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Post-HIPAA Medical Chart Review to Assess Perinatal Testing Rates

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Overview

- Background on Perinatal Testing Assessment
- HIPAA Issues
- Procedures to Anticipate Concerns
- Results

Perinatal Testing Assessment

- Objectives
 - Assess hospital screening rates for HIV, Group B Streptococcus, Hepatitis B Surface Antigen, Rubella, Syphilis, Chlamydia among expecting and new mothers and infants
 - Estimate screening rates for each disease for hospitals and for area
 - Develop a protocol that can be adopted by State Health Departments for use in continuing assessment activities

Perinatal Testing Assessment

- Assessment conducted in eight areas (counties and states) selected because they meet these criteria:
 - high prevalence of HIV among women of childbearing age
 - high numbers of cumulative pediatric AIDS cases, or
 - have state policies likely to have some impact on testing rates

Perinatal Testing Assessment

- Sample Design
 - Frame is Vital Records for each area
 - Births occurring in each area in 2003
 - Hospitals selected proportional to the number of births in the hospital in 2003
 - Sample of approximately 1,000 births in each area
 - Allocated so that each hospital has either 200 or 400 births

Perinatal Testing Assessment

- Procedures
 - Names and other information necessary to match sampled birth records to hospital charts are provided to the assessment team
 - Site managers contact the Medical Records Director of selected hospitals to explain the purpose of the assessment, initiate approval processes, identify appropriate staff to abstract records

Perinatal Testing Assessment

- Procedures (continued)
 - Once hospital agrees to participate, appropriate approvals are secured, and staffing is in place and trained, site manager sends sample of birth records to abstractors along with blank abstract forms
 - Site manager has weekly status calls with abstractors to assess progress and respond to questions
 - 10% of cases are abstracted by a second abstractor to assess reliability

Confidentiality Concerns

- Concerns of Vital Records Departments in releasing individual data on birth records to RTI
- Concerns of hospital data that could be connected with identifiers

Perinatal Testing Assessment

- Because the project is considered “evaluation” and not “research,” it was determined that project does not require review by the CDC IRB
- Protocol was reviewed by RTI’s IRB, which determined that it presents minimal risk to subjects (mothers and infants)
- Also determined that the protocol qualified for a waiver of individual authorization for research use and disclosure of PHI under HIPAA

Procedures to Anticipate Concerns

- Advance Materials Mailed to Vital Records Departments and Hospitals explicitly discuss confidentiality issues and HIPAA, noting:
 - CDC is a public health authority as defined by HIPAA
 - RTI is granted authority under our contract to function in the same way
 - The Perinatal Testing Assessment is public health activity under the HIPAA Privacy Rule

Procedures to Anticipate Concerns

- The HIPAA Privacy Rule permits hospital to disclose protected health information (PHI) without patient authorization for:
 - Public health purposes or
 - Purposes that have been approved by an IRB with a waiver of authorization
- This assessment meets both criteria

Results

- State Health Departments and Departments of Vital Records
 - Expedited IRB review and acceptance of HIPAA waiver in 4 states
 - Full IRB review and review by Privacy Board in 3 states; one required modifications to the Confidentiality Plan to further protect the identification of individuals
 - Protocol Revised in One State

Results

- Hospitals
 - Selected hospitals in 5 of the 8 states, a total of 53 hospital
 - Contacted all 53 hospitals

Results

- 53 Hospitals contacted
- 34 Received IRB approval
 - 12 Data Collection Complete
 - 18 Data Collection Initiated
 - 4 Data Collection Pending Other Issues (Staffing, Scheduling)
- 12 In IRB Review
- 7 Not Yet Submitted to IRB

Conclusion

- *Confidentiality concerns and specifically HIPAA are a major factor in the decision to participate in the assessment, but not necessarily a barrier*
- *Able to obtain necessary approvals by carefully describing the relationship of this assessment to HIPAA and by illustrating specifically procedures to protect confidentiality*