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Sensitivity and Specificity of CDC Criteria for Routine Hepatitis C Testing in A STD Clinic: A Preliminary Analysis

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Introduction:
Hepatitis C virus (HCV) infection is the most common bloodborne infection in the United States. Injection drug use and history of blood transfusions prior to 1992 are known risk factors for hepatitis C. Several studies have shown that HCV is transmitted sexually and through non-injecting drug use (non-IDU). However, the extent to which HCV is sexually transmitted or by non-injecting drug use and other potential routes is still debated, and the need for routine testing among these populations is uncertain. We hypothesized that the prevalence of HCV among sexually transmitted disease (STD) clients at the Miami-Dade County Health Department (MDCHD) downtown STD Clinic was higher than the estimated 6% (range 1-10%) national prevalence among people with a history of a STD. The objective of the study was to determine the prevalence of risk factors for hepatitis C among clients presenting to the STD Clinic for a new problem, and to determine the effectiveness of screening criteria in this population. The Centers for Disease Control and Prevention (CDC) recommends routine HCV testing for people who:

- ever injected illegal drugs,
- were ever on long term hemodialysis,
- have persistently abnormal ALT levels,
- are recipients of blood transfusions or organ transplants before July 1992
- were notified they received blood from a donor who later tested positive for HCV infection
- are recipients of clotting factor concentrates prior to 1987
- are health care workers and have had needles stick exposure to HCV+ blood
- are children born to an HCV^{+} woman

In this article, we discuss the sensitivity and specificity of these criteria applied to the MDCHD STD Clinic population.

Methods:
We tested the first 710 clients for hepatitis C who presented to the STD clinic for a new problem. All eligible STD clients were introduced to the study by clinicians who referred interested patients to the hepatitis staff. All participants gave informed consent, received counseling and education about the disease, and were interviewed using the risk assessment questionnaire. The questionnaire assessed the CDC screening criteria as well as uncertain risk factors such as tattooing, body piercing, snorting drugs, exchanging sex for money or drugs, number of sex partners and a history of STD. After completion of the questionnaire, a blood specimen was drawn for hepatitis testing. An EIA (enzyme immunoassay) was performed to test for HCV. If the EIA test was repeatedly reactive, confirmatory testing was performed using RIBA™

Inside this issue:

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(recombinant immunoblot assay).

Results:

A total of 710 hepatitis tests were performed as part of the study. The overall acceptance rate among STD clients was 52%. Reasons for refusing testing included time constraints, work commitments, and a belief of not being at risk for hepatitis. Of the 710 tests performed, 21(3%) were not analyzable due to insufficient amount of blood or client not returning for a re-draw. Therefore, analysis was performed on 689 completed questionnaires and corresponding laboratory results. Of the 689 clients, 32 (5%) were HCV positive.

Only 22 (69%) of the HCV^+ persons met any of the CDC screening criteria. The sensitivity and specificity of the CDC screening criteria were 69% and 90% respectively. The positive predictive value (PPV) was 25% (Table 1). The most commonly reported risk factor was injection drug use (Table 2). Of the 32 cases of HCV, 10 (31%) did not meet CDC criteria for routine HCV screening. Three (30%) of the 10 reported receiving injections of vitamins/ medications outside the US; another 3 (30%) reported a history of spending at least one night in prison/jail, an additional 3 (30%) reported a history of snorting drugs and having spent at least one night in prison/jail, and one reported receiving injections of vitamins/medications outside the US and having spent at least one night in prison/ jail. Adding a history of having spent at least one night in prison/jail identified 7 more HCV^+ cases and increased the sensitivity to 91%, but decreased the specificity to 57% (Table 3). However, to identify these 7 additional cases, 220 additional people would have to be tested. Among non-injecting drug users, the only factor associated with being HCV^+ approaching significant, was a history of a prison/jail stay of at least one night (p=0.05).

Discussion:

The limitations of this study include a low response rate and a limited generalizability to a non-STD clinic population. The prevalence of hepatitis C (5%) among this STD clinic clientele, is higher than that for the general population (1.8%), and falls within the range (1-10%) of the prevalence for persons reporting a history of an STD. The study participants were relatively young with a mean age of 34 years, and hence may be less likely to have the risk factors which CDC has identified as putting one at risk of acquiring HCV (Table 2). Among non-injecting drug users, the only factor associated with being HCV^+ was a history of prison/jail stay of at least one night. It is not clear if this characteristic is the actual risk factor and/ or if being in prison/jail is a marker for some other behavior that puts a person at risk for hepatitis C. Multivariate analyses are ongoing, and additional results of this study will be shared via future Epi Monthly Reports.

Table 1. Sensitivity, Specificity and Positive Predictive Value of CDC Screening Criteria

	HCV(+)	HCV(-)	Total
Any CDC Criteria	22	66	88
No CDC Criteria	10	591	601
Total	32	657	689

Sensitivity: 69%, specificity: 90%, PPV: 25%

Table 2. HCV^+ Positivity by CDC Risk Factor Category for Routine Screening

Risk Factors	Status	Total N (%) Tested	HCV^+ N (%)
Injection Drug Use	yes	26 (4%)	15 (47%)
	no/don't know	663 (96%)	17 (53%)
Received Clotting Factor	yes	0 (0%)	0 (0%)
concentrates before 1987	no	689 (100%)	32 (100%)
Ever on hemodialysis	yes	1 (<1%)	0 (0%)
	no/don't know	685 (99%)	32 (100%)
Abnormal alanine	yes	25 (4%)	8 (25%)
aminotransferase levels	no/don't know	664 (96%)	24 (75%)
Received blood from	yes	0 (0%)	0 (0%)
donor tested + for HCV	no/don't know	689 (100%)	32 (100%)
Received blood transfusion	yes	36 (5%)	4 (13%)
prior to July 1992	no	653 (95%)	28 (87%)
Received organ transplant	yes	0 (0%)	0 (0%)
prior to July 1992	no	689 (100%)	32 (100%)

Table 3. Sensitivity, Specificity and Positive Predictive Value (PPV) of CDC Screening Criteria and History of Jail/Prison

	HCV(+)	HCV(-)	Total
Any CDC Criteria and History of Jail	29	279	308
No CDC Criteria or History of Jail/Prison	3	378	381
Total	32	657	689

Sensitivity: 91 %; specificity: 58%; PPV: 9%

National Shortage of Adult Td and TT Vaccines and Potential Shortage of DTaP Vaccine

Henry T. Janowski, MPH, Chief, Bureau of Immunization

[The following article appeared in EPI UPDATE, a weekly publication by the Bureau of Epidemiology, Florida Department of Health (For April 13, 2001)]

As many of you are aware, there is a national shortage of adult Tetanus and Diphtheria Toxoids (Td) and Tetanus Toxoid (TT) vaccines; and a potential shortage of Diphtheria and Tetanus Toxoids and Acellular Pertussis (DTaP) vaccines. The following information is provided to assist you in managing the anticipated supplies of these vaccines, necessary for prophylaxis in wound management.

Attached is a copy of the Notice to Readers: Update on the Supply of Tetanus and Diphtheria Toxoids and of Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine, *Morbidity and Mortality Weekly Report (MMWR)*, March 16, 2001 / Volume 50(10) / Pages 189-190. The Notice to Readers can also be found on the Centers for Disease Control and Prevention's (CDC) Web site at http://www.cdc.gov/mmwr//preview/mmwrhtml/mm5010a3.htm.

Nationwide Shortage of Adult Td and TT Vaccines:
Aventis Pasteur is now the sole nationwide distributor of Td and TT. They are shipping limited quantities of these vaccines to assure a wide distribution of available doses. While the company is increasing its production, the shortage is not expected to be resolved for 12 to 18 months. Wound care in clinics and hospitals continues to be the priority for Td and TT and this priority will remain in effect until adequate supplies are restored. Clinics and hospitals in need of vaccine for wound care should call Aventis Pasteur at 1-800-VACCINE or 1-800-822-2463.

Potential Nationwide Shortage of DTaP Vaccine:
There is a potential shortage of DTaP to vaccinate all children. On March 7, 2001, the Food and Drug Administration (FDA) approved a newly formulated version of Aventis Pasteur's Tripedia® in one-dose vials without preservative and with only a trace amount of thimerosal. With approval of this vaccine, the supply of DTaP should gradually improve.
Presently, there is no change in the national policy for the recommended DTaP immunization schedule.

The CDC is working closely with State Health Departments to ensure equitable distribution of available DTaP vaccine. The CDC and the FDA are monitoring the DTaP vaccine supply situation closely and will provide more guidance should significant supply problems occur.

If an insufficient supply of DTaP vaccine does develop, priority should be given to vaccinating infants with the three initial doses of DTaP since pertussis is most severe among children less than one year of age. If rationing becomes necessary, the fourth DTaP dose should be deferred. The CDC is recommending that the fourth dose-and not the fifth dose-be deferred because the preschool booster is important for maintaining immunity against diphtheria, tetanus and pertussis during the early elementary school years. Receipt of a primary series of DTaP confers adequate protection during the second year of life for many children, so the fourth dose is considered to be the safest to temporarily postpone. When adequate DTaP supplies are available, all children who did not receive the fourth DTaP dose should be recalled for vaccination.

If you have any questions regarding this information, please contact your local county health department.

Happy Nurses' Week!
(May 6-12)

Thank You for everything that you do for the Miami-Dade County Health Department, the residents & visitors of our county.

To report diseases or for information:

Office of Epidemiology and Disease Control

Childhood lead poisoning prevention program	(305) 324-2414
Hepatitis	(305) 324-2490
Other diseases and outbreaks	(305) 324-2413
HIV/AIDS Program	(305) 377-7400
STD Program	(305) 325-3242
Tuberculosis Program	(305) 324-2470
Special Immunization Program	(305) 376-1976
Nights, weekends, and holidays	(305) 377-6751

Monthly Report
Selected Reportable Diseases/Conditions in Miami-Dade County, March 2001

Diseases/Conditions	Reported Cases this Month	2001 Year to Date	2000 Year to Date	1999 Year to Date	1998 Year to Date
AIDS *Provisional	119	379	388	391	391
Campylobacteriosis	6	21	7	14	7
Chancroid	0	0	0	0	0
Chlamydia trachomatis	233	679	1092	1078	589
Ciguatera Poisoning	0	0	0	0	0
Cryptosporidiosis	0	4	1	0	1
Cyclosporosis	0	0	0	0	0
Diphtheria	0	0	0	0	0
E. coli , O157:H7	0	0	0	0	0
E. coli , Other	0	0	0	0	0
Encephalitis	0	0	0	0	0
Giardiasis, Acute	24	45	1	4	8
Gonorrhea	140	464	797	745	714
Granuloma Inguinale	0	0	0	0	0
Haemophilus influenzae B (invasive)	0	1	1	0	0
Hepatitis A	12	37	14	9	35
Hepatitis B	7	9	4	9	0
HIV *Provisional	127	391	427	374	482
Lead Poisoning	27	59	90	29	13
Legionnaire's Disease	0	0	0	0	0
Leptospirosis	0	0	0	0	0
Lyme disease	0	0	0	0	0
Lymphogranuloma Venereum	0	0	0	0	2
Malaria	3	8	0	6	5
Measles	0	0	0	0	0
Meningitis (except aseptic)	0	2	1	1	5
Meningococcal Disease	0	4	5	4	2
Mumps	0	0	0	1	0
Pertussis	0	0	0	2	7
Polio	0	0	0	0	0
Rabies, Animal	0	0	0	0	1
Rubella	0	0	0	0	0
Salmonellosis	14	34	24	27	43
Shigellosis	11	19	19	26	28
Streptococcus pneumoniae, Drug Resistant	28	45	23	9	14
Syphilis, Infectious	23	47	40	20	9
Syphilis, Other	83	180	222	286	155
Tetanus	0	0	0	0	0
Toxoplasmosis	1	1	0	0	0
Tuberculosis *Provisional	14	39	48	47	82
Typhoid Fever	0	0	0	13	1
Vibrio , *cholera*	0	0	0	0	0
Vibrio , Other	0	0	0	0	0

* Data on AIDS are provisional at the county level and is subject to edit checks by state and federal agencies.
** Data on Tuberculosis are provisional at the county level.