Post-HIPAA Medical Chart Review To Assess Perinatal Testing Rates

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Abstract

This evaluation, sponsored by the Centers for Disease Control and Prevention (CDC) and conducted by RTI International, seeks to estimate hospital screening rates for HIV and other perinatal infectious diseases among new mothers and their infants as documented in hospital medical charts. The evaluation is underway in selected geographic areas (counties and states) in 7 states and in selected hospitals within these areas. We will discuss the impact of efforts to anticipate concerns about the applicability of HIPAA to this project's protocol.

We are sampling births using state birth certificates from calendar year 2003 as the sample frame and abstracting data from the corresponding charts on screening for HIV and other infectious diseases. A letter outlining the status of the project with respect to HIPAA was included in the project materials mailed to health departments and to hospitals selected for the assessment.

We believe this letter was significant in allaying potential HIPAA concerns. The project has been approved by state health departments and HIPAA concerns have not been a barrier in any hospital thus far.

Keywords: Institutional Review Boards, HIPAA, Establishment Surveys, Vital Records, Hospital Chart Abstraction

1. Background on Perinatal Testing Assessment

Major scientific advances in the prevention of perinatal HIV transmission and the care of HIV-infected persons since 1994-1995 have increased the benefit of knowing a mother's HIV status, especially during pregnancy. In 1995, the CDC initiated recommendations that all pregnant women in the United States be offered an HIV test. The recommendation was strengthened in the 2001 "Revised Recommendations for HIV Screening of Pregnant Women," and again in 2003, when, as part of its Advancing HIV Prevention initiative, CDC reiterated that HIV screening should be a routine part of prenatal care. Other professional organizations such as the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists also have supported routine, voluntary HIV counseling and screening.

However, a study based on prenatal and labor and delivery records of births in 1998 and 1999 reported that documented HIV screening of pregnant women was less frequent than screening for other infectious diseases and that HIV screening rates varied widely across the country (Schrag, et al., 2003). That study reported screening rates (based on all women giving birth) in excess of 95% for hepatitis B surface antigen, syphilis, and rubella overall and in each of eight surveillance areas; for HIV screening, however, the overall rate was much lower—57.2%—and varied considerably by area—from 38.5% to 69.1% (Schrag, et al., 2003; Table 3).

In its congressionally mandated 2002 report, "Reducing obstetrician barriers to offering HIV testing," the Department of Health and Human Services' Office of the Inspector General recommended that CDC work with state health departments to establish monitoring mechanisms that track HIV testing during pregnancy by provider." Beginning in 2004, CDC now requires all states to provide an annual measure of their prenatal HIV screening rates. A standard methodology is necessary so that state health departments can measure screening rates in a consistent and comparable manner.

The purpose of the *HIV Perinatal Screening Assessment* is to measure hospital perinatal screening rates for human immunodeficiency virus (HIV) and other infectious diseases by abstracting screening information from medical charts. The project is initially being conducted in 7 areas (Florida, Georgia, South Carolina, Connecticut, Tennessee, Delaware and Washington D.C.) selected because they meet one or more of the following criteria:

(1) High prevalence of HIV among women of childbearing age (i.e., Survey of Childbearing Women HIV seroprevalence rates in 1994 $\geq$ 2/1,000,

(2) High numbers of cumulative pediatric AIDS cases (at least 150 cases through 2001 of perinatally-acquired AIDS),

(3) State policies likely to have some impact on screening rates.

The specific objectives of this project are (1) to develop estimates of screening rates for each of the eight areas selected for the project and for each participating hospital; (2) provide feedback on screening rates to hospitals and state health departments; and (3) develop a protocol that can be used by state health departments in continuing to monitor hospital screening practices.

2. Study Design

The target population for the project consists of live births with gestational age 20 weeks or greater, and including multiple births, that occurred between January 1, 2003 and December 31, 2003 (calendar year 2003) in delivery hospitals in the selected areas. These include births to women who do not reside in the selected areas. Eligible delivery hospitals are those that delivered 20 or more babies. The sampling frame excludes births that occurred in a hospital not in the selected area or in a hospital within the area that delivered fewer than 20 babies in 2003.

Sample selection is a two-stage process in which state birth certificates are first sorted by hospital in order to obtain a measure of hospital size (that is, number of births in calendar year 2003). After excluding hospitals with fewer than 20 births, a sample of the remaining birthing hospitals is selected with probability of selection proportional to the number of hospital deliveries. All hospitals in each area with more than 20 deliveries in 2003 have a chance to be included in the sample, but large hospitals are more likely to be selected. The number of hospitals selected in each area is typically 11 (for areas having fewer than 11 hospitals total, all hospitals are selected). In the second stage of sampling, births within each hospital are selected following a simple random sample design that yields a sample of 220 births in each hospital.

The information listed in Table 1 is obtained (when available) from state birth certificates for the sampled births. Identifying information (names of mothers, infants and hospitals) is necessary to link the sampled birth certificate to the correct hospital medical record. Demographic information (age, race, ethnicity, etc.) from the birth certificate will be used for nonresponse analysis and post stratification purposes, and to identify factors that might be associated with variability in screening rates.

Table 1: Information about Births Obtained from State Birth Certificates

- Hospital name (Birthing hospital)
- Mother's name (first, middle, last, maiden)
- Mother's race
- Mother's ethnicity
- Mother's date of birth
- Mother's country of birth
- Mother's county and state of residence
- Mother's education level
- Prenatal care (date of first visit, number of visits)
- Infant's name (first, middle, last)
- Infant's date of birth (Delivery date)
- Infant's birth weight
- Gestation at delivery

3. Data Collection

Initial contacts with hospitals are made with the Director of Medical Records. A set of materials is mailed to the Director of Medical Records in each hospital and followed by a call from RTI project staff to explain the purpose of the project, address concerns, and identify the hospital abstractor. The same set of materials may also be sent to other hospital staff on the advice of the Director of Medical Records.

The sample of selected births in the hospital is sent in a separate package once the hospital has agreed to participate, the project has been approved by the hospital IRB and privacy boards, and the abstractors have been identified. A secure carrier is used to minimize risk to the individual identifiers, assure that the package is delivered promptly to the medical record abstractor, and maintain a record to track the location of the sample.

Generally, hospital staff members perform the record abstraction tasks (during after-duty hours with their time compensated by this project). Hospital staff members are familiar with the format of the hospital's medical records and can more easily locate the requested information. Abstractors from outside the hospital can be used when hospital employees are unavailable. Hospital medical records for the mother and infant corresponding to sampled births are reviewed and data pertaining to recommended screening for infectious diseases (HIV/AIDS, group B streptococcus, genital group B streptococcus, hepatitis B surface antigen, rubella, syphilis, chlamydia) and some disease prevention practices are abstracted onto a paper form.

An Instruction Manual for Chart Abstraction is provided containing information regarding project background and purpose, abstractor roles and responsibilities, discussion of items contained in the data forms, instructions for use of the data management system, and procedures for data transmission.

Training medical record abstractors relies on self-study followed by a telephone training session. Much of the abstractors' work depends on familiarity with the particular format of the hospital's medical record system, which the hospital's own staff members already know. Training covers several topics:

- confidentiality of the mother's and infant's data and security procedures for maintaining the sample list
- accuracy in matching cases to medical records
- understanding of definitions and concepts underlying the medical abstract form
- consistency in completing the forms, and
- schedule for completing the abstracting task.

Completed forms are returned to RTI for further processing. The sample information, including names of mothers and infants, remains at the hospital and is destroyed following confirmation of receipt of the completed forms at RTI.

4. HIPAA Issues

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted to protect health insurance coverage of workers when they change or lose their jobs. New health information privacy standards under HIPAA were enforced in April 2003, just as the protocol for the perinatal screening assessment was being developed. HIPAA includes provisions for the protection of personal health information (PHI) and establishes conditions for its use and disclosure by certain health care providers (as well as health insurance and other entities).

Although the HIPAA Privacy Rule expressly permits PHI to be shared for specified public health purposes, the authors were concerned that hospital and health department misinterpretations of HIPAA's application to public health practice would hinder participation. The protocol calls for abstracting PHI that could be linked to information identifying mothers and infants. One concern was the hospitals would mistakenly believe that authorization would be needed from every woman chosen for the sample. For this reason, the HIPAA Privacy Rule and the confidentiality of patient information received considerable attention in the study design and in the development of operational procedures. Project staff anticipated addressing concerns at both vital records departments, in order to obtain the sample frame and birth certificate data, and at the hospital, in order to link the information abstracted from birth certificates to medical records.

5. Procedures To Anticipate Concerns

Several features of this assessment are important to note. First, the CDC determined that the assessment is non-research because its primary intent is to monitor the incorporation of guidelines concerning universal testing into hospital screening practice and to prevent the perinatal transmission of disease. Second, the RTI IRB issued a waiver of individual authorization for research use. The RTI IRB ruled that the assessment involved only minimal risk to the sampled mothers and infants, that it was impractical to obtain individual authorization and that the assessment could not be completed without using the protected health information.

This background was summarized in a letter that was sent to each department of vital records and each hospital selected for the assessment. The letter explained that (1) CDC is a public health authority as defined by HIPAA; (2) the perinatal testing assessment is a public health activity under HIPAA; and (3) by virtue of the contract with CDC, RTI is granted authority to function as a public health authority for purposes of this project.

In addition, a summary of the assessment protocol was provided to vital records departments and hospitals. The protocol included a confidentiality plan that described in detail the procedures to assure the confidentiality of patient names, including discussions of data processing steps and file layouts to illustrate how identifying information about mothers and infants are maintained in separate files from data abstracted from medical charts.

Project site managers are responsible for contacting vital records departments to request the sample frame and for recruiting hospitals for the assessment. They were trained in HIPAA and patient confidentiality. Where necessary, project staff members have been available to meet with IRBs to discuss concerns and to consider possible modifications of procedures to address specific concerns.

6. Results

As of October 2005, we have received approval from vital records departments in seven areas selected for the assessment. Reviews were expedited in four states

and went to full board review in three states. RTI was invited to participate either in person or by telephone in the full board review.

In the five states where data collection is underway, all 53 selected hospitals have been contacted. IRBs have approved the project in 34 hospitals (abstraction is complete in 12 hospitals, underway in 18, we are negotiating staffing or other issues in 4 hospitals); materials are in IRB review in another 12 hospitals, and in 7 hospitals materials have not yet been submitted for IRB because of other considerations.

7. Discussion and Conclusion

We anticipated HIPAA concerns, and more generally, confidentiality issues to be a major factor in decisions by both vital records departments and hospitals to participate in this assessment of perinatal screening. Indeed, while these concerns have not been barriers to participation, confidentiality of personal health information, particularly related to screening for HIV, has been an important issue with each type of organization. The project is unusual in its requirements for information from both vital records and hospital medical charts and linking the two data sources. By carefully describing the relationship of this request to HIPAA and illustrating specific confidentiality procedures, we have been able to obtain necessary approvals from IRBs and Privacy Boards in all of the required state vital record departments and most of the hospitals selected for the assessment.

Reference

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