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A BUDGET IMPACT ANALYSIS OF RAPID HUMAN IMMUNODEFICIENCY VIRUS SCREENING IN VETERANS ADMINISTRATION EMERGENCY DEPARTMENTS

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Abstract

Background—Human immunodeficiency virus (HIV) screening is cost-effective and recommended in populations with low disease prevalence. However, because screening is not cost-saving, its financial feasibility must be understood.

Study Objectives—We forecast the costs of two Emergency Department-based HIV testing programs in the Veterans Administration: 1) implementing a non-targeted screening program and providing treatment for all patients thusly identified (Rapid Testing); and 2) treating patients identified due to late-stage symptoms (Usual Care); to determine which program was the most financially feasible.

Methods—Using a dynamic decision-analysis model, we estimated the financial impact of each program over a 7-year period. Costs were driven by patient disease-severity at diagnosis, measured by CD4+ category, and the proportion of patients in each disease-severity category. Cost per CD4+ category was modeled from chart review and database analysis of treatment-naïve HIV-positive patients. Distributions of CD4+ counts differed in patients across the Rapid Testing and Usual Care arms.

Results—A non-targeted Rapid Testing program was not significantly more costly than Usual Care. Although Rapid Testing had substantial screening costs, they were offset by lower inpatient expenses associated with earlier identification of disease. Assuming an HIV prevalence of 1% and 80% test acceptance, the cost of Rapid Testing was \$1,418,088, vs. \$1,320,338 for Usual Care ($p = 0.5854$). Results support implementation of non-targeted rapid HIV screening in integrated systems. Conclusions: This analysis adds a new component of support for HIV screening by demonstrating that rapid, non-targeted testing does not cost significantly more than a diagnostic testing approach.

Keywords

HIV; screening; budget impact; Rapid Testing; Emergency Department

INTRODUCTION

It is estimated that there are 1–1.2 million people living in the United States with human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS), with 21% of them unaware of their disease status (1,2). Many HIV-positive persons are identified only when they develop symptoms, indicating that they are severely immunosuppressed and less likely to respond optimally to antiretroviral therapy. Screening programs that diagnose patients early and offer them treatment can therefore substantially improve health outcomes (3).

Recently, four separate analyses have indicated that HIV screening is cost-effective from a societal perspective compared to no screening and compared to current practice, prompting the Centers for Disease Control and Prevention (CDC) and the American College of Physicians to encourage routine HIV screening as a part of normal medical practice (4–9). However, although HIV screening has been found to be cost-effective, it is not cost-saving. Therefore, even though HIV screening is economically justifiable, it may not be a financially viable option for an organization. A Budget Impact Analysis (BIA) can provide information about the financial feasibility of a program by examining the economic value of the health investment and the resources needed for its implementation (10).

This study examines the budget impact of implementing a new HIV testing program in a Veterans Health Administration (VA) Emergency Department (ED) vs. the financial impact of following standard care. The standard care program examined is Usual Care, which in the ED setting involves blood-based diagnostic testing, or testing a patient when (s)he presents with symptoms suggestive of HIV/AIDS. The new program examined is Rapid Testing, or offering an HIV test to any previously untested patient in the ED, regardless of risk factors or symptoms (non-targeted testing). The rapid test in question is the OraQuick Advance HIV-1/2 Oral Specimen Collection Device (OraSure Technologies, Bethlehem, PA), a Food and Drug Administration-approved point-of-care test. Of particular interest for ED settings, the results of HIV rapid tests are available within 1 h, compared to the 24–48 h turnaround for blood-based testing.

This analysis estimates the number of people who would be identified as disease-positive through Rapid Testing at various levels of program intensity and HIV prevalence rates. The model forecasts treatment costs for patients in the Rapid Test program and compares them to the expenses incurred by these same patients were they to be identified at later stages of disease through Usual Care. The program with the lowest overall costs, both in terms of implementation costs and cost offsets, represents the most economically-efficient strategy.

MATERIALS AND METHODS

We built a first-order stochastic decision-analysis model to determine the costs of treating a hypothetical cohort of patients identified due to a Rapid Testing screening program vs. costs of treating this same cohort of patients were they identified due to symptoms of disease (Usual Care). Cohort size indicates the number of HIV-positive persons identified by the screening programs in the ED. The ED was chosen as the screening site due to its ability to access an otherwise difficult-to-reach population and its predicted higher prevalence of HIV infection compared to primary care locations (11,12). This analysis used cost and economic data from an urban VA ED and Infectious Disease clinic located in a major metropolitan

area. The VA was chosen due to the extensive data available from its cost databases and electronic medical records. Institutional Review Board approval was obtained from the VA system.

Due to the fact that the VA generally keeps patients for life, this analysis assumed all patients would be identified at some point in the system due to their symptoms. Therefore, sizes for the Rapid Test and Usual Care cohorts were identical. We modeled a variety of cohort sizes to reflect uncertainty in the number of patients offered testing, the percentage of patients accepting testing, and the prevalence of HIV (Table 1). This analysis evaluated the financial impact of three different offer rates: five per business day, 10 per business day, or universal. The former two rates were used to reflect realistic levels of testing that can occur in environments with existing capacity constraints; the latter was used in accordance with CDC recommendations. The model assumes HIV prevalence is independent of test acceptance.

Costs of Rapid Testing include both program implementation and treatment of disease. Costs of Usual Care include disease-treatment costs only, but health care utilization is more intensive in this population due to late identification of disease. Treatment costs were calculated for the following budgets: inpatient, outpatient, pharmacy, and global (where global indicates the sum of the former three sub-budgets). All treatment costs were assumed to be dependent upon disease severity at diagnosis (measured by CD4+ count). Disease severity was noted by the following four categories: CD4+ < 50, CD4+ 50–199, CD4+ 200–350, and CD4+ > 350 cells/mm³ at diagnosis (where low CD4+ values indicate higher disease severity). Costs were projected over a time horizon of 7 years. A horizon of 7 years is longer than usual for BIAs; however, we felt this longer horizon was necessary to capture the delay between when patients are diagnosed through screening and when they begin accruing costs of treatment.

Treatment cost was a function of cost per disease-severity category and the proportion of cohort members in each disease-severity category. Estimated costs were calculated on an annual basis for each budget using 2007 dollars. The following equation was used to model the total estimated costs of treating disease:

$$C_j = \sum_{i=1}^4 \sum_{t=0}^6 (C_{jit} * N_{jit})$$

Where:

C_j is the average cost per case in sub-budget category j

i is the disease-severity category (CD4+) assigned at time of diagnosis

t is the year in which costs are accrued

C is the average cost per case of disease

N is the number of people

Cost per disease-severity category was determined by examining utilization patterns of HIV-positive patients and allocating VA-specific direct medical cost values to this utilization. VA-specific costs were used, following best practice recommendations for conducting BIAs. (10). Utilization data came from chart review of all treatment-naïve patients diagnosed and treated at this site from Fiscal Year (FY) 2000 to FY 2007 ($n = 112$). Although this number is small, the analysis required the use of these actual data, due to the dearth of literature available on treatment-naïve patients and the fact that data from treatment-experienced

patients would substantially overestimate treatment costs. Modeling HIV-related utilization over time also poses significant difficulties, given that drug treatment efficacy decreases over time, is influenced by patient adherence, and that the relationship between adherence and consequences of much highly active anti-retroviral therapy (HAART) is not fully understood (13). For example, partial adherence increases the risk of drug resistance more so than complete non-adherence (13).

Only HIV-related utilization was included in the model. All inpatient stays with HIV as a primary or secondary diagnosis were reviewed by two infectious disease physicians who had treated the majority of these patients; only those inpatient stays unanimously deemed to be due to HIV were included in this analysis.

Once the cost per disease-severity category was calculated, we populated the model with the program-specific CD4+ distributions. As Usual Care patients are diagnosed at later, more advanced stages of disease than are patients identified through Rapid Testing, the disease-severity distributions differed across the programs; a larger proportion of Usual Care patients had lower CD4+ counts at diagnosis. The CD4+ distribution for the Usual Care program was determined using patients from the national Veterans Aging Cohort Study (VACS) Virtual Cohort, which contains clinical data on all HIV-infected veterans in the country (14). Disease severity at diagnosis was obtained for VACS Virtual Cohort members who had ED visits in a VA facility before their HIV diagnosis ($n = 3355$), which represents the Usual Care patients in this model.

We used a back-calculation scheme to determine the CD4+ distribution for the Rapid Testing program. Annual CD4+ decline in the absence of treatment can be estimated by the following equation: $CD4+^{1/2} = -.0584 - 0.918 [\log(vRNA/1000)]$ (15). Entering patients' viral load at diagnosis, CD4+ count at diagnosis, as well as the length of time elapsed between first ED visit and HIV diagnosis into the equation yields an estimate of patients' CD4+ count had they been diagnosed with HIV at the time of first ED visit (a Rapid Testing approach). For example, a patient presenting 2 years after his first ED visit with an initial CD4 count of 150 cells/mm³ and viral load of 100,000 copies would be back-calculated to have had a CD4 of 292 cells/mm³ had he been diagnosed at the time of initial ED visit (Table 2).

As identified HIV-positive patients, persons in the Rapid Testing arm begin accruing treatment costs immediately. However, it takes some time for Usual Care patients to display symptoms of disease, be diagnosed, and therefore start incurring treatment costs. Data from the VACS Virtual Cohort indicate a mean 1.25-year delay between the first ED visit and diagnosis of HIV. All estimated costs in the Usual Care program were adjusted back 1.25 years to reflect this delay to diagnosis. Over the entire analysis, the Rapid Test program therefore had 7 years of data, whereas the Usual Care program had 5.75 years of data.

In the outpatient and pharmacy models, cost values associated with the Usual Care and Rapid Test programs were identical. The model assumed drug costs and office visits were not driven by method of HIV diagnosis, but simply by the severity of patient illness. However, cost values for the inpatient and thus global models differed across the Usual Care and Rapid Testing programs; inpatient utilization, and cost, was dependent upon whether a patient was diagnosed through Rapid Testing or Usual Care. Inpatient stays within 3 months of HIV diagnosis were excluded from the Rapid Testing costs. These hospitalizations represent patients who were diagnosed due to opportunistic infections; their exclusion was more indicative of the clinical scenario of Rapid Testing patients, who are not diagnosed due to opportunistic infections and therefore would not have experienced such inpatient stays.

Once the model was populated with the cost per CD4+ category and the distributions of CD4+ counts, we ran the analysis and employed statistical techniques to mitigate the noise associated with small samples. Probabilistic sensitivity analyses (with 10,000 Monte Carlo iterations) were run to gain a more accurate estimate of cost per CD4+ category, with each iteration randomly sampling from each distribution of cost per CD4+ category. This re-sampling increases the likelihood that outlier cost inputs would not have an undue influence on cost estimates. Model analyses were conducted using TreeAge Pro 2008 software (TreeAge Software Inc., Williamstown MA).

Usual Care program costs were directly obtained from model results. Rapid Testing program costs were obtained by adding program implementation costs to model results. Implementation costs were determined by micro-cost estimates of resources used in offering and conducting HIV tests, including testing kits and labor. Time-and-motion data were obtained by direct observation of HIV rapid testing in the ED. An applied rate of 85% was used for all salary calculations. Two-tailed *t*-tests of significance were run on the total costs of each program to determine if the overall 7-year global costs of the Rapid Test program were significantly different from the Usual Care program. Tests of significance were run using STATA version 9.2 (StataCorp LP, College Station, TX).

To summarize, the following assumptions were made in conducting these analyses:

1. Patients can be properly stratified into four CD4+ count categories.
2. All health care utilization, and therefore cost, is contingent upon CD4+ count at diagnosis.
3. Utilization patterns of patients identified through these programs can be modeled using utilization data from past HIV-positive patients treated at the same location.
4. All persons diagnosed are immediately linked to treatment.
5. All patients identified by Rapid Test would be diagnosed an average of 1.25 years later in the Usual Care program.

RESULTS

At all test offer rates and cohort sizes, there is no significant difference in total 7-year estimated costs of the Rapid Test and Usual Care programs (Table 3). At lower cohort sizes, the Rapid Test program is more costly than the Usual Care program, across all offer rates. As cohort size increases, there is a threshold at which Rapid Testing becomes less costly than Usual Care. The threshold is not consistent across offer rates due to the inclusion of implementation costs, which do not increase linearly with cohort size.

Implementation costs are responsible for the higher Rapid Testing costs at lower cohort sizes, as the organization is spending money in screening many patients but finding few who are HIV-positive. At lower cohort sizes, treatment costs are smaller; implementation costs thus represent a large percentage of overall costs. As cohort size—or number of patients identified as HIV-positive—increases, treatment costs increase substantially, whereas implementation costs increase only slightly. This is due to the fact that implementation costs are driven by test acceptance rates, whereas cohort size is substantially driven by disease prevalence. Hence, at large cohort sizes, when treatment costs are substantial in relation to implementation costs, Usual Care becomes the more costly program. Estimated costs for the Rapid Testing program differ across the same cohort size for the same reason. For example, the overall Rapid Testing costs for a cohort of size 11 may be \$464,529 or \$485,701 or \$561,386. The reason for this discrepancy is implementation costs; the cost of offering tests to 10 patients in the ED is higher than the cost of offering HIV tests to 5 ED patients.

An examination of the relative cost components of each program reveals that the higher cost for Usual Care patients is largely due to more inpatient stays, reflecting more hospitalizations for these patients due to opportunistic infections (Table 4). Outpatient costs represent approximately one-fifth of costs for both programs, whereas pharmacy comprises the greatest percentage of costs for both programs. However, total pharmacy costs are lower for the Usual Care program, due to the fewer years of cost data.

As noted previously, the Usual Care program had no implementation costs, and only 5.75 years of data. This biases the cost estimates in its favor, as implementation costs for the Rapid Testing program range from \$18,211 to \$141,002. As statistical tests revealed no significant difference in the overall costs of the two programs, this suggests that once Usual Care patients are identified, their costs are higher than those for Rapid Test patients. Estimates of cost per capita reveal global costs per Usual Care patient to be \$7237 annually vs. \$5836 annually per Rapid Test patients.

DISCUSSION

Results indicate that over a 7-year period, an HIV screening program using a Rapid Testing approach is financially equivalent to following a Usual Care approach within the VA system. Given that early detection of HIV and linkage to treatment is also associated with better health outcomes, this analysis provides support for the implementation of a non-targeted oral Rapid Testing program.

Inpatient costs were substantially lower for Rapid Testing patients, offsetting the costs of implementing screening, and resulting in similar costs for the two HIV testing programs. Patients in the Usual Care program had higher inpatient costs, due to the fact that many of them were hospitalized for opportunistic infections (OIs). When modeling utilization of the Rapid Testing cohort, we excluded any hospitalization occurring within 3 months of HIV diagnosis. The model's exclusion of these inpatient costs for the Rapid Testing patients is partly responsible for the lower inpatient costs for this program. This exclusion was warranted, as we sought to quantify the marginal cost of implementing a non-targeted HIV Rapid Testing program. Including the inpatient costs of patients who were diagnosed due to hospitalization from OIs would misrepresent the clinical scenario of Rapid Testing patients, as patients who have acute OIs would have been diagnosed by Usual Care regardless of whether a Rapid Testing program was in place.

This analysis provides support for a non-targeted screening-based program. Although the initial investment of such a screening program may be as high as \$141,000, the smaller treatment costs of patients identified at lower disease-severity offset the initial financial impact. This observation is crucial, as data from the VA and other health care systems indicate that targeted (risk-based) testing fails to capture a significant portion of the HIV-positive population (13,16).

This analysis also provides support for rapid testing. Although costs of rapid tests are higher than conventional assays, oral rapid tests are particularly attractive for use in ED settings due to higher patient acceptance rates and virtually immediate turnaround (5). Short turnaround increases the likelihood that patients will receive test results, which is especially important in an ED-using population, where continuity of care can be problematic and many patients have difficulties returning for test results. Studies indicate that 21–30% of patients testing positive and 25–39% of patients testing negative for HIV do not return for the results of their tests (17,18).

This analysis used clinical and economic data from the VA. The advantage of using VA-specific data is that the VA is a non-profit, non-revenue-generating organization, which

ensures that financial data used represent actual costs, rather than profit or cost-shifting from uncompensated care. Use of actual data, rather than projections, serves to more accurately demonstrate the relationship between a program and its clinical and economic effects. Therefore, the results shown here are more indicative of the true cost of screening. Furthermore, this analysis demonstrates that the initial costs of ED-based screening are offset by lower inpatient utilization—data that are applicable to any integrated health system. Such results can guide other integrated systems in providing support for HIV screening in high-prevalence locations (defined as 0.5% or greater).

Limitations

The major limitation of this analysis lies in the small sample size used to determine utilization and estimate costs. This analysis had a sample size of 112, divided up into four disease-severity categories. First-order probabilistic sensitivity analyses were employed to gain more accurate estimates of the means with a small sample, but could not mitigate variation around the mean. Variation in inputs results in large confidence intervals, therefore increasing the likelihood of non-significance.

However, there were also important benefits from using these actual data. First, use of actual data takes into account the various drug (and therefore cost) combinations of HAART therapy, as well as the cost of modifying HAART therapy over time. Second, it better captures the relationship between patient drug use and hospitalization than modeling practices. Use of actual clinical data also takes into account that although all HIV-positive patients are referred to care, some did not actually enter care or cycled in and out of the system, and that rates of adherence to care vary considerably. Lastly, use of actual clinical data captures true physician practice patterns; using clinical practice guidelines to model care does not take into account physician deviation from these guidelines. Use of actual cost data, rather than charges or billing data, provides a more accurate indication of the real economic impact of each program.

In a clinical setting, it is likely that some patients would be lost to follow-up and not initiate treatment. However, this model assumed that all patients diagnosed were linked to treatment, as we believed that an organization should be prepared to allocate enough funding to a program such that all patients can be offered proper care for their disease.

This analysis was conducted using data from the VA system, which may limit generalizability of cost results to other settings. However, perhaps even more important than producing actual cost estimates, this analysis demonstrates the relationship between non-targeted screening and usual care—and provides evidence that a non-targeted screening program does not pose a significant cost burden to the organization. These findings are of use for decision-makers in any integrated system.

Treatment patterns for HIV may have changed over time, raising the issue of the appropriateness of using past data to model future utilization. Although new drugs may have come to market from FY 2000 to FY 2007, analyses of these data indicate that annual pharmacy costs have not changed over time. Inpatient costs have also not changed significantly, suggesting that even if drug therapy has altered, neither its costs nor its effect on inpatient utilization have been modified. Therefore, using past utilization data to inform this model was appropriate.

CONCLUSION

This article demonstrates the practical, real-world effect of implementing evidence-based policies, and adds a new component of support for HIV screening, by demonstrating that an

HIV screening program that utilizes rapid, non-targeted testing in an ED will not cost substantially more than a diagnostic testing approach.

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Table 1**Cohort Sizes ***

Offer Rate	Acceptance Rate	HIV Prevalence	Cohort Size
5/day	55%	0.5%	4
5/day	80%	0.5%	6
5/day	55%	1.0%	8
5/day	80%	1.0%	11
5/day	55%	3.0%	22
5/day	80%	3.0%	32
5/day	55%	5.4%	39
5/day	80%	5.4%	57
10/day	55%	0.5%	8
10/day	80%	0.5%	11
10/day	55%	1.0%	15
10/day	80%	1.0%	21
10/day	55%	3.0%	43
10/day	80%	3.0%	63
10/day	55%	5.4%	78
10/day	80%	5.4%	113
Universal	55%	0.5%	11
Universal	80%	0.5%	16
Universal	55%	1.0%	21
Universal	80%	1.0%	31
Universal	55%	3.0%	63
Universal	80%	3.0%	91
Universal	55%	5.4%	113
Universal	80%	5.4%	164

HIV = human immunodeficiency virus.

* Cohort size is dependent on four factors: the number of people visiting the Emergency Department annually, the percentage of patients offered testing, the percentage of patients accepting testing, and the prevalence of HIV. Due to uncertainty regarding the latter three rates, a variety of cohort sizes were modeled. Cohort size is calculated in the following manner: at an offer rate of 10 tests per business day, 2600 tests would be offered annually. If 55% of patients accept testing, 1430 tests would be conducted. At a 1% prevalence of disease, 14.3 patients would be identified as disease positive. Rounding up to the next whole person results in a cohort size of 15.

Table 2

Model Inputs: Percentage of Patients in Each CD4 Category

	CD4 < 50	CD4+ 50–199	CD4+ 200–350	CD4+ 350+
Usual Care	22%	26%	23%	29%
Rapid Testing	8%	24%	24%	43%

Table 3

Mean Overall Costs of Usual Care and Rapid Testing Programs in US Dollars *

Cohort Size	Offer Rate	Usual Care (95% CI)	Rapid Testing (95% CI)
4	5/day	131,143 (78,216–207,825)	175,114 (88,703–258,035)
6	5/day	244,115 (164,527–371,386)	262,056 (147,585–359,946)
8	5/day	311,373 (220,358–447,352)	332,389 (209,608–449,539)
11	5/day	449,675 (338,619–616,541)	464,529 (314,689–602,906)
22	5/day	918,463 (748,608–1,142,224)	916,894 (706,683–1,129,739)
32	5/day	1,373,520 (1,162,783–1,652,871)	1,334,239 (1,067,545–1,581,769)
39	5/day	1,661,119 (1,422,059–1,959,388)	1,638,520 (1,350,054–1,938,275)
57	5/day	2,448,055 (2,145,675–2,805,595)	2,383,208 (2,029,588–2,728,171)
8	10/day	311,373 (220,358–447,352)	348,036 (209,608–449,539)
11	10/day	449,675 (338,619–616,541)	485,701 (314,689–602,906)
15	10/day	630,549 (491,905–826,743)	653,836 (459,256–823,184)
21	10/day	878,091 (709,926–1,101,970)	899,234 (667,040–1,082,325)
43	10/day	1,840,167 (1,585,901–2,150,653)	1,828,215 (1,510,733–2,107,502)
63	10/day	2,692,457 (2,380,472–3,063,322)	2,679,336 (2,286,097–3,022,789)
78	10/day	3,372,705 (3,020,850–3,787,061)	3,287,460 (2,862,653–3,679,837)
113	10/day	4,874,310 (4,435,917–5,363,469)	4,773,087 (4,262,200–5,250,449)
11	Universal	449,675 (338,619–616,541)	561,386 (314,689–602,906)
16	Universal	671,123 (528,158–866,439)	785,252 (489,145–852,453)
21	Universal	878,091 (709,926–1,101,970)	976,253 (667,040–1,082,325)
31	Universal	1,320,338 (1,106,092–1,583,112)	1,418,088 (1,050,690–1,559,001)
63	Universal	2,692,457 (2,380,472–3,063,322)	2,756,595 (2,286,097–3,022,789)
91	Universal	3,936,820 (3,540,501–4,388,040)	3,927,737 (3,369,597–4,255,351)
113	Universal	4,874,310 (4,435,917–5,363,469)	4,848,802 (4,262,200–5,250,449)
164	Universal	7,103,144 (6,574,161–7,686,456)	7,011,975 (6,280,554–7,459,161)

* No differences were statistically significant.

Table 4

Average 7-year Cost Components

	Pharmacy	Inpatient	Outpatient
Usual Care	59%	22%	20%
Rapid Testing	64%	14%	21%