Data Acquisition Issues in a Survey of Healthcare Professionals in Hospitals and Health Departments Invited To Participate in the U.S. Smallpox Immunization Program

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In 2003 the U.S. Department of Health and Human Services (DHHS) developed important new regulations as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), providing more protection for individually identifiable information and data. These changes to HIPAA resulted in the first national standards for the protection of health information.

Shortly after these new regulations were accepted, RTI International began a program evaluation to be conducted with health employees at hospitals and state and local health departments. This paper briefly describes how we adapted our data collection procedures to comply with the HIPAA regulations and how those changes impacted our data collection processes and results.

1. Brief Overview of HIPAA

HIPAA was created and designed to protect individual health information by limiting the release of medical records and medical information to the general public. Medical records and information could still be made available to researchers and government agencies; however, the onus was on medical providers (referred to as "covered entities" in HIPAA) to ensure that the requests for such information were legitimate.

In April 2003 the new regulations were developed under the Privacy Rule, which further limited access to medical records and medical information. The Privacy Rule states that no personal identifiable medical information can be released without the patient's written authorization. The rule does allow release of an individual's personal medical information to legitimate research organizations and government agencies conducting certain types of research (e.g., public safety research). However, because of the new Privacy Rule, some medical providers have decided not to release medical records at all without the patient's written authorization, no matter who is requesting the information. In other words, some providers tend to err on the side of caution to avoid potential liability in the event of inappropriate release of records.

In addition, one might expect medical professionals to be less likely to participate in research due to the changes in HIPAA. Because of the Privacy Rule, they might be hesitant to participate for fear of disclosing information whose release could be punishable by law.

2. Evaluation of Non-participants in the Smallpox Vaccination Program

Since the atrocities of September 11, 2001, and the anthrax exposures that occurred shortly thereafter, concern for the security of our nation has increased with the probability of additional bioterrorist incidents producing potentially devastating consequences. Although naturally occurring outbreaks of smallpox have been eradicated, the threat of smallpox as a biological weapon remains.

Smallpox is a virus identified in two forms: variola major, accounting for approximately 90% of all cases, and variola minor.[1] A smallpox outbreak, spread through person-to-person transmission by droplet, airborne, or fomite (an inanimate object contaminated with a pathogen) contact, represents the possibility of a catastrophic, population-level health event among approximately 119 million unvaccinated U.S. residents.[2,3] Concerns that the virus could fall into the hands of terrorists have motivated preparations for the possibility of outbreaks resulting from deliberate attacks.

In response to this potential threat, on December 13, 2002, President George W. Bush announced a plan that included the formation of Smallpox Response Teams (SRTs) to provide critical services in the event of a smallpox attack.[4] The Centers for Disease Control and Prevention (CDC) asked health care workers (HCWs) and other critical personnel to volunteer to receive the vaccine against smallpox. Vaccinations began on January 24, 2003, with a goal of vaccinating 0.5 million HCWs to form SRTs (Phase 1) and a subsequent goal of vaccinating 10 million HCWs and emergency response workers (Phase 2).[5] In March 2003, however, CDC considerably reduced the Phase 1 vaccination goal to 50,000 HCWs.[5] The program was administered through 62 state and county health departments (SHDs) that worked with hospitals to identify and inoculate health care workers who formed the SRTs.[5] In May 2003, the Institute of Medicine (IOM) Committee on Smallpox Vaccination Program

Implementation recommended to CDC that the program be suspended for three reasons: (1) safety (e.g., adverse events), (2) adjustments for changing circumstances (e.g., refinement of educational materials), and (3) a reassessment of overall smallpox preparedness (e.g., number of persons required for vaccination).[6] Although some states and local health departments had paused vaccination efforts in response to the IOM report, the program implementation had continued.[7,8] Sixty-two state/ program sites had requested and received 291,400 doses of the vaccine[9] as of July 31, 2004. Previously, 31,297 HCWs received the vaccine as of April 2003, representing 54 of the 62 state/program sites; nearly half of the persons vaccinated came from eight states: Florida, Minnesota, Missouri, Nebraska, North Carolina, Ohio, Tennessee, and Texas.[5]

To gain further insight into why many HCWs apparently chose not to be vaccinated and how the program was actually conducted, CDC contracted with RTI to conduct a program evaluation in five states: Tennessee, Utah, Michigan, Nebraska, and California (listed here in the order in which the states were recruited). States were chosen in consultation with CDC to reflect the diversity of states and programs participating in the Smallpox Vaccination Program. This project, entitled *The Evaluation of Non-Participants in the Smallpox Vaccination Program*, was designed to provide an opportunity to learn about factors related to the decision not to be vaccinated. Information from this effort will be used to enhance the efficacy of this program and, possibly, subsequent similar programs. The evaluation may also enhance planning for other vaccination programs that might need to be directed toward adults and/or health care staff. As CDC's prime contractor for implementing this evaluation, RTI was charged with several tasks: list acquisition, frame construction and sampling, data collection, data processing, questionnaire design, and reporting and analysis on the study's findings. This paper will focus on the list acquisition, frame construction, and sampling tasks to show how we adapted our procedures to the changes in HIPAA.

3. Overview of List Acquisition, Frame Construction, and Sampling

To achieve the analytic goals of the study, we gathered information from an appropriate number of nonparticipants in the Smallpox Vaccination Program. To this end, RTI supported SHDs in the acquisition and development of lists of the eligible HCWs and health department employees who declined to participate in the Smallpox Vaccination Program.

RTI worked with the SHDs in Tennessee, Utah, Michigan, Nebraska, and California to obtain from the participating hospitals and health departments in their respective states the following information:

- name,
- place of employment,
- state of employment,
- phone number of eligible health care workers, and
- health department employees who declined to participate in the smallpox vaccination program.

Originally, these lists were to be categorized into three groups of nonparticipants:

1. eligible HCWs who declined to participate in the Smallpox Vaccination Program or who did not volunteer within their occupational category,
2. HCWs who opted out during or after prescreening but before being scheduled for a vaccination, and
3. HCWs who opted out after completing the prescreening process and being scheduled for vaccination.

However, because of the lack of records kept by hospitals and health departments, the lists of health care workers could not be compiled in this way. We will discuss this topic in more detail later in this paper.

After list acquisition activities were complete, frame construction and sampling activities were conducted. Originally, the study protocol called for an entire sample of 10,000 persons; 2,000 within each state would be drawn from the tripartite list described above. Because of several factors, including delays, smaller-than-expected numbers of agencies available to participate in the evaluation, and smaller-than-expected numbers of persons listed in agency lists, the sampling plan was modified to reduce the sample to 5,000 individuals (approximately 1,000 from each state). This paper will discuss how these problems were overcome and how our sample was obtained.

3.1 List Acquisition Procedures

RTI's first task was to obtain a list of all persons who were identified to receive the smallpox vaccination but did not get vaccinated.

Originally, CDC asked SHDs to recruit their own hospitals and regional health departments for participation in this study. The RTI list-building team

was to play a supporting role during list acquisition. We provided assistance to SHDs in the following ways:

- *Maintaining regular contact with the SHDs*. The purpose of these regular calls was to identify barriers to list acquisition, develop effective and responsive recruiting strategies and materials, monitor list acquisition progress, and to serve as a liaison between the SHDs and CDC.
- *Preparing and shipping personalized advance packets to hospitals and health departments.* Designed to promote efficiency in the list acquisition process, the packets were sent prior to list acquisition calls so that the hospitals and health departments would be alerted to the study and could refer to the documentation while discussing it with the SHD. Advance packets included a letter from CDC, a personalized letter from the SHD, a project overview, and a link to RTI's project Web site with a personalized username and password.
- *Providing talking points to guide the SHDs in their conversations with the hospitals and health departments.* The talking points document included a list of suggested topics to discuss to ensure that the hospital or health department was thoroughly briefed on the background of the study and on what was being requested of them.
- *Directly recruiting hospitals and regional health departments upon request by the SHDs.* Although CDC envisioned that SHDs would do most of the list acquisition, RTI prepared materials and systems and assembled a list acquisition team in the event that RTI was called upon to take a leadership role.

In practice, RTI's responsibilities varied by state depending on the extent to which the state smallpox coordinator wished to be involved in the project. However, most states requested that RTI take a leadership role and directly recruit hospitals and regional health departments.

3.2 Challenges to List Acquisition

Early on in the recruiting, it became clear that list acquisition was more challenging than the states originally anticipated. The states found that many agencies that were contacted refused participation due to the great level of effort required on their part to prepare a list or due to confidentiality concerns. Of the states that participated in this study, they reported two major hurdles:

1. Agencies did not have a readily accessible list of individuals who were offered the vaccine. Compiling these lists was a burden to the smallpox coordinators at hospitals and health departments who often wore "multiple hats" at their agency with many typically being infection control nurses.
2. Agencies were reluctant to provide employee names without the employees' permission.

The first challenge changed the way we created and obtained our sample. Because of the lack of lists of individuals who were offered the vaccines, RTI was unable to compile lists of the three different groups of health care workers that CDC had requested. Many hospitals and health departments did not keep updated lists of the people who did receive the vaccine. RTI in conjunction with CDC did have access to the PVS list (people who were vaccinated) and were able to match PVS data to hospital and health department data to identify vaccinated persons. This also created, in some instances, a great burden for those who were compiling the list of employees to send to RTI. There was no standard way of administering the Smallpox Vaccination Program; each hospital and health department administered the program in a way that best suited its needs. In some instances employees were personally invited to receive the vaccine. At some agencies, an announcement was placed in the cafeteria announcing the time and place the vaccine would be offered. Hence, the agency smallpox coordinators who were compiling lists had to identify which employees were offered the opportunity to receive the vaccine. Because of the variety in how the program was implemented, the burden of creating the lists varied by agency.

The second major challenge we faced in obtaining lists of employees related to privacy. Many agencies were reluctant to release their employees' names, work phone numbers, and home phone numbers. In fact, we did not receive any home contact information from any agency. Some of the privacy issues related to protection of their employees; others stemmed from concerns about releasing information about the employees, hospitals or health departments, which would be protected under the HIPAA regulations.

These two challenges caused delays in acquiring lists of health care workers. The SHD coordinators did

what they could to address the issues raised by the hospitals and health departments in their states, but they were unable to resolve all of the concerns. RTI, in cooperation with CDC, came up with new procedures and solutions to help address the qualms of the hospitals and health departments.

3.3 Solutions to Challenges

By offering incentives to all participating agencies, RTI succeeded in overcoming the first challenge, which related to the burden on the agency smallpox coordinator in compiling the list. RTI and CDC worked together to come up with incentives that would be meaningful to each agency. It was decided that hospitals would be offered a $500 honorarium. Regional health departments would be provided with complementary copies of two useful publications (*2003 Red Book, Report of the Committee on Infectious Disease* and *Epidemiology and Prevention of Vaccine Preventable Disease Immunization Guide).* These incentives were very favorably received by both hospitals and health departments. Because of the promise of these incentives, we received prompt responses from those agencies that did not refuse and that did not have privacy concerns.

A procedure was developed to address the privacy concerns. RTI created a "passive consent" letter for the agencies to distribute to their eligible staff. Each state had an individualized letter that would be sent to health care workers at each agency, requesting passive consent to participate. The letter described the study and requested that the employees contact the smallpox coordinator within 2 weeks if they *did not* want their name provided to RTI.

3.4 List Acquisition Detailed Procedures

List acquisition procedures varied by state for several reasons. First, states varied in the extent to which the state smallpox coordinators wished to be involved in the project in general and in the acquisition of lists in particular. Second, there was some variation among states in the information that they wished to obtain through their participation in the study. Most states were interested in only nonvaccinees; however, California was also interested in vaccinees. Third, the states varied in the extent to which hospitals and health departments were comfortable releasing employee names, mainly due to HIPAA concerns. Fourth, the implementation of the Smallpox Vaccination Program varied by state in terms of schedule, amount of participation, and record-keeping practices. A number of different processes were created to meet the individual needs of each state in helping to recruit hospitals and health departments to participate in the evaluation.

In each state, RTI worked with CDC to create materials that would be sent to the hospital or health department smallpox coordinator asking for their participation. The following materials were sent to each agency selected to participate in the study:

- letter from CDC;
- letter from the individual state health department;
- an overview of the study, with frequently asked questions;
- instructions for uploading the employee lists to RTI's secure project Web site; and
- refusal conversion letter to nonresponding agencies.

All three letters—from CDC, from the state health department, and the refusal conversion letter—explained that the evaluation that CDC was conducting was exempt from the HIPAA regulations.

In addition to these materials that were sent to each agency, RTI conducted follow-up calls with some agencies. During these calls RTI addressed privacy concerns by referring to the letters and explaining why the evaluation was exempt from the HIPAA regulations.

Also, as mentioned earlier, some states requested that their employees provide consent before participating in the study. For these instances, RTI drafted a "passive consent" letter to be distributed to all eligible employees at each hospital and health department. The letter was printed on the individual state's letterhead. It informed employees of the purpose of the study and instructed them to contact their smallpox vaccination program coordinator prior to a pre-established cut-off date if they *did not* wish to be contacted in conjunction with this study. The letter also explained that the program evaluation was exempt from HIPAA regulations.

3.5 Results of List Acquisition

The process of recruiting agencies was conducted over several months. The number of agencies that would eventually participate and the total number of persons per list were not definite until nearly the end of the data collection period. Thus the project team had to constantly monitor the agency lists as the agencies were recruited to ensure that there would be enough subjects to meet the specifications of 5,000 total individuals sampled. At the same time, they had to guard against the premature depletion of resources

that would result if the list size were to grow larger than the agreed-upon 5,000 persons.

In total, 113 agencies furnished lists in the five states: 59 (52.2%) were hospitals, 48 (42.5%) were health departments, and 6 (5.3%) were agencies that did not submit lists but agreed to distribute hard-copy survey instruments for voluntary completion by personnel and to mail them to RTI. After receiving lists from TN and UT, it became apparent that many institutions were not agreeing to participate and a sampling revision was necessary. Therefore, we further revised our plan to sample 100% of the agencies in all states except California to be certain of meeting the 1,000-person-per-state specification. The characteristics of the agencies and of the lists they submitted are shown in ***Table 1***.

State	Total No. of Agencies	No. of Agencies for Hard Copy	No. of Agencies with Lists	No. of Hospitals with Lists	No. of Health Depts. with Lists	No. of Total Cases Sent to RTI	No. of Exclusions Due to Vaccinated Status	No. of Total Cases Available for Sampling
CA	36	1	35	23	12	3,995	209	3,786
MI	33	3	30	8	22	936	6	930
UT	24	1	23	13	10	804	2	802
TN	16	0	16	12	4	1,045	116	929
NE	4	1	3	3	0	88	0	88
Total	**113**	**6**	**107**	**59**	**48**	**6,868**	**333**	**6,535**

4. Conclusions

RTI and CDC had anticipated a fairly quick recruitment of hospitals and health departments for this program evaluation. Upon the commencement of the recruiting efforts, numerous problems arose that caused new procedures and processes to be implemented. One of the major problems was concerns about privacy, especially because the recruitment of agencies began shortly after the changes to the HIPAA regulations were put in place. RTI and CDC developed new procedures and worked with state-level employees as well as individual agencies to overcome these concerns.

One procedure was to provide the agencies with an incentive which was intended to address the burden of work being assumed by the agency. The incentive was given after the agency agreed to participate in the program evaluation and furnished its list of program participants who did not become vaccinated. These incentives ($500 for each hospital recruited; two useful reference books for health departments) proved successful in recruiting agencies.

The other procedures presented hospitals and health departments with information about the program evaluation that showed how HIPAA related to the program evaluation that was to be conducted. This proved vital to the success of recruiting hospitals and health departments to participate.

Another key factor in overcoming potential barriers and problems was the anticipation of HIPAA and privacy concerns. At the beginning of the recruiting phase of the project, we held discussions with CDC about potential barriers and questions that hospitals or health departments might have had. In response to these anticipated concerns, we included specific text about the recent changes in the HIPAA regulations and how they applied to the program evaluation. This anticipation of concerns also aided in follow-up procedures that were developed after the recruiting had begun. We were able to tailor and personalize our responses to specific questions about HIPAA because of our preparation and knowledge about the new regulations.

From this program evaluation we learned that the changes in the new HIPAA regulations did not apply just to patients but that hospitals and health departments also interpreted that the new changes applied to their employees as well. Many concerns were raised about the release of personal employee information. However, due to advance preparation and acquiring knowledge about HIPPAA and how it applied to the program evaluation, we were able to address many of these questions and concerns. When new ones arose, we were able to adapt our procedures and processes to develop materials that helped address those concerns. In the end we were able to obtain more lists of health care employees than what was anticipated.

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References

1. Centers for Disease Control and Prevention (CDC) (2004). "Smallpox Factsheet." Atlanta, GA: CDC. Available at http://www.bt.cdc.gov/agent/smallpox/overview/overview.pdf.
2. Weber, D.J. (October 2001). "Recognition and Management of Bioterrorism Agents." Presented at the University of North Carolina at Chapel Hill School of Public Health, Chapel Hill, NC.
3. Bicknell, W.J. (2003). "The Case for Voluntary Smallpox Vaccination." *New England Journal of Medicine* 346(17):1323-1325.
4. CDC (2002). "Protecting Americans: Smallpox Vaccination Program." Atlanta, GA: CDC. Available at http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-statement.asp.
5. General Accounting Office (GAO) (2003). "Smallpox Vaccination: Implementation of National Program Faces Challenges." Report to the Chairman, Committee on Governmental Affairs, U.S. Senate. Washington, DC: GAO.
6. Institute of Medicine (2003). "Review of Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation." Letter Report No. 3. Washington, DC: National Academies Press.
7. Kuhles, D., and Ackman, D.M. (2003). "The Federal Smallpox Vaccination Program: Where Do We Go from Here?" *Health Affairs* W3-503-W3-510.
8. Arkansas Department of Health (2003). "Agency Suspends Smallpox Vaccinations, Reviews CDC Guidance." Little Rock, AK. Available at http://www.healthyarkansas.com/news/pr_smallpox_040103.html.
9. CDC (2004). "Smallpox Vaccination Program Vaccine Doses Shipped and Released for Use." Atlanta, GA: CDC. Available at http://www.cdc.gov/od/oc/media/smallpox.htm.