Overcoming Policy and Financing Barriers to Integrated Buprenorphine and HIV Primary Care

Bruce R. Schackman,1 Joseph O. Merrill,2 Dennis McCarty,3 Jeffrey Levi,4 and Christine Lubinski5
1Department of Public Health, Weill Medical College of Cornell University, New York, New York; 2Department of Medicine and the Alcohol and Drug Abuse Institute, University of Washington, Seattle; 3Department of Public Health and Preventive Medicine, Oregon Health & Science University, Portland; 4Department of Health Policy, George Washington University, Washington, DC; and 5HIV Medicine Association, Alexandria, Virginia

Treatment for substance abuse and human immunodeficiency virus (HIV) infection historically have come from different providers, often in separate locations, and have been reimbursed through separate funding streams. We describe policy and financing challenges faced by health care providers seeking to integrate buprenorphine, a new treatment for opioid dependence, into HIV primary care. Regulatory challenges include licensing and training restrictions imposed by the Drug Addiction Treatment Act of 2000 and confidentiality regulations for alcohol and drug treatment records. Potential responses include the development of local training programs and electronic medical records. Addressing the complexity of funding sources for integrated care will require administrative support, up-front investments, and federal and state leadership. A policy and financing research agenda should address evidence gaps in the rationales for regulatory restrictions and should include cost-effectiveness studies that quantify the “value for money” of investments in integrated care to improve health outcomes for HIV-infected patients with opioid dependence.

There are many challenges faced by HIV care providers seeking to integrate opioid dependence treatment into primary care. Regular substance abuse monitoring is important to assess drug use, adverse effects of medication, and participation in psychosocial treatment and self-help groups, as well as for assessment of the mental health and addiction problems that might surface once drug use subsides. Substance abuse monitoring activities share some structural features with HIV primary care responsibilities, including monitoring of HIV disease, behavioral risk factors and medication adherence, and provision of prophylaxis and health care maintenance. However, treatment for substance abuse and treatment for HIV infection historically have been provided by different health care providers, often in separate locations, and have been reimbursed through separate funding streams. Provider training, record keeping, and reimbursement policies are frequently quite different for substance abuse and HIV care, even when reimbursement comes from the same payer.

HIV care providers have expressed an interest in integrating buprenorphine, a new treatment modality for opioid dependence, into primary care provided at HIV clinics [1]. In this article, we describe some of the policy and financing challenges faced by these providers. In particular, we examine licensing and training restrictions imposed by the Drug Addiction Treatment Act of 2000 (DATA 2000), federal confidentiality regulations for alcohol and drug treatment records (42 Code of Federal Regulations part 2), and the complexity of funding sources for integrated care. We also consider possible solutions to some of these challenges. Finally, we propose a policy and financing research agenda, including cost-effectiveness studies that could quantify the potential “value for money” of investments in integrated care to improve health outcomes for HIV-infected patients with opioid dependence.

FEDERAL REGULATIONS

Personal attitudes (e.g., stigma) and knowledge (e.g., lack of training) combine with policy (e.g., laws and regulations) to construct barriers that inhibit integra-
tion of primary medical care and treatment for substance abuse. Federal regulations regarding provider licensing and training and confidentiality of medical records play a particularly important role in maintaining these barriers.

**DATA 2000 licensing and training restrictions.** Since the passage of the Harrison Narcotic Act of 1914, formal and informal federal policy has prohibited physicians from using narcotics as maintenance medications and promoted a separation of drug dependence treatment services from primary care [2–4]. DATA 2000, however, amended the Controlled Substance Act and authorized qualified physicians to prescribe Schedule III, IV, and V medications for the treatment of drug dependence if the Food and Drug Administration has approved the medication for maintenance or detoxification treatment. DATA 2000 provides an unprecedented opportunity to integrate medical care and substance abuse treatment but also constrains the possibilities of integration.

Licensed physicians are qualified if they have specialty certification in addiction treatment or have completed an approved 8-h training course in treatment and management of opioid dependence (see [5] for specific details). Physicians must apply to the Substance Abuse and Mental Health Services Administration for a waiver from the Controlled Substances Act and receive a special identification number from the Drug Enforcement Administration. More than 3300 authorized physicians were listed on the Substance Abuse and Mental Health Services Administration’s physician locator in August 2005, although some of these physicians are not actively prescribing buprenorphine [6].

Additional DATA 2000 restrictions include the so-called “30-patient rule”—that is, any physician or group practice was restricted to the treatment of no more than 30 patients simultaneously. Thus, a solo practitioner and a 1000-physician practice were each allowed to treat only 30 patients, presenting a formidable obstacle for health plans and academic medical centers. Legislation recently modified the restriction, and each physician with a waiver is now permitted to treat 30 patients. Medical centers and health plans now have the potential to treat substantial numbers of opioid-dependent patients. Only physicians, however, and not mid-level practitioners, such as physician assistants and nurse practitioners, may prescribe buprenorphine. This limits the use of these mid-level practitioners.

**Fulfilling DATA 2000 physician training requirements.** The DATA 2000 physician training requirements are aimed at ensuring that physicians have a basic understanding of addiction and its pharmacologic treatment and that such training fits within existing continuing medical education expectations. Practitioners, however, must have the time and interest to complete the training and submit a waiver application. The historical separation of medical and substance abuse treatment has led to limited education and clinical experience in addiction medicine for most physicians in the United States.

Models for physician education are limited in this arena but are crucial for the implementation of buprenorphine and future pharmacotherapies being developed for opioid dependence treatment. The Seattle methadone medical maintenance treatment program is one example. In this program, generalist physicians were trained and supported to provide methadone maintenance treatment and primary medical care to stable patients receiving methadone maintenance treatment [7]. Training occurred in two 3-hour sessions, one of which included a visit to a methadone maintenance program. Participating physicians also had access to expert clinical support when questions arose in practice. Patients who transferred to the program were retained at high rates, addressed previously unmet medical needs, and showed some evidence of improved medical status. Physician satisfaction was high, and physicians developed more-positive attitudes toward methadone treatment. The Substance Abuse and Mental Health Services Administration is developing a national mentor network to support physicians who wish to provide buprenorphine, in an effort to overcome the historical lack of physician training in this area.

Oregon provides another model for physician training. The Office of Mental Health and Addiction Services collaborated with the American Society of Addiction Medicine and offered training for county teams. Local physicians, counselors from substance abuse treatment programs, pharmacists, and nurses collaborated on the development of a county plan for the treatment of opioid dependence and promoted formal linkages among prescribing physicians, pharmacists, and substance abuse treatment programs [8].

**Confidentiality of substance abuse treatment medical records.** Although DATA 2000 represents a substantive modification of federal policy, other regulatory restrictions enacted in the era of separate medical care and substance abuse treatment programs also complicate the integration of buprenorphine into HIV primary care. In particular, federal confidentiality regulations for alcohol and substance abuse treatment records (42 Code of Federal Regulations part 2) are stricter than the standards applied to medical records [9]. Medical providers wishing to implement opioid dependence treatment with buprenorphine must accommodate these confidentiality concerns. This means either keeping separate records for the substance abuse treatment components of care or identifying records concerning substance abuse treatment in such a way that they are released only under appropriate circumstances. For medical providers, these are artificial and constraining distinctions—a patient presenting with a symptom such as fatigue might require evaluation for both medical and substance abuse–related problems. Electronic medical record systems have the potential for enhancing clinical integration of medical and substance
abuse treatment records while maintaining compliance with confidentiality regulations.

**FINANCING**

HIV care in the United States is financed primarily through the public sector. This is true for people with HIV infection in general (only 31% have private health insurance) but is even more of a factor for injection drug users with HIV infection, of whom only 15% are estimated to have private health insurance. Most HIV-infected injection drug users are enrolled in Medicaid (49%) or Medicare (22%, including many who are also eligible for Medicaid). The remainder are uninsured and, thus, are likely to be relying on the Ryan White CARE Act program for their HIV-related medical services and/or publicly funded substance abuse treatment services [10]. The eligibility criteria and coverage of these public programs can pose challenges for ensuring coverage of HIV medical services and, particularly, substance abuse–related services.

**Medicaid.** Poverty alone does not ensure eligibility for Medicaid, the federal/state program of health insurance for the poor. Individuals with HIV infection usually become eligible for Medicaid when they become disabled, even though current clinical guidelines recommend intervention much earlier in disease progression. Addiction is no longer considered to be a disability for the purpose of disability payments and related Medicaid eligibility (as it was until 1996); Public Law 104-121 now denies Supplemental Security Income and Social Security Disability Insurance disability benefits and, by extension, access to Medicaid for persons disabled by alcoholism or drug addiction. Thus, an individual who is opioid dependent must have another qualifying status (e.g., having a mental health or HIV-related disability, being a pregnant woman, or being a single parent of dependent child) to receive Medicaid benefits for substance abuse treatment. A single opioid-dependent adult with HIV infection who is not disabled with AIDS is not eligible for Medicaid in most states.

As a federal/state partnership, the Medicaid program is administered by states on the basis of general parameters set by the federal government. This results in significant state-by-state variability in eligibility criteria and covered services, including prescription drugs and the scope of substance abuse benefits. Although every state Medicaid program in the country, with the exception of those in Kentucky and Louisiana, includes buprenorphine in its formulary, additional administrative barriers (beyond coverage) imposed by these programs can impede access to buprenorphine. At least 6 states—California, Delaware, Illinois, Minnesota, Washington, and Vermont—require prior authorization before reimbursing for buprenorphine. An example of another administrative barrier occurs in Washington State, where the Medicaid pharmacy benefit for buprenorphine requires that patients maintain enrollment in a state-certified chemical dependency program. Patients must find a physician qualified and willing to prescribe buprenorphine and must find a chemical dependency program willing to work with that physician to provide substance abuse treatment services. System rigidity makes integrated services difficult unless medical and substance abuse treatment services are already colocated. Requirements for Medicaid coverage of buprenorphine in Washington State also include regular urine drug testing and a limitation of the duration of buprenorphine pharmacy coverage to 6 months, with 1 additional 6-month extension available. Pharmacies must verify that urine drug testing has been performed, maintain specific paperwork documenting enrollment in chemical dependency services, and limit dispensing of buprenorphine to, at most, a 2-week supply. These stipulations are logistically burdensome and costly and inhibit the integration of care.

Many state Medicaid programs use managed care contracts to deliver health care, and these contractors can limit access to buprenorphine as they have previously limited access to methadone [11]. For instance, in Arizona and Oregon, buprenorphine is not included in the Medicaid managed care plan formulary. In addition, simple inclusion of buprenorphine as a covered drug does not ensure that a managed care plan will have physicians licensed to prescribe buprenorphine within its network or that counseling and case management services that are part of the standard of care for treatment with buprenorphine will be covered by the Medicaid program of that state.

**Medicare.** Medicare provides coverage for ~85,000 persons living with AIDS who are receiving care, and 55,000 of these persons are dually eligible for Medicare and Medicaid [12]. Most of these individuals are eligible for Medicare because they are disabled rather than elderly. Prescription drug coverage under Medicare did not begin until January 2006; individuals who are dually eligible for Medicare and Medicaid are required to enroll in Medicare drug plans, in which formularies can be restricted. Buprenorphine for the treatment of opioid dependence is not listed on the United States Pharmacopeia Model Guidelines for the Medicare prescription drug benefit [13]. Health plans have broad discretion in formulary development, and it seems unlikely that most plans will actually cover the drug.

**Ryan White CARE Act.** The CARE Act is the safety-net program for people living with HIV infection. Through grants to states, metropolitan areas highly affected by HIV infection, and community-based clinics, the CARE Act provides a variety of primary care, pharmaceutical, and support services. The principal means for supporting prescription drug coverage is through the AIDS Drug Assistance Program, with funding at $787 million in fiscal year 2005. Each state develops its eligibility criteria and formulary on the basis of demand and resources that also may include local and state funds. Eligibility criteria range from 125% to 500% of the federal poverty level; 3 states (Massachusetts, New Hampshire, and New Jersey) have open...
formularies, whereas some states have severely restricted formularies (covering only antiretroviral drugs and not even treatment or prophylaxis for opportunistic infections) [14]. No states with formularies currently list buprenorphine; the 3 states with open formularies could cover buprenorphine.

**Substance abuse prevention and treatment block grants.** The federal substance abuse block grant is the largest source of public funding for the treatment of alcoholism and drug abuse, funded at $1.77 billion in fiscal year 2005. States have broad discretion in the use of these funds. In a 2003 survey by the National Association of State Alcohol and Drug Abuse Directors, one-third of the respondents reported that their state planned to expend Substance Abuse Prevention and Treatment block grant funds or other funds controlled by the state substance abuse agency to cover the cost of buprenorphine for patients in the public substance abuse treatment system [15]. Approximately half of the states reported that they expected to expend federal block grant funds in support of counseling and case management services for clients treated with buprenorphine.

**Integrating funding streams.** The complex structure of public financing programs results in significant state-by-state variability in eligibility and covered benefits and also in gaps in coverage for people with HIV infection and addiction. The challenge for the individual clinic or provider in attempting to offer comprehensive HIV and substance abuse treatment services to a client is in melding these funding streams in a way that maximizes access. Buprenorphine treatment can be expensive, and efforts to incorporate buprenorphine into the treatment of HIV infection and substance abuse are occurring at a time when the CARE Act and block grants have been funded at virtually constant levels and states have made cuts in their Medicaid programs, particularly prescription drug coverage.

Although it can be argued that the use of buprenorphine will facilitate integration of HIV primary care and substance abuse treatment in a way that other interventions cannot, there are at least 4 financial and administrative barriers that the federal government must address to convince Medicaid programs, the AIDS Drug Assistance Program and other CARE Act programs, and HIV clinics to expand access to buprenorphine treatment:

1. Although a theoretical case can be made for buprenorphine resulting in long-term cost savings (because of the more efficacious use of antiretroviral medications, reduced HIV infection transmission, increased productivity of individuals, etc., that could result), additional targeted resources are required to assist providers in making the transition to providing integrated services (i.e., training and hiring of specialized personnel).
2. Although many HIV clinics have become creative in mixing and matching funding streams to maximize the services provided to clients, this approach comes at significant administrative cost, and some clinics do not have the staffing levels to manage these multiple funding streams.

3. Resource allocations within the CARE Act provide for relatively little funding of substance abuse services, and CARE Act providers have relatively little access to substance abuse block grant funds.
4. For those clinics that want to move forward with integration, there are few experienced models to follow. Before taking additional steps, many may be awaiting the outcomes of integrated care demonstration projects currently being undertaken at 10 sites funded by the Special Projects of National Significance program of the Health Resources and Services Administration [16].

There is little doubt that the services associated with comprehensive, integrated HIV and substance abuse treatment could be funded through a combination of funding streams. If integration of HIV and substance abuse services in the primary care setting is a policy priority, however, then federal and state leadership is required to address these barriers. The federal agencies that run these programs (the Centers for Medicare and Medicaid Services, Health Resources and Services Administration, and Substance Abuse and Mental Health Services Administration) must work with individual states to provide upfront investment resources that catalyze the adoption of an integrated strategy. They must also work collaboratively to remove barriers to integrating funding streams at the clinic level, require greater coverage of substance abuse treatment in the various titles of the CARE Act, and facilitate access to state block grant funds for HIV care providers. They can use the demonstration programs already in place to provide models of service delivery and to make the cost-effectiveness case for intervention.

**COST-EFFECTIVENESS ANALYSIS**

Cost-effectiveness analysis is a tool for evaluating how the net cost of a program, when offsetting savings on future spending are taken into account, compares with the expected benefits. It can provide a measure of the “value for money” of spending on integrated care compared with alternative programs. Conducting cost-effectiveness analyses is an important component of the research agenda for the economic evaluation of substance abuse services [17]. The goals of a cost-effectiveness analysis of integrated buprenorphine and HIV primary care should be to effectively evaluate whether investments in integrated care can deliver health benefits at a cost that is comparable to or lower than other interventions and to determine the sensitivity of these findings to the selection of alternative programs, perspectives, and time horizons.

**Cost-effectiveness study design.** The choice of alternative programs is important in assessing the policy relevance of any cost-effectiveness analysis. When evaluating the cost-effectiveness of integrated buprenorphine and HIV primary care, it is necessary to know what alternative programs are actually avail-
able in the community (e.g., nonintegrated care with buprenorphine, integrated substance abuse care without buprenorphine, and nonintegrated care with an alternative treatment modality, such as methadone) or whether none of these programs are available. Potential costs and benefits will differ depending on whether the integrated care program is a potential substitute for available services or is increasing capacity [18].

Cost-effectiveness analyses can be designed from the perspective of society as a whole, the federal government, or a particular payer, such as Medicaid [19]. A societal perspective would include the costs incurred by patients (such as medication copays, transportation to the clinic, and the opportunity cost of time spent receiving treatment) and societal benefits (such as reduced crime), but a health-care-payer perspective would not include these costs and benefits. The differences can be large. In a hypothetical scenario, the cost of buprenorphine treatment from a payer perspective was found to be similar to that of methadone in the first year (additional cost of buprenorphine, $250 to $753); in subsequent years, additional costs of buprenorphine were slightly lower ($518 to $158). When patient costs were included, however, buprenorphine was much less costly than methadone (first year, $2716 to $2107; subsequent years, $3110 to $3018) [18]. The choice of perspective also affects the time horizon of the analysis. For instance, Medicaid demonstration projects typically do not consider a time horizon beyond 5 years, which is a relatively short time frame in which to evaluate the costs and benefits of HIV treatment for patients with early-stage disease [20].

Previous cost-effectiveness studies of buprenorphine. Buprenorphine treatment has been the subject of a limited number of cost-effectiveness studies. Barnett et al. [21] applied a model that had previously been developed to assess the cost-effectiveness of methadone treatment. This model considers only the benefits of substance abuse treatment related to avoiding HIV transmission when injection drug use is the mode of transmission. The authors evaluated both scenarios in which buprenorphine was a substitute for methadone and scenarios in which methadone was not available. They accounted for all healthcare costs and used a 10-year time horizon. Their results indicate that buprenorphine has a cost-effectiveness ratio of <$50,000 per quality-adjusted life-year in most scenarios. This cost-effectiveness ratio is frequently used as a maximum threshold by policy analysts, although others have argued that a higher threshold is more appropriate [22].

Two cost-effectiveness analyses have been conducted in Australia alongside randomized controlled trials of buprenorphine versus methadone maintenance treatment. Doran and colleagues [23] conducted a study using data from a trial conducted in a population of opioid-dependent patients seeking treatment in 2 Australian cities [24]. The time horizon was only 6 months, and the perspective was that of the Australian service provider. Both the buprenorphine and methadone treatment populations were seen daily for the first 13 weeks, which means there was no opportunity to observe cost savings associated with potentially fewer visits by patients receiving buprenorphine during that period. The authors found a nonsignificant cost-effectiveness difference in favor of methadone treatment (i.e., methadone had a lower cost and resulted in more heroin-free days per month). Harris et al. [25] conducted a study of opioid-dependent patients currently receiving methadone treatment or seeking treatment. The time horizon was 12 months, and the perspective was societal. All patients were seen daily for the first 4 weeks, and then patients receiving buprenorphine treatment could receive daily, alternate-day, or 3-day dosing, whereas methadone take-home doses were limited to a maximum of 1 per week. Outcome differences between the buprenorphine and methadone treatment groups were not statistically significant, and cost-effectiveness results varied depending on outcome (heroin-free days or quality-adjusted life-years), inclusion of the cost of criminal activity, and whether the patient was receiving methadone treatment at baseline. Statistical analyses taking into account uncertainty in the parameter estimates indicated that the probability of one therapy being a better value for money than the other was close to 50%.

Finally, another study conducted alongside a clinical trial in Australia compared buprenorphine detoxification and treatment in specialist clinic versus primary care settings and followed patients for 90 days. Similar costs and outcomes were observed in both treatment groups, so there was little information on which to base a calculation of a valid cost-effectiveness ratio [26]. All 3 of the studies conducted alongside clinical trials are limited by their short time horizon and the pattern of visits required by the clinical trial protocols. Moreover, the treatment options evaluated in these studies reflect clinical practice in urban Australia, where specialist substance abuse treatment is more available than it is in many parts of the United States.

Framework for future cost-effectiveness studies. No studies to date have examined the cost-effectiveness of buprenorphine treatment for HIV-infected patients with opioid dependency. Data collected for cost-effectiveness analyses of integrated buprenorphine and HIV primary care will need to include a wide range of cost categories (see the Appendix). Medication costs include not only the funds expended to acquire the drugs but also the dispensing costs, which may be substantially higher for a patient receiving medication on site at a methadone clinic than for a patient filling a buprenorphine prescription at a pharmacy [18]. As has been noted previously, costs incurred as a result of regulatory requirements that will vary by setting include the frequency of toxicology screens, counseling sessions, and pharmacy prescription refills. HIV-specific medical care costs need to be carefully considered, because there may be increased utilization of HIV medical services as patients who
have addressed their opioid dependence become more engaged in HIV care and are more likely to continue to receive anti-retroviral therapy. Finally, none of the cost-effectiveness studies of buprenorphine treatment to date appear to have explicitly accounted for potential effects on hospital admissions (related to detoxification, other substance abuse-related issues, or HIV disease) or differences in rates of incarceration. Savings associated with potential beneficial effects of buprenorphine treatment on these outcomes could offset some of the increased drug and medical service utilization costs that might be expected.

Nevertheless, there should not be an expectation that integrated care programs will save money when the net financial impact is calculated. Very few interventions in modern medicine are cost saving, and effective substance abuse treatment increases the ability of patients to take advantage of other publicly available services to further improve their health and the quality of their lives. Therefore, it will also be important to identify the benefits of integrated care that represent the value of this investment. Many cost-effectiveness analyses of health care interventions use a standardized outcome measure, such as quality-adjusted life-years, to facilitate comparisons between interventions to treat or prevent different diseases in different populations. To estimate quality-adjusted life-years, several intermediate outcomes should be measured, such as clinical progression, duration of substance abuse, incidence of chronic and acute illnesses, and self-reported health (see the Appendix). These intermediate outcomes can themselves be measures of effectiveness in a cost-effectiveness analysis, if the objective is to compare alternative investments to treat the same population. In addition, outcomes should be measured that yield benefits to others outside of the population being treated; these benefits include changes in criminal behavior and changes in risk behavior for HIV transmission. This may require utilization of techniques of cost-benefit analysis that assign monetary benefits to some of these outcomes [27].

CONCLUSION

Overcoming policy and financing barriers to integrated buprenorphine and HIV primary care will require creative local solutions, additional administrative and financial resources, and federal leadership. It will also require policy-oriented research findings to support these innovations. A policy research agenda for integrating buprenorphine into HIV primary care needs to address evidence gaps in the rationales that support some existing regulatory restrictions. In particular, restrictions that increase the clinical costs associated with providing buprenorphine need to be addressed. For instance, the prohibition of the prescription of buprenorphine by appropriately trained mid-level practitioners, such as physician assistants and nurse practitioners, should be examined by evaluating demonstration projects in which these practitioners provide care under supervision. Similarly, patient-monitoring requirements should be tested in controlled studies that compare different monitoring frequencies and/or organizational approaches to the monitoring of patients by use of case managers, nurses, and pharmacists. In other cases, policy research should evaluate potential solutions to problems created by regulatory restrictions. For instance, research can evaluate the implementation of electronic medical record systems that restrict access to confidential medical records while allowing necessary clinical interfaces between substance abuse treatment and primary care providers.

At the system level, demonstration projects can provide evidence that merging local funding streams is a feasible way to provide buprenorphine as part of a core set of HIV primary care medical services. Another important part of the policy research agenda is cost-effectiveness studies of integrated buprenorphine and HIV primary care that quantify the “value for money” of investments in integrated care. Although DATA 2000 did not eliminate all barriers to the integration of services, it represents a substantive modification of federal policy and creates opportunities for practitioners, researchers, and policy makers to work together to promote more integration of care that will improve health outcomes for HIV-infected patients with opioid dependence.

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APPENDIX

DATA REQUIRED FOR COST-EFFECTIVENESS ANALYSES OF INTEGRATED BUPRENORPHINE AND HIV PRIMARY CARE

Startup

- Costs:
  1. Recruitment
  2. Training
  3. Materials and equipment
  4. Storage facilities

Outpatient care

- Costs:
  1. HIV infection and substance abuse medications
  2. Medication dispensing
3. Urine toxicology screens
4. Clinical staff time costs, calculated on the basis of (1) the number of staff members by profession and duties, work hours, and patient load and (2) the number and type of encounters, by staff member, for participants
5. Administrative time costs related to patient care (scheduling appointments, record keeping)
6. Cost of care provided at other sites (substance abuse, psychiatric referrals, medical referrals)

- Outcomes observed (effectiveness):
  1. HIV clinical outcomes (HIV RNA level, CD4 lymphocyte count, opportunistic infections)
  2. Urine toxicology test results
  3. Psychiatric evaluations

Inpatient care/incarceration
- Costs:
  1. Number of nights in the hospital, by type of hospitalization (psychiatric [detoxification/other], medical)
  2. Number of days incarcerated
- Outcomes observed (effectiveness):
  1. Episodes of acute illness
  2. Criminal behavior

Other medical
- Costs:
  1. Ongoing training
  2. Staff turnover
  3. Space and administrative overhead
- Patient costs (societal perspective):
  1. Time spent receiving treatment
  2. Time spent waiting at clinic
  3. Time spent traveling to clinic
  4. Cost of transportation to clinic
- Patient-reported outcomes (effectiveness):
  1. Medication adherence
  2. Quality of life
  3. HIV risk behavior

References