

Original investigation

# Cost-Effectiveness of a Health System-Based Smoking Cessation Program

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## Abstract

**Introduction:** Project CLIQ (Community Link to Quit) was a proactive population-outreach strategy using an electronic health records-based smoker registry and interactive voice recognition technology to connect low- to moderate-income smokers with cessation counseling, medications, and social services. A randomized trial demonstrated that the program increased cessation. We evaluated the cost-effectiveness of CLIQ from a provider organization's perspective if implemented outside the trial framework.

**Methods:** We calculated the cost, cost per smoker, incremental cost per additional quit, and, secondarily, incremental cost per additional life year saved of the CLIQ system compared to usual care using data from a 2011–2013 randomized trial assessing the effectiveness of the CLIQ system. Sensitivity analyses considered economies of scale and initial versus ongoing costs.

**Results:** Over a 20-month period (the duration of the trial) the program cost US \$283 027 (95% confidence interval [CI] \$209 824–\$389 072) more than usual care in a population of 8544 registry-identified smokers, 707 of whom participated in the program. The cost per smoker was \$33 (95% CI 28–40), incremental cost per additional quit was \$4137 (95% CI \$2671–\$8460), and incremental cost per additional life year saved was \$7301 (95% CI \$4545–\$15 400). One-time costs constituted 28% of costs over 20 months. Ongoing costs were dominated by personnel costs (71% of ongoing costs). Sensitivity analyses showed sharp gains in cost-effectiveness as the number of identified smokers increased because of the large initial costs.

**Conclusions:** The CLIQ system has favorable cost-effectiveness compared to other smoking cessation interventions. Cost-effectiveness will be greatest for health systems with high numbers of smokers and with the high smoker participation rates.

**Implications:** Health information systems capable of establishing registries of patients who are smokers are becoming more prevalent. This economic analysis illustrates the cost implications for health care systems adopting a proactive tobacco treatment outreach strategy for low- and middle-income smokers. We find that under many circumstances, the CLIQ system has a favorable cost-per-quit compared to other population-based tobacco treatment strategies. The strategy could be widely disseminable if health systems leverage economies of scale.

## Introduction

Each year 53% of the 42 million smokers in the United States make a quit attempt, but only 6% succeed despite the availability of effective tobacco cessation treatments.<sup>1-3</sup> Population-level outreach is a novel strategy for connecting with smokers and encouraging them to make a cessation attempt.<sup>4-8</sup> Outreach can provide the necessary motivation for moving smokers through stages of change towards cessation and connect smokers with treatments that improve their chances of quitting.<sup>8-10</sup>

In 2013 we completed Project CLIQ (Community Link to Quit), a population-based randomized controlled smoking cessation trial of smokers living in geographic areas with median household incomes <US \$67 050 who had recently received primary care in a large non-profit health system.<sup>11</sup> Smokers were identified in electronic health record (EHR) documentation and offered treatment using interactive voice response (IVR) technology—a computerized telephone outreach system. Intervention patients were also offered connections to social services<sup>12</sup> to help manage stressors that impede quitting among low- and moderate-income smokers.<sup>13</sup> The program was found to increase cessation rates. The present study evaluates the cost-effectiveness (cost per quit, cost per life year saved) of the intervention relative to usual care (office-based brief counseling for smoking cessation).

## Overview of the Project CLIQ Study

Details of the Project CLIQ study have been published elsewhere.<sup>11</sup> The pragmatic trial recruited patients from 13 primary care practices which share an EHR-based registry of smokers within Partners HealthCare, a large nonprofit health care delivery system in Massachusetts. Between November 2011 and June 2013, 8544 patients were identified in the registry as smokers who had medical visits in the past month. Each was sent a letter describing the study and offering the opportunity to opt out of participation. Those not opting out were randomized to treatment or control and contacted by IVR, which delivered a standard informed consent script. Patients who consented confirmed their smoking histories. The IVR system automatically updated smoking histories in the EHR.

At the end of the IVR call, patients in the control arm received only nonsystematic smoking cessation counseling (“brief counseling”) by physicians during existing office visits. Patients in the intervention group were asked if they wanted to speak on the phone to a tobacco treatment specialist (TTS) about smoking cessation counseling and the opportunity to receive a free 6-week course of nicotine patches dosed according to the number of cigarettes smoked per day by the patient. Intervention patients opting to speak with a TTS received on average 75–100 minutes of counseling in up to four calls delivered during an 8- to 10-week period. The TTS promoted use of the nicotine patch and answered questions about cessation and patch use. In addition, the TTS offered to connect patients with social services via HelpSteps.com, a web-based clearing-house for local social services relevant to low-income individuals.<sup>12</sup> Most of these services are free. When patients encountered out-of-pocket costs, the patient, not the study, paid. Those in the intervention arm may also have received brief tobacco treatment counseling by physicians during existing office visits.

Of those identified in the registry as smokers, 455 (5.3%) lacked valid phone numbers or indicated they had stopped smoking. Of the 8089 remaining, the IVR never reached 5008 (61.9%) and 2374 (29.3%) declined to participate. Thus 707 of 8544 registry-identified

smokers (8.3%) participated in the study. Study participants were mostly women (68%) and the median age was 50. Over a quarter were non-Hispanic black (28%), 20% were Hispanic, 62% were white, and the remainder were of “other” race/ethnicity. A third (34%) were Medicaid recipients and nearly half (47.5%) lived in low-income (<\$45 000/y) census tracts. Median cigarette consumption was 15 cigarettes per day. Most participants (75%) had their first cigarette within 30 minutes of waking, and more than half of participants (53%) made a quit attempt in the 6 months prior to randomization.

Among participating patients, at the end of the trial (9 months post-randomization), 17.8% of intervention patients and 8.1% of control (limited IVR contact and brief counseling) patients reported 7-day tobacco abstinence ( $p < .001$ ; risk difference 9.7%, 95% confidence interval [CI] 4.8–14.5) according to intention-to-treat (ITT) analysis assuming those with missing smoking status were smokers. Analyses using multiple imputation for missing smoking status found 26.8% in the intervention group and 12.4% in the control group were abstinent at follow-up ( $p < .001$ , risk difference 14.5%, 95% CI 8.8–20.2).

The IVR system and linkage to the EHR were relatively low-cost means of identifying and connecting smokers to evidence-based smoking cessation treatment as well as referral to social services. Though low cost, the outreach system needs to be evaluated in the context of low patient participation and cessation rates. We evaluated the cost-effectiveness compared to usual care of implementing the program tested in Project CLIQ within a technologically robust health care system over the 20-month period of the trial. We measured value in incremental cost per additional quit from the primary care system’s perspective. Secondly we calculated the incremental cost per additional life year saved. Further, we assessed the initial and ongoing costs of the program and projected how cost-effectiveness would change based on the size and reach of the program. Our goal was to understand the requirements for and challenges of implementing the program in other primary care systems.

## Methods

### Overview

Our analysis took the perspective of and is designed to inform decision-making for a primary care network, a common type of provider organization in the United States’ fragmented payer/provider system. As such, we modeled how a health system adopting a program integrating an EHR-based smoker registry, an IVR system, and the proactive offer of tobacco treatment (counseling, nicotine replacement therapy) compared with one where smokers were only offered brief counseling during existing office visits. Estimates for the difference in costs and effects of these two alternatives were drawn from the CLIQ trial, which tested alternatives that do not perfectly match the policy-relevant modeling scenario. However, using the CLIQ trial data yielded conservative cost-effectiveness estimates, that is, estimates biased against favorable cost-effectiveness for the novel program as detailed in [Table 1](#).

### Cost Data

#### Hardware and Infrastructure

Hardware and infrastructure costs were determined from purchasing records. The cost of the IVR system represents the one-time cost of buying and installing the equipment. In addition, we included the

**Table 1.** Differences Between Scenario Model in the Cost-Effectiveness Analysis and Data Used From Project CLIQ

|               | Scenario modeled in cost-effectiveness analysis                                  | Data from trial used to approximate model scenario                               | Impact on cost-effectiveness analysis  |
|---------------|--|--|--|
| <b>Cost</b>   |  |  |  |
| Intervention  | EHR registry, IVR, TTS counseling, NRT, brief counseling <sup>control</sup>      | EHR registry, IVR, TTS counseling, NRT, brief counseling <sup>intervention</sup> | The cost in the modeling scenario is potentially overestimated because using the trial data we are not able to credit the intervention for reducing the need for brief counseling in the office (brief counseling <sup>intervention</sup> ≤ brief counseling <sup>control</sup> ). |
| Control       | Brief counseling <sup>control</sup>  | Brief counseling <sup>control</sup>  |  |
| <b>Effect</b> |  |  |  |
| Intervention  | EHR registry, IVR, TTS counseling, NRT, brief counseling <sup>intervention</sup> | EHR registry, IVR, TTS counseling, NRT, brief counseling <sup>intervention</sup> | The effect size in the modeling scenario is potentially underestimated because the control group in the trial data received IVR outreach (IVR outreach effect ≥ 0).  |
| Control       | Brief counseling <sup>control</sup>  | IVR, brief counseling <sup>control</sup>   |  |

EHR = electronic health record; IVR = interactive voice recognition system; NRT = nicotine replacement therapy; TTS = tobacco treatment specialist. Note that brief counseling (office-based smoking cessation advice from clinicians) is not explicitly modeled.

cost of ongoing phone use for the IVR system. We included one-time programming costs (consultant fees) for adding a registry of smokers to the existing EHR and for linking the IVR and EHR systems allowing updates to a patient's smoking status. We do not include the cost of the EHR itself. We also included one-time and ongoing personnel costs (wage and fringe) associated with developing the system used by staff to track patient contacts. We included the cost of full-service office space. Lastly, we assumed a one-time cost for licensing access to HelpSteps.com.

#### Personnel

We assumed the TTS arrived with no prior experience and included one-time costs for training and certification. TTS costs were a function of the time the TTS devoted to outreach, counseling, and data entry as well as a supervisor's time, and were estimated using personnel budgets (wages and fringe benefits). In sensitivity analyses, we assumed a program twice the size of Project CLIQ would require an additional counselor and therefore additional one-time training costs. In addition to the TTS, we included the cost of a tobacco treatment coordinator who was responsible for managing the smoker registry and packing/shipping nicotine patches. We assumed the coordinator's effort was completely scalable.

#### Supplies and Medication

All supply and medication costs are based on study records. Costs of supplies included outreach materials to verify contact information and smoking status, as well as the cost of letters inviting patients to participate in the program. We also included the one-time cost of translating the written materials into Spanish. Medication costs included a 6-week supply of nicotine patches (using the institution's acquisition cost), one-time set-up costs for the pharmacy, dispensing costs, and express shipping costs.

#### Discounting

Analyses of data over the 20-month study period discounted second-year costs at 3.5% (see below). Analyses presenting first year and subsequent year costs (second year and beyond) are reported without discounting to illustrate start-up (first year) versus ongoing (any subsequent year) costs.

#### Incremental Cost-Effectiveness

To calculate incremental cost per additional quit, we used cessation rates from the CLIQ trial. We secondarily projected the incremental

cost per additional life year saved based on estimates published by Stapleton and West in *Nicotine and Tobacco Research* modeling changes in life expectancy for former versus current smokers.<sup>14</sup> Except where stated otherwise, these analyses considered costs over the 20-month CLIQ intervention period and benefits over a smoker's lifetime. All analyses are reported in US \$. Program effects on lifetime medical costs are discussed but not calculated.

Total costs and effects were estimated assuming that the entire population of registry-identified smokers ( $n = 8544$ ) was offered the proactive intervention tested in the CLIQ trial, or alternatively, brief counseling alone (usual care). Confidence bounds on costs, program-induced quits, and the cost per quit were estimated using Monte Carlo methods. Cost parameters were drawn from Gamma distributions with means defined by costs incurred in the CLIQ trial and standard errors set at 10% of the mean. Effectiveness parameters were drawn from the sampling distributions used in the CLIQ outcomes assessment. In sensitivity analyses, we varied the number of smokers to demonstrate economies of scale. To estimate the incremental cost per additional quit we divided the additional cost of the intervention compared to usual care by the number of quits achieved through the intervention above what would have occurred through usual care.

To estimate the cost per additional life year saved, we applied methods described by Stapleton and West.<sup>14</sup> They calculated life years saved based on the risk difference in continuous abstinence between two cessation strategies as a function of the smoker's age at cessation, taking into account potential future cessation in the control group as well as relapse in the intervention group. Project CLIQ measured 7-day point prevalence abstinence at 9 months following randomization. Because the likelihood of future relapse decreases with time from cessation, we conservatively considered the Project CLIQ measures to be point prevalence abstinence at 6-months follow-up for purposes of applying the Stapleton and West model. While continuous and point prevalence abstinence measures differ, available evidence suggests that risk differences based on point prevalence abstinence are smaller (more conservative) than those based on continuous abstinence.<sup>15</sup> The Stapleton and West model uses a 3.5% annual discount rate for life years saved, which is slightly more conservative than the 3% rate often used in US analyses.<sup>16</sup> It also assumes 51% of those abstinent at 6 months will relapse, and conservatively assumes that all relapses will happen immediately at that time point. The cost per additional life year saved analyses used the ITT risk difference from the Project CLIQ trial as the primary

effectiveness measure, but also considered the multiple imputation-based risk difference. Because the Stapleton and West model is designed to be conservative in all its component parameters, we do not try to assign a standard error and statistical variability to the estimated life years gained in our Monte Carlo analyses; rather we assume all variability in life years gained stems from variability in the risk difference estimates. Though the Stapleton and West model estimates life years saved due to smoking cessation based on data from a study of British male physicians, near identical gains in life expectancy are estimated in the general US population, irrespective of sex. As such, use of the Stapleton and West model should not bias estimates of life year gains.<sup>17</sup>

### Sensitivity Analyses

Our primary cost-effectiveness analysis uses Monte Carlo methods to assess the impact of uncertainty in model parameters on cost per quit estimates. By reporting costs disaggregated into their components, we also allow readers to assess the sensitivity of our conclusions to their own locally relevant parameters. We conducted two sets of one-way sensitivity analyses with the goal of illustrating how economies of scale would affect cost-effectiveness. Differences in numbers of EHR-identified smokers and the ability to reach them are key concerns for primary care systems considering adopting the intervention.

In our first one-way sensitivity analysis, we estimated outcomes while varying the number of EHR-identified smokers in the first year of the program to illustrate how volume affects the short-run cost-effectiveness. We also estimated outcomes as a function of volume in subsequent years, which may or may not be the same as in the first year. This was designed to illustrate costs once start-up costs are “sunk,” but also to estimate costs for the different steady states that might arise once the initial population of smokers has been reached by the program. “Subsequent year” estimates may be considered independently from the first year estimates.

The second one-way sensitivity analysis considered how outcomes would change over the 20-month study period if the numbers of smokers successfully recruited into the program varied. In the base case, 707 of 8544 (8.3%) agreed to participate. We considered halving and doubling the proportion of smokers who participate, assuming outreach efforts were unchanged but treatments provided (personnel time and medications) were scaled proportionally. This analysis was designed to illustrate differences that might arise if the smoking population was more or less receptive to participation. We also considered the effect of halving the quit rate for all participants above the base case number of 707 in the event that additional smokers attempting to quit are less likely to succeed.

## Results

### Total Costs

We estimate that over the 20-month study period, the intervention applied to 8544 registry-identified smokers would cost \$283 027 (95% CI \$209 824–\$389 072) more than usual care (Table 2). Of that amount, \$78 583 (28%) is one-time start-up costs. The largest individual start-up cost is the IVR system itself, followed by the development of program infrastructure. Ongoing costs are dominated by personnel (TTS, supervisor, and coordinator wages), totaling \$145 365 (51% of total costs, 71% of ongoing costs). Medication costs (medication, pharmacy, and shipping) are a much smaller proportion

of costs, totaling \$41 381 (15% of total costs, 20% of ongoing costs). See Supplementary Appendix for detailed cost inputs.

### Cost-Effectiveness

We calculated a cost of \$33 (95% CI \$28–\$40) per registry-identified smoker. Comparing intervention to usual care, we estimate a risk difference of 9.7%, or approximately 69 (95% CI 33–108) incremental quits (9.7% x 707 smoker participants) based on the ITT analysis. The incremental cost per additional quit is \$4137 (95% CI \$2671–\$8460) over the 20-month study period. Based on the Stapleton and West model, those 69 quits are expected to save 39 (95% CI 18–63) life years for an overall incremental cost per additional life year saved of \$7301 (95% CI \$4545–\$15 400). Under the multiple

**Table 2.** Cost Parameters and Cost-Effectiveness Over 20-Month Study Period

| Intervention cost parameters                       | Total     | 95% CI                         |
|--|-----------|--------------------------------|
| IVR system   | \$55 750  | (\$45 335–\$67 174)            |
| EHR linkage  | \$5000    | (\$4059–\$6017)                |
| HelpSteps license                                  | \$5000    | (\$4062–\$6035)                |
| Program infrastructure                             | \$11 583  | (\$9975–\$13 398)              |
| TTS startup  | \$1250    | (\$1056–\$1462)                |
| Total one-time costs                               | \$78 583  | (\$67 924–\$90 219)            |
| IVR phone lines                                    | \$1440    | (\$1075–\$1875)                |
| Office space and services                          | \$11 250  | (\$9154–\$13 566)              |
| TTS and supervisor wages                           | \$83 906  | (\$49 780–\$134 612)           |
| Coordinator wages                                  | \$61 459  | (\$36 693–\$98 569)            |
| Outreach supplies                                  | \$5008    | (\$3735–\$6516)                |
| NRT (medication and shipping)                      | \$28 955  | (\$17 696–\$45 638)            |
| Pharmacy management and dispensing                 | \$12 426  | (\$7345–\$20 059)              |
| Total ongoing costs                                | \$204 444 | (\$132 621–\$309 207)          |
| Total costs  | \$283 027 | (\$209 824–\$389 072)          |
| Effectiveness parameters                           | Parameter | 95% CI                         |
| Reach rate   | 8.3%      | (7.7%–8.9%) <sup>a</sup>       |
| Incremental quits (ITT)                            | 69        | (33–108) <sup>a,b</sup>        |
| Incremental quits (multiple imputation)            | 102       | (60–151) <sup>b</sup>          |
| Incremental life years saved (ITT)                 | 39        | (18–63)                        |
| Incremental life years saved (multiple imputation) | 58        | (33–89)                        |
| Cost-effectiveness                                 |           |                                |
| Cost per smoker                                    | \$33      | (\$28–\$40)                    |
| Cost per quit (ITT)                                | \$4137    | (\$2671–\$8460) <sup>b</sup>   |
| Cost per quit (multiple imputation)                | \$2765    | (\$1918–\$4664) <sup>b</sup>   |
| Cost per life year saved (ITT)                     | \$7301    | (\$4545–\$15 400) <sup>c</sup> |
| Cost per life year saved (multiple imputation)     | \$4880    | (\$3240–\$8572) <sup>c</sup>   |

CI = confidence interval; EHR = electronic health record; IVR = interactive voice recognition system; ITT = intention-to-treat; NRT = nicotine replacement therapy; TTS = tobacco treatment specialist. Confidence bounds based on 100 000 simulations. Values presented are rounded to the nearest dollar, though calculations were based on raw values.

<sup>a</sup>Reach rate and quit rate variability based on CLIQ trial data using normal approximation to the binomial distribution.

<sup>b</sup>Intervention-attributable quits are a function of the reach rate and the efficacy of the IVR, counseling, and NRT. However, we are not able to model/estimate these components separately. Therefore, the variability in quit rates used in the Monte Carlo simulation and the resulting variability in cost per quit estimates are slightly inflated.

<sup>c</sup>Additional life years gained vary conditionally on the quit rate.

imputation analysis, there were 102 (95% CI 60–151) incremental quits and 58 (33–89) life years saved for a cost per additional quit of \$2765 (95% CI \$1918–\$4664) and a cost per additional life year saved of \$4880 (95% CI \$3240–\$8572).

### Sensitivity Analyses

Table 3 presents component costs, total costs, and cost-effectiveness estimates as a function of the number of smokers identified in the registry during the first year and subsequent years of the program using the ITT trial results. With each doubling of the number of smokers identified in the first year of the program from 1000 to 8000, costs increased, but cost per smoker, incremental cost per additional quit, and incremental costs per additional life year saved decreased. The gains in incremental cost-effectiveness were greater when considering a shift from 1000 to 2000 smokers identified (cost per additional quit and cost per additional life year saved reduced 39%) than when the number of smokers identified increased from 4000 to 8000 (cost per additional quit and cost per additional life year saved reduced 21%) due to the larger role of fixed costs for a smaller program. However, costs per additional quit and costs per additional life year saved for subsequent years of the program were generally consistent, irrespective of the number of smokers identified annually. Should future quit rates diminish, cost per additional quit and cost per additional life year saved would change proportionally.

Variations in the numbers of smokers agreeing to participate in the program also affected cost-effectiveness (Table 4). If 354 smokers participate (half of what was observed in CLIQ), the cost per additional quit would rise to \$5318 over the 20-month period and the cost per additional life year saved would rise to \$9387. If double

the number of smokers participated, the cost per additional quit would fall to \$3468 and the cost per additional life year saved would be \$6121. However, if the additional participants were half as likely to quit, the cost per additional quit would be \$4623 and the cost per additional life year saved would be \$8161.

### Discussion

Until recently, most population-based tobacco cessation efforts used passive enrollment. For example, quitlines advertise their presence, but individual smokers must call seeking cessation assistance. Active efforts to identify smokers and encourage smoking cessation have largely been limited to clinical encounters, be they ambulatory care visits<sup>18,19</sup> or hospitalizations.<sup>20</sup> With recent advances in and adoption of health information technology and increased efforts to document patients' smoking status in EHRs following "meaningful use" requirements,<sup>21,22</sup> smokers in a population are easier to identify and can be actively engaged to encourage smoking cessation outside the context of a clinical visit. The advantages of such an approach include the ability to target efforts at suspected smokers, the ability to regularly encourage cessation even when clinical encounters do not occur regularly, the ability to manage tobacco treatment using specially trained staff whose time is less expensive than physicians, and the ability to free-up time in clinic visits for other important health topics. The present study was designed to help primary care provider systems considering programs similar to CLIQ understand the cost-effectiveness of the intervention relative to usual care.

We estimated that CLIQ cost \$33 per registry-identified smoker and had an incremental cost per additional quit of \$4137 (95% CI

**Table 3.** Effect of Number of Registry-Identified Smokers on Program Costs and Cost-Effectiveness (US \$)

| Number of smokers                      | First year       |                  |                  |                  | Subsequent years |                 |                 |                 |                  |
|--|------------------|------------------|------------------|------------------|------------------|-----------------|-----------------|-----------------|------------------|
|  | 1000             | 2000             | 4000             | 8000             | 500              | 1000            | 2000            | 4000            | 8000             |
| <b>Start-up costs</b>                  |                  |                  |                  |                  |                  |                 |                 |                 |                  |
| IVR system                             | \$55 750         | \$55 750         | \$55 750         | \$55 750         |                  |                 |                 |                 |                  |
| EHR linkage                            | \$5000           | \$5000           | \$5000           | \$5000           |                  |                 |                 |                 |                  |
| Help Steps license                     | \$5000           | \$5000           | \$5000           | \$5000           |                  |                 |                 |                 |                  |
| Program infrastructure <sup>a</sup>    | \$11 415         | \$11 415         | \$11 499         | \$11 667         |                  |                 |                 |                 |                  |
| TTS startup                            | \$1250           | \$1250           | \$2500           | \$5000           |                  |                 |                 |                 |                  |
| <b>Ongoing costs</b>                   |                  |                  |                  |                  |                  |                 |                 |                 |                  |
| IVR phone lines                        | \$216            | \$432            | \$864            | \$1728           | \$216            | \$216           | \$432           | \$864           | \$1728           |
| Office <sup>b</sup>                    | \$1688           | \$3375           | \$6750           | \$13 500         | \$1688           | \$1688          | \$3375          | \$6750          | \$13 500         |
| TTS wages                              | \$9820           | \$19 641         | \$39 282         | \$78 564         | \$4910           | \$9820          | \$19 641        | \$39 282        | \$78 564         |
| Coordinator wages                      | \$7754           | \$14 811         | \$28 926         | \$57 156         | \$4225           | \$7754          | \$14 811        | \$28 926        | \$57 156         |
| Outreach supplies <sup>c</sup>         | \$586            | \$1171           | \$2343           | \$4686           | \$293            | \$586           | \$1171          | \$2343          | \$4686           |
| NRT                                    | \$2693           | \$5387           | \$10 773         | \$21 547         | \$1347           | \$2693          | \$5387          | \$10 773        | \$21 547         |
| NRT shipping                           | \$696            | \$1391           | \$2782           | \$5565           | \$348            | \$696           | \$1391          | \$2782          | \$5565           |
| Pharmacy <sup>d</sup>                  | \$1454           | \$2909           | \$5817           | \$11 635         | \$727            | \$1454          | \$2909          | \$5817          | \$11 635         |
| <b>Total</b>                           | <b>\$103 321</b> | <b>\$127 532</b> | <b>\$177 286</b> | <b>\$276 796</b> | <b>\$13 753</b>  | <b>\$24 907</b> | <b>\$49 117</b> | <b>\$97 538</b> | <b>\$194 379</b> |
| Cost per smoker                        | \$103            | \$64             | \$44             | \$35             | \$28             | \$25            | \$25            | \$24            | \$24             |
| Program-attributable quits             | 8                | 16               | 32               | 64               | 4                | 8               | 16              | 32              | 64               |
| Program-attributable life years gained | 4.86             | 9.72             | 19.45            | 38.90            | 2.43             | 4.86            | 9.72            | 19.45           | 38.90            |
| Cost per additional quit               | \$12 902         | \$7963           | \$5535           | \$4321           | \$3435           | \$3110          | \$3067          | \$3045          | \$3034           |
| Cost per life year saved               | \$21 249         | \$13 114         | \$9115           | \$7116           | \$5657           | \$5122          | \$5051          | \$5015          | \$4997           |

EHR, electronic health record; IVR, interactive voice recognition; NRT = nicotine replacement therapy; TTS, tobacco treatment specialist.

<sup>a</sup>Development of program and pharmacy protocols, document translation, databases.

<sup>b</sup>Space, computer, phone.

<sup>c</sup>Stationary, postage, printing.

<sup>d</sup>Management, dispensing.

**Table 4.** Effect of Smoker Enrollment on Program Costs and Cost-Effectiveness Over 20-Month Study Period (US \$)

|  | Number of smokers participating (proportion of base case) |             |             |           |  |           |
|--|---|-------------|-------------|-----------|--|-----------|
|  | Base case   |             |             |           | Quit rate diminishes with increased population size <sup>a</sup> |           |
|  | 354 (0.5x)  | 530 (0.75x) | 884 (1.25x) | 1414 (2x) | 884 (1.25x)  | 1414 (2x) |
| Total costs                            | \$184 605   | \$233 814   | \$332 232   | \$481 461 | \$332 232  | \$481 461 |
| Cost per smoker                        | \$22  | \$27        | \$39        | \$56      | \$39   | \$56      |
| Program-attributable quits             | 35  | 52          | 87          | 139       | 78   | 104       |
| Program-attributable life years gained | 19.67   | 29.50       | 49.16       | 78.66     | 44.25  | 59.00     |
| Cost per additional quit               | \$5318  | \$4491      | \$3828      | \$3468    | \$4254   | \$4623    |
| Cost per life year saved               | \$9387  | \$7926      | \$6758      | \$6121    | \$7508   | \$8161    |

<sup>a</sup>Assumes the quit rate is reduced by half for all participants above the base case number of 707.

\$2671–\$8460) over the 20-month course of the program. If the project continued and reached out to at least 1000 smokers per year, it would have continuing costs of no more than \$25 per smoker and \$3110 per quit. Over the range of the 95% CI for the effectiveness estimates, cost-effectiveness ratios could decrease by about 35% or increase by 100%. Under the less conservative but now state-of-the-art multiple imputation estimate of effectiveness, CLIQ's cost-effectiveness improves by 33% at the mean relative to ITT. The closest comparable study to this was the Direct to Smoker (DTS) study in which smokers were similarly contacted by mail and phone on a proactive basis, offered brief counseling and free smoking cessation medications, and encouraged to contact the state quitline.<sup>8</sup> Compared to participants in CLIQ, DTS smokers were similar in age and sex, more likely to be white, less likely to be on Medicaid, and more likely to have a chronic condition (diabetes or cardiovascular disease). In the DTS study, the authors found a risk difference of 7.7% and a cost per additional quit of \$464 at 3 months follow-up. Assuming that 55% of those smokers relapsed by 6 months follow-up,<sup>14</sup> the cost per additional quit more than doubles to \$1031. The CLIQ intervention had a higher incremental cost-effectiveness ratio than DTS, but it sought to engage a more vulnerable and possibly less motivated population which would be expected to have a lower likelihood of quitting.<sup>13</sup> CLIQ's cost-effectiveness is within the range of estimates for other population-level interventions which yielded costs per additional quit ranging from \$923 to \$4319 for state quitline programs,<sup>9,10,23,24</sup> \$487 to \$9685 for mass media campaigns,<sup>25,26</sup> and \$584 to \$5811 for hospital-initiated smoking cessation programs,<sup>27–29</sup> all adjusted for inflation to 2013 dollars.<sup>30</sup>

Differences in cost-effectiveness between CLIQ and DTS were greater in terms of cost per additional life year saved. Applying the Stapleton and West model to the effectiveness estimates reported in the DTS study we find a cost per additional life year saved of \$1091 compared to the \$5380 per additional life year saved expected for ongoing implementation of CLIQ if at least 1000 smokers per year are identified in the registry. CLIQ might become more cost-effective from a private health system's perspective by referring patients to a quitline in place of program-provided counseling and by providing a shorter course of nicotine patches. In New York State, the quitline was found to be equally effective when dispensing 2, 4, or 6 weeks of nicotine patches in conjunction with telephone counseling.<sup>10</sup> However, lower costs would need to be balanced with quitlines' potentially lower quit rate.<sup>31</sup> We do not consider the value of reduced future health expenditures. Conservative modeling efforts assume no difference in health care expenditures between continuing

and former smokers,<sup>25,32,33</sup> though the best evidence suggests quitting smoking reduces lifetime health care expenditures<sup>34–36</sup> which will reduce the costs per additional life year saved for both CLIQ and DTS.<sup>37</sup> In addition, the Stapleton and West model does not provide estimates of incremental quality-adjusted life years saved. However, published ratios of quality-adjusted life years saved to life years saved in smoking cessation studies generally range from 0.7 to 1.4, with ratios >1 reflecting the higher quality of life experienced by former smokers compared to current smokers.<sup>35,38</sup> Considered in the context of commonly-cited cost-effectiveness thresholds of \$50 000–150 000 per additional quality-adjusted life year saved, both CLIQ and DTS are highly cost-effective.<sup>39</sup>

Another main contribution of the current study is an illustration of the relationship between the volume of smokers seen by a primary care system and cost-effectiveness. Because infrastructure costs for implementing the CLIQ service were high relative to ongoing program costs, costs per additional quit and per additional life year saved in the first year were substantially higher when there were fewer smokers in the population. A third-party vendor providing the CLIQ service could operate with the necessary economies of scale to more efficiently bring population-based smoking cessation services to smaller care systems and those with relatively few participating smokers. Cost-effectiveness estimates were also affected by the proportion of smokers contacted that agreed to participate in the program. Even absent specific efforts to increase reach, we expect that reach would be higher outside the randomized clinical trial context we observed, as some people in our study were reluctant to participate in a research study of randomly assigned treatment. Cost-effectiveness would diminish if it cost more to reach additional smokers or if the effectiveness of the intervention diminished as the population of smokers became, on average, less likely to quit.

Despite promising cost-effectiveness estimates, fragmented payment systems such those found in the United States represent a barrier to population-based smoking cessation outreach. Under fee-for-service payment, health systems are rarely reimbursed for care provided outside the context of office visits. Fully or partially capitated payment systems, including accountable care organizations, are designed to make care decisions more holistic and amenable to prevention, but only if the benefits of prevention accrue in the short term, which is not the case for many smoking-related diseases.<sup>40–42</sup> To maximize the implementation of population-based smoking cessation programs, payers need to give providers incentives tied to population smoking outcomes.

This analysis is subject to certain limitations. Project CLIQ was designed to improve smoking cessation success for low- to moderate-income smokers in a large health care delivery system. Our health system's costs may not be representative of all health systems' costs. Also our health system has well-established, robust health information technology. Development costs might be different when built onto more basic systems. The Stapleton and West model for calculating additional life years saved was developed using estimates of continuous abstinence at 6 months and data from a narrowly defined, all-male population. We are assuming that the risk difference based on point prevalence abstinence at 9 months is a reasonable approximation of the risk difference for continuous abstinence at 6 months. The life expectancy estimates used by Stapleton and West are nearly identical to those calculated in US population-based studies of men and women<sup>17,43</sup> and longevity gains from smoking cessation in this setting are principally a function of age at cessation. The Stapleton and West model was designed to be broadly applicable, conservative in all its parameters, and thus biased against cost-effectiveness. Lastly, the participation rate in CLIQ (8.3%) was low in absolute terms, but was highly favorable relative to other population-based initiatives like quit lines where participation rates average 1.0%.<sup>44</sup>

In conclusion, the proactive population-based smoking cessation program tested in Project CLIQ under conservative assumptions did not appear as cost-effective as a related strategy (DTS), but demonstrated favorable cost-effectiveness compared to other smoking cessation programs and is likely to be highly cost-effective by common cost-effectiveness thresholds (\$50 000–\$150 000/additional quality-adjusted life year) compared to other health interventions. Cost-effectiveness will be greatest for health systems with the highest numbers of smokers and with the highest smoker participation rates.

## Supplementary Material

Supplementary Appendix can be found online at <http://www.ntr.oxfordjournals.org>

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## Declaration of Interests

DEL has received consulting fees from CVS/Caremark. NAR reports royalties from UpToDate and has served as an unpaid consultant to Pfizer outside the submitted work. HelpSteps.com is freely available on the web for general use. There are no intended patents. The other authors report no financial disclosures.

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