

# National Smallpox Vaccination Program Update

**National Immunization  
Conference  
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# BACKGROUND



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# The Federal Plan

(announced 12/13/03)

- Vaccinate civilian smallpox response teams
- Vaccinate Department of Defense personnel
- Vaccinate selected staff in overseas assignments (Department of State)
- Vaccination not recommended for the general public at present – However, accommodate those who insist..



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# Smallpox Public Health Response Teams

- **Public health and medical personnel needed to investigate initial suspected cases and initiate control measures**
- **Includes medical, public health, epidemiologic, laboratory, and nursing personnel, vaccinators, others**



# Smallpox Healthcare Response Teams

- Healthcare personnel from participating hospitals who will be asked to evaluate, manage, and treat the initial suspect/diagnosed cases
- Teams identified by state and local public health officials and hospital officials.
- Voluntary hospital participation in the program.



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# NATIONAL PROGRAM GOAL



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**In partnership with state and local health authorities; DHHS/CDC is establishing a smallpox preparedness program that:**

- Provides **vaccination and follow-up service**, on a voluntary basis, immediately to those individuals who would respond to a smallpox emergency (including, but not limited to, those who would treat the victims, provide security, vaccinate the population, and perform disease case investigation), then, based on knowledge gained, expand the program to include those responders who would be occupationally at risk during a smallpox outbreak; and
- Enhances **community awareness and clinician expertise** about smallpox disease and smallpox vaccination through education and training;
- Performs **disease surveillance and laboratory analysis** to rapidly detect a single case of smallpox and any subsequent cases;
- Implements **public health interventions**, based on careful consideration of epidemiology and mode of transmission of smallpox, in the safest possible manner; and
- Provides for the **capability to rapidly vaccinate a greater number of responders or the entire population** should a case occur or threat levels of a possible smallpox terrorist attack increase.



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# PROGRAM DESCRIPTION



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# Key Program Components

- Pre-screening
- State/local program support
- **Data management**
- Evaluation
- **Vaccine safety**
- Education and training
- **ACIP Smallpox Vaccine Safety Monitoring Workgroup**
- **Communication**
- Surveillance and Research



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# Pre-Screening Materials

- Cover letter
- Vaccine Information Statement (VIS)
- VIS supplements:
  - Reactions after vaccination
  - Vaccination site care
  - Skin conditions/contraindications
  - Weakened immune system
  - Pregnancy



# Pre-Screening Materials

(continued)

- Screening worksheet
- Contacts' information sheet (NEW)
- Information on VIG
- Cidofovir information
- 11 minute video
- Medical history and consent form
- Post-vaccination follow-up sheet



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# New Materials

- Household contacts' information sheet (IOM recommended)
- Lower literacy materials (in process)
- CDC has reviewed additional local materials from 17 areas, dealing with HIV screening, additional exclusions from vaccination, recordkeeping



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# Medical Screening

- Individual may opt out after:
  - Reading the pre-vaccination info packet (before appt.)
  - Getting test results (before appt.)
  - Presenting at clinic
- Advised not to present to clinic if contraindication to vaccination or chose not to participate
- Repeat screening questions for contraindications on clinic history form
- Cover letter acknowledges vaccine safety concerns



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# State and Local Support

- **State, local public health conference calls every week previously on Monday, Wednesday, Thursday, and Friday, now Wed, Thurs.**
- **Group e-mails (e.g., reporting, revision of education materials)**
- **E-mail help for PVS and other technical assistance needs available**
- **Technical assistance/evaluation site visits**



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# Working with Partners

- **CDC regularly communicates with FDA about package label and VIG, Cidofovir IND issues**
- **Strong partnership formed with DOD to share data and information about spx program rollout**
- **Ongoing partnership with VA**
- **Day-to-day involvement of ASTHO, NACCHO, CSTE, and APHL and others**



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# Program Evaluation

- **Studies underway or planned to assess:**
  - individual and hospital participation/non-participation factors
  - knowledge, attitudes, practices of primary care providers
  - program costs
  - immunological responses to vaccination
- **safety, communications evaluations**





# Surveillance and Research

- Needlestick surveillance
- Evaluation of site care, dressings
- Laboratory:
  - immunological responses to vaccination, primary and secondary vaccinees
  - genomic studies of Dryvax related to adverse events



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# PROGRESS TO DATE



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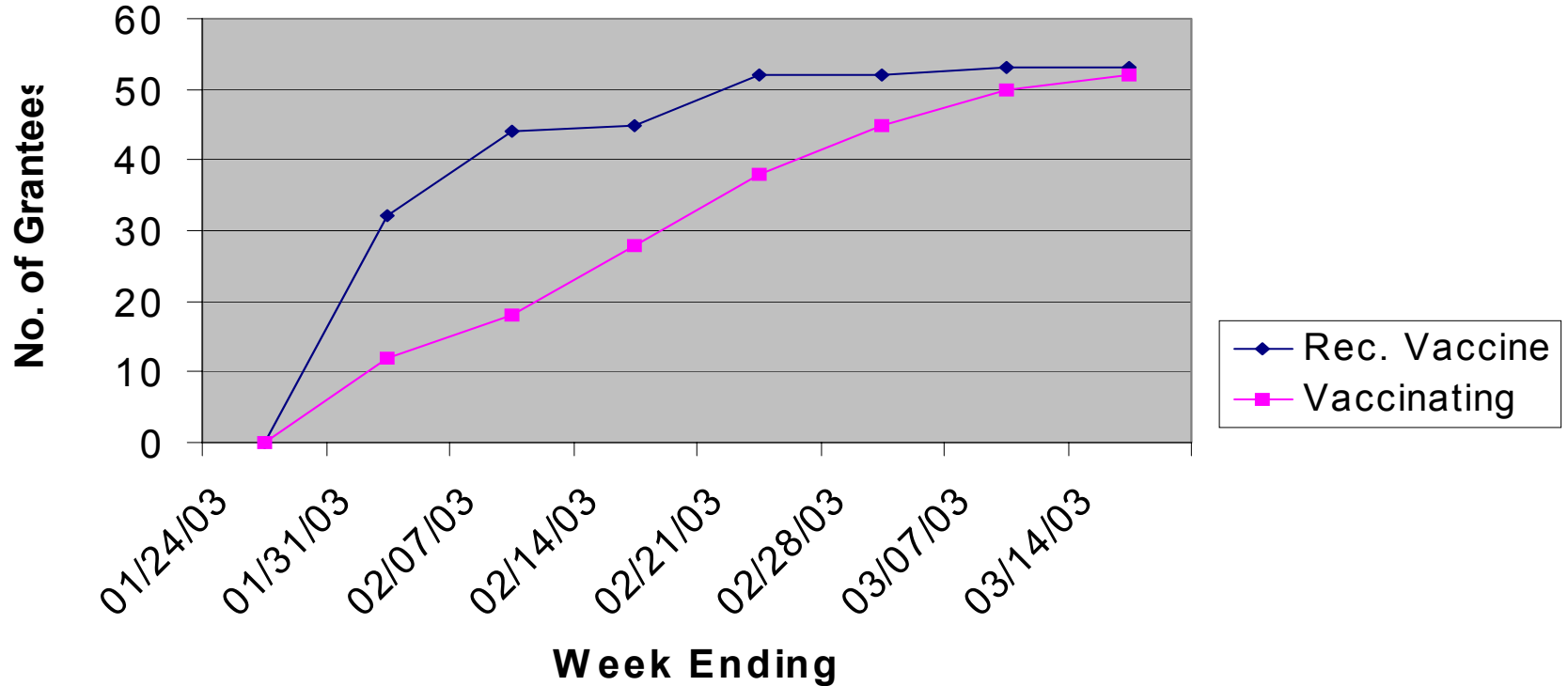


## PROGRAM SUMMARY

as of COB Friday, March 14, 2003

52	Grantees Vaccinating as of 3/14/03
3	Grantees with Vaccination Start Dates AFTER 3/14/03
7	Grantees with NO DATA

### Number of Grantees Participating by Program Component



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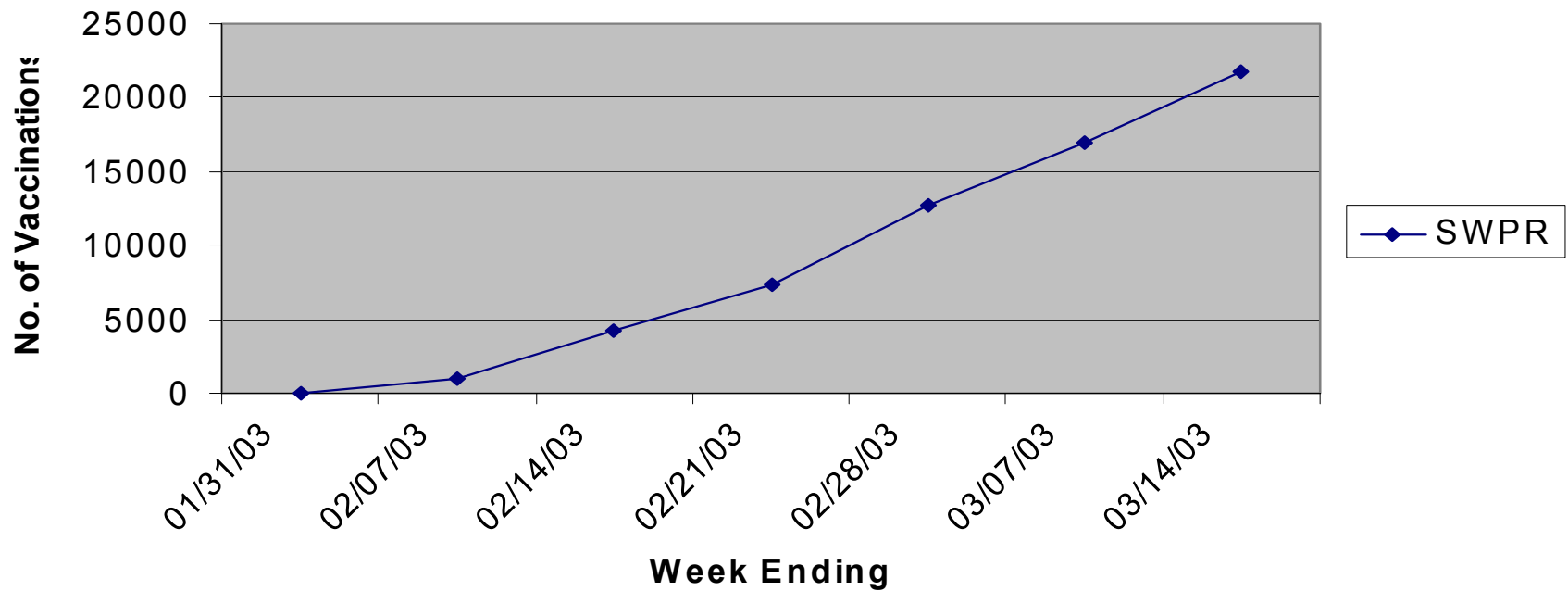


# Participation, 3/14/03

- 21,698 vaccinated:
  - 8,504 public health team members
  - 12,129 health care team members
  - 1,065 other
- 1,186 hospitals with at least one worker vaccinated (24% of acute care hospitals)



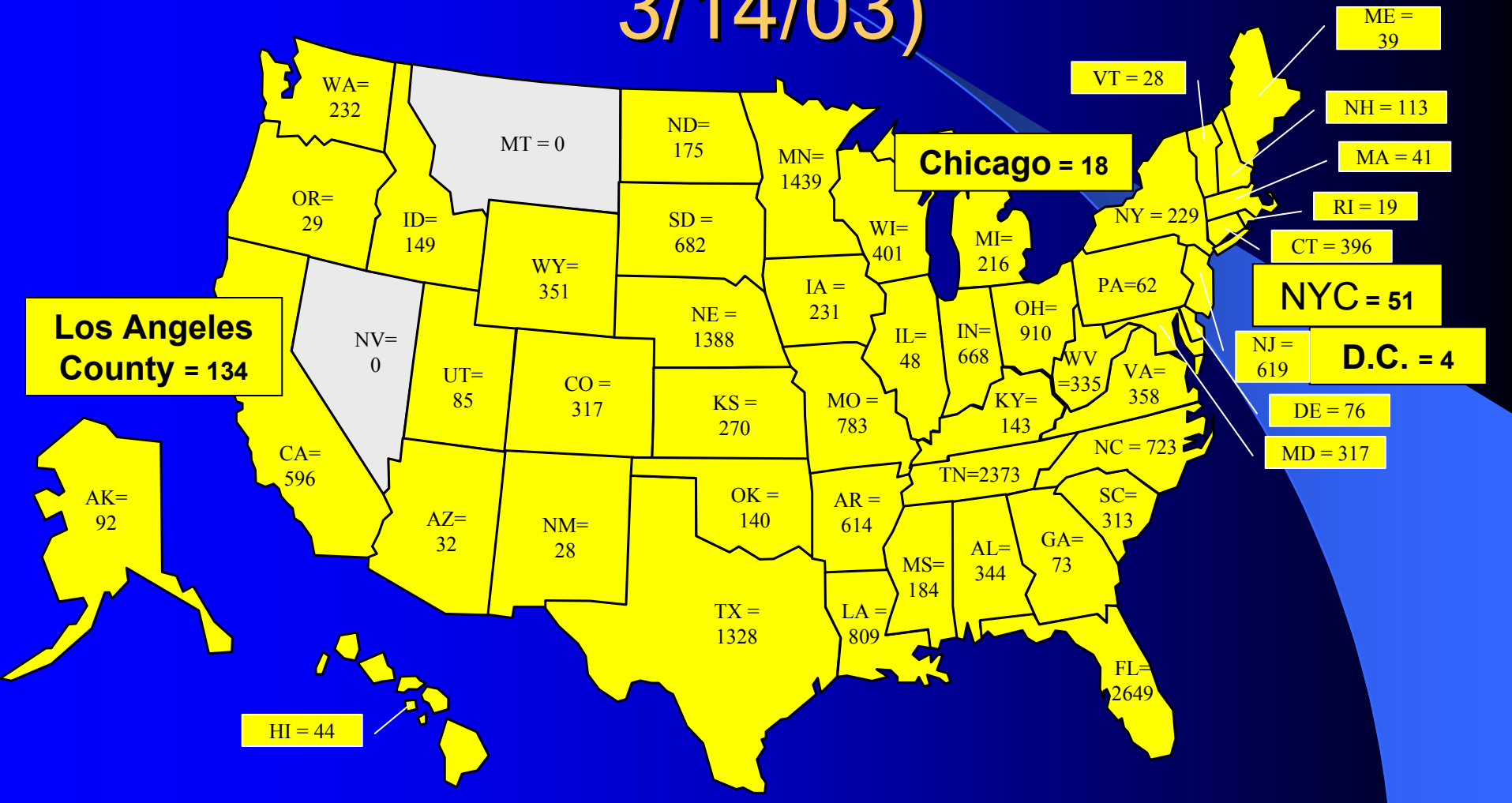
## Cumulative Count of Vaccinations *(as reported by grantees)*



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# Projects That Have Vaccinated 21,698 Vaccinated (COB, 3/14/03)

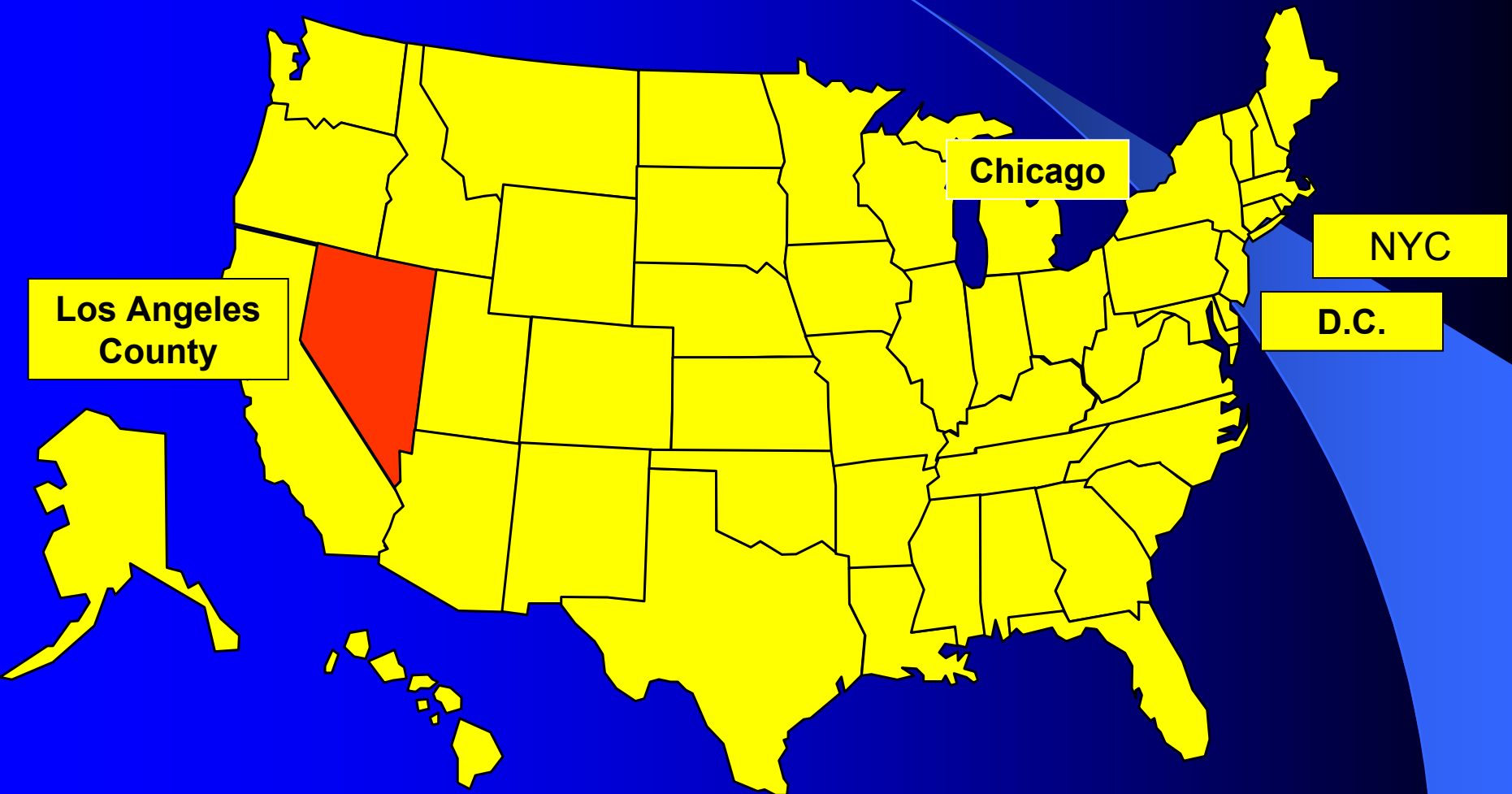


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# Scheduled to Vaccinate after 3/21/03

## 279,000 Doses Released (3/14/03)



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# Program Reporting

- **Weekly reports from the projects asking for:**
  - **Vaccination totals by Public Health, Healthcare Teams and Other**
  - **Numbers of hospitals where one or more staff have been vaccinated**
- **Optional information being requested:**
  - **Community awareness campaigns**
  - **Education and training programs conducted**
  - **Rash illness surveillance**
  - **Laboratory diagnostics**
  - **Exercises that test capability to conduct large-scale vaccination should a case of smallpox be discovered**





# Program Reporting

## (continued)

- **PVS to be used as the reporting engine once fully up and running**
- **From CDC:**
  - **vaccine shipments**
  - **training activities**
  - **telephone inquiries**
  - **PVS summaries**
  - **VAERS reports**



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# Other Progress (from Plans)

- **Plans approved for all states, D.C., NYC, Chicago, Los Angeles, Puerto Rico, and Palau**
  - **Public health teams:**
    - 1,154 teams
    - 21,821 people
  - **Healthcare teams:**
    - 4,744 teams
    - 407,552 people



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# Training and Education Progress

- 64 training and education sessions through 3/10/03
- Reaching 1,528,798 healthcare professionals
- Conducted via satellite broadcast, Internet, CD-ROM, classroom, videotape, and audioconference
- 32 different training products available



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# Adverse Events after Smallpox Vaccination, 3/7/03

Health Event, by Severity	
Potentially Life Threatening Events	0
Moderate to Severe Events*	6
Other Severe Events	8
Other Events of Concern	
Transfer of vaccinia virus to contacts**	0
Treatments with vaccinia immune globulin (VIG)	1

\* Related to vaccination, e.g., inadvertent inoculation, generalized vaccinia

\*\* This category refers to the number of vaccinia virus transmissions from civilian vaccinees. No cases of transmission from civilian vaccinees have been reported. Five cases of transmission from military personnel to civilian contacts have been reported.



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## Smallpox Vaccination Report Status and Adverse Events

State-by-state vaccination numbers and adverse events numbers **will be updated on Friday, February 14 by 5 p.m. ET.**

As of **February 11, 2003**, these are the vaccination numbers being reported to CDC by state and local health departments.

### Smallpox Vaccination Program Status by State

State or Locality	Persons Vaccinated
Colorado	44
Connecticut	20
Georgia	68
Iowa	61
Kansas	11
Kentucky	21
Los Angeles County	27
Missouri	119
Nebraska	137

## Safety Assessment

Preliminary data about health events following smallpox vaccination are provided to the Vaccine Adverse Event Reporting System (VAERS). These data include cases currently under investigation. Numbers and classification of the adverse events may change as more information becomes available. A more detailed description will be provided in periodic [MMWR](#) reports.

Adverse events reported following smallpox vaccination may be coincidental illnesses that would have occurred anyway or may be caused by the vaccine. The Centers for Disease Control and Prevention (CDC) and local health officials will make every effort to determine whether reported adverse events may have been caused by vaccination and will report these determinations in the *MMWR*. [Adverse events](#) can affect persons who were vaccinated as well as persons who have come into close contact with them.

Health Event, by Severity	Cases Reported
Potentially Life Threatening Events	0
Moderate to Severe Events	0
Other Severe Events	0
Other Events of Concern	
Transfer of vaccinia virus to contacts	0
Treatments with vaccinia immune globulin (VIG)	0

### Category Definition\*\*

#### **Potentially Life Threatening Event**

Life threatening events require hospitalization. These include eczema vaccinatum – a serious skin rash caused by widespread infection of the skin in people with skin conditions such as eczema or atopic dermatitis; progressive vaccinia, also called vaccinia necrosum -- ongoing infection of the skin with tissue destruction; postvaccinal encephalitis – inflammation of

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## Smallpox Vaccine Shipment Numbers

The Centers for Disease Control and Prevention has begun distributing smallpox vaccine to state and local governments that will coordinate the vaccination of smallpox response teams. The teams are part of the nation's voluntary vaccination program to protect Americans from the potential threat of a terrorist attack involving the release of the smallpox virus. Several months of detailed planning and training, and the development of scientifically sound and informative educational materials have prepared us for the safe and rapid implementation of the plan to vaccinate those healthcare professionals who would be on the front lines in the event of a smallpox attack.

Date	State/County	Doses
2-11-03	Alabama	10,000
	Hawaii	4,500
	Ohio	4,000
	West Virginia	2,500
2-6-03	Texas	30,000
	Arkansas	8,000
	Washington State	4,000

# CHALLENGES



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# Declaration, Administration of Smallpox Countermeasures, 1/24/03

- **From Secretary, HHS: reiterated President's vaccination recommendations; to last one year**
- **Notes liability protection for those “Determining who is contraindicated; monitoring, management, and care of the countermeasures ...”**
- **Countermeasures include vaccine, VIG, Cidofovir**
- **Covers health care entities, their employees, agents, and officials**



# Compensation for Vaccine Injury

- No uniform compensation program as yet
- HHS/CDC continue to work aggressively with the Office of Management and Budget and Congress to address this serious issue.
- Legislation to address compensation pending



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# NEXT STEPS



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# Program Next Steps

- Focus on development of program guidance to be issued 4/01/03
- Establish program for the general public who insist on vaccine
- Enhance use of PVS
- Enhance program reporting



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