



Adherence to HIV Medications in a Cohort of Men Who Have Sex With Men: Impact of September 11th

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ABSTRACT Adherence to highly active antiretroviral therapy (HAART) regimens remains a challenge for people living with human immunodeficiency virus (HIV). Severe traumas like that of September 11, 2001, can exacerbate the difficulties already associated with adherence. A community-based sample of 68 HIV-seropositive men who have sex with men (MSM) living in New York City who were on protease inhibitor HAART regimens completed quantitative assessments to examine adherence in the aftermath of September 11th. Data were drawn from a larger study of drug use and HIV medication adherence. Assessments conducted from September 24, 2001 to October 24, 2001 were compared to assessments taken 2–4 months prior to September 11th. Repeated measures analyses of variance were used to analyze the number of missed and suboptimal doses (doses taken outside the prescribed time by ± 4 hours) reported in the 2 weeks prior to each respective assessment. The results indicated a significant increase in the number of missed doses and the number of suboptimal doses immediately after the events of September 11th. Differences in adherence were not influenced, however, by sociodemographic characteristics. These results suggest that the events of September 11th had an impact on adherence to HIV medications among MSM in New York City and provide further support for the notion that the events of September 11th may have adversely impacted the lives of seropositive individuals. Attention should be paid by clinicians working with HIV-positive individuals on how this event has been incorporated into lives of individuals already burdened by a chronic and demanding disease.

KEYWORDS Adherence, Drug users, HIV, MSM, Terrorism.

INTRODUCTION

Highly active antiretroviral therapy (HAART) has become the standard of care in the treatment of human immunodeficiency virus (HIV) infection.^{1,2} Beneficial effects of HAART rely on strict adherence to complex regimens. Multiple studies have examined reasons for missing doses of medication and have found that the reasons stem from a combination of biopsychosocial factors.^{3–7}

In the most stable of times, adherence to HIV medication is difficult.⁶ As the effects of the traumatic events of September 11, 2001, are still being uncovered, it

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is clear that the lives of many people across the nation, especially in the New York City metropolitan area, were upset. Questions about how this event had an impact on the practice of medication adherence in HIV seropositive men who have sex with men (MSM) in New York City were examined.

METHODS

The data presented here were drawn from Project PILLs (Protease Inhibitor Longitudinal Life Study), which seeks to characterize the relationship between recreational drug use, as well as other cognitive, emotional, and contextual factors, and HIV medication adherence in a cohort of 300 MSM in New York City. The sample of 300 men was drawn from the community between 1999 and 2001 across all five boroughs using active targeted sampling recruitment methodologies.

Participants in the study were assessed at eight measurement points during the course of a 12-month period (baseline, 2 weeks, and 2, 4, 6, 8, 10, and 12 months postbaseline). Adherence behavior was measured with regard to the protease inhibitor in each participant's regimen using quantitative self-report measures where participants were asked to report the number of doses that they missed in the 2 weeks prior to assessment (i.e., "How many full doses of your protease inhibitor have you missed taking in the last 2 weeks?") as well as the number of "suboptimal" doses taken outside the appropriate schedule (i.e., "In the last 2 weeks, how many doses of your protease inhibitor have you taken outside the scheduled time?"). Our assessment focused on a 2-week period, which has been shown to be an appropriate period for recall of adherence behaviors.⁸ To assist participants in the recall of adherence during the past 2 weeks, we utilized Timeline Follow-back techniques,⁹ by which participants completed a personalized calendar of events that had happened during the past 2 weeks (e.g., birthdays, paydays, parties, vacations, etc). The Drug Abuse Screening Test (DAST-10) was utilized to classify participants as drug abusers, drug users, or non-drug users.¹⁰

For the purposes of our analyses, 68 participants were identified from the larger sample per the following criteria. Each participant was assessed for one of his follow-ups between the period of September 24 and October 24, 2001. These men were selected as we sought to characterize adherence behavior for a period immediately preceding and immediately following September 11th. In our sample, 36.8% ($n = 25$) were measured at months 2 and 4, 17.6% ($n = 12$) were measured at months 4 and 6, 11.8% ($n = 8$) were measured at months 6 and 8, 10.3% ($n = 7$) were measured at months 8 and 10, and 23.5% ($n = 16$) were measured at months 10 and 12. Since the participants varied with regard to the assessment point at which they were measured for these analyses, we conducted tests of the moderating effect of assessment period and detected no significance.

To ensure that these 68 men were not different in terms of their major socio-demographic characteristics, we compared this sample to the remaining 232 men and found no differences in terms of age, race/ethnicity, income, characteristics of recreational drug use, acquired immunodeficiency syndrome (AIDS) diagnosis, viral load, and protease inhibitor being monitored in the study.

RESULTS

The average age of the 68 participants was 42 years ($SD = 6.35$). On average, the participants had tested positive for HIV 12 years ($SD = 4.34$) prior to beginning the

study, and 62.7% ($n = 42$) had received an AIDS diagnosis. As per the criteria for inclusion in the study, all 68 men were being treated with HAART that included a protease inhibitor; participants were on an average of 3.1 (SD = 0.77) medications in their regimens. In terms of recreational drug use, 41.2% ($n = 28$) were non-drug users based on our assessment using the DAST-10, and 58.8% ($n = 40$) were classified as drug users or abusers. Table 1 provides further descriptive data for the sample.

Based on the assessment prior to September 11th, the participants reported an average of 2.67 missed doses of their protease inhibitors within a 14-day period (see Table 2). After September 11th, the mean number of doses missed was 5.07, demonstrating a significant decrease and subsequent decline in rate of adherence (from 90.5% to 81.9%). Furthermore, when we assessed doses taken outside the 4-hour scheduling window (i.e., suboptimal doses), participants reported significantly more suboptimal doses after September 11th compared to before September 11th (4.34 doses versus 2.34). When missed and suboptimal doses were combined into a single indicator of adherence, participants reported significantly worse rates of adherence post-September 11th. The analyses indicated no difference in these changes in adherence when controlling for race/ethnicity, income, educational level, sexual orientation, and level of drug use. Furthermore, no differences were noted across the two time points with regard to use of individual drugs, including alcohol.

CONCLUSIONS

Data from Project PILLS, a longitudinal investigation of HIV medication adherence behaviors among MSM, suggest that there are significant changes in adherence to medications after the events of September 11th. In our cohort of 68 men who were assessed pre- and post-September 11th, we detected significant increases in both the number of missed doses and suboptimal doses reported for the protease inhibitor in each participant's HAART regimen. When we considered the missed doses for the participants, adherence rates decreased from 90.5% for a 2-week period prior to September 11th to 81.9% for a period post-September 11th. Further, we noted no differences in drug use pre- and post-September 11th. This has also been noted in other investigations.¹¹ Preliminary results from our qualitative data suggest that the disaster of September 11th may have had an impact on drug use, but in the long term and not the short term, as we report here. These data also begin to suggest that there was no sharp increase immediately after, in part due to the difficulty in drug trafficking that ensued after the September 11th events.

These decreases of adherence have significant clinical implications. Poor adherence has been related to virologic failure and to the potential development of medication resistance.¹²⁻¹⁵ The importance of this potential problem is compounded by studies that indicate that viral mutations can confer cross resistance, so that if resistance is developed to one protease inhibitor, the individual may become resistant to other protease inhibitors,¹⁶⁻²³ to the medication, or class of medications being administered.

These analyses represent a small subset of MSM from a larger study of drug use and adherence; thus, these initial findings should be cast in light of the study framework. Further analyses from both quantitative and qualitative investigations are required to elucidate the potential mediators of the relationship between the events of September 11th and adherence. As such, our findings represent an initial

TABLE 1. Characteristics of study participants

	N	%
Race/ethnicity		
African American	30	44.1
Latino/Hispanic	11	16.2
White	22	32.4
Other	5	7.4
Sexual orientation		
Gay/homosexual	51	75.0
Bisexual	10	14.7
Straight/heterosexual	1	1.5
Other/unsure	6	8.8
Annual income		
<\$10,000	22	32.4
\$10,000–\$19,999	24	35.3
\$20,000–\$29,999	8	11.8
\$30,000–\$39,999	7	10.3
\$40,000–\$49,999	2	2.9
\$50,000+	5	7.4
Self-reported HIV viral load		
Undetectable	27	39.7
<500 copies/mL	7	10.3
500–5000 copies/mL	9	13.2
5001–10,000 copies/mL	6	8.8
10,001–49,999 copies/mL	9	13.2
50,000 copies/mL or more	3	4.4
Missing/Not sure	7	10.3
Current protease inhibitor in HAART		
Amprenavir (Agenerase)	4	5.9
Indinavir sulfate (Crixivan)	10	14.7
Lopinavir + Ritonavir (Kaletra)	15	22.1
Nelfinavir mesylate (Viracept)	23	33.8
Ritonavir (Norvir)	9	13.2
Saquinavir (Fortovase)	7	10.3
Date initiated treatment with HAART		
1995	11	16.2
1996	9	13.2
1997	17	25.0
1998	11	16.2
1999	2	2.9
2000	8	11.8
2001	2	2.9
Don't know	8	11.8

HAART

impression of the behavior change that followed those tragic events. Causal inferences, however, should be viewed with caution.

The events of September 11th have certainly been related to issues of mental health.^{24,25} For HIV-positive individuals who are already living with a lifelong health condition, like HIV disease, these events may have had more intricate effects in

TABLE 2. Impact of September 11th on adherence

	Prior to 9/11	After 9/11	F	df	P
Missed doses					
Mean (SD)	2.67 (5.27)	5.07 (11.06)	4.80	1, 66	.03
Rate of adherence	90.5%	81.9%			
Suboptimal doses					
Mean (SD)	2.34 (4.19)	4.34 (4.01)	10.10	1, 63	<.01
Combined missed or suboptimal doses					
Mean (SD)	4.91 (6.55)	9.50 (12.07)	12.34	1, 63	<.01

terms of issues of survival and life meaning. For clinicians working with the seropositive population, the events of September 11th and how these events may have had an impact on the HIV-related physical and mental health of their clients should be examined.

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