Impact of BW Name Reporting and Partner/Contact Notification on HIV Testing Among Individuals in Upper West Manhattan, New York City

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A. Introduction

a. Background and Rationale

Since its onset in the early 1980s, the Acquired Immunodeficiency Syndrome (AIDS) epidemic has created much alarm in all facets of society and thus mobilized the medical profession, the public including many advocacy groups and public health officials to devise ways to monitor its course. Since 1985, large-scale publicly funded Human Immunodeficiency Virus (HIV) counseling and testing (CT) programs have been in place in all states along with AIDS name reporting to all state health departments. It was felt that by gathering as much demographic information about those affected with AIDS as possible, it would allow more accurate epidemiologic surveillance which could provide the basis for targeted planning, resource allocation and public health initiatives at both the state and federal levels.

With the advent of newer therapies for individuals with AIDS, the climate of public health policy started to shift. In 1988 Michigan required HIV name reporting and by 1996, 32 states had the same policy. In other words, the names of all HIV positive (+) would be reported to a state health department registry. This change in policy was debated vigorously by everyone interested or concerned in the AIDS epidemic. The rationale for the evolution of public policy was that AIDS reporting underestimated the impact of the epidemic (1). For example, 3% of AIDS cases compared to 14% of HIV infections were attributed to adolescents and 45% AIDS cases vs. 57% HIV infections were among African Americans (2). This expanded reporting of HIV infection would provide greater accuracy in epidemiologic monitoring and thus better, more appropriate education, prevention and other services to those who would benefit from them.

The risk/benefit ratio of HIV name reporting and the subsequent loss of anonymity and confidentiality is an ongoing debate. There have been opposing viewpoints among and between members of all groups ranging from individual patients, special interest or advocacy groups, grassroots organizations, lawyers, health care providers, public officials to theorists and philosophers. The studies done do not show any clear, definitive answer as they are heterogenous, in design and often conflicting in results. To illustrate some of the strong sentiments, the American Civil Liberties Union stated in a recent position statement that "name reporting is a counterproductive public health measure that will cause individuals to avoid testing" and alluded to the policy as "a violation of privacy" (3).

The Centers for Disease Control & Prevention (CDC) realized the sensitive nature of the policy. Also, several studies came out suggesting that anonymous testing centers would allow individuals who did not want to participate in confidential testing and have their names reported to still remain in the health care system and seek care as needed (4). Since then, the CDC has encouraged all states to offer anonymous testing centers as an alternate option for confidential testing. So the question still remains, will MV name reporting deter certain patient populations from getting confidentially tested or will some patients be driven out of the health care system in order to avoid HIV testing?

The debate became even more relevant to us here in New York City after June 2000 when New York State Legislature passed Part 63 of Title 10 of the New York Code of Rules and Regulations. These were the final amendments and thus put into effect Chapter 163 of the Public Health Laws of 1998. Under this Law, HIV name reporting is mandatory by physicians and all personnel authorized to order HIV tests. In addition, laboratories, blood banks and tissue banks are required to report all HIV + individuals to the New York State Department of Health (NYS DOH). Also, any laboratory tests indicative of HIV infection besides a HIV + antibody test such as CD4 count < 500 or CD4 < 29% total lymphocytes fall

under the same regulations. Finally, providers are required to report names and addresses of any known sexual contacts or IV needle sharing partners of known FIIV infected individuals to NYS DOH. And then, providers are required to request the voluntary participation of all individuals getting HIV tested to disclose further names of sexual or IV needle sharing partners. Of course, the change of HIV testing policy is required to be explained to patients in the Pre-Test Counseling session for all those approached for HIV testing. So will these new laws deter certain high-risk groups from being tested either confidentially or not at all here in New York City (NYC)? In 1989, the NYS DOH thought they would (5) so the Laws were not compiled until 1998.

b. Literature Review

A longitudinal study of 574 homosexual men at sexually transmitted diseases (STD) clinics in San Francisco revealed that only 1/3 of them would consent for MV testing if their results were reportable. Interestingly, it also showed that only 40% would seek treatment for their STI)s if MV testing was required to receive care. In addition, 1/3 of those seeking treatment for AIDS or AIDS-related complex symptoms would avoid getting care if HIV testing was required (6).

A cross-sectional study of the knowledge, attitudes, and behaviors pertaining to AIDS of predominantly Black and Hispanic populations visiting NYC inner-city STD clinics in 1988 revealed that among 1047 respondents, 22% reported that they would not consent to FIIV testing if names were reported (5).

Another cross-sectional study involving 2370 HIV negative or untested persons at risk for I-IlV infection in nine different states were surveyed for knowledge of state HIV reporting laws, self-reported HIV testing history, and reasons for delayed testing or no testing at all. The most common deterrent to testing in all risk groups was first, fear of learning they were HIV + and second, lack of perceived risk for IRV infection (i.e. thought they were unlikely to have been exposed to HIV). The concern about reporting as the main factor for not being tested or delaying testing was 4% in homosexual men, 3% in non-Hispanic whites, 3% in Hispanics, <1% in non-Hispanic Blacks, 1 % in IV drug users and I% in heterosexuals. So it appeared from this study that reducing fear and increasing knowledge about HIV risk were integral to designing effective prevention programs. It was unclear, however, how much impact name reporting had on HIV testing given the high proportion of individuals who were not aware of their state reporting policies (7).

Most recently, a large longitudinal, observational study was performed by the CDC to describe the trends in FHV testing at publicly funded MV CT sites twelve months before and twelve months after implementation of FHV reporting policies in six state health departments (8). Specifically, the number of FHV tests, the number of FHV + tests, and distribution of tests by various demographic and risk categories was measured in CT programs in Louisiana, Tennessee, Michigan, Nevada, Nebraska and New Jersey for a total twenty-five month period as described above. Results showed a decline in testing in only two of the six states. In Louisiana, the declining trend began before the policy was introduced and continued the same trend after policy implementation. In Michigan, there was a transient decrease of testing immediately after the name reporting policy was implemented but returned to baseline at the end of the twelve months. IRV testing decreased among homosexual men in Louisiana and Tennessee whereas it increased among high-risk heterosexuals in all states. Testing also decreased among IV drug users in Louisiana, New Jersey, and Michigan and among Blacks in Michigan, New Jersey and Louisiana. The Poisson model was used to show there was no statistically significant difference in the declining overall trends in Louisiana and Michigan whereas a statistically significant increasing trend in the before-and-after trends was found in Nevada, New Jersey, and Tennessee.

This most recent large CDC sponsored study did not show the dramatic adverse effects of HIV name reporting which many of the earlier survey-based studies demonstrated. There are several explanations for these differences. First and foremost, it is essential to remember that this recent study measured the number of tests generated instead of number of persons being tested and was therefore unable to differentiate duplicate tests for a given individual. There may have been secular trends such as governmental funding, media, etc. concurrent with the HIV reporting policies which may have affected

results. Also, the highly active antiretroviral therapies (HAART) and protease inhibitors (PI) which offer advantages of early diagnosis and more effective treatments may truly provide more powerful incentives to testing that outweigh concerns regarding reporting, and this possible shift in attitudes is reflected in the newer study. Finally, a longer and more extensive history with governmental and administrative agencies in handling confidentiality, security and discrimination issues surrounding AIDS reporting and data may have eased concerns among patients thus leading to this difference in data. Despite all this, though, the CDC data in this study should be used with caution when extrapolating to testing trends in providers' ambulatory settings and community health service sites.

The purpose of this study is to determine if the numbers of persons who consent for HIV tested are affected as a result of name reporting, stratified into various demographic and risk groups, and whether any of these groups will decide to undertake anonymous HIV testing instead.

B. Hypothesis

The HIV Name Reporting and Partner/Contact Notification policies enacted as of June 2000 will decrease the numbers of individuals getting HIV tested confidentially in certain demographic and at-risk groups. Whereas in some groups the testing burden will shift from confidential to anonymous testing centers, in other groups the persons not being tested may be lost from the health care system with regards to HIV testing altogether. Specifically for example, whereas Hispanic patients may turn to anonymous testing, adolescent patients may not get tested now at all.

C. Study Design and Statistical Analysis

This is a twelve month, randomized single blind clinical trial with a concurrent control. The patients will be recruited from The Columbia-Presbyterian Medical Center's Ambulatory Network Center clinics, Helen B. Atkinson Health Center, Ryan Community Health Center, the SHOUT Van Program and other community ambulatory clinics.

a. Eligibility

Patients must be at least 15 years old, males and females, not known to be HIV +, not known to be pregnant, have at least one IIIV risk factor warranting HIV testing, and have the ability to give written informed consent. Adolescents aged 15-17 year old were included because under New York State Law, minors are able to consent for HIV without parental notification and consent if they are able to demonstrate informed consent (9).

b. Enrollment

Patients will be enrolled from the above mentioned clinics, some of which are affiliated with The Columbia-Presbyterian Medical Center and others which are completely community based without any ties to a hospital all in Upper West Manhattan. The goal is to enroll 760 patients (380 in each type of counseling session) without attempts to equalize numbers of patients in the various demographic and risk groups. The sample size was determined using a chi-squared power analysis using estimates of the proportion of patients in each group to see the expected outcome. It is estimated that 70% of patients in the standard HIV Pre-Test counseling session group and 60% in the modified Pre-Test counseling session group will consent to have HIV testing. This expected 10% decrease in consent for HIV testing is likely conservative given earlier studies representing similar ethnic and racial population groups as will be expected in our study given the geographic localizations of the chosen clinics.

c. Randomization

If a patient is deemed eligible for the study, he or she will be randomized to either the standard HIV Pre-test counseling session or to a modified Pre-Test counseling session. The patient will be blinded to which type of Pre-Test counseling he or she will receive. The counselor, whether this be a physician,

nurse practitioner or social worker will be informed which type of Pre-Test counseling he or she is to provide the patient. The assignment of session type will be made by a third party who has not seen the patient and who is not involved in the patient-counselor session.

d. Study Design

The group receiving the standard HIV Pre-Test counseling shall hereafter be called "the control." For this group, an HIV Counselor (physician, nurse practitioner, social worker) will inform them about the new HIV Name Reporting and Partner/Contact Notification Program and the implications of these policies prior to asking for consent for HIV testing. The group receiving the modified HIV Pre-Test counseling shall hereafter be called "the intervention group." The patients in the intervention group will asked for HIV consent after receiving counseling in a manner conducted prior to June 2000. In other words, the intervention group will not be told about the new policies until after consent has already been requested. If a patient in the intervention group consents to IRV testing, then he or she will be informed about the new HIV Name Reporting and Partner/Contact Notification Program and their implications. The patients in the intervention group will then be asked for consent again after having been given information about the new policies. The responses of the patients in the intervention group before and after the disclosure of the new policies will be noted (yes before and after vs. yes before and no after).

Both groups will be asked to fill out an anonymous questionnaire without regard to group assignment and response for consent. All patients in control and intervention groups will be requested to complete the same questionnaire. Patients will be informed that their names will not be on the questionnaires, but their final responses for HIV consent will be written on the form along with their answers for the purposes of the study. The questionnaire will ask for numerous demographic and HIV risk factors. It will also ask if the patient was aware of the new HIV testing and reporting before coming to the pre-test counseling session and if so, where or from he or she was told. Finally, if the individual declines HIV testing, the form will leave space for that person to list the three main reasons why he or she declined in order of most to least importance, and whether the patient intends to go to anonymous testing center to get tested. For those individuals who consent to testing, they will need to complete the HIV Consent Form as is routinely done in addition to the study questionnaire. For those persons who do not wish to write out answers to the questions but would prefer to verbally respond to the questions, the Counselor will fill out the form for the patient, just transcribing the responses to the questions.

Finally, nearby anonymous testing centers will be monitored for trends in numbers of individuals getting tested during the study period. Zip codes matching those patients in the various clinics who participated in the study will be screened for at the anonymous testing centers.

e. Statistical Analysis

The proportion of patients who consented to HIV testing in the control and intervention group will be analyzed using the chi-squared test. These proportions will be further subdivided according to the various demographic and risk groups and compared again using the chi-squared test. The number of zip code matches in anonymous testing sites near study clinics and the trend when compared to testing refusal rates at the study clinics will be described using a Poisson loglinear model.

D. Study Procedures

There will no instrumentation, machines or devices used in this study. The duration of the entire study will be twelve months.

The duration of a patient's participation in the study will be one Pre-Test Counseling session lasting from thirty minutes to an hour.

If the patient consents to HIV testing, he or she will be requested by the counselor in the pretest counseling session to return for one or more follow up post-test counseling as deemed necessary for routine HIV counseling and care, but no longer as part of the study.

E. Study Drugs:

None

F. Medical Devices:

None

G. Study Questionnaire

The questionnaire will ask for age, gender, race, ethnicity, nationality, zip code only, IV drug use, unprotected sex with known or suspected HIV + individual, more than two lifetime sexual partners, sexual preference/orientation, prostitution, current or past STDs. It will also ask if the patient was aware of the new HIV testing and reporting before coming to the pre-test counseling session and if so, where or from whom he or she was told. If a patient declines HIV testing, the form will leave space for that person to list three main reasons why he or she declined in order of most to least importance, and whether the patient intends to go to an anonymous testing center to get tested.

H. Recruitment of Subjects

Patients will be recruited from the Ambulatory Network Center of The Columbia-Presbyterian Medical Center and other community ambulatory clinics or free-standing health services with the knowledge and assistance of their primary care physicians or health care providers. It will be the primary care providers at all sites who will identify which patients are eligible for the study based on the eligibility criteria outlined above. Those identifying the patients will not be the ones providing the counseling or assigning the counseling session type, however.

There is no specific informed consent form as this would defeat the blinding of the subjects. Completion of the questionnaire is voluntary though will be strongly encouraged.

I. Confidentiality:

All study data will be kept confidential.

J. Potential Conflict of Interest

None

K. Location

Study will be conducted at The Columbia-Presbyterian Medical Center Ambulatory Network Center and various community ambulatory clinic sites and free-standing health care centers. The study poses no risk at all to patients.

L. Potential Risks

None

M. Alternative Therapies

N/A

N. Compensation to Subjects

None

O. Costs to Subjects

Cost of HIV Pre-Test Counseling session, but not specifically related to the study. No extra cost added secondary to involvement in the study.

P. Minors as Research Subjects

Ages 15-17 year olds are included in this study because the adolescent population is one of the fastest growing HIV population groups in this nation currently. Since under New York Law minors are able to consent for HIV on their own if they are able to demonstrate informed consent, including this group is crucial in testing the impact of new public health policies that will potentially shape the HIV epidemic (9).

Q. Radiation or Radioactive Substances

None

R. Bibliography

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9. N.Y. Public Health Law 2780 (5) and 2781 (McKinney 1993)

ANONYMOUS QUESTIONNAIRE FOR INDIVIDUALS GETTING HIV TESTING

AGE: GENDER: M F RACE: ZIP CODE:

ETHNICITY: NATIONALITY:

IV DRUG USE PAST OR PRESENT: Y N

UNPROTECTED SEX WITH KNOWN/SUSPECTED HIV + PERSON: Y N

NUMBER OF LIFETIME SEXUAL PARTNERS:

PROSTITUTION: Y N

PAST OR CURRENT SEXUALLY TRANSMITTED DISEASES: Y N

SEXUAL PREFERENCE OR ORIENTATION:

AMOUNT YOU KNEW ABOUT HIV REPORTING BEFORE COMING HERE TODAY:

SOURCE OF INFORMATION REGARDING HIV REPORTING:

CONSENTING TO GET HIV TESTED TODAY:

IF NOT, LIST 3 MAIN REASONS WHY NOT (IN ORDER OF MOST TO LEAST IMPORTANT TO YOU):

IF NOT, ARE YOU GOING TO AN ANONYMOUS TESTING CENTER FOR HIV TESTING?Y N