

# Innovative Data Collection Methods in Smallpox Program Evaluation

Evans, Brian M.  
Burke, Brian J.  
Levy, Paul  
Baxter, Rodney K.

RTI-International  
3040 Cornwallis Rd.  
Research Triangle Park, NC 27709  
[evans@rti.org](mailto:evans@rti.org)  
[bjb@rti.org](mailto:bjb@rti.org)  
[levy@rti.org](mailto:levy@rti.org)  
[rbaxter@rti.org](mailto:rbaxter@rti.org)

## Overview

Since the atrocities of September 11, 2001, and the anthrax exposures that occurred soon after, concern for the security of the United States has increased with the probability of additional bioterrorist incidents producing potentially devastating consequences, including widespread death and disease. Although naturally occurring outbreaks of smallpox have been eradicated, the threat of smallpox as a biological weapon remains.

In late 2002, as part of the national response to the threat of bioterrorist attacks related to the smallpox disease, Smallpox Response Teams were formed to provide critical services in the event of such an attack. The National Immunization Program (NIP) within the Centers for Disease Control and Prevention (CDC) asked for volunteers among health care workers (HCWs) and other critical personnel to receive the vaccine against smallpox and established a voluntary Smallpox Vaccine Program (SVP) for the health care workers. This CDC-NIP program was administered through 56 state and county health departments that were working with hospitals to identify and inoculate HCWs who constituted the Smallpox Response Teams. However, given the decentralized nature of the program, there was considerable variation in how it was administered across hospitals, health departments, and other state agencies. CDC-NIP developed the *Evaluation of Non-Participants in the Smallpox Vaccination Program* as an opportunity to evaluate the success of the SVP, to learn about factors related to how the vaccination program was administered, and to understand the reasons that HCWs chose not to receive the vaccination. RTI International was contracted by CDC-NIP to conduct this evaluation. Questionnaires were administered to both HCWs and Smallpox Vaccination Coordinators at each agency. This paper analyzes how data collected from two separate questionnaires aided in achieving the three goals of the study.

## Program Evaluation

The respondent questionnaire was administered to HCWs who decided not to receive the vaccination, asking specifically about factors that had influenced their decision not to be vaccinated. However, these data provided only one point of view about the SVP, that of the HCW. To supplement the potentially subjective view of the SVP by the health care workers, RTI and CDC-NIP agreed on an innovative approach to obtain a potentially more objective perspective on the vaccination program and how it was administered. An additional questionnaire was developed for the Smallpox Vaccination Coordinators at each hospital and health department that participated in the program evaluation. Among other things, this questionnaire asked the coordinator to provide information on how the program was administered, the employer's compensation policies, and barriers encountered during the SVP administration.

Administering an additional questionnaire has allowed CDC-NIP to analyze data from these two different perspectives to gain a better understanding of how the SVP was administered and why some HCWs chose not to get vaccinated. The HCW questionnaire provides data about reasons for not receiving the vaccine, whereas the coordinator questionnaire data provide perspectives about SVP administration. These data from the coordinator questionnaire offer valuable insight into reasons for nonresponse in the SVP. Additionally, by obtaining data from the smallpox coordinators, aggregate-level analysis by hospital and health departments can be performed by linking these data to the interview information provided by the HCW to give an overall picture of how the SVP was administered and why so many HCWs decided not to be vaccinated. Patterns of consistencies or disconnects in opinions about the SVP between the smallpox coordinator and those employed at the hospital or health department about the promotion and administration of the SVP could also be identified. These data also provide

insight into how a vaccination program of this magnitude could be carried out in the future, including how CDC might better prepare for future adult vaccination programs.

### Data Collection Results

RTI administered the coordinator questionnaire to 113 smallpox coordinators, 110 of whom completed the questionnaire for a 97% response rate. In this paper we analyze questions about promotion of the SVP, compensation to HCWs, and potential barriers or reasons for not being vaccinated. Analysis of these questions in both the respondent and the coordinator questionnaires shows how the administration of the coordinator questionnaire increased our understanding of the reasons for nonparticipation in the Smallpox Vaccination Program.

One of the purposes of evaluation was to identify reasons that HCWs declined to be vaccinated. Key pieces of information that might explain nonparticipation could be provided by the hospital and health department smallpox coordinators. RTI and CDC discussed this issue and agreed that it would be important to follow up and complete an interview with each smallpox coordinator to obtain specific information about his or her hospital or health department and how the Smallpox Vaccination Program was conducted at that particular location. Subsequently, RTI developed a questionnaire on topics such as the size of the agency, the process for starting the vaccination program, the number of staff vaccinated, advertising and promotion for the vaccination program, barriers encountered by the coordinator during the program, and the agency's compensation policies for those who received the vaccination. This information proved to be extremely important in determining reasons for nonresponse in the Smallpox Vaccination Program.

To better understand why many HCWs chose not to be vaccinated and how the program was actually conducted, CDC contracted with RTI to conduct an evaluation in five states (in the order in which they were recruited): Tennessee, Utah, Michigan, Nebraska, and California. This evaluation was designed to provide an opportunity to learn about factors related to the decisions not to receive the vaccination. Information from this effort will be used to enhance the efficacy of this program and, possibly, subsequent similar programs 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.

### Discussion

In the following tables, a random effects logistic model (specifically, *xtlogit* in Stata Release 9.0) was estimated using the respondent's answer as the dependent variable and the coordinator's response to the equivalent question as the independent variable and with hospitals/health departments as the random effect. A *p*-value less than 0.05 indicates significant concordance between respondents' and coordinators' answers adjusting for the clustering within hospitals/health departments.

When agencies were asked to administer the Smallpox Vaccination Program, no instructions were provided on how to do so. We asked respondents whether they were personally invited by someone to receive the vaccination. If they were not personally invited, we provided a list of items from which they could choose all that applied to them and asked them how they were notified about the program (see Table 1). We gave coordinators a similar list and asked how the agency had notified employees about the program.

**Table 1. How staff were notified about the vaccination program**

Question	N	% Yes		% Agreement			Significance <i>p</i>
		Coordinator	Respondent	Yes	No	Total	
Asked/invited to be vaccinated	1,217	75.4	83.2	62.5	3.9	66.4	0.240
Notified in a group setting	503	94.6	38.0	37.0	4.4	41.4	0.060
Provided with sign up sheet	487	34.1	17.3	9.5	58.1	67.6	0.006
General announcement, e-mail, or memo	489	91.6	60.3	56.7	4.7	61.4	0.040

Coordinators and respondents clearly agreed that one way of notifying employees about the program was to invite them personally, with 75.4% of coordinators saying that they invited people, and 83.2% of respondents saying they were personally invited. The other options were much more disconnected: 94.6% of coordinators said that they notified employees

of the program in a group setting, but only 38.0% of employees who were not personally invited said that they had been notified in a group setting. However, the agreement between respondents and coordinators was not significant for either of these first two announcement methods in the logit analysis.

Sign-up sheets were used much less often than the other methods, with coordinators saying they were used 34.1% of the time, and respondents saying they were used only 17.3% of the time. However, there was 67.6% agreement that was significant between the two groups mainly because most of them said the sign-up sheets were not used ( $p = .006$ ). For the final method, 91.6% of coordinators said there was a general announcement to employees, but only 60.3% of employees said they were notified through a general announcement. The logit analysis was significant for this comparison as well ( $p = .040$ ).

These data are very important in understanding how the vaccination program was administered at agencies. If we had only the respondent data, we would have inferred that agencies did personally invite people but that they did not effectively use other means of announcement. With the coordinator data, we see that agencies did report announcing the program in many different ways, but they were not necessarily effective in reaching respondents.

After learning how staff were notified about the program, we wanted to know how actively agencies actually promoted their vaccination programs: 73.4% of coordinators and respondents agreed that the agency either somewhat or very actively promoted the program (see Table 2). We found a high degree of agreement with these two items ( $p = 0.002$ ), which indicates that agencies were actively trying to carry out the vaccination program. With the coordinator data affirming the activity of the agency in promoting the program, we can assume that the lack of participation in the vaccination program was not due to a lack of promotion at the agency level. There is one set of outliers in this table, where 161 respondents indicated that staff were “somewhat actively recruited, but coordinators said that recruiting was “Not at all active.” This could be attributed to the different perceptions of HCWs and coordinators.

**Table 2. How actively staff were recruited**

	Respondent									
	Very actively		Somewhat actively		Not actively		Not at all		Row total	
	N	%	N	%	N	%	N	%	N	%
Coordinator										
Very actively	406	52.5	253	33.3	35	16.9	9	17.0	703	39.2
Somewhat actively	242	31.3	285	37.5	69	33.3	18	34.0	614	34.2
Not actively	61	7.9	61	8.0	13	6.3	3	5.7	138	7.7
Not at all	64	8.3	161	21.2	90	43.5	23	43.4	338	18.9
Column total	773	43.1	760	42.4	207	11.5	53	3.0	1,793	100.0

$p = 0.002$

In the coordinator questionnaire, we asked a question about what they considered the major barriers to the vaccination program. One of the hypotheses of CDC was that the safety of the vaccination was one of the reasons that so many health care workers were not getting vaccinated. We asked respondents how safe they thought the smallpox vaccine was, and coordinators how much of a barrier safety was to the vaccination program (see Table 3). In this case, if a respondent said the vaccine was very unsafe, and the coordinator said it was a major barrier, then there would be a positive correlation between the responses. 63.4% of coordinators said that safety was a major barrier to health care workers receiving the vaccine; however, many of the employees at those agencies felt the vaccine was fairly safe. (81.7% of respondents felt the vaccine was very safe or somewhat safe.) Expanding this a little, at agencies where the coordinator said safety was either a major barrier or a barrier, most of the employees said that the vaccine was safe. The disagreement between respondent and coordinators was significant in the logit analysis as well ( $p = 0.0000$ ). We can make a couple of inferences about this disconnect between the responses. It could be that the coordinators were not as aware of employees’ concerns as they had thought. Coordinators may have answered the safety question from a personal perspective (i.e., they themselves might have thought the vaccine was not very safe, thus indicating it as a major barrier). The definition of “safety” could also have been interpreted differently by the two groups. The respondent data imply that safety may not have been as large a factor in the decision by employees not to receive the vaccination, whereas the coordinator data imply that they saw it as a major factor in respondents’ decisions to receive the vaccine.

**Table 3. How safe was the vaccination**

Coordinator	Respondent									
	Very safe		Somewhat safe		Unsafe		Very unsafe		Row total	
	N	%	N	%	N	%	N	%	N	%
A major barrier	180	54.1	682	63.0	186	73.5	51	78.5	1,099	63.4
A barrier	94	28.2	264	24.4	48	19.0	5	7.7	411	23.7
A small barrier	53	15.9	127	11.7	18	7.1	9	13.9	207	11.9
Not a barrier	6	0.9	10	0.6	1	0.4	0	0.0	17	1.0
Column total	333	19.2	1,083	62.5	253	14.6	65	3.8	1,734	100.0

$p = 0.0000$

During the implementation of the evaluation, concerns were raised about how unions might potentially affect HCWs' decisions to receive the vaccination. To understand what role unions actually played in this process, we asked respondents whether they were aware of union participation in the vaccination program, and we asked coordinators how much of a barrier they felt unions had posed to the vaccination program (see Table 4). Coordinators indicated that for the most part unions were not a barrier at all to the vaccination program, even if employees were aware of union participation. Respondent data show that 37.5% of respondents were aware of their agency's union involvement, but the coordinator data show that 88.1% of coordinators did not consider it a barrier to participation in the program. Having the coordinator data report this information is very important and shows that the unions did not have as much of an effect on health care workers' decisions to participate as we may have thought they had. While the logit analysis is significant ( $p = 0.028$ ), this is due mainly to the majority of the respondents' reporting that they were not aware of the unions, whereas their coordinators indicated that unions were not a barrier ( $n = 758$ ).

**Table 4. Awareness of union position**

Coordinator	Respondent					
	Yes		No		Row total	
	N	%	N	%	N	%
A major barrier	11	2.2	9	1.1	20	1.5
A barrier	31	6.3	13	1.6	44	3.3
A small barrier	49	9.9	44	5.3	93	7.1
Not a barrier	404	81.6	758	92.0	1,162	88.1
Column total	495	37.5	824	62.5	1,319	100.0

$p = 0.028$

Shortly after the implementation of the vaccination program, the media reported three deaths of persons (CNN.com, 2003) who had recently received the smallpox vaccine. There was nationwide media coverage of these deaths, prompting concern that the reports were negatively affecting health care workers' decisions about whether to receive the vaccine. We asked respondents what kind of an effect the media had had on their decision to receive the vaccine, and we asked coordinators how much the media reports had been a barrier to the program. As indicated in Table 5, 42.2% of health care workers reported they had already made their decision about their participation before the media reports. In addition, another 45.5% indicated that the media reports had little or no effect on their decision to receive the vaccine. However, 41.8% of coordinators reported they thought the media reports were a major barrier to employees' participating in the program, and 26.6% reported it was a barrier. This disagreement could again be attributed to the lack of communication between the coordinators and employees. Another possibility is that coordinators may have heard talk of the media reports among employees at the hospitals and health departments and thought that this had influenced their decisions. According to the respondents, the media reports were not a major factor in their decision to participate. However, the coordinator data indicate it may have been more of a factor than respondents reported.

**Table 5. News of cardiac effects publicized in media reports**

	Respondent									
	No effect		A little effect		A large effect		Made decision before side effect known		Row total	
	N	%	N	%	N	%	N	%	N	%
Coordinator										
A major barrier	165	44.2	117	41.5	106	59.9	213	35.1	601	41.8
A barrier	98	26.3	90	31.9	37	20.9	158	26.0	383	26.6
A small barrier	54	14.5	43	15.3	18	10.2	132	21.8	247	17.2
Not a barrier	56	15.0	32	11.4	16	9.0	104	17.1	208	14.5
Column total	373	25.9	282	19.6	177	12.3	607	42.2	1,439	100.0

$p = 0.107$

Compensation and liability were major concerns of health care workers during the Smallpox Vaccination Program, as indicated by the fact that the issue was taken to Congress and legislation was passed concerning these issues. We asked respondents whether they felt they would be adequately compensated if they suffered an adverse event from the vaccine (see Table 6). Coordinators were asked if their agency would compensate employees if they suffered an adverse event. Not surprisingly, 62.2% of the coordinators said they would offer compensation, but only 33.1% of overall respondents said they would be adequately compensated. Only 22.8% of respondents at the agencies where coordinators said they would offer compensation said that they would be adequately compensated. Overall, 50.2% of coordinators and respondents agreed in their responses ( $p = 0.013$ ). This agreement is not surprising given all the attention that compensation received in the media and in government circles.

**Table 6. Compensation and liability**

Question	N	% Yes		% Agreement			Logit
		Coordinator	Respondent	Yes	No	Total	$p$
Staff compensation for adverse event	1,017	62.2	33.1	22.8	27.4	50.2	0.013
Staff covered by liability insurance if virus transmitted	720	68.3	73.3	51.9	10.3	62.2	0.626

In addition, we asked respondents whether they felt they would be covered by liability insurance if the vaccinia virus were transmitted from them to a patient. Coordinators, in turn, were asked the same question; 68.3% of coordinators said their staff would be covered by liability insurance, and 73.3% of respondents also said they would be covered. However, there was only 51.9% agreement between the groups on the employer's policy that they would be covered by liability insurance. Although the agreement level of the liability insurance question was higher than that of the compensation question, the logit analysis was not significant.

Again we can draw a few inferences about these data. We could say that health care workers and coordinators knew more about their agency's liability coverage than they did about its compensation policies. There is also a fairly low level of agreement in both, although it is higher in the liability question. This could indicate a lack of communication at one or multiple levels within the organization. The low level of agreement also shows that employees are not necessarily familiar with their agency's policies. Both of these assumptions may have had an impact on health care workers' decisions to participate in the vaccination program.

## Conclusion

During the *Evaluation of Non-Participants in the Smallpox Vaccination Program*, we administered a questionnaire both to health care workers and agency smallpox coordinators. By conducting an interview with both populations, we collected comparable data with which to gauge how the Smallpox Vaccination Program was administered at different hospitals and health departments. Without data from both questionnaires, we would have only one point of view from which to draw conclusions about the vaccination program. Instead, data from both questionnaires can be utilized and compared to understand factors related to the effectiveness and administration of the program. For several items, health care workers and coordinators had some agreement in their responses. For example, data from the coordinator questionnaire indicated that agencies tried to promote the program in many different ways, something that we may not have been able to conclude with

confidence from the respondent questionnaire only. By analyzing the level of agreement, we can make inferences about how the program was administered and try to answer the question of why so few health care workers received the smallpox vaccine.

Administering a separate questionnaire was vital in helping us understand how the Smallpox Vaccination Program was administered and implemented. In addition, it provided us with another viewpoint, that of the smallpox coordinators. In the future, we hope to continue this research and compare other questions from the health care worker and coordinator questionnaires. Future analysis may help us better understand reasons that the program was less successful than anticipated, as well as factors that influenced the program's success, which might be useful for other vaccination programs. Additional analysis may also lead to the understanding of why many HCWs did not receive the vaccine. The administration of two questionnaires will prove vital to this analysis and understanding of the program. In addition, future research on how to effectively and efficiently administer multiple questionnaires to subpopulations of the same sample will benefit the field, especially subpopulations that might have different views of the subject matter. Additional data can be obtained from them to help strengthen and support findings of the general sample.

## **References**

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