Surveys of Workers Possibly Exposed to Anthrax and Obtaining Medical Records from Their Providers before and after 2003 HIPAA Revisions

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On April 14, 2003, the world of medical record collection changed forever. The U.S. Department of Health and Human Services (DHHS) created new regulations for the Health Insurance Portability and Accountability Act of 1996, commonly known as HIPAA. According to the Centers for Disease Control and Prevention (CDC), "the new regulations provide protection for the privacy of certain individually identifiable health data, referred to as protected health information (PHI)."[1] These changes created the first national standards for the protection of health information.

At RTI International, we were about to begin the medical records collection phase of a large data collection effort for the CDC. This paper briefly describes the changes we had to make to 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 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 written authorization of the patient. 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 written authorization from the patient, 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.

2. Anthrax Project

In Fall 2001, the CDC recommended a course of at least 60 days of antimicrobial prophylaxis for more than 10,000 persons with suspected or confirmed exposure to *Bacillus anthracis* related to bioterrorist attacks. In addition, the Strategic National Stockpile (NPS) and the CDC supported state and local health departments by distributing antimicrobial agents and providing technical assistance in the management of issues arising from their distribution. The CDC also initiated a 30-day follow-up that entailed interviewing some of the participants about their experiences with the antimicrobial prophylaxis.

To evaluate their response to this public health threat, the CDC contracted with RTI to evaluate the number of antibiotic-related adverse events in a project titled "Program Monitoring of the Adverse Events Among Persons Enrolled in the Anthrax Vaccine and Antibiotics Availability Program" (the Anthrax Project). It is anticipated that results of this program monitoring will guide the design of similar future campaigns.

In Phase 1 of the project, RTI administered computer-assisted telephone interviews (CATIs) to those persons recommended to receive the 60 or more days of antibiotics. The interviews posed questions about any health problems the participants had experienced since receiving the antibiotics. Data were collected for 6,482 individuals during the initial 60-Day Program Evaluation from January through April 2002.

During Phase II of this evaluation, RTI requested medical records from medical providers for participants who reported potentially serious adverse events (PSAEs) related to the prophylactic antibiotic during CDC's 30-day follow-up interview or in RTI's Phase I interview. Upon receipt, medical records were abstracted and a clinical summary was completed for any case in which the health problem reported was indeed a severe adverse event (SAE), according to the definitions of the Food and Drug Administration (FDA).

CDC requested that follow-up interviews and medical record collection (Phases 1 and 2) be conducted with participating program participants 6 months, 12 months, and 24 months after the receipt

of antibiotics. To complete both phases during each follow-up, RTI obtained verbal consent from program participants who reported a PSAE during the CATI interview to request medical records from their medical providers. Interviewers signed and dated a hard-copy consent form stating that verbal consent had been obtained from participants authorizing their medical providers to release medical records to RTI. A copy of this form was then sent to the medical provider in the initial mailing to request the medical records. Note that these consent procedures were not required under HIPAA because this evaluation project is considered public safety research and thus is exempt from HIPAA regulations.

3. 6-Month CATI Interview

Among the 6,482 individuals who completed the initial program evaluation, 1,112 participated in the Anthrax Vaccine and Antibiotics Availability Program (AVAAP) under an Investigational New Drug (IND) protocol. These individuals chose to receive additional antimicrobial prophylaxis or antimicrobial prophylaxis plus anthrax vaccine. Individuals who participated in AVAAP were contacted in the fall and winter of 2002 to complete a 6-month follow-up interview.

RTI telephone interviewers contacted and interviewed persons who had completed a previous interview with the CDC or RTI and those who received a vaccine from the CDC's IND. The sample list was obtained from the CDC and consisted of program participants living in Connecticut, Florida, New Jersey, New York, and Washington, DC. The CDC provided contact information to RTI.

The interview focused on side effects that participants may have experienced while taking antibiotics or a vaccine for exposure to anthrax. If participants reported possible adverse events, RTI attempted to collect their medical provider contact information as well as their consent to collect their medical records for subsequent investigation.

4. Sample Building

Using answers provided in the 6-Month CATI interview, RTI identified participants who may have had a PSAE. The criteria for consideration were as follows:

- Respondents who had hospital visits
- Respondents who had emergency room visits for reasons other than routine follow-up, allergy shots, accidents, etc.
- Respondents who had doctor office visits for reasons other than routine follow-up, allergy shots, accidents, etc.
- Respondents who were deceased

CDC staff reviewed the list of PSAEs and selected the cases for RTI to follow up with medical record collection and abstraction.

5. Medical Provider Follow-up Procedures

If participants gave consent for RTI to contact their medical providers, RTI obtained the providers' locating information from the CATI interview and verified it through RTI's Tracing Operations Unit (TOPS). TOPS staff called the provider's office to verify name, address, and phone number, then sent the information back to RTI project staff, who then called each provider for another round of verification and to alert them of the provider mailing. The few cases for which provider information could not be verified were coded accordingly in the Control System.

RTI obtained verbal consent authorizing release of their medical records from all participants who reported PSAEs. During the 6-Month CATI interview, RTI tried to obtain verbal consent from participants. If verbal consent was not obtained, follow-up with medical providers was not done.

RTI staff sent a letter to the medical provider explaining the purpose of the Anthrax Project and including the doctor visit information provided by the participant. The letter also requested that the provider mail the participant's medical records to RTI. Two weeks from the time the initial provider letter was sent, RTI staff called the provider or the provider's medical records office to remind them to send the records to RTI.

The initial letter informed medical providers that verbal consent for the release of medical records was obtained from the participant. However, some providers required an additional written consent form signed by the participant. Most of the providers who required written consent used an RTI-developed form; only a few providers required the use of their own forms.

For cases identified as needing written consent, RTI attempted to contact the participant by phone to explain the request for written consent. If the participant agreed, this form was sent with a cover letter explaining the consent procedure. The participant signed the form and mailed it back to RTI, which then forwarded it to the provider.

RTI hired field representatives to help prompt medical providers to return the medical records to RTI. These representatives were sent locating information for providers who had not responded to initial promptings to mail back the medical records. The field representatives visited each provider to obtain the medical records and then sent these records to RTI via Federal Express.

RTI continually followed up with the providers as necessary through telephone calls, site visits, and faxes, with a targeted goal of a 74% cooperation/return rate for the requested medical records.

Upon receipt of a participant's medical records, RTI staff created an electronic medical abstraction form for the participant and merged any information available from previous data collection efforts by CDC (e.g., the IND data). A medical abstractor completed the medical abstraction form except for the last two questions, which were assigned to an SAE expert for completion. A few weeks into the abstraction process, the CDC sent RTI information that was collected for the National Immunization Program (NIP) IND cases. This information was reviewed and added to the abstraction form when applicable.

The SAE expert created a clinical summary form to clarify and elaborate on the severity of the PSAE and prepared a written summary explaining the relationship of the program medication to the PSAE.

6. HIPAA Concerns

During the 6-Month Medical Provider Follow-Up, RTI developed procedures to ensure that all HIPAA guidelines and regulations would be followed. Because this project is considered to be public safety research, it is exempt from all HIPAA regulations. However, anticipating that some medical providers would still have concerns about HIPAA, RTI developed an optional step describing how written consent would be obtained from participants if requested by medical providers.

7. Results of the 6-Month Medical Provider Follow-up

In the 6-Month Follow-Up, RTI requested medical records from 106 medical providers, 79 of whom complied, for a cooperation/return rate of 74.5% (see Table 1). Of the medical providers, 16.0% of our provider sample (17) requested that written consent be obtained from the respondent, meaning that the verbal consent that RTI had obtained did not meet their requirements and interpretation of HIPAA. We were able to obtain written consent for 6 program participants, and we obtained medical records for 4 of them, a 66.7% cooperation/return rate. We were unable to obtain written consent for the other 11 participants. The 6-Month Medical Provider Follow-Up ended on March 31, 2003.

8. Changes to HIPAA

Changes to the HIPAA regulations and the Privacy Rule took effect for all providers on April 14, 2003, which fell directly in between the 6-Month Medical Provider Follow-Up and the 12-Month Medical Provider Follow-Up that RTI was conducting. During this period, we researched HIPAA and the Privacy Rule to better understand the changes that were taking place and how they would affect our data collection methods and procedures.

Based on our research, we hypothesized that medical providers contacted during the 12-Month Follow-Up would be less willing to release medical records without written consent than were those contacted during the 6-Month Follow-Up. We met with the chairperson of RTI's Institutional Review Board (IRB) and with our CDC Technical Monitor to discuss in detail the changes to HIPAA and their implications for the Anthrax Project. All parties had similar expectations: that the cooperation/return rate from medical providers would drop in the 12-Month Follow-Up because of the new HIPAA regulations. We also anticipated that many more medical providers would not accept the verbal consent procedures we developed for our project and that more providers would request written consent from participants before sending medical records to RTI.

RTI, in conjunction with CDC, developed the following procedures to help overcome these anticipated obstacles:

- Lead letter sent to medical providers: added specific text explaining that this Program Monitoring is exempt from the HIPAA regulations because it is considered to be Public Safety research. The lead letter was signed by the Deputy Director of the National Center of Infectious Diseases at CDC.
- Follow-up calls: developed text to be read to providers during the Medical Provider Follow-Up calls with nonresponding

Table 1
Record of Data Collection for Potentially Severe Adverse Events at 6-Month Follow-Up

Description	Number of Cases
Potential PSAE reported in CATI	231
Participant gave consent during CATI	177
CDC selected for follow-up	106
Provider-level report	
Total providers identified	106
Medical records request mailed to provider	102
Request not mailed to provider	4
Total medical records received from provider	79 (74.5%)
For partial cases	0 (0%)
For completed cases	79 (74.5%)
Participant withdrew consent at a later date	2 (1.9%)
Unable to obtain written consent from participant	11 (10.4%)
Unable to obtain complete provider information from participant	8 (7.5%)
Unable to obtain medical records from provider	6[a] (5.7%)
Case-level report	
Total cases	106
Data abstraction complete	79 (74.5%)
Lite clinical summary created[b]	24 (22.6%)
Full clinical summary created	17 (16.0%)
No clinical summary needed	38 (35.9%)

[a]This was due to incomplete contact information for the providers.

[b]A lite clinical summary is a shortened version of the full clinical summary form created by one of the serious adverse event experts.

providers, explaining that the Program Monitoring is exempt from the new HIPAA regulations.

- HIPAA card: developed a card for field staff who were sent to the medical providers' offices to collect the medical records. This HIPAA card contained the exact text from the medical provider lead letter about HIPAA and the new regulations and was printed on CDC letterhead.

9. 12-Month Follow-up

In the 12-Month Follow-Up, RTI attempted to complete a CATI interview for all of the responding program participants from the 60-day interview period. If program participants reported PSAEs during the CATI interview, RTI contacted their medical providers to prompt them to send RTI the participant's medical records so that medical abstractions and clinical summaries could be completed.

The same procedures used in the 6-Month Follow-Up were followed in the 12-Month Follow-Up, with one exception. In the 6-Month, RTI obtained medical records from only one provider for each participant; for the 12-Month Follow-Up, medical records from one to three providers were obtained for each participant.

RTI sent each provider a package containing an introductory letter, a copy of the participant's consent to release records, and a request that the photocopied records be sent to RTI in the FedEx return package. Once the records were received, RTI completed medical abstractions and clinical summaries for those cases that contained an SAE.

Table 2
Record of Data Collection for Potentially Severe Adverse Events at 12-Month Follow-Up

Description	Number of Cases
Potential PSAE reported in CATI	838
Participant gave consent during CATI	569
CDC selected for follow-up	257
Provider-level report	
Total providers identified	542
Medical records request mailed to provider	541
Request not mailed to provider[a]	1
Total medical records received from provider	473 (87.3%)
For partial cases	53 (9.8%)
For completed cases	420 (77.5%)
Participant withdrew consent at a later date	21 (3.9%)
Unable to obtain written consent from participant	13 (2.4%)
Unable to obtain complete provider information from participant	24 (4.4%)
Unable to obtain medical records from provider[b]	11 (2.0%)
Case-level report	
Total cases	257
Data abstraction complete	208 (80.9%)
Lite clinical summary created[c]	54 (21.0%)
Full clinical summary created	52 (20.2%)
No clinical summary needed	102 (39.7%)

[a]One provider was located in Mexico; CDC decided not to follow up with this case.

[b]This was due to incomplete contact information for the providers.

[c]A lite clinical summary is a shortened version of the full clinical summary form created by one of the serious adverse event experts.

10. Results of 12-Month Medical Provider Follow-up

RTI attempted to obtain records from 542 medical providers and received a total of 473 medical records, an 87.3% cooperation/return rate (see Table 2). Once again, some providers requested that written consent be obtained from the respondent, meaning that the verbal consent obtained did not meet their requirements and interpretation of the new HIPAA regulations. Through our new procedures, we were able to resolve most of their concerns. Of the medical providers, 15.9% of our provider sample (86) requested that we obtain written consent from the sample member. We were able to obtain written consent for 47 program participants, and we obtained medical records for 35 of them, for a 74.5% cooperation/return rate. We were unable to obtain written consent for the other 39 participants. The 12-Month Medical Provider Follow-Up ended on September 30, 2003.

11. 24-Month Follow-up

In the 24-Month Follow-Up, RTI attempted to complete a CATI interview for all of the responding program participants from the 60-day interview period. If program participants reported PSAEs during the CATI interview, RTI contacted their medical providers to prompt them to send RTI the participant's medical records so that medical abstractions and clinical summaries could be completed.

The 12-Month Follow-Up and the 24-Month Follow-Up used the same procedures with one exception. In conjunction with CDC, RTI developed a Records Abstraction Form designed to capture relevant data from the reviewed medical charts. This form was revised from the Medical Records Abstraction Form used in the 12-month Phase II medical provider follow-up. With approval from CDC, RTI combined the 12-month Medical Records Abstraction Form and the Clinical Summary Form into one Records Abstraction Form. This form contained all information collected from the medical records, as well as assessment information completed by the clinical reviewer.

RTI sent each provider a package containing an introductory letter, a copy of the participant's consent to release records, and a request that the photocopied records be sent to RTI in the FedEx return package. Once the records were received, RTI completed the Records Abstraction Forms for those cases that did contain an SAE.

12. Results of 24-Month Medical Provider Follow-up

RTI attempted to obtain records from 385 medical providers and received a total of 319 medical records, an 82.9% cooperation/return rate (see Table 3). Once again, some providers requested that written consent be obtained from the respondent (i.e., the verbal consent obtained did not meet their requirements and interpretation of the new HIPAA regulations). Through our new procedures, we were able to resolve most of their concerns. Of the medical providers, 5.2% of our provider sample (20) requested that we obtain written consent from the sample member. We were able to obtain written consent for 9 program

Table 3
Record of Data Collection for Potentially Severe Adverse Events at 24-Month Follow-Up

Description	Number of Cases
Potential PSAE reported in CATI	924
Participant gave consent during CATI	646
CDC selected for follow-up	318
Provider-level report	
Total providers identified	385
Medical records request mailed to provider	383
Request not mailed to provider[a]	2
Total medical records received from provider	319 (82.9%)
For partial cases	62 (16.1%)
For completed cases	257 (66.8%)
Participant withdrew consent at a later date	0 (0.0%)
Unable to obtain written consent from participant	1 (0.3%)
Unable to obtain complete provider information from participant	29 (7.5%)
Unable to obtain medical records from provider[b]	20 (5.2%)
Ineligible—no visit occurred during the 24-Month Follow-Up period	16 (4.1%)
Case-level report	
Total cases	318
Data abstraction complete	253 (79.6%)
Lite clinical summary created[c]	80 (25.2%)
Full clinical summary created	79 (24.8%)
No clinical summary needed	94 (29.6%)

[a]We did not have any contact information for 2 providers.

[b]This was due to incomplete contact information for the providers.

[c]A lite clinical summary is a shortened version of the full clinical summary form created by one of the serious adverse event experts.

participants, and we obtained medical records for 7 of them, for a 77.8% cooperation/return rate. We were unable to obtain written consent for the other 11 program participants. The 24-Month Medical Provider Follow-Up ended on September 13, 2004.

13. Conclusions

We achieved a 12.8% higher cooperation/return rate on the 12-Month Follow-Up than we did on the 6-Month Follow-Up, despite having more than five times as many providers to contact for medical records. In addition, the same percentage of medical providers (approximately 16%) requested written consent of program participants in both follow-ups. We had anticipated that an increased number of providers would request written consent during the 12-Month follow-up due to the Privacy Rule and changes in HIPAA regulations and that fewer would respond once we did obtain written consent. Yet, in the 12-Month follow-up, we achieved a 7.8% higher cooperation/return rate from medical providers for whom we did obtain written consent. We attribute this to the additional information we provided through the changes in data collection procedures in response to the new HIPAA regulations.

During the 6-Month Follow-Up, we developed written consent procedures to be used at the request of the medical provider. During the 12-Month Follow-Up, in addition to those same written consent procedures, we included additional HIPAA text in the provider lead letter, developed HIPAA script for our follow-up calls, and provided our field interviewers with HIPAA cards containing text from the provider lead letter to help address concerns of the medical providers. These positive trends continued through the 24-Month Follow-Up, where we achieved a cooperation/return rate that was 8.4% higher than the 6-Month Follow-Up, though down from the 12-Month Follow-Up. In addition to these trends, a lower percentage of medical providers (5.2%) requested written consent of program participants in the 24-Month Follow-Up. Also in the 24-Month Follow-Up, we achieved the highest cooperation/ return rate from medical providers for whom we obtained written consent (11.1% higher than the 6-Month Follow-Up and 4.3% higher than the 12-Month Follow-Up).

One of the key factors in these procedural changes was the early identification of potential barriers or problems and anticipation of their effect. We held many discussions with our client, CDC, and jointly developed procedures that we thought might help address concerns about HIPAA. CDC's buy-in and participation in our suggested changes facilitated the process, and changes to protocol were quickly made.

The information we provided through the different avenues of follow-up procedures eased medical providers' concerns and helped gain their trust. Once the providers trusted RTI and understood the legitimacy of the Program Monitoring, they were more willing to provide us with the information that we requested.

The HIPAA regulations are still relatively new, and the area of patient privacy is a growing topic of discussion at many levels of government. The future may bring even more stringent laws and rules. We were able to develop and test data collection procedures with medical providers for this program monitoring. We constantly reviewed our own procedures and those of others to develop ways to ease the burdens on those with whom we are working, help them understand the importance of our research, and follow the laws and regulations that govern this research.

The final outcome was the desired one, the maintenance of high cooperation/return rates for the 12-Month and 24-Month Follow-Ups.

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References

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