

# **Pre-Event Smallpox Vaccination Plan: Considerations for Participation**

Greater New York Hospital Association

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# Decision-Making Framework

- Experience from World Trade Center disaster and anthrax attacks
  - WTC: 7,300 patients went to over 100 hospitals
  - Anthrax: at least 6 states plus D.C. affected
  - Conclusion: all hospitals must be prepared
- Development of GNYHA Emergency Preparedness Coordinating Council (EPCC)
  - Providers: hospitals, nursing homes, medical society, home health agencies, community health centers
  - Agencies: Federal, state, and local emergency management, public health, and law enforcement
  - Meetings, briefings, and/or workgroups (each week)

# Smallpox Planning

Numerous membership meetings (EPCC and broader) beginning in December 2001

- Discussions of CDC plan and conclusion that “smallpox hospital” model not realistic/viable
  - No one wanted to be a smallpox hospital
  - No one knows where first cases would present—hospitals affected would become the smallpox hospitals, at least initially

# Smallpox Planning

- Smallpox briefing: the disease and the vaccine (Jan. 2002—see [www.gnyha.org](http://www.gnyha.org))
- Extensive discussions of regional models for preparedness and response
- Discussions of need to have vaccinated staff
  - To ensure workforce would stay on job
  - To have staff who could establish vaccination clinics

# Smallpox Planning

“Benefit” of smallpox scare in NYC in August 2002

- Raised many questions about management of a suspect case
- Extensive discussions of questions raised and need for protocols
- Result: Guidelines for Management of Suspect Smallpox Case ([www.gnyha.org](http://www.gnyha.org))
  - Protocols
  - Facility issues
  - Security
  - Reporting/authorities
  - Communications

# Pre-event Vaccination Position

- GNYHA comments at CDC forum in June 2002: urged availability of voluntary pre-event vaccine for health care workers
- GNYHA letter to Secretary Thompson (7/30/02) urging availability of vaccine
- GNYHA closely followed/publicized CDC Advisory Committee on Immunization Practices October 2002 guidelines:
  - Categories of workers recommended
  - Furlough position (not routinely needed)
  - Contraindications

# Pre-event Planning by Health Authorities

- Extensive planning efforts by NYCDOH and NYSDOH on pre-event program
- November 2002 directives by NYC and NYS:
  - Create framework for implementing program
  - Must be prepared to respond to smallpox cases
  - Must implement guidelines on management of cases
  - Made clear that vaccination is an important part of preparedness

# GNYHA/NYC/NYS Briefings on Pre-event Plan

- Kick-off meetings (Dec. 12/13)
- Meeting to facilitate institutional decision-making regarding participation (Jan. 9)
- GNYHA Executive Committee meeting with NYCDOH and NYSDOH (Jan. 9)
  - Important part of preparedness
  - Expectation that all hospitals must be able to manage cases
  - Discussion of furlough (not routinely needed)

# GNYHA Executive Committee

## Resolution

- Strongly urges hospitals to participate in Phase I of pre-event plan
- Cites importance to
  - Protection of patients and communities
  - Protection of workforce
  - Emergency preparedness/response (treatment of smallpox cases, participation in post-event vaccination clinics)
- Press release

# Hospital Participation

- New York City
  - Due date for responses: Jan. 13
  - 68 of 72 hospitals said “yes”
  - Train-the-trainer sessions have been held
  - NYCDOH workers began vaccinations week of Feb. 17
  - Hospital vaccinations begin in late March
- New York State (outside NYC)
  - Due date for responses: Jan. 31
  - Coordination with local health departments (LHDs)
  - Focuses on regional trauma centers (a/k/a resource centers)
  - Similar timeline to NYC

# Workforce Concerns

- Voluntary/no reprisals
- Adequate education and training
- Adequate screening and monitoring
- Payment for lost time and injuries
- Indemnification for accidental transmission
- Staff support/coverage for participating workers
- Safe needles (but: the needles requested are not FDA-approved)

# 1199 SEIU Delegates Meeting

- Approximately 1,500 delegates (1/23/03)
- NYSDOH/NYCDOH presentations
- Panel of experts from hospitals/agencies
- Educational materials
  - CDC fact sheets
  - NYCDOH template letter and Q&A document for staff
  - GNYHA resolution
  - 1199 SEIU Q&A and vaccine alert

# Homeland Security Act

- Federal assumption of liability for claims arising from “Administration of Smallpox Countermeasures”
- Act became effective January 24, 2003
- Liability provision became effective upon declaration by HHS (1/24/03)
  - Need for countermeasure based on “potential bioterrorist incident”
  - Includes policy determinations and who is covered

# Homeland Security Act

- Applies to claims made by individuals receiving vaccine as well as those made by individuals who might contract vaccinia from vaccinated person
- Covered persons:
  - Manufacturers/distributors of countermeasures
  - Health care entities under whose auspices such countermeasures are administered
  - Qualified persons who administer the countermeasures
  - Official, agent, or employee of the foregoing categories

# Homeland Security Act

- Exclusive remedy (except Workers' Compensation as applicable in each state)
- Federal liability/remedies are under Federal Tort Claims Act, which is negligence-based (i.e., it is not a no-fault system for claimants)
- Thus, claimants must prove negligence
  - Negligent screening
  - Negligent injection
  - Failure to warn
  - Negligent transmission

# Homeland Security Act

- Gross negligence, willful misconduct, and recklessness fall outside of coverage
- Requests to create no-fault fund
  - Support for creation of fund
  - Discussion to include broad array of countermeasures

# HHS Guidance Documents

- HHS guidance document: clarifies that coverage extends to
  - Hospitals acting as vaccination clinics
  - Hospitals offering program but that send employees to another site for vaccination
- CDC question and answer document
  - Updated to conform to HHS guidance document regarding covered entities

# Workers' Compensation and Health Insurance (NYS)

- NYSDOH guidance states Workers' Compensation Board has advised that workers' compensation will cover injuries from the vaccine
  - Must be employee/situation covered by insurance
  - Covers medical costs of adverse events
  - Lost wages from adverse events (with limits)
    - No compensation for first 7 days
    - Unless disability lasts more than 14 days, in which case compensation is allowed from date of disability
- Comprehensive health insurance should cover adverse events subject to all other policy provisions

# Workers' Compensation (NJ)

- NJ Attorney General's letter:
  - Workers' compensation program should cover adverse events experienced by public employees and hospital employees
  - Will also cover unpaid volunteers participating in authorized "civil defense activities" under NJ Disaster Control Act of 1952

# Observations About Process

- Public health risk/benefit analysis is viewed somewhat differently in NYC region
- Smallpox is probably not most likely attack agent/method but
  - High fatality rate
  - No proven treatment
  - Vaccine is available
- Phase I is conservative and calls for extensive screening/monitoring

# Observations About Process

## Need to address concerns/barriers

- Concerns about adverse events: over time, actual experience may reduce concerns (see [www.smallpox.army.mil](http://www.smallpox.army.mil))
- Concerns about transmission to patients: requires greater comfort with ACIP guidelines/experience will be instructive
- Liability and compensation concerns: experience with adverse events may alleviate concerns/creation of no-fault fund will help significantly
- Considerable demands of education/screening/consent/monitoring: experience with process may minimize resources after initial start-up/process may be adjusted
- Costs to institutions/detraction from other initiatives: experience may minimize time commitment/costs over time

# Observations About Process

Important part of preparedness

- Core group of workers to respond if needed
- Core group of workers who can set up post-event clinics (NYC clinic model: 8 million people to be vaccinated)
- Education of health care workers, health authorities, and public about smallpox, the vaccine, setting up clinics, etc.