

Assessing the Accuracy of Parent Recall of the Hepatitis A Immunization Status of Their Children: Data Collection Issues in a Telephone Survey Combined with Provider Record Check¹

Lisa R. Carley-Baxter (RTI International), Paul Levy (RTI International), Anthony Fiore (Centers for Disease Control), and Susan Twiddy (RTI International)

Keywords: Telephone Survey, Hepatitis A Immunization, Two-Phase Survey

Abstract: In an effort to determine whether a relatively inexpensive random-digit-dial (RDD) telephone survey could provide accurate estimates of immunization coverage for Hepatitis A, we conducted such a survey of parents of children between 2.5 and 15 years of age and, for those parents who gave permission, contacted children's medical care providers by mail to obtain vaccination records for the children. This two-phase survey presented several data collection challenges, including adapting the survey instrument used in the National Immunization Survey to older children and different immunizations, and protecting the confidentiality of the medical records obtained. The major challenge was in obtaining written consent from the parents to contact the health care providers, even though more than 80% of parents had given verbal consent during the telephone interview. In the pre-HIPPA era, verbal consent alone would be sufficient for contacting the providers. Obtaining provider reports also required more effort than originally planned, as did meeting other IRB and HIPPA requirements surrounding collection of medical records for minors. This paper focuses on these obstacles and the measures we took to overcome them.

Introduction

Understanding the occurrence of various diseases among different segments of the U.S. population is an important part of public health research. Hepatitis A is one disease of interest because of its health effects on the liver of those who contract the disease. The Centers for Disease Control (CDC) is interested in examining the rates of hepatitis A, particularly among children. One way to obtain information on the occurrence of any disease, hepatitis A included, is to survey providers who actually administer the vaccine. Provider reports, while not perfect and very expensive, are considered the "gold standard" in obtaining vaccination coverage estimates. The goal of this project was to determine whether a relatively inexpensive random-digit-dial (RDD) telephone study without a provider record check could provide accurate estimates of immunization coverage for hepatitis A. To evaluate the accuracy of the parent reports, provider reports were also obtained for cases where parent consent was given. The success of the study was dependent upon getting a sufficient number of cases with both parent and provider data.

The hepatitis A vaccine was first licensed in the United States in 1995; and routine vaccination of children in 17 states was recommended in 1999. Since 1999, the Advisory Committee on

¹ This project was made possible through a Cooperative Agreement between the Centers for Disease Control and Prevention (CDC) and the Association of Teachers of Preventive Medicine (ATPM), award number U50/CCU300860 TS-1225; its contents are the responsibility of the authors and do not necessarily reflect the official views of CDC or ATPM.

Immunization Practices (ACIP) has recommended routine childhood vaccinations for hepatitis A in areas where its incidence is twice the national average, meaning 20 cases per 100,000 individuals (ACIP, 1999). At the time this study was designed, rates of hepatitis A among children were more than double the national average in both Arizona and Oregon despite the availability of a vaccine for the disease. Because of these high values, these two states were chosen for inclusion in this study.

Multiple data collection challenges were faced during the course of this project, and the two most serious challenges were related to the 2003 Health Insurance Portability and Accountability Act (HIPAA) regulations. This paper discusses the data collection challenges encountered, our strategies for overcoming these challenges, and provides recommendations for future similar studies.

Methodology

In the fall of 2004, a list assisted random-digit-dial (RDD) survey was conducted with parents of children between 2.5 and 15 years of age in Arizona and Oregon. Since the earliest that a full series of vaccinations for hepatitis A can be complete is 2.5 years of age, this became the lower age bound for eligible children in this study.

In the parent telephone survey, parents or guardians were asked [questions on demographic characteristics of their household](#); the status of their children with respect to vaccinations [for hepatitis A, hepatitis B and varicella](#); and for permission to contact healthcare providers to obtain data on these vaccinations. All cases received questions about hepatitis A and varicella (chicken pox) vaccinations. In addition, [one-half](#) of the cases were randomly assigned to receive questions about hepatitis B vaccination.

Interviews were completed with 650 households, representing approximately 1,266 children, in Arizona and Oregon. [Of](#) the 650 completed parent interviews, 532 parents (82%, representing 1027 children) gave verbal permission to contact their children's healthcare providers to obtain shot records. These parents were then mailed a consent form to complete and return to RTI. Parent non-respondents (those who did [not](#) return the consent form) [received](#) follow-up [contacts](#) via mail and telephone. These efforts resulted in a 58 percent return rate with 306 parents (representing 560 children) returning written consent forms.

For cases where written parental consent was obtained, medical providers were contacted to request vaccination records for the children. Parents may have given contact information for multiple healthcare providers during the telephone interview and on the written consent form, but owing to budgetary constraints only one of these providers was contacted initially for each child. Providers were contacted both via mail and by telephone. Providers were asked to return the Immunization History Questionnaire (IHQ) or a shot record in a postage-paid envelope, or [by](#) faxing the forms to a project-specific fax machine monitored by a project staff member. Of the 306 cases (representing 560 children) mailed to providers, 274 cases (90%, representing 493 children) returned shot records or completed IHQ surveys.

Challenges Encountered and Solutions Utilized

There were four main data collection challenges for this project: creating the survey instrument, obtaining written parental consent to contact providers for the shot record for their child(ren), [obtaining provider reports](#), and [protecting the confidentiality of obtained medical records](#).

The first challenge was in creating the survey instrument. We used the National Immunization Survey (NIS) as a starting point for developing the hepatitis A vaccination of children survey because the NIS asks parents about vaccinations for their children. The adaptation of the NIS survey instrument for use on this study was complicated by: [1\) the need for more complete information on hepatitis A than is available in the NIS](#); [2\) differences in the target age range of the children between this study and the NIS](#); and [3\) differences between this study and the NIS with respect to the types of immunizations asked about](#).

Hepatitis A vaccine is not licensed for children less than 24 months old. Pediatric hepatitis A vaccine is given in a 2-dose series (a 3 dose series was available until 1997). The second dose is given 6 to 12 months after the first dose, making 30 months of age the youngest that a child can be fully vaccinated against Hepatitis A. The NIS, which is considered the best source of vaccine coverage estimates among young children, is only administered to 19-35 month olds; therefore the NIS is not as useful for estimating hepatitis A vaccine coverage as it is for other vaccines. Our survey focused on interviewing parents of children aged 2.5 to 15 years in an effort to obtain more complete hepatitis A vaccine coverage information for a wider age range of children.

Hepatitis A vaccine was first licensed in the United States in 1995, and therefore was not available to older children when they were infants. Many vaccinations ([e.g., Diphtheria-Pertussis - Tetanus, Hemophilus Influenza](#)) are available for infants and small children, and are routinely given in a series of appointments targeted for receipt of these vaccinations. These vaccinations are often recorded on a "shot card" that parents take to each appointment. These shot cards are used to help parents keep track of which shots their child has completed and which still need to be obtained. Parents may be more cognizant of shots that are routinely given to infants and small children than they are of shots given to older children, in part, [because of the presence of the shot card](#). Also, since the hepatitis A vaccination was not available to older children when they were infants, it may be more difficult for parents to recall whether their older children have received the hepatitis A vaccination because they may not have the shot card in hand. Parent reports may also be subject to more recall and potential misclassification problems for older children.

The need to expand the age range of children in this study in order to obtain more complete information on hepatitis A vaccination coverage resulted in the possibility of households having more diverse family scenarios than those encountered on the NIS survey where the oldest child is 35 months of age. Interviewing parents with children up to age 15 allows more time for family composition to change owing to circumstances such as marriage, divorce, re-marriage, as well as the addition of children and step-children. The more diverse family compositions resulted in the need to allow parents to report data for more children in the target age range (2.5-15 years) in the household. While the computer-assisted telephone interview (CATI) was designed to allow

interviewers to enter up to 20 children per household in the target age range, all households reported 5 or less children in the target age range.

More diverse households also created the possibility of having to obtain permission to contact the child's medical providers from someone other than the person who completed the interview. For each household, interviewers initially asked to speak with the person most knowledgeable about the child's health records in order to complete the survey. For households where the most knowledgeable respondent was not the parent or legal guardian, the parent or legal guardian was then contacted to obtain permission to contact the medical providers for the child's shot record. This complication took additional resources to complete, including additional time to complete each case as well as additional labor hours.

The second, and largest, challenge to this study was in obtaining written parental consent to contact providers for the shot records for their child(ren). The 2003 Health Insurance Portability and Accountability Act (HIPAA) has been interpreted by many health care providers as requiring written consent before they can release medical records to researchers (Ness, 2005). However, HIPAA regulates the release of medical records by health care providers (i.e., covered entities) and does not require written consent. Section 164.512 of the HIPAA regulations state that health care providers are allowed to release medical records for research purposes (subsection i) when patients give oral consent (Centers for Medicare & Medicaid Services, 2003).

In addition, the HIPAA Privacy Rule allows medical providers to disclose protected health information without written consent for public health purposes. Since the hepatitis A vaccination of children study was conducted using a grant from the Association for Teachers of Preventive Medicine (ATPM) and CDC, it could have been interpreted as not falling under the public health exception to the Privacy Rule.

Despite the fact that the HIPAA regulations only require research studies to obtain oral permission for the release of medical records, research organizations are faced with the reality of responding to beliefs held by providers concerning the release of these records if their research is to be a success. In a pre-HIPAA era, verbal consent alone would have been sufficient for contacting medical providers and obtaining medical records. Other studies, such as the NIS, do not obtain written consent prior to requesting medical records, rather they rely on verbal consent only. For this study, we were concerned that providers may interpret HIPAA as requiring written consent to release medical records and therefore would not provide medical records from oral consent of patients only. Obtaining written consent helped to ensure that this study would obtain a sufficient number of parent-provider matches for analysis. Written consent also helped combat the potential misinterpretation of the HIPAA Privacy Rule by providers or using the Privacy Rule as an excuse for not sending back the shot record.

The additional step of obtaining written parent consent proved more problematic than initially anticipated and required additional project resources. As stated earlier, approximately 82% of parents (532 cases, representing 1027 children) gave verbal permission to contact their child's (childrens') healthcare providers to obtain shot records. Upon receipt of verbal consent, these cases were sent a mailing requesting consent followed by a reminder postcard, and replacement

consent mailing. These initial efforts resulted in only 35% (187 cases, representing 331) of those cases returning signed consent forms.

Since the success of this study depended on obtaining a sufficient number of parent-provider matches to conduct analysis, further follow-up procedures were devised. In an attempt to achieve maximum response, these efforts concentrated on varying the mode of contact, as well as the type of mailing as advocated by Dillman (2000). Parents who did not return signed consent forms after the initial mailing efforts next received telephone calls prompting them to sign and return the consent forms. We believed that the telephone calls would elicit additional returns because they used a different mode than the mail surveys, and because they were the initial means through which parents completed interviews.

This was followed shortly thereafter by a final Federal Express mailing with an additional incentive offer. We believed that a FedEx mailing would be more likely to be opened than a mailing via USPS. Additionally, the FedEx mailing was different in appearance than prior mailings, and would be more likely to get the attention of the parent (Dillman, 2000). The mailing included a brief letter reminding parents of their participation in our telephone survey in the fall of 2004, and a request that the consent forms be completed, signed, and returned in an enclosed envelope. To maximize returns from the FedEx mailing, two other procedures were used: prompting calls and increased incentives.

Parents who were sent the FedEx mailing were called approximately 1-2 days before the package was sent to notify them that the project would be sending them a package via Federal Express. A few days after the FedEx packages were sent, allowing time for them to be received, a final call was made to parent consent non-respondents to ensure that the package had been received and to answer any questions parent might have about completing and returning the consent form.

Parents were offered \$10 for completing the initial telephone interview, and in the final FedEx mailing were offered an additional incentive for signing and returning the consent form. The additional incentive was added to help increase response and as a token of appreciation for the time parents had to spend completing and returning the consent form. Each consent form required the parent to fill out contact information (name and address) for up to 2 providers per child, as well as sign and return the form. Parents with one or two eligible children were offered an additional incentive of \$10. The forms had to be completed individually for each child, so parents with three to five eligible children were offered \$15. At the time of the FedEx mailing, 85% of the cases with returned consent forms had come from households with either one or two children.

Ultimately, 58% (306 cases, representing 560 children) of cases where parents gave verbal permission returned signed consent forms. While this is a very good return rate for written consent forms, if we had only had to rely on verbal parental consent we could have followed up on 42% more of our completed cases (226 cases, representing 467 children). This likely would have resulted in nearly doubling the final number of parent-provider matches we obtained (from 274 cases representing 493 children to nearly 550 cases representing approximately 1,000 children).

The third challenge encountered was in obtaining provider shot records or returned Immunization History Questionnaires (IHQs). Our initial data collection plans called for utilizing multiple follow-ups with providers to return completed shot records or IHQs. For cases where written parental consent was obtained, providers received an initial records request comprised of a lead letter, IHQ, a copy of the signed parent consent form, and business return envelope. Providers were also advised that they would receive \$20 per child for completing the IHQ or returning the shot record for the target child. We also contacted providers via telephone to prompt their response, and to answer any questions they may have had concerning the study.

Throughout the data collection period, we customized our response to providers as necessary to obtain completed shot records. For example, if the provider indicated in a follow-up telephone call that the IHQ had not been received, we would fax or re-mail the IHQ and/or shot record request to providers. This proved to be a useful strategy for obtaining provider responses. These combined efforts resulted in 90% of providers returning the shot record or IHQ (274 cases/families, representing 493 children).

Protecting the confidentiality of obtained medical records was the final data collection challenge encountered. Careful planning and clear specification of protocols ensured for successfully managing this challenge. Medical records were returned to only one project staff member and included either a completed shot record or an Immunization History Questionnaire (IHQ). The IHQ asked about all of the shots of interest, as well as had a few questions about the medical practice. All provider mailings, and each IHQ, directed providers to one project staff member as a contact for questions about the study and to whom to return to the medical record.

Providers had the option of either returning the shot record/IHQ via mail or faxing in the materials. A fax machine dedicated to the project was located in the one project staff member's office. The staff member's office was locked at all times. In addition, all project staff members signed confidentiality agreements, as did the office mate of the staff member processing the shot records/IHQs.

Discussion and Recommendations

The hepatitis A vaccination of children project encountered multiple data collection challenges, and was able to successfully overcome all of them. The new HIPAA regulations contributed to the two most significant challenges: obtaining written parent consent to request medical records for their child(ren), and subsequently obtaining medical records from providers. We were able to utilize multiple and varied contact approaches for both parents and providers to obtain a sufficient number of parent-provider matches for analysis. Implementing these additional steps used more project resources including time (extending the data collection period), project staff labor (to manage the increased efforts), and money (additional parent incentives) than was initially anticipated.

This project allowed an evaluation of the impact of the HIPAA regulations by taking a proactive, somewhat conservative approach during data collection. The challenges faced and solutions rendered allowed us to evaluate our efforts and devise four main recommendations for future studies utilizing medical records. First, we recommend following up with parents via mail as

soon as possible after receiving verbal consent. Parents who completed the telephone interview early in the study were not mailed consent forms for approximately 2-3 weeks. We believe that sending the consent mailings sooner may have resulted in parents returning completed consent forms quicker, in part, because they would have remembered the telephone interviewer more clearly than if they obtained the consent materials a few weeks after the interview.

We would also advocate that projects plan for a longer data collection period from the outset to allow sufficient time to obtain written parent consent. This study demonstrates that multiple follow-ups with parents are required to obtain written consent, and planning for a longer data collection period would ensure that the schedule is not compromised and that sufficient project resources are designated for this effort.

Third, we would recommend that projects plan for increased and more in-depth interaction with some health care providers to obtain medical records. Our experience has shown that contacting individual providers via telephone aids in obtaining completed shot records. By allowing time and effort for these additional follow-ups, projects can ensure that the resources needed to obtain provider responses are in place from the beginning.

Finally, we would recommend that projects consider using interviewer signature as a proxy for parent written consent. We are aware of at least one other study that has used this approach successfully. In this study, after obtaining oral consent from the respondent, interviewers signed a hard copy consent form indicating permission had been obtained, and these forms were then mailed to providers. This would allow projects to leverage the value of written consent for obtaining medical records which would alleviate medical providers concerns, while conserving resources that would have been used to obtain written consent from the parents in addition to the receipt of verbal consent.

We have carefully considered the question of whether written consent is necessary for research organizations conducting studies seeking medical records in this post-HIPAA era. Our view is that while the HIPAA regulations do not require written consent for research studies, providers still believe that written consent is required. However, we are withholding final judgment of the appropriate use of written consent forms for other research studies seeking medical records. Instead, we would recommend that some systematic research be completed that compares the provider response rates from cases where verbal and written consent are obtained with cases where only verbal consent is obtained. Until such research is completed, however, we would recommend the use of written consent forms for research studies attempting to obtain medical records to proactively address provider concerns about written consent and as a means to obtain higher provider response.

References

Advisory Committee on Immunization Practices. (1999). *Prevention of Hepatitis A Through Active or Passive Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4812a1.htm>

Dillman, Don A. (2000). *Mail and Internet Surveys: The Tailored Design Method*. New York: Wiley & Sons.

Centers for Medicare & Medicaid Services. 2003. *Health Insurance Portability and Accountability Act, Part 160 General Administrative Requirements*. <http://www.cms.hhs.gov/hipaa/hipaa2/regulations/privacy/finalrule/PvcTxt01.asp>

Ness, Roberta B. (2005). "A Year is a Terrible Thing to Waste: Early Experience with HIPAA." *Annals of Epidemiology*, 15(2): 85-86.