

Evaluation of Discrepant HBsAg Results of Screening Tests for Chronic Hepatitis B Virus (HBV) Infection—Project Summary

Primary Contacts:

Trudy Murphy, MD

Tanja Walker, MPH

CDC, NCHHSTP, Division of Viral Hepatitis, Prevention Branch

Lisa Jacques-Carroll, MSW

CDC, NCIRD, Immunization Services Division, Program Operations Branch

Summary

This pilot project seeks to identify the important reasons for discrepant results of screening tests for hepatitis B surface antigen (HBsAg) among pregnant women who present for perinatal case management, and among other persons who are screened for chronic HBV infection. Information will be collected through passive reports on a standard data collection form. Forms will be solicited first from perinatal hepatitis B program coordinators (and possibly from hepatitis coordinators) for a minimum of 1 year. CDC will provide consultation if requested and additional testing when submitted through existing state health department channels. However, at this time, there is no plan for systematic collection of blood from subjects with the discrepant laboratory results.

Objective

This project seeks to determine the array of causes of discrepant HBsAg test results and to estimate their frequency among pregnant women (and possibly other risk groups) that are evaluated by serological screening for chronic HBV infection.

Project Goals and Program Needs

Information from this project will be used to decide the appropriate “next steps” (if any) to address discrepant HBsAg results for perinatal hepatitis B case-management, and possibly for case-management of hepatitis B virus infected people in other settings.

Eligible Discrepant Results

Data will be derived from pregnant women and possibly other subjects who are screened for chronic HBV infection. Data will consist of passive de-identified reports to CDC. Data submission will begin in April 2009.

Eligible subjects will have had two or more tests with discrepant results for HBsAg within 12 months. Eligible patterns of discrepant results include one or more positive tests followed by a negative test, or one or more negative tests followed by a positive test. Other combinations of discrepant results are eligible, e.g., when results from three or more tests do not agree.

Coordinators will be asked to provide information on the types of tests and identify the laboratories performing the tests. Other pertinent health information about subjects will be requested, e.g., sex, pregnancy status, hepatitis B vaccination dates and types of vaccine, the

presence of hepatitis C virus infection and major medical conditions e.g., immunosuppression, cancer, etc., if known.

The information will be transmitted on a standard data collection form that is anonymous for the patient except for the state's unique patient identifier. Data sheets will be transferred electronically to CDC using a unique email address.

CDC will provide consultation and additional testing if requested. Serum or plasma submitted for additional testing will be accepted through existing state health department channels. The results of any supplementary tests performed at CDC will be linked to the data collection form using the state's unique patient and specimen identifiers. However, CDC has no plan for systematic collection of blood from subjects with the discrepant laboratory results. For details on how to submit a blood sample, please contact: DSA_HepB@cdc.gov

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