The HIV/AIDS Treatment Adherence, Health Outcomes and Cost Study: conceptual foundations and overview

HIV/AIDS TREATMENT ADHERENCE, HEALTH OUTCOMES AND COST STUDY GROUP

Abstract
A growing population of people living with HIV/AIDS have co-morbid psychiatric and substance abuse diagnoses, increasing the need for integrated services for persons with multiple diagnoses. This article reviews models of integrated services for multiply diagnosed persons living with HIV/AIDS. We focus on the HIV/AIDS Treatment Adherence, Health Outcomes and Cost Study to highlight the elements of multifaceted and integrated service delivery systems for people with HIV, substance abuse, and mental health disorders. Study organizational features and models of integrated services are discussed, including details of models for assessing mental health and substance abuse, outcomes, and the cost-effectiveness of integrated services.

Introduction
The AIDS epidemic continues to expand, with an estimated doubling time of 10 years and with AIDS surpassing tuberculosis and malaria as the leading infectious cause of death in the world (World Health Organization, 1998). At the end of the second decade of the US AIDS epidemic, over 700,000 cases of AIDS had been diagnosed in the USA and 1 in 250 people in the USA was infected with HIV (Centers for Disease Control and Prevention (CDC), 2000). Ethnic and gender disparities also continue to widen: rates of HIV infection and AIDS cases among African American, Latinos, and women have increased steadily, whereas HIV rates among whites have levelled (CDC, 2000).

Recognition of HIV infection affecting mental health and quality of life was evident in the earliest days of the AIDS epidemic (e.g. Coates et al., 1984). It has become clear that many HIV-infected persons have co-morbid psychiatric conditions, including substance abuse disorders. For example, in a prospective study conducted among persons at risk for HIV infection, Perry et al. (1990) found high rates of psychiatric conditions among HIV risk groups prior to receiving their HIV test results. Similarly, Treisman et al. (1998) reported that 44% of new HIV care intakes had a current substance abuse disorder and 30% had prior substance abuse disorders. People living with HIV/AIDS who also have mental health and addictive disorders are at high risk for multiple problems, including limited coping capacities and poor health outcomes. Co-morbidity of psychiatric conditions, substance abuse, and HIV infection can complicate the course of HIV-related illness by disrupting...
treatment and increasing the need for hospitalization (Uldall et al., 1998), therefore placing added burdens on health care resources.

Multiply disordered patients challenge health care services by raising several interactive and complex problems. For example, both psychiatric conditions and substance abuse can interfere with the medical management of HIV/AIDS, particularly by interrupting adherence to medication regimens. Likewise, the stress of living with a chronic and debilitating medical condition can exacerbate psychiatric symptoms and lead to substance abuse relapse. Despite the growing public health priorities posed by increasing numbers of multiply diagnosed people living with HIV infection, there is limited information about the health services accessed by people living with HIV/AIDS, mental illness, and substance use disorders.

To address these complex issues, the HIV/AIDS Treatment Adherence, Health Outcomes and Cost Study (hereinafter referred to as the HIV Cost Study) is the first federally funded multi-agency investigation of the cost-effectiveness of integrated interventions for HIV primary care, mental health, and substance abuse. The HIV Cost Study represents a collaboration of eight research sites, six federal entities, and a co-ordinating centre. The HIV Cost Study addresses two urgent public health needs: (1) the need for efficacy tests of integrated interventions that could be used by service providers with underserved clients infected with HIV who also have diagnosed mental health and substance use disorders; and (2) the need to establish the cost-effectiveness of integrated interventions that are associated with demonstrably improved health outcomes. In this article, we briefly overview integrated services for people living with HIV/AIDS, mental health, and substance abuse disorders. Next, we describe responses to integrated service needs, ultimately leading to the HIV Cost Study. Finally, we provide a brief overview of the HIV Cost Study, including its models of health service integration, organizational structure, and major entities, methods, and economic evaluation.

Emerging needs for integrated services

Integrated mental health and substance abuse treatment, as described by Minkoff (1989), emphasizes the correspondence between treatment models for mental illness and addiction. Minkoff (1989) stressed a parallel view of recovery, and concomitant treatment of mental illness and substance abuse, using treatment stages, and employing treatment strategies from both the mental health and drug treatment fields. During the last decade, integrated treatment has continued to evolve, and several integrated treatment models have been described (Drake et al., 1991, 1996; Zimberg, 1993). There is now a need to extend models of integrated treatment to HIV/AIDS populations with co-occurring mental illness and substance abuse disorders.

A number of changes in the HIV/AIDS epidemic have led to the emerging need for integrated services for the multiply diagnosed. HIV spread from injection drug users to a broader population of people with drug addictions, particularly networks of crack cocaine and methamphetamine users. Also, HIV was introduced into the sexual networks of people with serious mental illnesses. The overlap between these populations has resulted in a high prevalence of co-occurring substance abusing and psychiatrically diagnosed persons among people living with HIV/AIDS (Kessler et al., 1996; Krakow et al., 1997).

There was also an abrupt change in the nature of the medical management of HIV infection that occurred in the mid-1990s. During these years, HIV treatment was revolutionized by the use of combinations of new drug classes, particularly protease inhibitors in conjunction with nucleoside analogue reverse transcriptase inhibitors, which
were shown to improve the health status of large numbers of HIV-infected individuals. For many people living with HIV/AIDS, combination medications have been successful in producing sharp reductions in HIV concentrations (viral load) in peripheral blood, often to levels below detection. In addition, improvements in immune system functioning were shown by increasing numbers of CD4 (T-helper) cell counts (Deeks et al., 1997; McDonald & Kuritzkes, 1997). Anti-HIV combination therapies rapidly became the new standard of HIV medical care. With their demonstrated efficacy, these new medical treatment advances came to signify that many persons living with HIV could expect longer lives and better health, as opposed to imminent death. While combination drug therapies have improved the health outlook for many persons with HIV infection, they have placed further burdens on individual patients’ clinical care and service delivery systems for what has become an increasingly chronic condition.

The most effective treatments for HIV infection involve taking multiple drugs that demand strict adherence to complex medication regimens. The demand for HIV treatment adherence, where missing even one dose can compromise the success of therapy, far exceeds the need for adherence to treatments for other chronic illnesses (Deeks et al., 1997). Failure to closely adhere to anti-HIV medications also risks the rapid development of treatment resistance, potentially rendering entire classes of drugs ineffective (Rabkin & Chesney, 1999) and risking transmission of treatment-resistant strains of HIV (Cohen & Fauci, 1998; Hecht et al., 1998). Close adherence to long-term medication regimens is difficult for most persons, but especially challenging for those who have multiple stressors and limited resources, including people with mental health and substance use diagnoses (Bangsberg et al., 1997; Lyman, 1997). Thus, the growing population of people living with HIV/AIDS, mental health, and substance abuse disorders is particularly vulnerable to treatment non-adherence and increasingly unlikely to benefit from potentially effective medications.

There are two overlapping populations that were targeted by the HIV Cost Study. The first comprised HIV-infected individuals with substance abuse disorders and co-morbid mental illnesses. As has been well documented in the area of dual diagnosis, these persons have high rates of mood, anxiety, and post-traumatic stress disorders that complicate their substance abuse (Gala et al., 1993; Lipsitz et al., 1994; Regier et al., 1990). The second comprised seriously mentally ill adults, who have HIV infection rates 13–76 times greater than the general population (Carey et al., 1995), as well as high prevalence rates of substance abuse disorders (Rabkin, 1996). In general, co-morbid diagnoses are associated with earlier onset and a more chronic course of HIV infection. Social instability, unemployment, and loss of interpersonal relationships are common experiences for people with multiple diagnoses and can impede treatment. Moreover, co-morbid conditions have important economic consequences, such as necessitating multiple therapies, costs associated with increased disability, and burdens placed on clinical care and service delivery systems.

Responding to the need for integrated care approaches

Previous research has identified promising models for the provision of primary prevention interventions for persons at risk for HIV (e.g. National Institute of Mental Health, Multisite HIV Prevention Trial Group, 1998) and mental health services to low-income underserved HIV-positive individuals who also have mental and substance abuse disorders (Acuff et al., 1999). The need for studies of integrated treatment programmes has been driven by poor outcomes observed in multiply diagnosed clients within traditional sequential and parallel approaches to care, i.e. patients obtaining treatment in one system before entering into
another versus pursuing independent treatments in multiple service delivery systems. The failure of sequential and parallel approaches to care stems from barriers to accessing functionally separate care systems, with different eligibility criteria and different schedules for services. Consequently, functionally independent care approaches place the burden of co-ordinating unintegrated services on patients rather than on providers.

Comprehensive integrated approaches for mental health and substance abuse treatments for non-HIV-infected populations have shown promising results. Drake et al. (1996) found positive outcomes in a comprehensive review of studies that were designed to provide multiple interventions and support. Successful service models included motivational interventions, assertive outreach, intensive case management, individual counselling, and family interventions. Drake et al. (1996) concluded that comprehensive, integrated treatment, especially when delivered for 18 months or longer, demonstrated significant reductions in substance abuse, meaningful increases in remission rates, reductions in hospital use, and other improvements in health outcomes. These findings suggested the need to test models of integrated treatment for people living with HIV/AIDS, mental illness, and substance abuse disorders. It was out of this need that the HIV Cost Study was initiated (GFA No. SM 98-007, HIV/AIDS Treatment Adherence, Health Outcomes and Cost Study).

Central objectives and research questions of the HIV Cost Study

The HIV Cost Study represents an attempt to provide co-ordinated HIV, mental health, and substance abuse interventions through integrated treatment tailored for co-morbidity and accomplished through the use of multidisciplinary teams. While integrated treatment may be superior to non-integrated treatment for patients with co-occurring mental illness and substance abuse disorders, little is known about integrated treatment programmes for persons with these disorders who also are living with HIV infection. Since people living with HIV/AIDS and co-morbid conditions are at high risk for poor health outcomes (Kalichman, 1998), it is important to remove barriers that they face in accessing comprehensive HIV primary care, mental health, and substance use services.

The HIV Cost Study addresses several urgent public health issues, including: (1) the need to establish the feasibility and appropriateness of a diverse set of locally derived interventions designed to integrate and/or co-ordinate HIV/AIDS primary medical care, mental health, and substance abuse treatment services for triply diagnosed clients; (2) the need to demonstrate that such interventions are associated with improved health outcomes when compared to local care-as-usual conditions; and (3) the need to establish the cost-effectiveness of such interventions. As local service system conditions vary in both basic capacity and co-ordination, the eight funded sites of the HIV Cost Study proposed a variety of strategies for enhancing, co-ordinating, and integrating mental health and substance abuse services for HIV-infected populations. In each of the study sites the success of the new integrated intervention was compared against the outcomes achieved by a care-as-usual comparison condition. In most sites study participants were randomly assigned to either the comparison group or the new integrated intervention. It is a central premise of the HIV Cost Study that the findings should lead to a set of best practices for triply diagnosed clients that could be applied across a range of local service system conditions.
Organization of the HIV Cost Study

While the eight funded sites proposed a variety of service interventions reflecting the needs of their local communities, all sites participated in the joint development and implemented multisite battery. The first project year was devoted to planning the common multisite assessment protocol and establishing common standards for experimental design issues (i.e. randomization protocols and intent-to-treat strategies). The HIV Cost Study has multiple organizational levels composed of collaborating entities (i.e. eight individual research sites, six federal funding agencies, a consumer liaison, and a co-ordinating centre) and organizational structures (i.e. Steering Committee, working groups, consumer advisory boards, and field staff). The sections below briefly describe the major organizational entities of the HIV Cost Study.

Models of integrated HIV care services: the HIV Cost Study

Among the many possible models for integrating care services for people living with HIV infection, the HIV Cost Study sites adopted one or both of two major integration strategies: (1) **co-location** of mental health and substance abuse services with HIV/AIDS medical care; and (2) **interagency co-ordination** of care. Specifically, co-location of care can be defined as situating mental health and substance abuse services, and HIV treatment adherence interventions, in the same location. Alternatively, interagency co-ordination of care involves co-ordinating bodies or individual care co-ordinators who integrate services across physically separated primary care, mental health, and substance abuse service agencies. Table I summarizes the service integration and enhancement models adopted by the eight sites in the HIV Cost Study.

While the eight geographically diverse intervention sites of the HIV Cost study all have the common goal of increasing the co-ordination of services, they vary along two important parameters. The first source of variability relates to the existing service system capacity in the community at the start of the study. For communities where mental health and substance abuse services for people living with HIV infection were limited at baseline, intervention resources were utilized to establish such services. Such was the case in the NC and St Louis sites, where mental health and substance abuse treatment capacity for triply diagnosed individuals was minimal to non-existent at the start of the study. Capacity enhancement was also required in those sites where a new type of intervention was appended to an existing mental health and substance abuse treatment system. In New York and Boston, structured psychotherapeutic interventions for diagnostic subgroups of the HIV-infected population were tested. In a similar vein, the Philadelphia site tested a new model of aftercare for triply diagnosed clients completing residential treatment. In the three remaining sites (Seattle, Detroit, and Chicago), existing mental health and substance abuse services were adequate at baseline. These sites tested the efficacy of various models for co-ordinating and/or integrating mental health, substance abuse, and medical care service systems.

The second major source of variability among the eight intervention models was in their ability to address the needs of triply diagnosed clients at different stages of treatment readiness. At one end of the spectrum were models like those in Detroit and St Louis, where hard-to-reach clients were engaged through street outreach and retained in services through active care co-ordination by staff who ‘met the client where they were’. It is presumed that such models were essential to make mental health, substance services, and medical care accessible to clients who were tenuously connected to services.
<table>
<thead>
<tr>
<th>Study site</th>
<th>Integration strategy</th>
<th>Treatment setting</th>
<th>Target population</th>
<th>Integrated service model</th>
<th>Care-as-usual condition</th>
<th>Study design</th>
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<tbody>
<tr>
<td>Well-Being Institute, Detroit, MI</td>
<td>Nursing co-ordination of care across medical care, mental health, and substance abuse services</td>
<td>Urban nursing provider partnering with HIV/AIDS medical clinics, a community mental health centre, and a private substance abuse treatment programme</td>
<td>Multiply diagnosed women who are lost to follow-up at partner HIV/AIDS clinics</td>
<td>Intensive personalized nursing services, including transportation, case management to facilitate engagement in care, and nurse-to-nurse co-ordination of HIV/AIDS medical care, mental health, and substance abuse services</td>
<td>Referral to off-site mental health and substance abuse services by HIV/AIDS medical providers</td>
<td>Random assignment to intensive personalized nursing services or to care as usual</td>
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<tr>
<td>University of Missouri-St Louis, MO</td>
<td>Multidisciplinary mental health, substance abuse, and case management services co-ordinated with off-site HIV/AIDS medical care</td>
<td>Community-based integrated mental health, substance abuse, and case management services provider</td>
<td>Multiply diagnosed individuals recruited from Ryan White-funded case management providers and HIV/AIDS medical providers</td>
<td>Multidisciplinary treatment team providing mental health, substance abuse, and case management services, including street outreach; ongoing co-ordination with HIV/AIDS medical providers</td>
<td>Referral by Ryan White case manager or medical provider to mental health or substance abuse treatment, with limited availability to multiply diagnosed individuals</td>
<td>Random assignment to multidisciplinary treatment team or case as usual</td>
</tr>
<tr>
<td>Duke University, Durham, NC</td>
<td>Integrated mental health and substance abuse treatment services co-ordinated with off-site HIV/AIDS medical care</td>
<td>Two dual-diagnosis outpatient mental health and substance abuse providers linked to regionally dispersed HIV/AIDS clinics</td>
<td>Multiply diagnosed individuals from 15 rural counties recruited from HIV/AIDS clinics</td>
<td>12 months of outpatient mental health and substance abuse counselling in conjunction with rural case management co-ordination and transportation services to facilitate treatment adherence</td>
<td>Limited availability of mental health and substance abuse services without transportation assistance</td>
<td>Wait list comparison group</td>
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Table I. Description of the eight study sites of the HIV integrated treatment study.
<table>
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<tr>
<td>CORE Center, Cook County Bureau of Health Services, Chicago, IL</td>
<td>Multidisciplinary mental health, substance abuse, case management, and HIV/AIDS medical care provider teams</td>
<td>State-of-the-art urban HIV/AIDS clinic with co-located mental health, substance abuse, and case management services</td>
<td>Multiply diagnosed individuals receiving medical care at the CORE Center</td>
<td>Formation of integrated medical care, mental health, substance abuse, and case management treatment teams that feature collaborative cross-disciplinary diagnosis and treatment planning, service delivery, and care co-ordination</td>
<td>HIV/AIDS medical care with referral to on-site mental health, substance abuse, and case management services</td>
<td>Serial assignment to integrated care treatment team clinics or care-as-usual clinics, dependent on slot availability at time of admission</td>
</tr>
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<td>University of Washington, Seattle, WA</td>
<td>Individual and group adherence counselling co-ordinated with on-site HIV/AIDS medical care and on- or off-site mental health and substance abuse services</td>
<td>Multiservice agency based in an urban medical centre providing HIV/AIDS clinical care, case management, and limited mental health and substance abuse counselling to women and families</td>
<td>Multiply diagnosed women recruited from the multiservice agency</td>
<td>6-month individualized adherence counselling combined with 3-month group adherence counselling</td>
<td>HIV/AIDS clinical care and case management with referral to on- or off-site mental health and substance abuse treatment services</td>
<td>Random assignment to adherence counselling plus care as usual or to care as usual</td>
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<tr>
<td>Boston Medical Center, Boston, MA</td>
<td>Specialized mental health and substance abuse treatment services co-located with HIV/AIDS medical care</td>
<td>Urban medical centre-based HIV/AIDS clinical care with limited on-site mental health services</td>
<td>Multiply diagnosed individuals with trauma-related symptoms recruited from HIV/AIDS clinic care</td>
<td>Co-location of new manualized treatment with 3 months of relapse prevention therapy followed by, for participants who have achieved acceptable levels of sobriety, 3 months of cognitive processing therapy for trauma-related symptoms. Compliance enhancement therapy to facilitate treatment adherence provided during both phases</td>
<td>HIV/AIDS medical care with on-site psychiatric and counselling services with referral off-site for substance abuse treatment</td>
<td>Random assignment to two-phased intervention or care as usual</td>
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<tr>
<td>Montefiore Medical Center, New York</td>
<td>Specialized mental health and substance abuse treatment co-located with methadone maintenance and HIV/AIDS clinical care</td>
<td>Urban methadone maintenance clinics with on-site HIV/AIDS clinical care and limited on-site mental health services</td>
<td>Multiply diagnosed individuals in methadone maintenance treatment with borderline personality disorder (BPD) or at least three features of BPD and suicidality</td>
<td>12-month dialectical behaviour therapy (DBT) that focuses on maladaptive behaviours such as treatment non-adherence, substance abuse, and self-injury</td>
<td>Methadone maintenance with co-located HIV/AIDS clinical care and limited mental health and substance abuse counselling services</td>
<td>Random assignment to DBT plus care as usual or care as usual</td>
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<tr>
<td>National Development and Research Institutes/Gaudenzia, Philadelphia, PA</td>
<td>Individual and group aftercare counselling in therapeutic community model with co-ordination with off-site HIV/AIDS medical care and mental health and substance abuse services</td>
<td>Urban modified therapeutic community treatment programme serving multiply diagnosed individuals with HIV/AIDS</td>
<td>multiply diagnosed individuals who complete the residential treatment programme</td>
<td>6-month therapeutic community aftercare programme that sustains affiliation with the recovery community, provides mental health and substance abuse counselling, and monitors treatment adherence to HIV/AIDS medical care and off-site mental health and substance abuse service</td>
<td>Upon completion of residential treatment programme, referral to off-site mental health, substance abuse services with minimal follow-up</td>
<td>Upon completion of residential treatment programme, random assignment to 6-month aftercare programme or care as usual</td>
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</table>
Next along the spectrum were specialized HIV mental health and substance abuse services that were linked or co-located with HIV medical care sites. In these sites (NC, Chicago, and Seattle), triply diagnosed clients were identified in the medical care system. They were offered individualized mental health and substance abuse treatment services, including harm reduction approaches for clients who were not ready to enter abstinence-based treatment. Ongoing co-ordination between medical and psycho-social service providers, including case managers, was a central element of such models, where provider communication and collaboration played an essential role in client engagement and retention in services.

One step further along the spectrum were structured psychotherapeutic interventions that provided treatment strategies specific to disorders presumed to be common in the triply diagnosed population. Boston tested the feasibility of a combined substance abuse/trauma treatment for clients recruited from a HIV medical care setting with trauma-related symptoms. New York studied the feasibility of dialectical behaviour therapy in clients with borderline personality disorder or features recruited from methadone maintenance clinics that provided co-located HIV medical care. Participation in both of these interventions required relatively high levels of client motivation and treatment readiness for retention in ongoing services, a significant challenge to implementing these treatment models.

At the high end of the treatment readiness spectrum was the Philadelphia intervention, where triply diagnosed clients who had completed abstinence-based residential treatment were offered ongoing aftercare with continuation of the therapeutic community model and care management to maintain adherence to off-site medical, mental health, and substance abuse services. Thus, the eight study sites provided a range of care models, integration strategies, and services that resulted in a fair representation of HIV/AIDS service delivery systems in the USA.

Consumer advisory boards. The HIV Cost Study defined ‘consumers’ as individuals living with HIV infection who, at some point, had utilized mental health and substance use treatment services. This definition recognizes the cycles of active, symptomatic, and remission states that characterize HIV infection, mental illness, and substance abuse. Consumer representation from each of the HIV Cost Study sites and the presence of a consumer liaison on the study Steering Committee provided valuable feedback in policy considerations, study design planning, developing quality assurance procedures, determining participant eligibility, reducing respondent burden of assessment instruments, and developing strategies for recruitment and retention.

Each of the study sites nominated a consumer representative, who led a local consumer advisory board consisting of other consumers, defined the same as the consumer advisory board member, local AIDS service providers, and research staff. Local consumer representatives were responsible for keeping their own consumer advisory board informed about the study and provided local feedback to the Steering Committee. Information was shared on monthly, multisite conference calls facilitated by the consumer liaison to the Steering Committee—an HIV-positive licensed clinical social worker with previous experience in multisite research. The consumer liaison was responsible for presenting feedback to the Steering Committee and updating each of the consumer representatives about issues germane to the national study. This ‘trickle up/trickle down’ model of consumer representation is unique among federally funded multisite research projects and functioned well in the HIV Cost Study. Consumers remained involved in a continuous and active dialogue from the start of the project. In addition to monthly conference calls,
consumer representatives attended an annual Steering Committee meeting that focused on consumer concerns.

**Priority populations.** To meet the needs of a multisite evaluation, all of the individual study sites targeted patient populations that met four objective criteria: (1) having tested positive for HIV antibodies; (2) 16 years of age or older (children and adolescents under age 16 were excluded due to the inappropriateness of study measures and the widely different needs and services accessed by children and adolescents living with HIV/AIDS); (3) diagnosable mental health disorder of sufficient duration to meet psychiatric diagnostic criteria during the preceding 12 months; and (4) a substance abuse disorder in the past 12 months as also determined by a structured psychiatric interview. In addition to these four cross-site participation criteria, some individual study sites had additional eligibility criteria that were tailored to their specific settings (see Table I for site-specific eligibility criteria).

**Measurement instrumentation.** We selected instruments representing the state of the science in mental health measurement, particularly with attention to demonstrated reliability and validity in dually diagnosed mental health and substance abuse populations. Like any large assessment battery, measures were also chosen with consideration to their importance to the primary objectives of the multisite study, potential respondent burden, and their appropriateness to the study population. Consumer representatives provided feedback on the assessment process and assisted in the pilot testing of the assessment battery. Including consumer representatives at the early stages of study helped streamline the assessment battery and reduce its burden on participants. The study required diagnostic tools as well as outcome measures of mental health and substance abuse, and indicators of physical health, quality of life, adherence to medications and care, utilization of services, and engagement in high-risk behaviours. The complex nature of a multiply diagnosed population presented challenges to selecting optimal instrumentation.

Table II summarizes the instruments included in the HIV Cost Study core assessment battery, including a description of the instruments, the rationale for their inclusion, and points of administration. To determine psychiatric conditions in the patient population, we used the Structured Clinical Interview for DSM-IV (SCID-I and SCID-II), administering the following diagnostic modules: (1) psychotic screen; (2) mood disorders (major depression, bipolar, and dysthymia); (3) anxiety disorders (panic, generalized anxiety disorder, and agoraphobia); (4) adjustment disorders; and (5) antisocial and borderline personality disorders (First et al., 1996). Because its use was for descriptive purposes and because of its respondent burden, the SCID was only administered at the baseline assessment. To meet the need for a mental health outcome measure that would be sensitive to changes in symptom presentations, the Brief Psychiatric Rating Scale was administered across all assessment points (Lukoff et al., 1986). In addition, the Addiction Severity Index (ASI-Lite), using a 12-month symptom window (Kosten et al., 1983; McLellan et al., 1992) was included to test changes in substance use. Health status (e.g. CD4 cell counts and HIV viral load) was determined in clinical interviews with chart abstraction when possible and quality of life was assessed with the Short Form Health Survey (SF-36) (Ware et al., 1993). Risk behaviours (Kauth et al., 1991), HIV service utilization, adherence to services, and adherence to medications (Chesney et al., 2000) were also measured. In addition, a random subset of participants (10%) provided urine specimens for toxicology screening to assess the point prevalence of active substance use. The interviews were
Table II. Core assessment instruments included in the HIV integrated treatments study.

<table>
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<tr>
<th>Instrument</th>
<th>Description</th>
<th>Purpose</th>
<th>Assessment points</th>
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<tbody>
<tr>
<td>Structured Clinical Interview for DSM-IV (SCID)-I and SCID-II</td>
<td>Administered using computerized modules for psychotic screen, mood disorders, anxiety disorders, adjustment disorders, antisocial and borderline personality disorders, and Global Assessment of Functioning Scale</td>
<td>To provide reliable psychiatric diagnoses using objective criteria and psychiatric nomenclature</td>
<td>Baseline only</td>
</tr>
<tr>
<td>Brief Psychiatric Rating Scale</td>
<td>Trained interviewer ratings of 24 psychiatric symptoms presented in clinical interviews to yield scores for anxiety/depression, thought disorder, paranoia/suspiciousness, withdrawal, and motor activity</td>
<td>Outcome measure for psychiatric symptoms</td>
<td>Baseline and all follow-ups</td>
</tr>
<tr>
<td>Addiction Severity Index (ASI-Lite)</td>
<td>Semi-structured clinical and research interview assessment of functioning across multiple domains, with each domain creating composite scores that reflected severity of problems in each area</td>
<td>Outcome measure for alcohol and other drug use and other areas of psycho-social functioning</td>
<td>Baseline and all follow-ups</td>
</tr>
<tr>
<td>Short Form Health Survey (SF-36)</td>
<td>Health profile for 8 scales and indexes for health-related quality of life</td>
<td>Outcome measure for quality of life, used as the denominator in calculating quality-adjusted life</td>
<td>Baseline and all follow-ups</td>
</tr>
<tr>
<td>HIV treatment adherence</td>
<td>Interview for determining HIV medications regimen and missed doses for a 3-day recall period. Reasons for non-adherence and adherence to medical services are included. Measure was adapted from the adherence interview of the Adult AIDS Clinical Trials Group trials</td>
<td>Used as the HIV treatment adherence outcome measure</td>
<td>Baseline and all follow-ups</td>
</tr>
<tr>
<td>Health status</td>
<td>HIV-related symptoms and health markers, self-reported CD4 cell counts, and viral load and chart abstracted values when available</td>
<td>Outcome measure for physical health and immune functioning in cost-effectiveness ratios</td>
<td>Baseline and all follow-ups</td>
</tr>
<tr>
<td>High-risk sexual drug use behaviours</td>
<td>Self-reported risk acts assessed over 3-month time periods</td>
<td>Outcome measure for changes in sexual drug use behaviours associated with HIV transmission</td>
<td>Baseline and all follow-ups</td>
</tr>
<tr>
<td>Service Utilization Battery</td>
<td>Respondents were first asked screener questions to determine services received in past 3 months. For each class of service used, respondents detailed information on services and assessors’ contact providers to directly obtain further information</td>
<td>Provides units for calculating costs for services in the cost-effectiveness analyses</td>
<td>Baseline and all follow-ups</td>
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conducted over 2 days to reduce participation burden. Follow-up interviews were conducted every 3 months for 1 year.

Service utilization was measured through a battery of questions developed by an interdisciplinary, cross-site working group. The Service Utilization Battery was loosely based on previous studies of HIV-positive patients. Questions were modified and added in order to take the particular characteristics of the HIV Cost Study population into account. For example, mental health and substance abuse services were investigated in greater detail than in other studies, in recognition of the fact that all of the HIV Cost Study patients were triply diagnosed. The following types of services were asked about in the Service Utilization Battery: inpatient, nursing home and hospice facility, day hospital, residential treatment, emergency room, hospital outpatient, community clinic, doctor's office, mental health and substance abuse specialty services, self-help and support group, dental care, alternative and complementary medical, case management and social services, formal and informal home care, and services provided within jails, prisons, and homeless shelters. Information about the type and duration of prescription drugs and herbal supplements used was also elicited.

Utilization of intervention services was also measured through an intervention service record completed by the intervention providers at each service contact. Participants were asked to report on the use of all services, including but not limited to services received as part of the intervention. For individual meetings, the service record documented treatment encounters such as counselling sessions, crisis intervention, and case management. For group sessions the instrument also documented attendance. Adherence to services was also captured because the form tracked cancellations and no-shows as well. The forms were compiled to evaluate the dose of mental health, substance abuse, and case management services provided for each patient at each of the intervention sites. In addition to patient and provider reports, at some sites data on health status and utilization of services were enhanced through chart abstractions, Medicaid claims, and other administrative databases. The service utilization data were essential to the main outcome analyses, as well as the economic evaluation of the integrated services under study.

**Economic evaluation.** A major component of the HIV Cost Study was a prospective cost-effectiveness analysis. Cost-effectiveness analysis combines information on the costs and effectiveness of an intervention in order to determine its value relative to competing uses of societal resources. The cost-effectiveness ratio is the difference in average costs between the intervention and comparison (in this case, care-as-usual) patients, divided by the difference in average effectiveness. An intervention is considered cost-effective if the cost-effectiveness ratio is below some threshold, often estimated at US$40,000 per quality-adjusted life year.

In the HIV Cost Study, cost-effectiveness analyses were conducted from the perspective of a ‘social planner’, meaning that to the extent possible, all costs and benefits were included, regardless of to whom they accrued. For example, the social planner analysis included the opportunity costs of the time of informal caregivers that could have been spent on other productive activities. The primary effectiveness measure of the HIV Cost Study was quality-adjusted life years, which combined information on mortality and health-related quality of life into a single measure. Heath-related quality of life estimates were based on the SF-36, which was not designed to produce utility scores but is a well-established instrument for constructing non-preference-weighted health-related quality of life scores. Other health and treatment adherence outcomes were also used as secondary effectiveness measures. The measurement period for cost and effectiveness data was 1 year. Short follow-up periods tend to underestimate the true cost-effectiveness of interventions.
because the cost of providing intervention services is incurred early on, while health benefits may show up over a longer period of time.

Economic costs represent the value to society of the resources used to provide services. Our basic approach to measuring costs was to apply unit costs for each service to the number of units of the service received by the patient, and adding up across service types. Cost measures constructed as the weighted sum of utilization have the advantage that one can use a uniform set of unit costs for all sites and can plug in either national or site-specific unit costs, depending on whether one wants to know if the intervention is cost-effective on average or given the cost structure at a particular site. The intervention may either increase the use of non-intervention services (through referral) or decrease their use (through cost offset), so both intervention and non-intervention services were costed out. We relied on patient-reported utilization data for the cross-site analyses, since no other sources of data were available uniformly across sites. Patient-reported utilization data were validated using provider records or insurance claims at sites with access to these administrative databases.

Conclusions

HIV/AIDS is an epidemic closely connected to social disadvantage and poverty. Among those on the lower rungs of the social ladder, and therefore disproportionately affected by AIDS, are persons with serious and persistent mental illnesses and substance abuse disorders, many of whom have co-existing mental illnesses and substance abuse. With increasing numbers of newly HIV-infected persons with multiple diagnoses and with increasing availability of effective HIV treatments to all persons living with HIV, we can expect a growing population of people living with HIV/AIDS and co-morbid conditions. On a national scale, US service delivery systems have not yet accommodated to the complex needs of dually diagnosed patient populations, much less patients with HIV, mental illness, and substance abuse disorders. The HIV Cost Study represents one effort to better understand the effectiveness and costs providing integrated services for people with HIV and co-morbid conditions. The HIV Cost Study has shown that models of integrated services, characterized by co-location of services and/or co-ordination of services, are available for addressing the needs of multiply diagnosed patient populations. Future research is needed to examine how integrated services manage multiple diagnoses, each of which has its own cyclical pattern of symptoms and disease progression. Research is also needed to evaluate the capacity of service delivery systems for addressing newly identified needs of multiply diagnosed persons living with HIV/AIDS. The most successful integrated service models will anticipate changes in HIV/AIDS patient populations, emerging co-occurring conditions, and treatment advances. Only through such forward thinking and proactive policy will the needs of multiply diagnosed patients be met.

HIV/AIDS Treatment Adherence, Health Outcomes and Cost Study Group

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