An Assessment of HIPAA-Compliant Methods for Achieving High Cooperation Rates from Medical Providers on a Medical Record Abstraction Program Evaluation

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On April 14, 2003, the world of medical record collection changed forever. New regulations were created by the U.S. Department of Health and Human Services (DHHS) for the Health Insurance Portability and Accountability Act of 1996 (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)." The change in regulations 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.

Brief Overview of HIPAA

The Health Insurance Portability and Accountability Act of 1996 (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 other 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 that 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 the written authorization of the patient, no matter who is requesting the information. That is, some providers tend to err on the side of caution to avoid potential liability in the event of inappropriate release of records.

Anthrax Project

In the fall of 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 involved 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 other similar campaigns in the future.

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 asked 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 of 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.

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 either 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 Florida, New York, DC, New Jersey, and Connecticut. Contact information was provided to RTI by the CDC.

The interview focused on side effects that participants may have experienced while taking antibiotics or a vaccine for exposure to anthrax. Information was also collected about adverse events that participants may have experienced. 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.

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

- 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.

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. RTI project staff then called each provider for another round of verification and to alert them of the provider mailing. The few cases for which the 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. An RTI-developed form was used by most of the providers who required written consent. 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; RTI then forwarded it on 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 FedEx.

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 if applicable.

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

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.

Results of the 6-Month

RTI requested medical records from 106 medical providers of whom 80 complied, for a cooperation/return rate of 75% (see Table 1). Of the medical providers, 16% of our provider sample (17), requested that written consent be obtained from the respondent, meaning that the verbal consent that RTI 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 67% cooperation/return rate. We were unable to obtain written consent for the other 11 program participants. The 6-Month Medical Provider Follow-Up ended on March 31, 2003.

Table 1
Record of Data Collection for Potentially Severe Adverse Events

Description	Number of Cases
Potential PSAE reported in CATI	231
Participant gave consent during CATI	177
Selected by CDC for follow-up	106
Total providers identified	106
Medical records request mailed to provider	102
Medical records request not mailed to provider	4
Received medical records from provider	80 (75.5%)
Medical records received from provider for partial cases	0 (0%)
Medical records received from provider for completed cases	80 (100%)
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	5[a] (4.7%)
Total cases	106
Data abstraction complete	80 (75.5%)
Lite clinical summary created[b]	24 (22.6%)
Full clinical summary created	17 (16.0%)
No clinical summary needed	39 (36.8%)

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

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

Changes to HIPAA

Changes to the HIPAA regulations and the Privacy Rule took effect for all providers by April 14, 2003, between the 6-Month Medical Provider Follow-Up and the 12-Month Medical Provider Follow-Up we were 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 not be as willing to release medical records without written consent as those contacted during the 6-month follow-up. We met with the chairperson of RTI's Institutional Review Board (IRB) and with CDC 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 due to the new HIPAA regulations. We all anticipated that it would be much more difficult to obtain medical records from providers and that providers would be much more stringent in their release of the records. 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:

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

12-Month Follow-Up

In the 12-month follow-up, RTI completed 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 follow-up, RTI obtained medical records from only one provider for each participant; for the 12-month follow-up, medical records from one to three different 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 Federal Express return package. Once the records were received, RTI completed medical abstractions and clinical summaries for those cases that did contain an SAE.

Results of 12-Month Medical Record Follow-Up

As indicated in Table 2, RTI attempted to obtain records from 542 medical providers. RTI received a total of 463 medical records, an 85% cooperation/return rate. 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, 16% of our provider sample (89) 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 75% cooperation/return rate. We were unable to obtain written consent for the other 39 program participants. The 12-Month Medical Provider Follow-Up ended on September 30, 2003.

Table 2
Record of Data Collection for Potentially Severe Adverse Events

Description	Number of Cases
Potential PSAE reported in CATI	838
Participant gave consent during CATI	569
Selected by CDC for follow-up	257
Provider level report	
Total providers identified	542
Medical records request mailed to provider	541
Medical records request not mailed to provider[a]	1
Total medical records received	463 (85.4%)
Medical records received from provider for partial cases	53 (9.8%)
Medical records received from provider for completed cases	410 (75.6%)
Participant withdrew consent at a later date	31 (5.7%)
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 (20.0%)
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 clinical summary lite is a shortened version of the full clinical summary form created by one of the serious adverse event experts.

Conclusions

We achieved a 10% higher cooperation/return rate on the 12-Month Follow-Up than we did on the 6-Month Follow-Up, despite the fact that we had four times as many providers to contact for medical records. In addition, the same percentage of medical providers 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. However, in the 12-Month follow-up, we achieved an 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.

One of the key factors in these 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 concerns of medical providers and helped gain their trust. Once medical 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 very 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 are constantly reviewing our own procedures and those of others to develop ways to ease the burdens of those we are working with, help them understand the importance of our research, and follow the laws and regulations that govern said research.

The final outcome was the maintenance of a high cooperation/return rate for the 12-Month Follow-Up, and our future goal is to maintain these rates through the 24-Month Follow-Up. We hope to do so by using the same procedures developed for the 12-Month Follow-Up, as well as testing new ideas and procedures to provide more information to providers and respondents about HIPAA and the Privacy Rule.