

## Abstract

### Background

Since the atrocities of September 11, 2001, and the anthrax exposures that began shortly thereafter, the threat of biological and chemical terrorism has emerged as an alarming challenge to the nation's public health and medical care systems. Although naturally occurring outbreaks of smallpox have been eradicated, the threat of smallpox as a biological weapon is very real. After the discovery of evidence that the smallpox virus may have been taken from the repository in the former Soviet Union, the Advisory Committee on Immunization Practices (ACIP) recommended in 2002 that personnel designated to investigate and follow up initial smallpox cases and selected health care workers in facilities designated as smallpox referral centers be vaccinated for smallpox. The ACIP later extended its recommendation for vaccination to all health care workers in acute care hospitals. On December 3, 2005, the president of the United States announced its official policy for vaccinating health care workers against smallpox, including the Administration's groups mentioned above, and a campaign to immunize all eligible health care workers was immediately launched. The Centers for Disease Control and Prevention (CDC) asked health care workers and other critical personnel to volunteer to receive the vaccine against smallpox. It became evident early in the immunization campaign that there was considerable resistance among these health care workers to being immunized, and early participation rates appeared to be very low. To help evaluate the vaccination program, the National Immunization Program, a center at the CDC, is sponsoring the *Evaluation of Non-Participants in the Smallpox Vaccination Program*. CDC has contracted RTI International, a not-for-profit firm, to conduct the evaluation.



The smallpox vaccination program has received much attention from the media and from government officials

## Purpose

To evaluate why individuals opted out of the vaccination program, to help CDC respond to any future bioterrorist threats, and to improve CDC's approach to future vaccination campaigns.

## Study Design

A sample survey of hospitals and local health departments was taken in 5 states. The sampling frame was developed as follows:

- Contacts within each of the 5 state health departments identified the hospitals and local health departments participating in the vaccination program. A convenience sample was taken of these entities. Each entity identified eligible persons within its institution who had opted out of participation in the vaccination program.
- These non-participants are being interviewed, primarily by telephone. A self-administered web survey and a self-administered mail survey are offered for those who decline to complete the interview by telephone.
- It was decided that 5,000 people would be interviewed, of whom approximately 20% received the vaccination.



RTI is conducting the study with 5 states representing all areas of the continental U.S. across 3 time zones

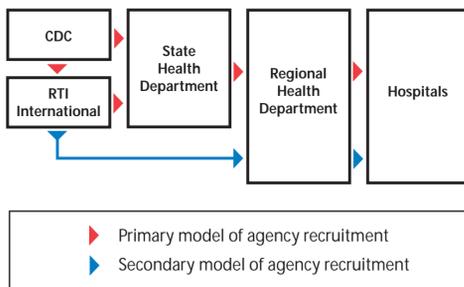
## Challenges and Solutions

### Hospital and Regional Health Department Recruitment

State health departments were charged with recruiting their own hospitals and regional health departments for participation in this study. To facilitate this recruiting, RTI:

- Maintained weekly contact with the state health departments during the list-building phase to develop effective and responsive recruiting strategies and materials.
- Prepared and shipped personalized advance packets to hospitals and health departments that included a letter from the client, a letter from the state health department, a project overview, and a link to RTI's project website with a personalized username and password.
- Provided talking points to guide the state health departments in their conversations with the hospitals and health departments.
- Created an easy-to-use and secure website that allowed hospitals to quickly upload files to RTI's system.
- Provided incentives for agency participation. Participating hospitals were given a \$500 honorarium. Participating regional health departments were given complimentary copies of useful publications (*2003 Red Book: Report of the Committee on Infectious Diseases*).
- Directly recruited the hospitals and regional health departments if the state did not wish to be directly involved with recruitment.

### RTI was flexible in its approach to recruiting hospitals



Incentives such as the 2003 Red Book were provided to hospitals and health departments for participating in the study



### List Building Challenges/Solutions

Some hospitals were uncomfortable providing contact information for their employees without their employees' permission. RTI addressed this concern by providing the hospitals with a "passive consent" letter that the hospital could distribute to the staff. The letter instructed staff to contact the hospital study coordinator within 7 business days if they did not want their name to be provided to RTI.

In some of the sample lists provided by hospitals and health departments, there was only one contact phone number for numerous staff. Problems arise when trying to contact 150 respondents at the same phone number: the receptionist becomes irritated, hospital procedures are interrupted, etc. RTI developed and implemented the following procedures to overcome this challenge:

- Sending postcards to respondents asking for best number and best time to call
- Contacting the hospital coordinator and switchboard operator to determine the best solution to contact staff
- Releasing only 3 cases with the same phone number at any given time
- Obtaining the best contact time for the group, based on workload—i.e., right before shift starts, break times, etc.
- Contacting the hospital coordinator to obtain e-mail address of respondents and sending respondents contact information via e-mail.

Other procedures that have been developed but not yet implemented are:

- Sending an RTI employee to the hospital to obtain the best contact info
- Calling groups of respondents to ask for the best time to contact respondents

### Data Collection

RTI has employed a number of data collection methods in order to contact and collect data from the highest number of persons possible. Each potential respondent can complete the evaluation interview through one of the following three methods:

- computer-assisted telephone interview
- self-administered interview via the web
- self-administered hard copy (paper and pencil) questionnaire

RTI is using outbound computer-assisted telephone interviewing (CATI) as the primary mode of data collection. A lead letter is being mailed to all respondents explaining the purpose of the evaluation. This letter contains a toll-free 800 number that respondents can call to complete the interview via telephone. Each participant is assigned a username and password for completion of the self-administered web interview, both of which are included in the initial lead letter. Outbound calls to respondents at hospitals and health departments commence 2 or 3 business days after the letters are mailed.

The outbound calling efforts involve locating, contacting, and interviewing sample members. If contact is made and he or she is not available to be interviewed at that time, information is obtained about other contact numbers and when the sample member is likely to be available. When an answering machine or voice mail is encountered, messages are left stressing the importance of participation and reminding the subject of the modes available. Inbound calls are routed to CATI interviewers to answer questions and/or complete the interview.

During the outbound call attempts, if a potential respondent declines to participate by phone, he/she is offered the options of completing the self-administered web interview or having a hard-copy questionnaire mailed to him/her for completion (all returned hard copy questionnaires are date entered). For those respondents who decide to complete the self-administered web interview, RTI provides a web-based help desk to assist sample members with technical and general questions. This design provides those who cannot be reached by telephone or who choose not to respond by telephone with convenient and secure methods of responding.

In coordination with CDC, RTI also developed a self-administered hard copy questionnaire for hospital and health department smallpox coordinators. This questionnaire characterizes the smallpox vaccination program process within each institution.



The Evaluation of NonParticipants in the Smallpox Vaccination Program seeks to uncover the reasons for low participation in the vaccination program

In the state of California, we are interviewing persons who received the vaccination as well as persons who did not participate in the vaccination program. To accommodate this development, RTI worked hand-in-hand with CDC to revise and modify the original questionnaire. Telephone interviewing staff were trained on the changes made to the questionnaire as well as the changes made to interviewing protocol, i.e., the vaccinees are contacted at their residential phone number instead of their work phone number. This is expected to provide an interesting analysis at the end of the program evaluation on various topics, such as reasons why some people chose to receive the vaccination and others did not.

### Sampling Issues Involved in the Study

#### Actual Sample Design(s) Used

- It was determined that the objectives could be obtained with a sample size of 5,000 decliners (1,000 per state), which would yield approximately 3,600 completed interviews.
- The sampling rate of hospitals/health departments in Tennessee, Utah, and Nebraska was reset at 100% and all decliners were to be selected within the participating hospitals. The reason for this was the much smaller number of hospitals/health departments that agreed to participate in these states.
- In Michigan, a relatively large number of hospitals/health departments agreed to participate (28 hospitals, 31 health departments). Based on these numbers, we stratified the hospitals by number of staffed beds (under 100, 100–299, 300–399, 400+) and took a sample of 5 hospitals in each stratum except the 400+ beds stratum, in which there were only 4 participating hospitals. We took all 4 in this stratum. To sample the health departments, we categorized them in 3 strata according to size of catchment area and took a stratified sample of 19 health departments.
- The number of hospitals/health departments sampled in Michigan was based on projections made from the Tennessee data.

#### Sampling for California

- California collaborators desired data on vaccine acceptors as well as the decliners, so the study design differed in that state. We expect to sample approximately 500 decliners and 500 acceptors from California. Also, county personnel (not RTI employees) are recruiting the entities and will be recruiting health departments and hospitals within the participating counties.
- We anticipate that approximately 20 hospitals and 8 health departments will participate in the survey, and that the sampling plan will be similar to that used in Michigan.
- The lists of acceptors and decliners in California is still incomplete.

### Potential Analytical Issues

- Because in all states except California the target group is the decliners, the main thrust of the analysis will be to descriptively characterize the decliners according to variables such as reason for declining the vaccine, knowledge/beliefs about the safety and efficacy of the vaccine, and demographic variables about the decliners.
- In California, where the target group includes both decliners and acceptors, a case-control approach can be used to estimate the strength of the relationship between variables associated with individuals as well as programmatic variables and the likelihood that an individual will accept or decline the vaccine.
- From a separate survey of the hospital/health department coordinators, we will attempt to characterize variations among these establishments with respect to how the program was implemented and the number and percentage of employees within each of the participating establishments that were offered the program.