

Frequent Hospitalization of HIV Patients in New York City: Is Female Gender a Risk Factor?

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A. Study Purpose and Rationale

With the advent of Highly Active Anti-Retroviral Therapy (HAART), HIV has shifted from an acute terminal illness to a treatable chronic disease. With this shift, hospitalization has become the most expensive and least effective way of altering the long-term course of the disease. However, for many disadvantaged patients, it remains an easily accessible and frequently used mode of care.

Epidemiologic studies show that after the introduction of HAART, hospitalization of patients with HIV declined precipitously, then began to level off. Further studies have delineated significant demographic differences and social disparities between those whose hospitalization rates continue to decline (notably white men), and those whose hospitalization rates remain the same and may even be increasing, by some estimates.

In addition to the clinical factors of CD4 count, viral load, and HAART, these variables include older age, non-white race, hepatitis C co-infection, substance abuse, mental illness, unstable housing, and lack of stable social support, which have all been associated with frequent hospitalization in multiple studies. Other potential risk factors, such as female gender and outpatient care, have showed more ambiguous association, with differing results in different settings.

The 2 main types of settings seen in the literature are either large, multi-state retrospective data analyses such as those undertaken periodically by the Agency for Healthcare Research and Quality, or local, institution-based studies that typically take place at urban teaching hospitals. Gender is a basic demographic characteristic addressed in almost all of these studies, but results have varied greatly. The most recent AHRQ Study published in 2005, analyzing multi-state data from 2000 to 2002, indicates that female gender, African American race, substance abuse, age > 50, and Medicaid/Medicare insurance status are all associated with higher rates of hospitalization. However, similar retrospective, high-powered studies from urban teaching hospitals have varied: A 2003 study from Rush in Chicago indicated that female gender did not play a role, a 2003 study from Johns Hopkins in Baltimore suggested that female gender is a risk factor, and a 2000 study from Harvard in Boston again showed no difference. Two New York studies in the late 1990's conducted by Cornell and Montefiore did not address gender specifically and were inconclusive. This suggests that in addition to variability between countries, states, and suburban vs rural areas (which have all been documented), even in urban teaching hospitals, the association of gender with frequent hospitalization is unclear and locally specific, perhaps based on differences in both the populations and services provided in those settings.

In response to the many disparities and risk factors that have been associated with poorly controlled HIV, significant government (as well as private) funding has been allocated to create programs that address the factors above, perhaps most notably the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which was initiated in 1991 and has been renewed several times. Title 1 provides emergency assistance to Eligible Metropolitan Areas (EMA's) most severely affected by the HIV/AIDS epidemic, and Title 2 provides funds to the state. This funding can be used by cities, states, public, or private entities, for numerous services, including outreach, testing, counseling, outpatient and inpatient medical services, health insurance and prescription coverage, dental care, mental health care, outpatient and inpatient case management, substance abuse counseling, treatment, and rehabilitation, housing, home care, meal support, transportation, and legal advocacy.

Of the 51 states that receive Ryan White funding, New York ranks #1 with 350 billion dollars, and New York City is the highest receiving EMA. In spite of this enormous allocation of resources, a significant number of patients continue to fall through the cracks and are seen most frequently in

hospitals, leading to high costs with and ineffective interventions. No comprehensive study looking specifically at gender as a risk factors for rehospitalization in the HAART era has been done using a population in New York City. Given the local variation evident in the literature, and New York's position as home to many of the most vulnerable, overlooked patients as well as distributor of some of the most marshaled resources, the association of female gender should be documented, in order to craft more effective interventions.

B. Study Procedure

This is a retrospective, case-control, longitudinal chart review of HIV+ patients admitted to CUMC, examining risk factors associated with frequent hospitalization, with the primary variable of gender and several secondary variable *as* listed above. The cohort of patients in this study will consist of all patients carrying the diagnosis of HIV by ICD-9 code, who were hospitalized with an HIV-related illness (as defined below) at Columbia University Hospital between the 3-year period of 1/1/2002 and 1/1/2005. This cohort will then be divided into 2 groups: Group 1 will be the patients with frequent hospitalization, defined as 3 or more inpatient stays of 24 hours duration or more at any hospital in New York City in the 365 days after the index hospitalization (which is not included in the number of hospitalizations). Group 2, the control group, will be the patients with infrequent hospitalizations, defined *as* zero hospitalizations in the 365 days after the index hospitalization. The Statewide Planning and Research Cooperative System (SPARCS) database of state-wide discharge data will be used to track hospitalizations, as frequently hospitalized patients often seek care at multiple institutions. The groups will be dichotomized, leaving out patients with 1-2 hospitalizations, to allow for clearer analysis, as hospitalizations likely do not have a normal distribution.

The proportion of patients with female gender will then be compared in each group to determine its association with frequent hospitalization. A chi-square test will be used to compare the proportions, and multiple logistic and linear regression analyses will be used to analyze the other predictive variables included in the data collection, including age, race/ethnicity, CD4 count, viral load, HAART use, substance abuse, unstable housing, co-morbidities (in particular Hepatitis C), mental illness, social support, insurance status, and outpatient follow-up.

In order to assess the power of the study, some preliminary numbers were gathered from the Webcis Data Warehouse. From 1/1/2002 to 1/1/2005, there were 2,456 hospitalizations associated with the ICD-9 code of HIV, of which 1,187 were unique patients. This reflects only hospitalizations at CUMC; since frequently hospitalized patients often obtain care at multiple sites, the total number of hospitalizations is likely even higher. Therefore 30% will be used *as a* conservative estimate of patients who meet the criteria for frequent hospitalization, which is in keeping with the literature. Of the 2,456 hospitalizations, 1076 (44%) were women, and 464 (39%) of the 1,187 unique patients were women. This in itself suggests that women may be hospitalized more, as the percentage of women with AIDS in New York during that time period was about 25%, per the Kaiser Family Foundation. A conservative estimate of women in the frequent hospitalization group would be 35%.

Using Webcis to estimate exclusion of new diagnoses, non-residents, non-HIV related admissions, and patients with cirrhosis leads to a rough estimate of 1,000 patients, of which 300 would be in the frequent hospitalization group and 105 (35%) would be female. Assuming that the control group with 0 hospitalizations after index is about 50%, we would be able to detect a 10% difference in that group at a power of 80% with p-value of 0.05. An effect of 10% (25% to 45% range) would certainly be clinically relevant, and as conservative estimates have been used, the power may be even higher.

C. Study Drugs

n/a

D. Medical Device

n/a

E. Study Questionnaires

n/a

F. Study Subjects

Inclusion Criteria:

1. Diagnosis of HIV by ICD-9 code
2. Hospitalization at Columbia between 2001 and 2005 for HIV-related illness, defined conceptually as any admitting diagnosis that is associated with HIV per IDSA guidelines. Operational definition: admitted to AIDS/TB service at CUMC.
3. Must have lived in New York City for 6 out of the last 12 months

Exclusion Diagnosis

1. Recent diagnosis of HIV (in the last 12 months)
2. Recent immigrant (has not lived in NY for 6 of the last 12 months)
3. Cirrhosis (b/c of frequent co-infection of HIV and Hep C)

HIV+ patients are often considered a vulnerable population because of the stigma associated with it. However, as this is a confidential, descriptive chart review of data already recorded, the study should not put the patients at any risk.

As charts will be selected from the Columbia University Medical Center database, it is expected that the cohort will include a significant number of minorities, particularly Dominicans and Puerto Ricans, as well as significant numbers of women. This is important, as both women and minorities make up a growing percentage of HIV cases.

G. Recruitment of Subjects

n/a

H. Confidentiality of Study Data

Each patient whose CUMC chart is accessed for the study will be assigned a unique code, for which the key will be stored in locked desk in the AIDS Outpatient Unit on Harkness-6, accessible only to the study investigators. However, when using the SPARCS database to assess number of hospitalizations, pt's names will need to be temporarily de-identified to link patient information from the 2 separate databases. The SPARCS database also has unique identifier allowing data within the system to be de-identified.

I. Potential Conflict of Interest

The investigator has no financial or other proprietary interest in the outcome of this study, so there is no conflict of interest.

J. Location of Study

Columbia University Medical Center, a private, urban teaching hospital in Upper Manhattan, New York City.

K. Potential Risks

Patients will have no risk in this study, as it uses data already collected that will not affect any future care, and because identifying information will be available only to the investigators.

L. Potential Benefits

The individual patients whose charts are used in this study will not immediately benefit, but the societal benefit of a better understanding of the risk factors of frequent rehospitalizations of HIV patients in New York City, and the subsequent implementation of programs to address those risk factors, will be of benefit to them and others with their illness in the future.

M. Alternative Therapies

n/a

N. Compensation to Subjects

n/a

O. Costs to Subjects

n/a

P. Minors as Research Subjects

n/a

Q. Radiation or Radioactive Substances

n/a

R. Selected Sources

1. Fleishman JA, Gebo KA, Reilly ED, Conviser R, Christopher Mathews W, Todd Korthuis P, Hellinger J, Rutstein R, Keiser P, Rubin H, Moore RD; HIV Research Network. Hospital and outpatient health services utilization among HIV-infected adults in care 2000-2002. *Med Care*. 2005 Sep;43(9 Suppl):11140-52.