Prevalence of Hepatitis B and C in an Urban General Medicine Practice

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A. Study Purpose and Rationale

Hepatitis B and C are the major causes of acute and chronic hepatitis, cirrhosis and primary hepatocellular carcinoma. To date, outpatient screening for hepatitis B and C has been dependent on risk factor assessment by physicians, with sceening tests offered to those at high risk for disease. Typical risk factors for either hepatitis B or C include a history of blood transfusions, drug use, tattooing, body piercing, multiple sexual partners, STD's and a history of a sexual partner with Hepatitis B or C.

Population surveys have suggested that certain demographic groups have increased prevalence of disease. Higher rates of disease have been noted among males, people who are foreign bom, metropolitan residents and among the poor.

Previous work in the AIM clinic has shown that the patients who attend clinic have demographic characteristics associated with an increased prevalence of hepatitis B and C. The majority of patients are poor with little formal education. Eighty-six percent reported a family income in 1998 of less that $12,000. Sixty percent had not completed high school. Seventy-one percent were born outside of the United States.[1]

Population based studies have shown that patients with hepatitis may be missed with selective screening based on risk assessment. Thirty to forty percent of patients with acute hepatitis B have no risk factor identified.[2] Similarly, no identifiable risk factor was found during the previous six months for 44% of patients with new infections of Hepatitis C.[3]

Hypothesis Patients in the ambulatory medicine clinics have higher than average prevalence rates of hepatitis B and C, and many go undiagnosed.

The purpose of this study is to determine the prevalence of diagnosed and undiagnosed hepatitis B and C among patients in the ambulatory medicine clinics affiliated with Columbia Presbyterian Hospital. If prevalence rates of hepatitis B and C are higher than average in the ambulatory medicine clinics, and if many patients do not have identifiable risk factors, then routine screening may be beneficial and cost effective in this population. Hepatitis B could be prevented with routine screening and vaccination. Cases and hepatitis B and C could be referred for treatment.

B. Study Design and Statistical Analysis

Operational Definitions
Hepatitis C+: HCV antibody positive
Hepatitis B+: Hepatitis B core or surface antigen positive

a. Study Design

[1] Olfson M et al. Prevalence of Anxiety, Depression and Substance Use Disorders in an Urban General Medicine Practice. Archives of Family Medicine 2000; 9:876.

[2] Alter MJ et al. The Changing Epidemiology of Hepatitis B in the United States. JAMA. 1990;263:1218.

[3] Alter MJ et al. Sporadic non-A, non-B hepatitis: Frequency and Epidemiology in an Urban United States Population. J Infec Dis 1982; 145:886.

This study is a prospective prevalence study. The goal is to determine the prevalence of diagnosed and undiagnosed hepatitis B and C among patients in the ambulatory clinic population in 2004.

b. Statistical Analysis

Data will be analyzed using the chi-square test comparing the prevalence of hepatitis B and C found in the ambulatory clinic population with the NHANES prevalence for the general population, 5.5% and 1.8% respectively.

c. Power Calculations

i. Hepatitis C

The overall prevalence of hepatitis C is 1.8%.[4] Unpublished data from NHANES shows a prevalence of 4.8% in low income, metropolitan community men. In order to show a prevalence of 4.8% (80% power, testing at p=0.05, one sample Chi-square), 307 male subjects would need to be recruited. For women, the expected prevalence hepatitis C is 2.2%. Since this prevalence is not significantly elevated from the baseline prevalence in the community, it would not be helpful to test at this prevalence. For this reason, a test prevalence of 4% was chosen. In order to show that the prevalence of disease in women was at least 4% (80% power, testing at p=0.05, one sample Chi-square), 501 women would need to be recruited.

ii. Hepatitis B

Data from the NHANES study suggests that the overall age-adjusted prevalence of hepatitis *B* is 5.5%.[5] Those with less than high school education and those who are born outside of the United States have a higher prevalence of disease, 8.8% and 15.7%, respectively. Non-age adjusted data extracted from the NHANES data set gives a hepatitis *B* prevalence of 9.4 % in low-income, metropolitan residents. (9.23% in men, 9.54% in women) In order to show demonstrate a prevalence of 9.4 % in the clinic population (80% power, testing at p=0.05, one sample Chi-square) 381 subjects would need to be recruited.

C. Study Procedure

A random day, time and room will be selected and a yellow note will be placed on the chart of the patient assigned to that appointment time and place. Primary care physicians will be asked to refer patients who have yellow notes affixed to the chart to the study.

The researcher will explain that the purpose of the study is to determine the prevalence of hepatitis *B* and C in the clinic population. Patients who agree to the study will be consented. Patients will be asked to complete a survey,

Webcis records will be reviewed. If hepatitis serologies have ever been positive in the past, the results will be documented at the bottom of the survey. If the pateint has been negative in the past but has not been tested in the last year, he/she will be sent for retesting.

Patients who have not been tested in the last year or who have never been tested for hepatitis B or C at CPMC will have their blood drawn. Blood will be sent for HCV antibody, hepatitis *B* antibody, hepatitis *B* surface and core antigens. Positive HCV will be confirmed with recombinant immunoblot assay.

If the results are positive for hepatitis C or hepatitis *B* surface or core antigen, the patient will be notified and referred to a primary care physician for further care. Patients will be told when they sign the consent for the study that if they test positive, they might be at risk for other diseases. Patients will be asked if they would like to be contacted for further testing, should they test positive.

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[4] Alter MJ et al. The Prevalence of Hepatitis C Virus Infection in the United States, 1988 through 1994. NEJM 1999; 341:556.

[5] McQuillan GM et al. Prevalence of Hepatitis *B* Virus Infection in the United States: The National Health and Nutrition Examination Surveys, 1976 Through 1994. American Journal of Public Health 1999; 89:14.

D. Study Drugs

N/A

E. Medical Device

N/A

F. Study Questionnaire

Data to be gathered by primary investigator. The goal of the questionnaire is to determine how many clinic patients have typical risk factors for hepatitis B or C.

G. Study Subjects

a. Inclusion Criteria

All patients who attend clinic at the AIM clinic and ACNC (181st) clinics.

b. Exclusion criteria

none

H. Recruitment of Subjects

Primary care physicians will be informed of the study and asked to refer all patients with marked charts to the study.

I. Confidentiality of Study Data

- All data will be coded with a unique code.
- Data will be stored in a secure location, accessible only to the investigators.
- Positive tab results will appear in webcis.

J. Potential Conflict of Interest

None

K. Location of the Study

Patients will be referred to investigators who will be located in the AIM and ACNC clinics. Blood draws will take place in the clinic.

L. Potential Risks

Patients who agree to the study will be subject to venipuncture.

M. Potential Benefits

Diagnosis of hepatitis B and C and referral for treatment.

N. Alternative Therapies

N/A

O. Compensation to Subjects

Patients will be compensated $5.

P. Costs to Subjects

None

Q. Minors as Research Subjects

N/A

R. Radiation of Radioactive Substances

N/A

Questionnaire Subject number _____

Date of Birth _____

Race:
□ White □ Black □Hispanic(Dominican) □Hispanic(non-Dominican) □ Other

Where were you born _____

Have you ever been diagnosed with Hepatitis B? ---------- □ Yes □ No □ Unsure
Have ever been diagnosed with Hepatitis C? ---------- □ Yes □ No □ Unsure

Have you ever had a blood transfusion? ---------- □ Yes □ No □ Unsure

Do you have any tattoos? ---------- □ Yes □ No

Have you ever had or been treated for a sexually transmitted disease (such as genital herpes, genital warts, gonorreah, chlamydia, syphilis) ---------- □ Yes □ No

Number of lifetime sexual partners
□ 0-1 □ 2-9 □ 10-49 □ 50 or more

Have you ever used drugs that you have injected into your vein (eg. heroine)?
□ Yes □ No

Have you ever used intranasal cocaine or other non-injection illegal drugs?
□ Yes □ No

Have you had a long-term steady sexual partner who has been diagnosed with Hepatitis B or C?
□ Yes □ No

Do you have any body piercing? (ears, nose, belly button, genitals ect.)
□ Yes □ No

For Official Use Only:

Webcis records:
Hepatitis B: sag + - sab + - cab + - _____ not tested
Date of last test

Hepatitis C: + - _____ not tested
Date of last test

Columbia Presbyterian Medical Center
Consent to Participate in a Research Study

The purpose of this consent form is to provide you with the information you need to consider in deciding whether to participate in the research study:

Prevalence of Hepatitis B and C in an Urban General Medical Practice

Study Purpose: You are invited to participate in a research study of hepatitis B and C. This study is trying to find out if there are a lot of patients infected with hepatitis B or C in this community.

You qualify as a possible participant in this study because you are a patient in this clinic. We have asked doctors in the ambulatory clinics at Columbia Presbyterian to refer patients to this study to help us learn how many patients have hepatitis B or C.

Study Procedures: If you decide to participate, we will check your records here at Columbia Presbyterian to see if you have been diagnosed with hepatitis B or C in the past. You will also be given a questionnaire to complete. If you have not been diagnosed with hepatitis B or C in the past, we will draw I teaspoon of your blood for testing today. The blood will be drawn in the clinic. We will keep your blood for one month.

If your blood tests positive for hepatitis B or C, you will be contacted by telephone and referred to your primary care provider.

If you test positive for hepatitis, you may be at risk for other diseases. We will ask your permission to contact you for further testing.

Study Risks: Your participation in this study involves the following risks: A blood draw.

Study Benefits: You may or may not personally benefit from this study. Benefits to you may include being diagnosed with hepatitis B or C and having the opportunity to get treatment for this disease.

Benefits to society may be that your doctors have a better understanding of how many patients in this clinic have hepatitis B or C. If a large number of people are infected, you doctors may start screening routinely for hepatitis B or C and more people may be diagnosed and treated.

Alternatives: You may choose not to participate in this study.

Costs: There are no costs to you to participate in this study.

Compensation: For your participation in this study you will receive $5 after your blood has been taken.

Confidentiality: Any information obtained during this study and identified with you will remain confidential. Results will be coded with a unique number so that your identity remains anonymous to other researchers. Data will be stored in a secure location, accessible only to researchers.. The results of the tests will be placed in your computer records so that your doctors may check on the results.

Participation is voluntary: Your participation in this study is completely voluntary. You can refuse to participate, or withdraw from the study at any time, and such a decision will not affect your medical care at Columbia-Presbyterian Medical Center, now or in the future. Signing this form does not waive any of your legal rights.

Questions: If you have any questions, please ask, ad we will do our best to answer them. If you have additional questions in the future, you can reach Dr. Jacobsen at (212) 568-8587.

If you have any questions on your rights as a research subject, you can call the Institutional Review Board at (212) 305-5883 for information.

Statement of Consent:

I have discussed this study with _____to my satisfaction. I understand that my participation is voluntary and that I can withdraw from the study at any time without prejudice. I have read the above and agree to enter this research study. Signing this form does not waive any of my legal rights.

I have been informed that if I believe that I have sustained injury as a result of participating in a research study I may contact the Principal Investigator Dr. Juliet Jacobsen at (212) 568 -8587 or the Institutional Review Board at (212) 305-5883, so that I can review the matter and identify the medical resources which may be available to me.

I understand that:

1. Presbyterian Hospital will furnish that emergency medical care determined to be necessary by the medical staff of this hospital;
2. I will be responsible for the cost of such care, either personally or through medical insurance or other form of medical coverage;
3. No monetary compensation for wages lost as a result of injury will be paid to me by the Columbia Presbyterian Medical Center, and;
4. I will receive a cop of this consent statement.

Signatures:

_____

Participant Date

_____

Investigator Eliciting Consent Date

If you test positive for hepatitis B or C, you may be at risk for other diseases. May we contact you for further testing?

□ Yes □ No _____

Initial Date