Updates of Lifetime Costs of Care and Quality-of-Life Estimates for HIV-Infected Persons in the United States: Late Versus Early Diagnosis and Entry Into Care

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Background: Lifetime costs of care and quality-of-life estimates for HIV-infected persons depend on the disease stage at which these persons are diagnosed, enter care, and start antiretroviral therapy. Updated estimates were used to analyze the effects of late versus early diagnosis/entry on US lifetime care costs, quality-of-life estimates, and HIV transmissions.

Methods: The Progression and Transmission of HIV/AIDS model was used to estimate discounted (3%) lifetime treatment costs ($US 2011) and quality-of-life variables from time of infection for cohorts of 10,000 HIV-infected index patients in 4 categories of CD4 count at diagnosis: (I) 200 cells/μL, (II) 201–350 cells/μL, (III) 351–500 cells/μL, and (IV) 501–900 cells/μL. It is assumed that index patient diagnoses were uniformly distributed across the CD4 count range in each category and that patients entered care at the time of diagnosis, remained in care, and were eligible to initiate antiretroviral therapy at a CD4 count of 500 cells/μL. Lifetime transmissions of the index patients were also estimated.

Results: Discounted average lifetime costs varied from $253,000 for category I index patients to $402,000 for category IV patients. Discounted quality-adjusted life years lost decreased from 7.95 to 4.45 across these categories, additional years of life expectancy increased from 30.8 to 38.1, and lifetime transmissions decreased from 1.40 to 0.72.

Conclusions: Early diagnosis and treatment of HIV infection increases lifetime costs but improves length and quality of life and reduces the number of new infections transmitted by nearly 50%.

INTRODUCTION

The lifetime costs of care for HIV-infected persons are an important measure of the economic burden of the epidemic in the United States. Researchers use these estimates in economic evaluations of HIV prevention interventions to compare the cost of an intervention with the treatment costs saved from infections averted by the intervention. Lifetime costs have been estimated by incorporating different categories of treatment costs, extracted from hospital and clinic records of persons living with HIV, into simulations of HIV disease progression.

HIV lifetime costs of care depend on the disease stage at which HIV-infected persons are diagnosed, enter care, and start antiretroviral therapy (ART), and the extent to which they adhere to therapy and are retained in care. Early initiation (ie, at a higher CD4 count) of care and treatment confers benefits to the health of infected persons and significantly reduces the risk of onward transmission. Thus, HIV costs of care are linked with corresponding quality-of-life estimates for HIV-infected persons.

Using a disease progression model, we updated estimates of lifetime costs of care for HIV-infected persons in the United States with recent health care utilization and ART costs, and we analyzed the effects of timing of diagnosis, entry into care, and ART initiation on these costs and associated quality-of-life variables from the time of infection.

METHODS

Model

We used a model developed by the Division of HIV/AIDS Prevention in the US Centers for Disease Control and Prevention, the Progression and Transmission of HIV/AIDS (PATH) model, to estimate lifetime costs of care, quality-adjusted life years (QALYs), additional years of life expectancy, duration on ART regimens, and years until onset of AIDS for a cohort of 10,000 HIV-infected index patients under different scenarios for diagnosis and entry into care.
We estimated lifetime costs and all quality-of-life variables from the time of HIV infection to death, assuming all persons were infected at an average age of 35 years. We also estimated lifetime transmissions of the index patients. We present a summary of key input parameters in Table 1 and a complete list of parameter values in the Supplemental Digital Content (see http://links.lww.com/QAI/A428).

The PATH model is a Monte Carlo health-state transition simulation of HIV-infected persons (index patients) and the partners they infect, in which both the index patients and the infected partners are individually tracked from time of infection to death. The model generates events such as testing for HIV infection, initiation of treatment, and change of ART regimen. The model updates HIV-specific parameters, including CD4+ T-lymphocyte count (CD4 count), plasma HIV RNA viral load (viral load), opportunistic infection (OI) incidence, onset of AIDS, and HIV transmission to sexual or needle-sharing partners every calendar quarter year based on disease stage and treatment status. The model also estimates costs incurred during the quarter (eg, HIV diagnosis, treatment, health care utilization) and assigns QALY estimates based on the CD4 count during the quarter. Costs were estimated from the provider perspective.

Assuming the CD4 count at infection was between 750 and 900 cells/µL, we simulated 10,000 index patients in each of the following categories of CD4 count at diagnosis: (I) 200 cells/µL, (II) 201–350 cells/µL, (III) 351–500 cells/µL, and (IV) 501–900 cells/µL. We assumed that index patient diagnoses were uniformly distributed across the CD4 count range in each of these categories and that these patients all entered care at the time of diagnosis. We defined the first 2 categories (I and II) as late diagnosis/entry into care and the latter 2 (III and IV) as early diagnosis/entry. Treatment with ART was initiated when the index patient’s CD4 count was at or below the eligibility criteria for initiation of treatment, for which guideline recommendations at the time we performed this analysis were strongest for a CD4 count of 500 cells/µL. Thus, we assumed that an index patient who was diagnosed and entered care at a CD4 count more than 500 cells/µL would not begin ART until his/her CD4 count decreased to 500 cells/µL. We also assumed that all index patients remained in care continuously once they were diagnosed and entered care. Our results, therefore, reflect optimal care for HIV-infected persons.

In the simulation, we applied HIV-related costs derived from Gebo et al supplemented with data from Schackman et al, all updated to SUS 2011 (Table 2). We applied the costs of medications for conditions not directly related to treatment of HIV from the start of infection to death and the costs of OI prophylaxis, and inpatient, outpatient, and emergency department utilization from the time of diagnosis to death. We also included the costs of CD4 count ($45) and viral load testing ($107) each quarter and HIV genotype testing ($452) at initiation of the first ART regimen and with every regimen change thereafter.

Based on current guidelines and expert opinion, we assumed that HIV-infected patients in the model were treated with up to 3 ART regimens (Table 1) followed by salvage therapy after failure of the last ART regimen. We simulated time in each regimen using rates that collectively represented regimen changes resulting from treatment failure, toxicity, and tolerability issues. We derived drug cost estimates for the initial 3 regimens from Gebo et al and those for salvage

<table>
<thead>
<tr>
<th>Variable</th>
<th>Values</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natural disease progression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 cell count when infected (cells/µL)</td>
<td>750–900*</td>
<td>22</td>
</tr>
<tr>
<td>HIV viral load set point (log_{10} copies/mL)</td>
<td>4.0–5.0*</td>
<td>39,40</td>
</tr>
<tr>
<td>Cumulative quarterly probability of developing an opportunistic infection (%)</td>
<td>0.3–35.3†</td>
<td>41,42</td>
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<tr>
<td>ART regimens</td>
<td></td>
<td></td>
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<tr>
<td>CD4 counts for ART initiation eligibility (cells/µL)</td>
<td>500</td>
<td>18</td>
</tr>
<tr>
<td>Suppressed HIV viral load level (log_{10} copies/mL)</td>
<td>1.0–2.7*</td>
<td>43</td>
</tr>
<tr>
<td>Rebound HIV viral load level (log_{10} copies/mL)</td>
<td>3.1–4.5*</td>
<td>44</td>
</tr>
<tr>
<td>Maximum number of ART regimens</td>
<td>3</td>
<td>†</td>
</tr>
<tr>
<td>Probability of initial virologic suppression in ART regimens 1–3</td>
<td>0.77–0.84§</td>
<td>45,46</td>
</tr>
<tr>
<td>ART regimen costs per person per quarter (SUS 2011)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I. EFV/TDF/FTC</td>
<td>3597</td>
<td>10</td>
</tr>
<tr>
<td>II. ATV/r + ABC/3TC</td>
<td>5006</td>
<td>10</td>
</tr>
<tr>
<td>III. RAL + TDF/FTC</td>
<td>4819</td>
<td>10</td>
</tr>
<tr>
<td>Salvage therapy</td>
<td>7628</td>
<td>11</td>
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<tr>
<td>Opportunistic infection treatment costs per episode (SUS 2011)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumocystis pneumonia (PCP)</td>
<td>9319</td>
<td>N</td>
</tr>
<tr>
<td>Mycobacterium avium complex</td>
<td>3721</td>
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<td>Toxoplasmosis</td>
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<td>Cytomegalovirus</td>
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<tr>
<td>Fungal infection</td>
<td>6341</td>
<td>N</td>
</tr>
<tr>
<td>Other</td>
<td>4247</td>
<td>N</td>
</tr>
<tr>
<td>Annual rates of sexual transmission (no. events per year per person)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>0.733</td>
<td></td>
</tr>
<tr>
<td>Nonacute unaware</td>
<td>0.091</td>
<td></td>
</tr>
<tr>
<td>Nonacute aware, not on ART/on ART, viral load not suppressed</td>
<td>0.039</td>
<td></td>
</tr>
<tr>
<td>Nonacute aware, on ART, viral load suppressed</td>
<td>0.004</td>
<td></td>
</tr>
<tr>
<td>Other variables</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at infection (yr)</td>
<td>30–40*</td>
<td>21</td>
</tr>
<tr>
<td>Discount rate for costs and QALYs</td>
<td>3%</td>
<td>24</td>
</tr>
<tr>
<td>Utility weights to estimate QALYs</td>
<td>0.935–0.702‡</td>
<td>25</td>
</tr>
</tbody>
</table>

*We assigned truncated normal distributions based on the ranges of these variables to reflect individual variability in disease progression.
†The lower and upper bounds reflect probabilities for CD4 counts of >500 cells/µL and 0–50 cells/µL, respectively.
‡Expert opinion.
§Probabilities vary by CD4 count at antiretroviral therapy initiation.
||We derived a quarterly probability of HIV transmission per infected person from the annual transmission rates, and we assumed that the acute phase of infection lasted one quarter.
¶We applied the utility weights from Tengs and Lin as follows: 0.935, asymptomatic, for CD4 count >350 cells/µL; 0.818, symptomatic, for CD4 count ≥200, <350 cells/µL; 0.702, AIDS, for CD4 count <200 cells/µL or for presence of an opportunistic infection. ABC/3TC, abacavir/lamivudine; ATV/r, atazanavir/ritonavir; EFV/TDF/FTC, efavirenz/emtricitabine/tenofovir; RAL, raltegravir.
therapy from Schackman et al. Costs of treating an OI, derived from Schackman et al, were applied during any quarter the model predicted an occurrence. HIV testing costs, derived from the program cost per positive test in an emergency department scenario ($2573), were applied at the time of diagnosis. We estimated both undiscounted costs and lifetime costs discounted at 3% to the time of infection.

The PATH model also tracked years until onset of AIDS, additional life expectancy, duration on ART regimens, and QALYs lost to infection for each index patient. We estimated QALYs lost by subtracting the sum of health utilities assigned every quarter of infection from the life expectancy of an uninfected person, assuming a utility value of 1 when not infected. Utility values for HIV infection were based on the index patient’s CD4 count and OI occurrence, as adapted from Tengs and Lin.

We estimated quarterly transmission probabilities on the basis of a model first developed by Pinkerton, updated by Prabhu et al, and then applied to HIV screening. We derived transmission probabilities for patients acutely infected and unaware of their infection, for patients nonacutely infected and unaware, for patients nonacutely infected who were aware and were not taking an ART regimen, and for patients taking an ART regimen whose viral load was not suppressed or who had a suppressed viral load. We used separate rates for sexual and injection drug use (IDU) transmission, and we assumed that 12.9% of the index patients would transmit through IDU. We evaluated secondary transmissions for a single generation of transmissions, that is, transmission of HIV from index patients to their partners.

To reflect individual variability in disease progression, we assigned truncated normal distributions based on ranges in the literature to input variables, which included age at infection, CD4 count at infection, viral load set point, and the viral load values associated with the acute phase of infection, suppression while taking ART, rebound when ART failed, and salvage therapy, and finally the rate of decline in CD4 count in specific viral load strata and health care utilization costs (inpatient, outpatient, emergency department, therapy from Schackman et al. Costs of treating an OI, derived from Schackman et al, were applied during any quarter the model predicted an occurrence. HIV testing costs, derived from the program cost per positive test in an emergency department scenario ($2573), were applied at the time of diagnosis. We estimated both undiscounted costs and lifetime costs discounted at 3% to the time of infection.

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For costs based on AMP – /C211 – increased discounts (all adjusted to $US 2011) for AMPs – # www.jaids.com

Sensitivity Analysis: Assume ART Initiation Eligibility Criteria Set at CD4 Count of 500 Cells/µL (Costs in $US 2011)

Diagnosis to early diagnosis/entry categories: 30.8 (category I) to 38.1 (category IV) years of added life expectancy and 9.4 (category I) to 19.5 (category IV) years until onset of AIDS. The average duration for ART increased from 18.9 years in category I to 32.3 years in category IV. Lifetimes, which were significantly different for index patients in each category, decreased from the late diagnosis to the early diagnosis/entry categories (1.40 in category I to 0.72 in category IV).

**Sensitivity Analysis**

Results of the sensitivity analysis (Table 4) showed that reversing base case ART regimens I and III under current ART eligibility guidelines increased discounted drug regimen costs by 14%–21% and discounted lifetime costs by 9%–14% in the 4 diagnosis/entry categories. Substituting ART regimen costs based on AWPs for costs based on AMPs increased discounted drug regimen costs by 62%–141% and discounted lifetime costs by 39%–46% in the 4 diagnosis/entry categories

**DISCUSSION**

Our updated estimates of lifetime HIV treatment costs and quality-of-life variables for the United States showed a consistent pattern that HIV-infected patients who are diagnosed and entered care at an early stage of disease and who remain in care incur greater lifetime costs but experience substantial clinical benefits and reduce the number of new infections transmitted. Patients diagnosed and entering care at a CD4 count of 500 cells/µL or above incurred discounted lifetime costs of $402,000 compared with $253,000 for patients who were diagnosed and entered care at a CD4 count of 200 cells/µL.

Although the lifetime costs of early diagnosis and care exceeded the costs associated with late diagnosis and care by almost 60%, persons starting care earliest lost 44% fewer discounted QALYs to illness, experienced a 24% longer additional life expectancy, gained double the years on average until the onset of AIDS, and transmitted almost 50% fewer new infections. Persons diagnosed early were taking an ART regimen an average 13 years longer than those diagnosed late.

Our cost analysis showed that input drug prices have a major impact both on lifetime costs and drug regimen costs. Substituting AWPs for AMPs (all adjusted to $US 2011) increased estimated discounted lifetime costs by more than 38% and drug regimen costs by more than 60%. With the wholesale prices, discounted lifetime costs ranged from

**TABLE 4.** Sensitivity Analysis: Assume ART Initiation Eligibility Criteria Set at CD4 Count of 500 Cells/µL (Costs in $US 2011)

<table>
<thead>
<tr>
<th>Category</th>
<th>CD4 Count at Diagnosis/Entry to Care (cells/µL)</th>
<th>Base Case Discounted Lifespan (yr)</th>
<th>Base Case Discounted Drug Regimen Costs</th>
<th>Reverse Base Case ART Regimens I and III*</th>
<th>Substitute 2012 Guidelines Prices for Base Case ART Regimen Prices†</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>≤200</td>
<td>253,222</td>
<td>157,290</td>
<td>275,224 (8.7)</td>
<td>350,583 (38.5)</td>
</tr>
<tr>
<td>II</td>
<td>201–350</td>
<td>326,705</td>
<td>219,386</td>
<td>364,182 (11.5)</td>
<td>468,019 (43.3)</td>
</tr>
<tr>
<td>III</td>
<td>351–500</td>
<td>372,344</td>
<td>256,430</td>
<td>426,006 (14.4)</td>
<td>544,526 (46.2)</td>
</tr>
<tr>
<td>IV</td>
<td>501–900</td>
<td>402,238</td>
<td>272,408</td>
<td>459,792 (14.3)</td>
<td>580,768 (44.4)</td>
</tr>
</tbody>
</table>

*See Table 1 for base case ART regimens and drug costs.
†Substitute prices from Appendix C, Table 1, Panel on Antiretroviral Guidelines for Adults and Adolescents for base case prices from Gebo et al.
Future modeling will be needed to account for the complexities of generic drug pricing and the possible effects on patient adherence and antiretroviral efficacy from generic drugs.

Our results are similar to other published estimates. Our cost estimate of $402,000 for early diagnosis/entry into care is slightly higher than that of Schackman et al, who estimated a discounted lifetime cost from time of infection of approximately $391,000 (SUS 2011). This difference probably results from the increased estimated life expectancy in our model. Sloan et al estimated a discounted lifetime cost from entry into care of $430,000 (SUS 2011) for a sample of patients in Northern France. (This estimate was derived using an average 2010 conversion rate of $1.3 per Euro and a medical care consumer price index adjustment from 2010 to 2011). Differences among these analyses arise from variations in the cohorts used in the models, the average age at HIV infection, the number of drug regimens, and the prices of the drugs. As with our analysis, Sloan et al estimated a greater life expectancy when patients presented to care early rather than late.

Our estimates of life expectancy have increased compared with earlier published estimates. Schackman et al estimated a life expectancy of 24.2 years from time of entry into care and 32.1 years from time of infection. Our estimate of 38.1 years from time of infection at an average age of 35 years, for those entering care early and initiating ART at a CD4 count of 500 cells/μL, reflects improvements in ART efficacy and increased length of treatment since the time of the analysis by Schackman et al. Sloan et al estimated a 26.5-year life expectancy from time of entry into care. Adding the approximate 8-year delay from infection until entry into care gives a life expectancy from infection of 34.5 years.

In their disease progression model of 30-year old men who have sex with men, Nakagawa et al estimated a life expectancy (from birth) of 75.0 years for men diagnosed early and 71.5 years for men diagnosed late. These estimates are close to our overall life expectancies. The North American AIDS Cohort Collaboration on Research and Design has estimated that life expectancy for a 20-year-old HIV-infected person in North America is an additional 52.3 years, which is also consistent with our results.

Our conclusions regarding the effect of late diagnosis versus early diagnosis/entry into care on HIV treatment costs differ from the conclusions of earlier studies that directly estimated HIV treatment costs from cohorts of infected patients. Those studies, which concluded that costs associated with late entry into care were greater than those of early entry, were based on cohorts of patients followed for 8–15 years. This period is insufficient to observe the entire range of costs incurred by HIV-infected patients over their lifetime. Sloan et al noted that, although lifetime costs and life expectancy were lowest for patients presenting with advanced disease, delayed entry into care resulted in higher immediate costs after treatment initiation. Although these higher immediate costs for late entry compared with early entry may persist for up to 15 years, lifetime costs are greater for those who enter care early rather than later.

In contrast to many previous studies, our study also estimated gains in QALYs, life expectancy, and years until onset of AIDS, as well as the reduction in lifetime transmissions associated with early diagnosis and entry into care of HIV-infected patients. These beneficial changes from treatment with ART for patients with HIV infection must always be considered when comparing cost estimates of late versus early treatment. Previous analysis has shown that screening HIV-infected persons in settings where these persons were diagnosed earlier in the course of their infection was cost-saving compared with settings with later diagnosis when the effects of reduced transmissions were included.

Our results were derived from a model-based analysis where we assumed that all HIV-infected patients entered the model with a CD4 count between 750 and 900 cells/μL and were diagnosed, entered care, and started ART according to the assumptions in the analysis. We assumed that all patients entered care at the time of diagnosis, began ART at a CD4 count of 500 cells/μL, and remained in care throughout their lives. Thus, similar to Schackman et al, our costs and quality-of-life measures are associated with optimal care.

Our results may differ from studies that begin their analyses with a cohort of HIV-infected patients drawn from clinical studies who differ with each other in their CD4 counts at the time of entry into the study and who may not have remained in care continuously. Given that our model assumes optimal care for HIV-infected patients, our results do not represent the costs associated with all HIV-infected persons in the United States. Recent data suggest that approximately 82% of these infected persons are diagnosed, 66% are linked to care, 37% are retained in care, 33% have been prescribed ART, and 25% have suppressed viral load.

We included the costs of comorbidities in HIV-infected patients only as they were measured in the data sources used in our analysis. Analyzing the impact of other chronic diseases and non-HIV conditions on treatment costs and length and quality of life of HIV-infected patients is a major goal of future research. Better data on the impact of ART initiation at CD4 counts ≥ 500 cells/μL on survival time and quality-of-life indicators for HIV-infected persons are also needed.

The PATH model contains numerous assumptions and data drawn from many sources, both of which need to be monitored and updated as HIV clinical events change. For example, we included only a single generation of transmissions from index patients to their partners. The percent of transmissions through IDU has also decreased slightly in recent years. However, the model can be used to project costs, other variables measuring length and quality of life of HIV-infected patients, and the number of transmissions from these patients over many years into the future, something that cannot be accomplished with existing cohorts of patients whose disease patterns are followed over shorter periods.

In conclusion, discounted lifetime costs for HIV-infected patients who are diagnosed and enter care at an early stage of disease and begin ART at 500 cells/μL are approximately $351,000 for late diagnosis/entry to $581,000 for early diagnosis/entry. Thus, any future increases or decreases in antiretroviral drug prices will have a significant impact on lifetime HIV treatment costs. These changes will become increasingly important as current antiretrovirals go off patent and generic options become available. Future modeling will need to account for the complexities of generic drug pricing and the possible effects on patient adherence and antiretroviral efficacy from generic drugs.

In conclusion, discounted lifetime costs for HIV-infected patients who are diagnosed and enter care at an early stage of disease and begin ART at 500 cells/μL are approximately $351,000 for late diagnosis/entry to $581,000 for early diagnosis/entry. Thus, any future increases or decreases in antiretroviral drug prices will have a significant impact on lifetime HIV treatment costs. These changes will become increasingly important as current antiretrovirals go off patent and generic options become available. Future modeling will need to account for the complexities of generic drug pricing and the possible effects on patient adherence and antiretroviral efficacy from generic drugs.
REFERENCES


5. Krentz HB, Gill J. Despite CD4 cell count rebound the higher initial costs of medical care for HIV-infected patients persist 5 years after presentation with CD4 cell counts less than 350 μl. AIDS. 2010;24:2750–2753.


8. Krentz HB, Gill J. Despite CD4 cell count rebound the higher initial costs of medical care for HIV-infected patients persists 5 years after presentation with CD4 cell counts less than 350 μl. AIDS. 2010;24:2750–2753.


$402,000 and may range as high as $581,000 depending on antiretroviral drug prices. The corresponding lifetime costs for persons diagnosed and entering care very late are approximately $253,000 and may range as high as $351,000. The additional lifetime cost of earlier diagnosis and more immediate therapy produces an average per-person gain in life expectancy of 7 years, an additional 3.5 QALYs, and, perhaps most importantly, an approximate 50% reduction in new infections. As improvements are made in the continuum of diagnosis and treatment in the United States, costs to treat HIV infection with current drug prices will increase together with gains in the quality of life for HIV-infected persons and substantial reductions in transmission of HIV to uninfected persons.


