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Cost of Behavioral Interventions Utilizing Electronic Drug Monitoring for Antiretroviral Therapy Adherence

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Abstract

Objective—To provide data on the actual costs associated with behavioral ART adherence interventions and electronic drug monitoring used in a clinical trial to inform their implementation in future studies and real-world practice.

Methods—Direct and time costs were calculated from a multi-site three-arm randomized controlled ART adherence trial. HIV positive participants (n = 204) were randomized to standard care (SC), enhanced counseling (EC), or EC and modified directly observed therapy (mDOT) interventions. Electronic drug monitoring (EDM) was used. Costs were calculated for various components of the 24-week adherence intervention. This economic evaluation was conducted from the perspective of an agency that may wish to implement these strategies. Sensitivity analyses were conducted to examine costs and savings associated with different scenarios.

Results—Total direct costs were \$126,068 (\$618/patient). Initial time costs were \$53,590 (\$262/patient). Base cost of labor was \$0.36/minute. EC costs for 134 patients were \$18,427 (\$137/patient) and mDOT for 64 patients cost \$18,638 (\$291/patient). Total per patient costs were: SC=\$880, EC=\$1,018, EC/mDOT=\$1,309. Removing driving costs evidenced the most variable impact on savings between the three study arms. The tornado diagram (sensitivity analysis) showed a graphical representation of how each sensitivity assumption reduced costs compared to each other and the resulting comparative costs for each group.

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Conflicts of Interest: None

Conclusion—This novel economic analysis provides valuable cost information to guide treatment implementation and research design decisions.

Keywords

Adherence; EDM; Cost Analysis; Behavioral Intervention; HIV; ART; Economic Evaluation

Effective antiretroviral therapy (ART) has led to durable viral load suppression and reduced morbidity and mortality.^{1,2} However these benefits are dependent on high levels of patient adherence which is difficult, especially over time.^{3,4} While the accepted definition of adherence for nearly all other chronic diseases is 80% of doses taken, early studies suggested that near-perfect ART adherence (>95%) was necessary to achieve these positive outcomes.^{5,6} More recent research indicates that the required level of adherence associated with viral suppression may be lower than originally thought and may vary with the type of ART being taken.⁷ Nevertheless, poor adherence leads to the development of resistance^{8,9} and subsequent reduction in viable treatment options for patients⁹ and is therefore an important clinical issue.

HIV treatment failure without resistance is usually attributable to problems with adherence.^{10,11} Moreover poorer adherence may result in treatment failure and counteractively increase drug costs by necessitating the use of more expensive ARVs.¹¹ The economic burden of regimen failure and HIV disease progression is huge. Recently a study estimated the economic burden of regimen failure and highlighted “the importance of ensuring optimal initial therapy choices and regimen succession”.¹² Therefore investment in adherence improvement interventions may be worthwhile to reduce expensive burden of treatment failure.

Over the last decade, an array of behavioral strategies to increase adherence to antiretroviral therapy (ART) have been examined. While several experimental interventions have been associated with improved adherence and/or HIV RNA suppression, findings have been inconsistent across studies.^{13–18} Most importantly, which intervention components are responsible for observed adherence gains and the costs associated with implementing them is still unclear. Clinicians are left to their own devices to determine which intervention aspects are worth the expense of implementing in their settings and researchers lack critical cost data to guide the planning of research studies.

Although some cost analyses of behavioral ART adherence interventions have been performed, they rely on simulated models and lack real world cost assessment.^{19–22} While the results of these studies suggest positive cost effectiveness results of behavioral interventions, the data has limited utility in guiding the design of contemporary adherence interventions for research or practice. Although conventional methods were used, simulation models are based on assumptions and extrapolations. Other shortcomings include outdated source costs, observed therapy costs based on tuberculosis treatment adherence models, and models based on obsolete ART regimens and guidelines.^{29–22} Likewise, no study has analyzed potential costs of utilizing an electronic drug monitor (the current gold-standard) to verify adherence rates.

Given the deleterious impact and cost of non-adherence, clinic settings are going to implement adherence interventions making real world cost information critical. Both behavioral interventions and modified directly observed therapy (mDOT) have been shown to be feasible adherence interventions in a variety of populations.^{23–36} Many studies have used electronic drug monitoring (EDM) systems to track adherence; however, few studies have also reported the actual costs of interventions combined with EDM.^{37–42} Consequently,

costs of improving adherence using behavioral interventions, especially when utilizing mDOT and EDM, are underreported in the literature. The goal of this cost analysis was to provide a real world perspective on not only the costs associated with behavioral adherence intervention, mDOT, and using EDM in a clinical trial, but also the potential costs associated with adapting these interventions and EDM for usual clinical care. By separating out the costs of the adherence intervention components, the research related costs, and adherence monitoring costs, individuals can make informed decisions when selecting adherence support pieces to transfer to future studies or practice.

METHODS

Study Population

Project MOTIV8 (R01MH68197) was a multi-site three-arm randomized controlled ART adherence trial.⁴³ HIV positive participants (n = 204) from 6 community HIV clinics in Kansas City were randomized to standard care (SC), enhanced counseling (EC), or EC and modified directly observed therapy (mDOT) interventions. The patients' demographic characteristics are presented in Table 1.

Intervention

Project MOTIV8 was designed to examine whether EC combined with mDOT is more effective than EC alone or standard care (SC) for increasing adherence to ART over 48 weeks.⁴³ The length of the EC and mDOT interventions was 24 weeks. The control arm received SC, which was consistent with the treatment that any HIV infected patient on ART could expect to receive in the U.S. The primary adherence measure used for all participants was electronic drug monitoring (EDM; <http://www.aardex.ch>).

Economic Evaluation

The direct costs and time costs associated with Project MOTIV8 were identified and analyzed in this study. The costs related to planning of the trial, research effort for study investigators, research data analysis activities, and other research activities that did not directly impact the participants were not included in this economic evaluation. However, participant related study costs, such as the study evaluations, recruitment, use of EDM and incentive payouts were included. All direct costs and time costs associated with the study were analyzed from the perspective of an agency that may wish to implement these strategies and are consistent with recently reported economic evaluation studies.^{44–48}

Direct Costs

The direct costs included hardware, software, printing, advertising, mileage, and study participation incentive items and payments. Items and services (e.g. mileage) that directly impacted the intervention were included in this section. Mileage was based upon the federal rate of reimbursement, which averaged \$0.50/mile for an average distance of 13 miles driven to participant homes per visit to conduct counseling sessions, evaluations and/or mDOT. The incentive items (e.g. mug, t-shirt, tote-bag, folder, keychain, pen) and payments were distributed to participants upon completion of study evaluations. Both research planning costs and implementation costs were considered for calculating activity and item based unit costs.

Activity-Based Time Costs

We estimated the amount of time required to carry out each study related activity and obtained salary information spanning the five years of the study so that initial time costs and costs associated with counseling could be determined for each aspect of the intervention.

The time-related cost centers were training, evaluation, recruitment, enhanced counseling (counseling time, set-up time, driving time), and observed therapy (driving time and four types of visits: observed, electronically recorded, phone, and delivered). To determine staffing time cost the average yearly salary from the middle of 2004 through the middle of 2009 was calculated by taking the total compensation received by each of the research staff and health educators over the course of the study and dividing by the number of years they worked on the study. The average pay per minute was then calculated based on a 52 week year, 5 work days a week, and 8 hour work days. The research staff and health educators were trained by the study investigators, which included Pharmacists, experts (PhDs) and Psychologists. The salaries can be adjusted to be commensurate with the type of individuals chosen to implement the selected activity in other research or practice settings.

Initial Time Costs

The three cost centers under initial time cost were training, evaluation, and recruitment. Training time was a one-time cost at the beginning of the project involving instruction of three staff members in the methods to be employed in carrying out evaluations and interventions. Each staff member received 84.5 hours of training divided among the following categories: HIV 101 for 20 hours, general and safety training for 1 hour, how to perform mDOT for 5.5 hours, and how to carry out EC for 58 hours. Evaluation time cost was the baseline time cost shared by all three arms of the study. Participants completed seven evaluation sessions comprised of demographic, adherence, psychosocial and medical self-report questionnaires administered via Audio Computer Assisted Self Interview and by staff. Also included were chart reviews and EDM data collection that accounted for the majority of the evaluation time cost. Recruitment time cost involved the amount of time it took to approach all potential participants. Although not every person approached was enrolled, the investigators felt it was necessary to capture the time cost for each attempt as well as each successful enrollment as both contributed to the overall cost.

Intervention Costs

The total amount of time the study staff spent on each intervention activity during the entire span of the study was calculated as well as the average amount of time spent per person. Each study participant received a specified amount of counseling and intervention based upon their study group assignment. Participants in standard care (SC) received no intervention. Delivery of the Enhanced counseling (EC) intervention involved 11 sessions during the first 24 weeks, which were conducted in their home or other desired location. Enhanced counseling sessions focused on increasing motivation and skills for adherence covering a range of topics typically targeted by ART adherence interventions (e.g., self-monitoring, problem-solving, talking to your doctor).

Modified directly observed therapy (mDOT) participants received both the 11 EC sessions and mDOT. The mDOT involved direct observation of patients taking one of their ART doses Monday through Friday for the first 16 weeks, tapered down by one day a week for weeks 17 through 19, and ending with one observation per week for weeks 20 through 23 for a total of 93 total possible mDOT visits per person. The observed dose was sometimes monitored by phone or other electronic method when direct observation was not possible. Driving time costs associated with the EC sessions, direct observations and delivery of ART for unobserved doses were also incorporated.

Method of Analysis

Microsoft® Excel was used to generate the spread sheets for tabulating data, and calculating overall, and patient specific time and dollar costs. It was also utilized for conducting a sensitivity analysis on which a tornado diagram was generated. The sensitivity analysis was

carried out examining the costs and savings associated with four different scenarios: excluding all driving related costs in scenario 1 if exclusively electronic methods of delivery could be utilized, using a reduced base labor cost of \$0.23/minute in scenario 2 which is more indicative of what typical clinic staff are usually paid,³⁶ excluding the cost of EDM in scenario 3 because clinics may not wish to incur the costs associated with that particular type of monitoring, and excluding the cost of the study-related evaluations in scenario 4 because this was empirical research and real-world clinics may not have the time, manpower, funds to do this kind study-related evaluation. We also calculated the total costs and savings of combining all four scenarios with and without direct costs. The tornado diagram (figure 1) generated from the sensitivity analysis used a central axis of \$881 based upon the cost of SC. Thus allowing the diagram to show how costs associated with each of the intervention arms changed in each scenario.

RESULTS

Total Costs

The base cost of labor within the study was calculated as \$0.36/minute (\$21.60/hour). Total calculated direct costs were \$126,068 (\$618/patient). Total activity-based time costs totaled \$90,658, which was distributed among three cost centers: initial time costs \$53,590 (\$262/patient), EC cost \$18,427 (\$137/patient), and mDOT cost \$18,638 (\$291/patient). The total cost per patient per arm of the study was: SC=\$881/patient, EC=\$1,018/patient, EC/mDOT=\$1,309/patient.

Direct Costs

Total direct costs, which are summarized in Table 2, equaled \$126,618. The direct costs generated from hardware (desktops, laptops, and PDAs), software (Microsoft® programs, statistical programs, EDM program), and EDM (\$173/each) was \$68,520. Costs for incentive items and study evaluation payments (Baseline/visit 1=\$20, visit 2=\$20, visit 3=\$40, visit 4=\$20, visit 5=\$65) added \$34,870. Other direct costs included printing \$570, advertising \$298, and mileage \$21,810.

Activity Based Time and Cost by Category

The total individual participant cost based on study group assignment is displayed in Table 3. While the total and per person time and costs are displayed for each study related activity are included in Table 4. The initial costs and intervention-based costs were included in the activity based time costs category.

Initial Time Cost—The total initial cost was \$53,590 (\$262/patient) and involved 148,864 minutes (730 min/patient). Initial costs included training, participant evaluation, and recruitment costs. Training costs included three staff members, who each received 84.5 hours of training at a total cost of \$5,470, or \$1,823 per staff member. Evaluation time costs covered each of the 204 study participants, who ideally, participated in 7 study evaluations. This resulted in an average of 81.6 minutes each at a cost of \$29.38 per session; 571 minutes total per person at a cost of \$205.63; and total time of 116,554 minutes for the entire study at a total cost of \$41,959. Recruitment time costs consisted of 1,710 attempts to recruit patients with an average of 10 minutes per recruitment session and 204 participants successfully enrolled in the study. A time expenditure of approximately 83.8 minutes was required for one enrollment. The cost of one recruitment attempt was \$3.60, but the cost of one successful enrollment was \$30.18.

Intervention Cost—Enhanced Counseling: One hundred and thirty four participants completed EC within the study for a total time of 51,188 minutes (382 min/patient) and a

total cost of \$18,427 (\$137/patient). EC was further subdivided into the three subsections of counseling, setup, and driving. The EC intervention consisted of 11 sessions varying in length from 10 to 25 minutes for a total time of 26,800 minutes (200 min/patient) and cost of \$9,648 (\$72/patient). Setup time was 7 minutes for each of the 11 sessions with a total time of 10,318 minutes (77 min/patient) and cost of \$3,714 (\$27.72/patient). Driving time for EC consisted of 938 separate trips with an average time of 15 minutes for a total time of 14,070 minutes (105 min/patient) and cost of \$5,065 (\$37.80/patient, \$5.40/trip).

Modified Directly Observed Therapy: Sixty four participants completed mDOT within the study for a total time of 51,773 minutes (809 min/patient) and total cost of \$18,638 (\$291/patient). Although each participant in the mDOT group should have received 93 delivered and observed doses by protocol, they actually received varied combinations of dose monitoring and medication delivery visits; these included directly observed, “phone contacts” (participant ingested medication during a study staff initiated phone call at the predetermined dose time), “med delivery” (meds delivered outside of target dosing time and participant reported by phone/ text when ingested), and “PDA visits” (meds delivered outside of target dosing time and participant retrospectively reported on all unobserved doses using PDA).”⁴³ Directly observed visits were partnered with driving time. There were 1,927 directly observed visits with an average of 5.2 minutes (approximate cost of \$1.87/visit) of direct patient contact. The total direct patient contact time was 10,020 minutes with a total cost of \$3,607. Each of these visits was coupled with a driving time which averaged 15 minutes and added to the direct contact time for a total time of 28,905 minutes and cost of \$10,406. Thus the average directly observed visits accounted for 20.2 minutes of staff time per patient at an average cost of \$7.27/visit. There were 124 electronically monitored visits with a total time of 496 minutes and cost of \$179. There were 1,324 phone visits with a total time of 5,295 minutes and cost of \$1,907. There were 1,764 visits to deliver medications without a dose observation, which totaled 7,096 minutes and a cost of \$2,540. Each of these kinds of visits: phone, electronic and delivered averaged 4 minutes in length with an average cost of \$1.44/visit.

Sensitivity Analysis—Sensitivity analysis results are highlighted in Table 4. There was a 10% to 23% cost savings associated with each of the four scenarios. The biggest cost savings came from scenario 4 which eliminated the initial cost of the study evaluations saving \$206 per patient with no difference between study arms. Likewise, scenario 3 showed that omission of adherence monitoring using EDM could save \$173 per patient. Scenarios 1 and 2 both showed cost savings, which varied between the study arms. Cutting out driving costs resulted in the most variable impact between the three study arms. Exclusion of driving costs impacted both direct and activity based time costs and resulted in the following savings: SC=\$107, EC=\$145, EC/mDOT=\$307. Similarly, reducing cost of labor from \$0.36/min to \$0.23/min resulted in variable cost savings across the groups by affecting the time-based initial cost and counseling costs. The savings for each group were, SC=\$95, EC=\$144, EC/mDOT=\$249. The tornado diagram in Figure 1 shows a graphical representation of how each sensitivity assumption reduced costs compared to each other and the resulting comparative costs for each group. To demonstrate additional plausible scenarios, the total savings of adding all of the sensitivity scenarios together as well as excluding all direct costs were included.

DISCUSSION

This cost analysis shows the cost components associated with implementation and delivery of two established adherence interventions, behavioral counseling and modified directly observed therapy (mDOT) in a controlled trial. We also examined the costs of utilizing electronic drug monitoring (EDM) and conducting study evaluations. Thus this report is the

first to provide detailed and relevant cost information that can inform decisions about implementation of adherence interventions in clinical and research settings.

This analysis compares favorably to previous studies, which demonstrated desirable thresholds of cost-effectiveness for adherence-improving interventions ranging from \$1200/year to \$1,600/year.^{19–21} Likewise, both of the MOTIV8 interventions fall on either side of the Freedberg et al. study, which cost \$340/year (\$28/month).²² The interventions themselves turn out to be some of the least expensive components (Table 5). The individual patient cost for EC was \$137 for the 24-week intervention or \$23/month if continued for a full year. EC costs included the cost of driving to participant homes or desired location to provide EC sessions. These costs could be eliminated by combining the intervention with scheduled visits to the clinic or offering them via electronic methods of delivery. The EC monthly cost assumes that the interventions are carried out on continuous 24-week cycles throughout a year, whereas a one year price based on providing a single 24 week intervention would correspond with \$137/year or \$11/month. A sizeable portion of the EC and mDOT expenses resulted from driving to participant homes or preferred locations to conduct counseling sessions and observe medication doses. As shown by scenario 1 in the sensitivity analysis, there would be substantial cost savings if these components were offered at the clinic, by phone, email, or other real-time media. Personnel cost is another variable amenable to savings when designing adherence interventions. Well trained and supervised community health care workers could serve as qualified adherence support staff and their salaries would be considerably lower than our study staff's.^{11,14–16} Alternatively, clinics may have existing staff who are able to absorb adherence treatment duties that are brief and/or delivered remotely. In scenario 2, the assumption of personnel compensation rate of \$0.23/minute (~\$13.71/hour) is based upon the 2000 HIV Costs and Utilization Survey conducted by AHRQ.⁴⁹ An alternate staffing cost can be found within the 2009 US Bureau of Labor Statistics National Compensation Survey which lists total compensation averages for healthcare and social assistance service workers within the \$16/hour range.⁵⁰ This scenario also likely provides a more realistic idea of the true clinical costs for personnel as compared to the much higher \$0.36/min (~\$22/hour) costs seen in this study.

A significant difference between this study and other cost analysis studies is the capture of real-world adherence data using EDM. Electronic drug monitoring has a preferred adherence measure among some researchers.⁵¹ It may have some advantages to supply information about therapeutic drug coverage and to be used in providing patient adherence feedback.^{42,52} However, EDM is not without its own concerns including cost, which was \$173 per patient. Clinicians may not choose to include EDM when implementing adherence interventions for their entire clinic population. Rather, it may be wise to include limited use of EDM for specific patients that may benefit most. For example, EDM may be helpful in distinguishing whether a patient is non-adherent or a treatment non-responder. Further, reviewing EDM results with patients during adherence intervention may be useful as it has been associated with increased adherence.^{42, 52} The incremental estimates for EDM cost provided here will greatly facilitate informed decision-making. Potentially less expensive methods of assessing adherence include patient self-report and pharmacy adherence measures.⁵³

The costs associated with study evaluations may have limited real world application and likely should be excluded from decisions about clinical applications. As previously noted, the greatest cost savings in this analysis resulted from elimination of the study related costs. These consisted of costs solely related to meeting research needs and were unrelated to providing the adherence intervention. However, this is the first study to report detailed research specific cost information, which is critically important to investigators who are planning new adherence studies.

Due to the variability in resources across HIV treatment settings, it was important to consider the costs and savings that would come from a bare bones adherence intervention, which would combine all four cost saving scenarios with or without including direct costs of implementation. Surprisingly these last scenarios may not only be applicable to resource poor settings but also well-funded clinics. For clinics that already have a significant amount of available technology, most of the direct costs for computer equipment and software would already be covered. Also, for those clinics interested in implementing the interventions at their most basic level, performing direct observation through phone calls and electronic devices, may see their costs decrease over time as the initial cost for training paid personnel extends over several years of service. For clinics utilizing volunteers to deliver intervention (e.g., peer support programs), the key cost is represented by the time required by paid staff to provide training rather than the costs associated with carrying out the interventions. Although most clinics would likely not employ incentive-based systems, there is limited evidence that incentivizing good adherence may have a positive impact.⁵⁴ Starting with an empirically supported adherence intervention (i.e., cognitive behavioral counseling, mDOT) and then taking an *a la carte* approach for the selection of other potentially useful services (e.g., EDM, evaluations, incentives, in-person direct observation and travel) will allow clinics to tailor their interventions most effectively and cost-efficiently to their patient populations.

One possible limitation to our cost analysis is that costs were not adjusted to account for missed or modified visits. Since this cost analysis is based on actual study data the total costs reflect completed visits, however; the per patient costs were based on the number of scheduled visits. In some instances this could result in underestimation of the total cost and overestimation of the per patient cost. The costs associated with providing mDOT were most vulnerable to these variations. In order to accommodate for participant schedules (e.g., work, vacations), confidentiality, and other situations, the mDOT participants ended up with varied numbers and combinations of observed, delivered, phone, and electronically monitored dose observation visits. Thus the costs for this intervention may underestimate the true costs if all 93 of the ideally planned mDOT visits were completed. However it is unlikely that any setting would see 100% appointment completion rate, so the rate observed here provides a reasonable estimate for planning purposes. Another limitation of this cost analysis is that the data were retrospectively collected. However, all cost and time data were concurrently and accurately recorded and available for retrieval. Lastly, this study was not able to examine costs from a societal perspective. In future cost effectiveness analysis of intervention with adherence outcome data would be beneficial. These cost data reported in this study are extremely useful for decision making and planning real world translations of these interventions.

CONCLUSION

This economic analysis provides guidance on personnel and materials costs for clinicians and researchers wishing to employ behavioral interventions to improve ART adherence for HIV infected patients. The cost of EC and mDOT compared favorably with other cost-effective interventions. To our knowledge, this is the first published cost analysis of these combined behavioral interventions to improve ART adherence. These cost data are extremely useful for planning real world translations of these interventions and future studies.

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Figure 1. Tornado Diagram of Sensitivity Analysis: SC vs. EC vs. EC + mDOT*

*This compound tornado diagram is a graphical representation of how the relative cost of each arm of the study changes with four sensitivity analyses. Each of the three intervention costs shown are per patient annual costs. The base cost for the SC arm is \$881 and was chosen to serve as the central tendency of the diagram. Relative savings per scenario results in decreased cost of intervention moving the bar to the left.

SC = standard care, EC = enhanced counseling, mDOT = modified directly observed therapy.

Table 1

Participant Demographic Information for Project MOTIV8

	Control		Treatment			
	SC n = 65		EC n = 70	EC/mDOT n = 69		
Age (Mean years, SD)	40.4	8.2	40.8	9.6	39.9	10.7
Male (n, %)	50	76.9	50	71.4	55	79.7
Ethnicity						
Hispanic (n, %)	4	6.2	8	11.4	7	10.1
Race						
African American (n, %)	38	58.5	35	50	43	62.3
White (n, %)	21	32.3	22	31.4	22	31.9
Other (n, %)	6	9.2	13	18.6	4	5.8
Married or Committed Relationship (n, %)	15	23.5	15	21.7	20	29.0
ART Naïve (n, %)	21	32.3	24	34.3	24	34.8

SC = standard care, EC = enhanced counseling, mDOT = modified directly observed therapy, ART = antiretroviral therapy

Table 2Activity Based Time Costs for Project MOTIV8[#]

	Total Time (minutes)	Total Cost (\$)	Time Per Patient (minutes)	Cost Per Patient (\$)
Initial Costs (n=204)	148,864	53,591.04	730	262.70
Staff Training: (84.5 hrs) 3 staff members	15,210	5,475.60	74.6	26.84
Evaluation Time: (1–2 hrs × 7 sessions)	116,554	41,959.44	571.3	205.68
Recruitment: (10 min) n=1,710	17,100	6,156.00	83.8	30.18
Intervention Cost				
Enhanced Counseling (EC) (n=134)	51,188	18,427.68	382	137.52
EC Counseling: (10–25 min × 11 sessions)	26,800	9,648.00	200	72.00
EC Setup Time: (7 min × 11 sessions)	10,318	3,714.48	77	27.72
EC Driving Time: (~15 min/trip) n=938 trips	14,070	5,065.20	105	37.80
Modified Directly Observed Therapy (mDOT) (n = 64)	51,773	18,638.42	809	291.23
mDOT Observed Visits: (5.2 min) n=1,927	10,020	3,607.34	156	56.36
mDOT Electronic Visits: (4 min) n=124	496	178.56	4 *	1.44 ⁺
mDOT Phone Visits: (4 min) n=1,324	5,296	1,906.56	4 *	1.44 ⁺
mDOT E-Delivered Visits: (4 min) n=1,764	7,056	2,540.16	4 *	1.44 ⁺
mDOT observed visit Driving Time: (15 min/trip) n=1,927	28,905	10,405.80	15 *	5.40 ⁺
Total Time Costs	251,825	90,657.14		
Cost Per Patient				
Training, Evaluation, Recruitment: (N=204)			730	262.70
Enhanced Counseling : (n=134)			382	137.52
Modified Directly Observed Therapy: (n=64)			809	291.23

min = Minutes

[#] All costs are in 2008 dollars and based on the activity cost of \$0.36/minute. SC = standard care, EC = enhanced counseling, mDOT = modified directly observed therapy.

^{*} Types of visits received by patient were variable over the course of their time in study, therefore these numbers only apply to an individual visit

⁺ The cost associated with ONE mDOT visit.

The n for EC and mDOT are less than in Table 1 because these costs are based upon patients who completed the study and are therefore closer to the actual costs incurred.

Table 3

Total Individual Patient Costs

	Initial Costs (\$)		Intervention Costs (\$)		Total Costs (\$)
	Direct	Initial	EC	mDOT	
Adherence group					
SC	618	262.70			880.70
EC	618	262.70	137.52		1,018.22
EC + mDOT	618	262.70	137.52	291.23	1,309.45

SC = standard care, EC = enhanced counseling, mDOT = modified directly observed therapy

Table 4
Sensitivity Analysis for ART Adherence Interventions and EDM Showing Costs and Savings for Each Study Arm

Scenarios	Costs According to *** Scenarios			Savings According to *** Scenarios		
	SC	EC	EC/mDOT	SC	EC	EC/mDOT
Basic Scenario (\$) (\$0.36/minute)	881	1,018	1,309	--	--	--
Scenario 1 (\$) (No Driving)	774	873	1,002	107	145	307
Scenario 2 (\$) (No Driving)	786	874	1,060	95	144	249
Scenario 3 (\$) (No EDM)	708	845	1,136	173	173	173
Scenario 4 (\$) (No Evaluation)	675	812	1,103	206	206	206
Combined Scenarios 1 – 4	300	350	374	581	668	935
No Direct Costs + Combined scenarios 1 – 4	57	179	308	824	839	1,001

* One-way sensitivity analysis
 ** Multiple-way sensitivity analysis
 *** Savings refers to reduction in the total cost of intervention per arm of the study as a result of assuming the sensitivity analysis scenario.
 SC = standard care, EC = enhanced counseling, mDOT = modified directly observed therapy, ART = antiretroviral therapy, EDM = electronic drug monitoring