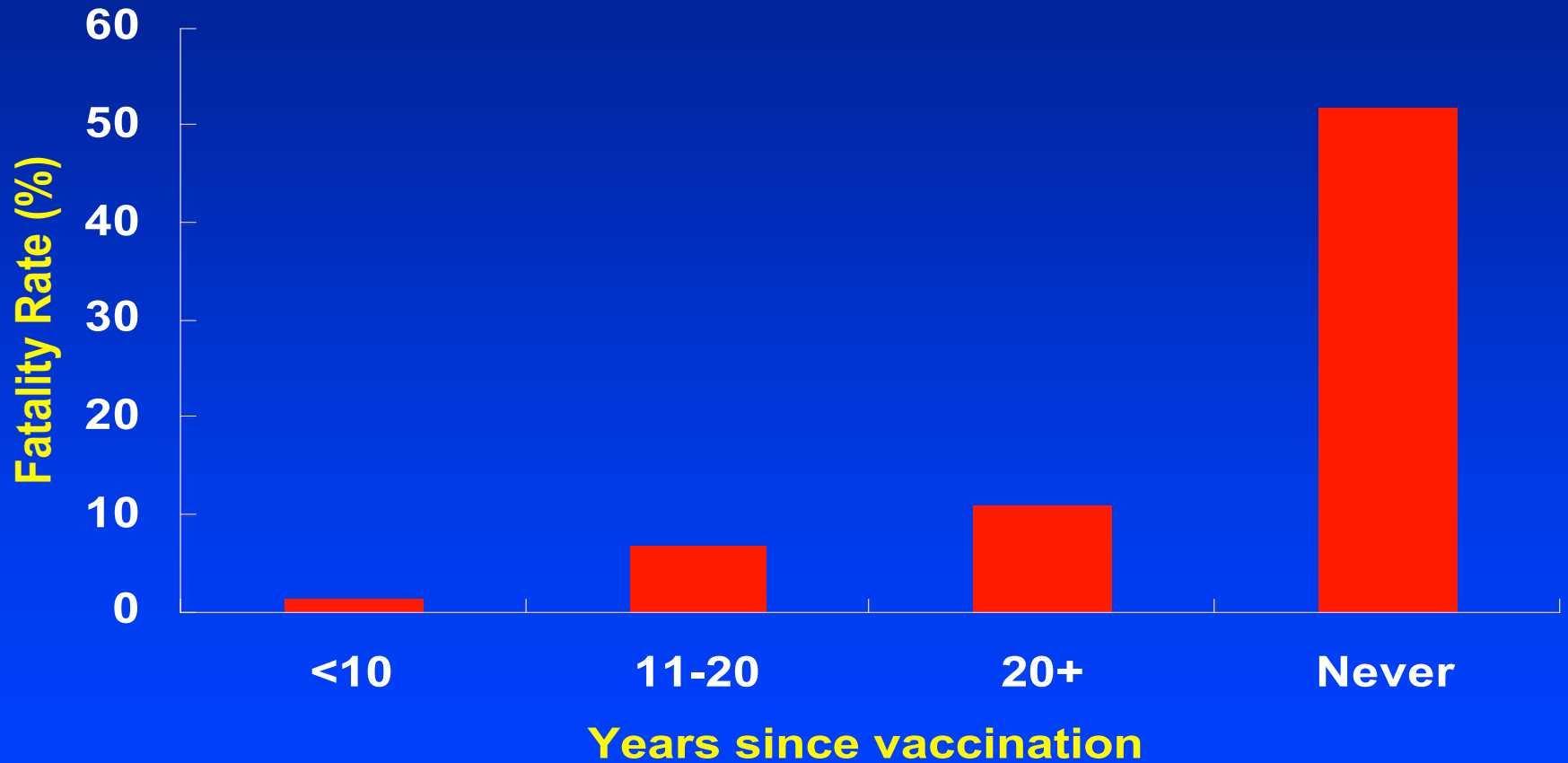
- **Infection control practices (standard, contact and airborne isolation precautions) as used with TB and chickenpox cases can protect health care workers from infection.**
- **Isolation measures are generally to control outbreaks effective even with limited vaccine use.**
- **Modern medical care has had many advances since the 1950s (last time smallpox treated).**

**I had a smallpox vaccination in the
past. Am I still protected?**

Vaccination and Immune Status

- Routine vaccination in US stopped in 1972;
The military vaccinated until 1990;
- Immunity from vaccine declines over time:
 - Neutralizing antibodies following single dose decline significantly over 5-10 years;
 - Multiple dose may provide longer protection
- Vaccination in the past probably provides some protection against severe smallpox disease.

Smallpox Fatality Rate by Time Since Vaccination - Europe, 1950-1971*



Mack TM. J Infect Dis 1972;125:161-9.

Is there enough smallpox vaccine?

Vaccine Update

- Dryvax (Wyeth):
 - Total 15 million doses (dilute to 75 million doses (experimental));
 - 1 million doses to be licensed for military use;
 - 1.7 million doses to be licensed for HHS use.
- Aventis Pasteur (“found vaccine”):
 - 75-80 million doses; Compared well in 1:5 dilution trial going head-to-head with Dryvax => 350-400 million doses available for emergency use.
- Acambis 1000 and 2000:
 - ACAM 1000 (54 million doses) ACAM 2000 (155 million doses)
 - Going into Phase I clinical trials in 10/02;
 - Licensure expected by the end of 2003/ beginning of 2004.

How is the vaccination done?

VACCINATION METHOD

Bifurcated needle (single use)



VACCINATION METHOD



The needle is dipped once into the vaccine vial and withdrawn.

VACCINATION METHOD

Rest wrist on arm of patient

Make 15 perpendicular skin insertions within a 5mm area

Use enough force to see a trace of blood at the site

Discard needle immediately



VACCINATION METHOD

**Absorb excess
vaccine on gauze pad**



**Immediately discard
gauze in a
Biohazard container**



VACCINATION METHOD



Use sterile gauze pad and tape
Semi permeable occlusive dressing

**What are the complications of
smallpox vaccination?**

Smallpox Vaccine Complications

- Most common mild side effects:
 - Sore arm, low grade fever, muscle aches – common
 - Missing a day of work – about 1/3
- In the past, vaccine reactions were less common in people getting immunized who were previously vaccinated (re-vaccinees).

Smallpox Vaccine Complications

- Moderate side effects:
 - Inadvertent inoculation (skin, eye) 25-529/million
 - Generalized vaccinia 250/million
- Severe side effects:
 - Encephalitis 3-12/million
 - Fetal vaccinia rare
 - Eczema vaccinatum 10-39/million - history of eczema
 - Vaccinia necrosum 1-2/million - underlying immunosupp.
- Death rate:
 - Primary vaccination – 1-2 deaths/million
 - Re-vaccination – 0.2 deaths/million [1 per 5 million]

Smallpox Vaccination: Complications



Accidental inoculation
of eye



Eczema vaccinatum - fatal



Vaccinia necrosum - fatal

How are side effects treated?

Treatment of Vaccine Side Effects

- Vaccinia Immune Globulin (VIG)
- Anti-viral drugs
 - cidofovir

Who should not get vaccinated?

Contraindications for Vaccination

In the person to be vaccinated or a household contact:

- Diagnosis now, or in the past, with eczema or atopic dermatitis (even mild or resolved conditions);
- Other acute, chronic or exfoliative skin conditions, while condition is active.
- Pregnancy; Breastfeeding (vaccinee only)
- Serious allergies to antibiotics polymyxin B, streptomycin, tetracycline, or neomycin (vaccinee only);

Contraindications for Vaccination

In the person to be vaccinated or a household contact:

- Immunodeficiency:
 - HIV/AIDS
 - leukemia, lymphoma
 - generalized malignancy
 - current cancer chemotherapy, including radiation
 - solid organ or stem cell transplant
 - systemic steroids
 - ($\geq 2\text{mg/kg/day}$ of prednisone, or $\geq 20\text{mg/day}$ for ≥ 14 days).

What steps will be taken in any vaccination program to minimize possible side effects?

Vaccination Precautions

- Voluntary, Voluntary, Voluntary.
- Education, Education, Education.
- Focus on re-vaccinees for response teams.
- Use of CDC materials and screening materials
 - Video
 - fact sheets
 - Screening form
 - CDC hotline for questions
- Pre-vaccination day 1-2 weeks prior to vaccination
 - Screening for contraindications
- Screening available for HIV and pregnancy
- Vaccination day education, consent process
 - Screening for contraindications

Vaccination Precautions

- Regular follow up of vaccination site
- Regional centers clinical consultation
- National CISA vaccination safety center – Columbia University
- CDC consultation for release of vaccinia immune globulin and cidofovir
- Ensure that workers compensation and health insurance will cover severe complications (awaiting final federal guidelines).

**How will my medical expenses and
lost wages be covered if I get sick
from the vaccine?**

Worker's Compensation Coverage

- Worker's compensation coverage available for:
 - health care workers who are vaccinated under the pre-event smallpox vaccination plan and who suffer a vaccine related illness, and
 - co-workers who are accidentally infected by a vaccinated colleague and who suffer a vaccine related illness.
- All claims are determined on a case by case basis and coverage assumes that you submit adequate proof of the claim.

Worker's Compensation Coverage

- Worker's Comp coverage includes:
 - Medical expenses
 - Lost wages after 7 days of disability due to vaccine related illness
 - Lost wages from the first date of disability if you are disabled for more than 14 days
- Some employers are making arrangements to assure that employees who are absent due to vaccine related illness for less than 7 days don't have to charge time to sick leave or vacation.

Health Insurance Coverage

- As with any other illness, health insurance should cover vaccine related illness in:
 - insured family members,
 - insured hospitalized patients.
- Health insurance won't cover if Worker's Comp does.
- All policy provisions will apply, such as prior approval,
- **IMPORTANT: READ THE TERMS OF YOUR HEALTH INSURANCE POLICY** and to contact your insurer to be sure about what coverage will be provided.

Liability Coverage

- Homeland Security Act, Section 304 during a Secretary's declaration, provides protection to :
 - legally qualified health care workers who administer the smallpox vaccine,
 - health care entities under whose auspices the vaccine is administered,
 - vaccine manufacturers and distributors,
 - and their officials, agents, and employees.
- Also covers cases of transmission of vaccine to others.

Liability Coverage

- Section 304 is not a no-fault statute,
- The vaccinated person must show that the injury is caused by the negligence,
- Where Workers' Comp does not cover an injury suffered by a vaccinated person, he or she must sue the Federal government under the Federal Tort Claims Act,
- There are remaining questions about Section 304. We expect some additional clarification in the declaration by the Secretary.

Summary

- Voluntary
- Education
- Safety
- Flexibility
- Remain calm

Websites

- **New York State Department of Health**
www.health.state.ny.us
- **Centers for Disease Control**
www.bt.cdc.gov/smallpox
- **Infectious Disease Society of America**
www.idsociety.org/BT/Toc.htm