Cost-effectiveness of population-level proactive tobacco cessation outreach among socio-economically disadvantaged smokers: evaluation of a randomized control trial

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ABSTRACT

Aims To estimate the cost-effectiveness at population-level of the OPT-IN proactive tobacco cessation outreach program for adult smokers enrolled in publicly funded health insurance plans for low-income persons (e.g. Medicaid). **Design** Cost-effectiveness analysis using a state transition model based on data from the Offering Proactive Treatment Intervention (OPT-IN) randomized control trial. **Setting** The trial was conducted in Minnesota, USA, and the economic analysis was conducted from the Medicaid program perspective. **Participants** Data were used from 2406 smokers who were randomized into the intervention or comparator groups. **Intervention and comparator** The intervention was comprised of proactive outreach (mailed invitation and telephone calls) and free cessation treatment (nicotine replacement therapy and intensive telephone counseling). The comparator was usual care, which comprised access to a primary care physician, insurance coverage of Food and Drug Administration (FDA)-approved smoking cessation medications and the state's telephone quitline. **Measurements** Smoking status, quality of life and health-care use at varying times, including at baseline and 1 year. **Findings** The OPT-IN program cost an average of $84 per participant greater than the comparator. One year after randomization, the population-level, 6-month prolonged smoking abstinence rate was 16.5% in the proactive outreach intervention group and 12.1% in the usual care group ($P < 0.05$). The model projected that the proactive outreach intervention added $78 in life-time cost and generated 0.005 additional quality-adjusted life-years (QALYs), with an expected incremental cost-effectiveness ratio of $4231 per QALY. Probabilistic sensitivity analysis found that the proactive outreach intervention would be cost-effective against a willingness-to-pay threshold of $50 000/QALY approximately 68% of the time. **Conclusions** Population-level proactive tobacco treatment with personal telephone outreach was effective in achieving higher population-level quit rates and was cost-effective at various willingness-to-pay thresholds, compared with usual care (i.e. reactive treatment). Taken together with prior research, population-level proactive tobacco cessation outreach programs are judged to be highly cost-effective over the long term.

Keywords Cost-effectiveness, health-care disparities, low-income population, Markov model, proactive outreach, smoking cessation.

INTRODUCTION

Tobacco-related health disparities are growing, and constitute a serious public health concern among socio-economically disadvantaged populations [1,2], including those enrolled in publicly funded health insurance programs such as Medicaid. Medicaid recipients are twice as likely to smoke as privately insured individuals (25.3 versus 11.8%) [3,4]. As a result, Medicaid recipients suffer disproportionately from smoking-related morbidity and mortality. Additionally, Medicaid spends more money on smoking-related health complications than other health

insurers. From 2006 to 2010, Medicaid spent approximately $39 billion annually (15% of its total budget) treating smoking-related complications, while private insurance spent just 5% [5]. Because public financing plays a key role in helping smokers to quit, policymakers need rigorous evidence to guide decisions toward high-value public investments.

Tobacco cessation has long been established as a cost-effective clinical preventive service for adults based on studies of various individual-level smoking cessation treatments (e.g. medications, counseling) [6–8]. Multiple evidence-based smoking cessation treatments [pharmacotherapy, including nicotine replacement therapy (NRT), bupropion and varenicline and/or counseling either in person or by telephone] are available. However, these treatment combinations are infrequently utilized, particularly by socio-economically disadvantaged smokers, and can be burdensome for health systems to administer [9].

Population-level proactive outreach strategies are increasingly being evaluated as a systematic approach to increase use of evidence-based tobacco cessation treatments [10]. Population-level proactive outreach is a model of patient engagement that systematically identifies smokers and proactively engages them with connection to evidence-based treatments. Proactive outreach integrates individual-level treatments and public health approaches to increase the population impact of treatment, which is the product of the effectiveness of treatment and the reach of treatment into the target population [11–13]. This strategy contrasts with the current model of tobacco cessation treatment based primarily on reactive care (a passive approach) that requires smokers to either initiate treatment or to have a clinical encounter in which their primary care provider has the time, willingness and capacity to offer and deliver smoking cessation care. While the US Public Health Service (PHS) guidelines for treating tobacco use recommend the use of the 5As (Ask, Advise, Assess, Assist, Arrange follow-up) at every clinical encounter by primary care clinicians, most smokers do not receive comprehensive treatment that includes both pharmacotherapy and behavioral counseling, which has been demonstrated to be most effective for smoking cessation [14]. In 2015, 29% of smokers used a smoking cessation medication, 6.8% used behavioral counseling, but only 4.7% used both medication and counseling [15]. In an effort to increase behavioral counseling, strategies such as Ask–Advise– Connect, where smokers who accept referral are directly connected with quitline cessation counseling, have been found to be effective [16,17]. This strategy, however, still relies on a reactive treatment model of care in which patients or providers must remember to address tobacco cessation during a clinical visit.

We previously reported the main outcome results from the Offering Proactive Treatment Intervention (OPT-IN) trial, which enrolled socio-economically disadvantaged, publicly insured (Medicaid and Minnesota Care) smokers to test whether a population-level proactive tobacco cessation outreach intervention would improve smoking cessation outcomes relative to usual care [9,18]. This trial demonstrated the effectiveness of proactive tobacco cessation outreach among socio-economically disadvantaged smokers for increasing treatment utilization and population-level prolonged smoking abstinence [9,18]. Three additional large randomized trials and one pilot trial of proactive tobacco cessation outreach have been completed to date [11,19–21]. Taken together, these studies demonstrate the effectiveness of proactive outreach for increasing both the use of medication and counseling as well as long-term, population-level smoking cessation rates, and thereby exert a profound public health benefit. However, most prior cost-effectiveness analyses in the literature have been conducted to evaluate individual-level smoking cessation treatments in clinical trials conducted among motivated smokers. Evidence is limited on whether population-level smoking cessation approaches that reach out to all smokers, with varying levels of motivation to quit, are cost-effective [22]. To address this gap, we report the long-term impact and cost-effectiveness of the proactive tobacco cessation outreach intervention tested in the OPT-IN trial compared to usual care on 6-month prolonged smoking abstinence. The findings from this study may be used to inform choices among policies to decrease the high rates of smoking among socio-economically disadvantaged populations.

METHODS

The OPT-IN trial was approved by the Institutional Review Boards at the University of Minnesota and the Minnesota Department of Human Services (DHS). The study protocol has been previously described [9,18]. Briefly, study participants were recruited using a mailed, baseline tobacco use screening survey that included an informed consent statement and notice of privacy practices. Respondents reporting cigarette use in the past 30 days were enrolled and randomized to receive either (1) usual care or (2) proactive outreach. The survey and study randomization were stratified by categories of age (18–24, 25–34, 35–64 years), gender and the two types of Minnesota Heath Care Programs (MHCP) coverage.

Usual care-arm participants were not offered any smoking cessation services through the study. However, as MHCP enrollees, they could access smoking cessation treatments through MHCP. Specifically, usual care participants could obtain prescriptions for smoking cessation medications, including: NRT, sustained-released bupropion

and varenicline (medications that assist with smoking cessation by decreasing cravings and feelings of nicotine withdrawal), at substantially reduced cost ($1–5 co-pay) or purchase NRT over-the-counter at retail costs. Telephone counseling was also available through a toll-free quitline (1-800-QUIT-NOW or 1-888-354-PLAN). In addition to the services available in the usual care arm, participants assigned to the proactive outreach intervention received personalized mailings and personal telephone outreach from trained study counselors inviting them to participate in evidence-based cessation treatments. The study counselors used motivational interviewing to encourage participants to engage in treatment and facilitated access to free, comprehensive, evidence-based treatment for tobacco dependence consisting of NRT and intensive, telephone-based behavioral counseling based on the California Helpline protocol.

Self-reported smoking abstinence and quality of life outcomes

For the state transition model, smoking abstinence or quitting was defined using 6 months' prolonged abstinence at the OPT-IN 1-year follow-up assessment, which was self-reported, as misreporting rates of smoking status are low in large population-based trials with minimal face-to-face contact [23,24]. In addition, to guard against misreporting, the follow-up assessment protocol used primarily a self-administered mailed survey to collect smoking abstinence outcomes with telephone follow-up of mailed survey non-respondents. Data collection was also conducted separately from the intervention and was blind to intervention condition. Participants without 6 months' prolonged abstinence or with missing abstinence outcome data were classified as continuing smokers. At the beginning and end of the trial (1 year post-randomization), quality of life (QoL) was measured using the EQ-5D and the US population–based preference weights generated by Shaw *et al.* [25]

State transition model

As most benefits of smoking cessation are realized in future years from improvements in health, we assessed the long-term effect of the proactive outreach intervention compared to usual care using a state transition model. A state transition model represents the progression of a population over time. In our model, our population consisted of the OPT-IN trial participants and their smoking behavior over time. We used the model to project the effect of smoking cessation on future smoking status and the associated QoL, health-care costs and mortality. We assumed the perspective of a Medicaid program. We conducted a cost-effectiveness analysis (CEA) by projecting the costs and quality-adjusted life years (QALYs) that would be realized

by each cohort in its designated intervention (proactive outreach or usual care) over a life-time horizon. CEA is a tool for producing evidence on the cost of achieving QALY outcomes that policymakers may consider when making decisions about whether or not specific interventions are worth their cost.

We used, as a template, a previously published state transition model which assessed the progression of smoking behavior in a cohort of smokers who were recruited during a psychiatric hospitalization [26]. We modified the model to incorporate parameters from our trial, including: participant age, gender, the initial cost of smoking cessation services and smoking status at the 1-year follow-up assessment. Further, population parameters used in the model were chosen to be reflective of a more general population rather than a population with prior psychiatric hospitalizations. Population parameters used in the model are presented in Table 1. The state transition model used these parameters to model subsequent transitions between current smoker, former smoker and death, starting from a participant's status at the 1-year follow-up to the end of life. These parameters were also used to model the associated health-care costs and changes in QoL over these transitions.

Transition probabilities

Using published data we applied a spontaneous quit rate of 4.3% per year [27]. Similarly, we used published data to estimate relapse to smoking among former smokers, which started at 16.8% in the first year after being abstinent for 1 year, and decreased to 2% after 6 or more years of abstinence [28]. We applied the Goldhaber-Fiebert and Jalal method to preserve rank order between relapse rates [29]. The additional impact of smoking on mortality was gathered from published data [30]. All model parameters and their values in sensitivity analyses can be found in Table 1.

Base-case analysis

In the base-case analysis we simulated the life-time impact of proactive outreach compared to usual care. The model started post-trial and accounted for the difference in cessation observed in our trial, relapse to smoking post-trial and the associated costs and impact on mortality and QoL in the long term. The model used a 3-month cycle for transition. All future life years, costs and QALYs were discounted at 3% per year per the US recommendations [31]. The model was constructed and analyzed in TreeAge version 2017. Graphics were plotted in RStudio version 1.0.136.

Table 1 Model parameters.

Variable	Base case mean	Standard error	Distribution
Effectiveness of intervention			
Proactive: abstinent at end of trial	0.165	0.0129	Beta
Usual care: abstinent at end of trial	0.121	0.0106	Beta
Cost of intervention: 2016 US dollars			
Additional cost of intervention/quit	$84	–	Probability density table containing trial data
Long-term smoking behavior [26,28]			
Annual spontaneous quit probability	0.043	0.006	Beta
Annual relapse rate			
Year 2	0.1683	0.0111	Beta
Years 3–4	0.0815	0.0068	Beta
Year 5	0.0430	0.0086	Beta
Years ≥ 6	0.0237	0.0041	Beta
Health-care expenditure: 2016 US dollars [32]			
Male			
18–24	$1169	$122	Gamma
25–44	$2354	$271	Gamma
45–64	$5690	$282	Gamma
65–100	$11 177	$527	Gamma
Female			
18–24	$2437	$245	Gamma
25–44	$3650	$139	Gamma
45–64	$6793	$318	Gamma
65–100	$10 495	$431	Gamma
Excess ratio of health care expenditure [26]			
Smokers	1.1881	0.0934	Log-normal
Quality of life [33]			
Current smoker: male			
16–24	0.9211	0.0065	Beta
25–34	0.9166	0.0062	Beta
35–54	0.8899	0.0060	Beta
45–54	0.8422	0.0063	Beta
55–64	0.7815	0.0070	Beta
65–74	0.7575	0.0079	Beta
75–100	0.7112	0.0082	Beta
Former smoker: male			
16–24	0.9342	0.0054	Beta
25–34	0.9306	0.0047	Beta
35–54	0.9058	0.0041	Beta
45–54	0.8596	0.0042	Beta
55–64	0.8020	0.0050	Beta
65–74	0.7802	0.0059	Beta
75–100	0.7358	0.0059	Beta
Current smoker: Female			
16–24	0.8952	0.0065	Beta
25–34	0.8835	0.0061	Beta
35–54	0.8716	0.0060	Beta
45–54	0.8317	0.0062	Beta
55–64	0.7648	0.0070	Beta
65–74	0.7520	0.0076	Beta
75–100	0.6778	0.0087	Beta
Former smoker: female			
16–24	0.9084	0.0053	Beta
25–34	0.8988	0.0045	Beta
35–54	0.8872	0.0041	Beta
45–54	0.8479	0.0041	Beta
55–64	0.7827	0.0051	Beta

(***Continues***)

Table 1. (Continued)

Variable	Base case mean	Standard error	Distribution
65–74	0.7709	0.0057	Beta
75–100	0.6978	0.0067	Beta
Excess mortality of smokers [30]			
Current smoker: male			
< 50	2.34	0.0689	Log-normal
50–59	2.82	0.0306	Log-normal
60–69	2.80	0.0204	Log-normal
70–79	2.52	0.0306	Log-normal
≥ 80	1.81	0.0332	Log-normal
Current smoker: female			
< 50	1.68	0.0612	Log-normal
50–59	2.32	0.0255	Log-normal
60–69	2.51	0.0153	Log-normal
70–79	2.46	0.0230	Log-normal
≥ 80	1.81	0.0255	Log-normal
Former smoker: male			
Age < 50			
Years 3–5	1.29	0.2066	Log-normal
Years 6–10	1.46	0.1454	Log-normal
Years 11–15	0.93	0.1658	Log-normal
Years ≥ 16	0.95	0.1352	Log-normal
Age 50–59			
Years 3–5	1.93	0.0893	Log-normal
Years 6–10	1.86	0.0587	Log-normal
Years 11–15	1.50	0.0587	Log-normal
Years ≥ 16	1.13	0.0408	Log-normal
Age 60–69			
Years 3–5	2.13	0.0587	Log-normal
Years 6–10	2.17	0.0357	Log-normal
Years 11–15	1.75	0.0332	Log-normal
Years ≥ 16	1.23	0.0204	Log-normal
Age 70–79			
Years 3–5	1.98	0.0663	Log-normal
Years 6–10	2.08	0.0332	Log-normal
Years 11–15	1.92	0.0281	Log-normal
Years ≥ 16	1.32	0.0153	Log-normal
Age ≥ 80			
Years 3–5	1.12	0.1760	Log-normal
Years 6–10	1.56	0.0663	Log-normal
Years 11–15	1.60	0.0434	Log-normal
Years ≥ 16	1.19	0.0204	Log-normal
Former smoker: female			
Age < 50			
Years 3–5	1.55	0.1939	Log-normal
Years 6–10	1.10	0.1556	Log-normal
Years 11–15	1.11	0.1403	Log-normal
Years ≥ 16	1.12	0.0995	Log-normal
Age 50–59			
Years 3–5	1.76	0.1199	Log-normal
Years 6–10	1.31	0.0816	Log-normal
Years 11–15	1.23	0.0714	Log-normal
Years ≥ 16	0.95	0.0434	Log-normal
Age 60–69			
Years 3–5	1.89	0.0867	Log-normal
Years 6–10	1.79	0.0510	Log-normal
Years 11–15	1.50	0.0434	Log-normal

(*Continues*)

Table 1. (Continued)

Variable	Base case mean	Standard error	Distribution
Years ≥ 16	1.06	0.0255	Log-normal
Age 70–79			
Years 3–5	1.55	0.1097	Log-normal
Years 6–10	1.80	0.0510	Log-normal
Years 11–15	1.70	0.0383	Log-normal
Years ≥16	1.20	0.0204	Log-normal
Age ≥ 80			
Years 3–5	1.64	0.2219	Log-normal
Years 6–10	1.53	0.0918	Log-normal
Years 11–15	1.47	0.0536	Log-normal
Years ≥ 16	1.21	0.0204	Log-normal

Cost of proactive outreach

We calculated the differential cost between proactive outreach and usual care. This means that in our cost-effective analysis, usual care costs were $0 and proactive outreach costs included all the costs associated with the additional services that proactive intervention participants received. Those services included free NRT, telephone counseling and targeted mailings. Costs were calculated in the following ways: the cost of NRT was derived from actual study costs ($18.50 for patch and gum units, $24.25 for lozenge units); staff hourly effort to deliver the intervention, including telephone cessation services and outreach and NRT and study material dissemination, was tabulated for each participant and assigned labor costs of $42/hour, including wages and benefits derived from study labor costs adjusted for the University of Minnesota fringe rate; postage costs for delivery of the NRT and study materials were tabulated for each participant; and self-reported cessation services obtained outside the study were assigned the unit costs of study provided services or unit costs obtained from literature review. Each intervention participant was assigned a pro-rata share of the computer, software, technical assistance and office space costs of the intervention program. In sensitivity analyses we sampled from actual trial data containing the cost of the intervention for each person.

Health services utilization and cost

We used the state transition model to project the future, long-term cost of medical services usage. Long-term age- and gender-specific health care utilization costs, among non-smokers, were obtained from the Agency for Healthcare Research and Quality [32]. Costs were inflated to represent 2016 dollars using CMS Personal Healthcare Expenditure Deflator [31]. The estimated additional effect of smoking on annual health-care costs was taken from a previously published study [26]. The study found that, on average, smokers spend 1.1881 times more on health care than the general public. Additionally, compared to the general public, former smokers have an initial increase in relative cost followed by a slight reduction in relative cost; however, this change was not significant and was not modeled. As a result, we assumed that former smokers incurred health-care costs commensurate with the general public. In sensitivity analyses, excess ratios were log-normally distributed (Table 1) [31].

QoL

In the simulation model, QoL for current and former smokers was taken from previously published age- and gender-specific estimates and applied to our cohort, as we did not follow our cohort during their life-time [26,33]. In sensitivity analyses, QoL was beta distributed (Table 1) [31]. We assumed that the impact of quitting on QoL was constant, regardless of at what age the cohort had stopped smoking. This assumption has been used by previous cost-effective models [34,35].

Cost-effectiveness analysis

For the cost-effectiveness analysis, we followed the guidelines outlined by the Second Panel on Cost-Effectiveness in Health and Medicine [31]. First, interventions were ranked by increasing effectiveness. Because neither strategy dominated the other (having lower costs and higher effectiveness), we calculated the incremental cost-effectiveness ratio (ICER), defined as the additional cost of the next costly strategy, divided by its additional QALYs gained.

Sensitivity analysis

We performed probabilistic sensitivity analysis (PSA). The ICER point estimates were determined using a random sample of 10 000 sets of parameters from their estimated probability distribution. A microsimulation (Monte Carlo)

probabilistic sensitivity analysis used these same data to construct a cost-effectiveness acceptability curve (CEAC).

RESULTS

A total of 2406 participants were enrolled into the study, with 1206 participants in the intervention group and 1200 participants in the usual care group. One-year post randomization assessments were completed by 826 (69%) of participants in the intervention arm and 944 (78%) of the participants in the usual care arm. These participants made up the sample on which the simulation model and other analyses are based.

Baseline characteristics of the sample

The average age of the sample was 37.3 years [standard deviation (SD) = 13.0] at the time of randomization. Participants had smoked an average of 20.3 years (SD = 13.1) and smoked an average of 13.6 cigarettes (SD = 9.2) per day. Most participants were female (70.6%, $n = 1699$). The sample was diverse; 10.6% were African American ($n = 256$), 6.9% American Indian ($n = 167$), 2.3% Asian American ($n = 56$), 1.8% Hispanic ($n = 42$) and 78% non-Hispanic white ($n = 1885$).

Follow-up characteristics by intervention condition

Costs for the intervention averaged $84 per participant more than the cost of usual care. We found that the proactive outreach intervention led to more than 4% more 6-month prolonged smoking abstinence than usual care (16.5 versus 12.1%, $P < 0.05$). However, QoL scores were statistically similar between groups at 1 year post-randomization; means [standard error (SE)] were 0.79 (SE = 0.01) and 0.78 (SE = 0.01), respectively, for the proactive outreach arm and the usual care arm. See Supporting information, Tables S1–S3 for more information describing QoL between both groups.

Cost-effectiveness findings

The base-case model estimated that, on average, participants enrolled in proactive outreach were expected to live 19.486 QALYs compared to 19.481 QALYs in usual care, resulting in a gain of approximately 0.005 QALYs in the proactive outreach intervention (Table 2). Discounted life-time health-care utilization costs with usual care and the intervention were: $155 980 per person and $156 057 per person, respectively; meaning that the intervention, on average, was associated with increased health-care costs of $78 more per person. One measure that helps policymakers to make sense of the costs and benefits of multiple interventions is the ICER. The ICER summarizes cost of gaining a QALY using the intervention, compared to usual care [31]. In the United States, interventions are considered worth conducting if the ICER is under $50 000, meaning that the cost of obtaining a QALY with this intervention is less than the value of a QALY to society. In our study, the expected incremental cost-effectiveness ratio of the proactive tobacco cessation outreach intervention was $4231 (Table 2), making proactive outreach cost-effective by this standard. However, because few decision-makers agree on the true value of a QALY, we have chosen to illustrate our results using a cost-effectiveness acceptability curve (CEAC) (Fig. 1). The CEAC shows the relationship between the various hypothetical willingnesses to pay (WTP) for a QALY (on the horizontal axis) and the probability that going ahead with the intervention will be cost less per QALY than a QALY is worth (on the vertical axis).

Sensitivity analysis findings

At a WTP threshold of $50 000/QALY, 68% of 10 000 simulations resulted in an ICER below the WTP threshold (Fig. 1), meaning that if the proactive outreach intervention were to be undertaken, this intervention would have a 68% chance of costing less than $50 000. At a WTP threshold of $100 000/QALY, more than 75% of the simulations favored proactive outreach.

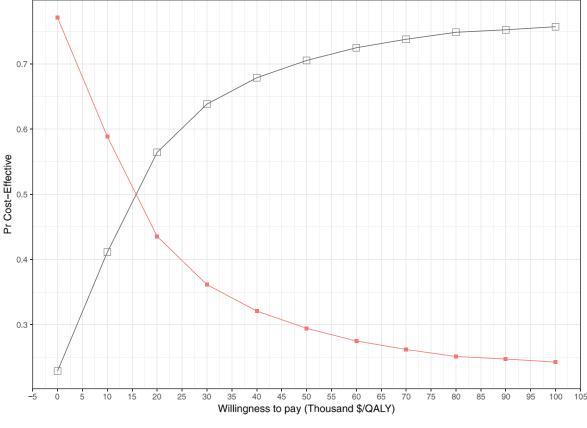**Table 2** Base case incremental cost-effectiveness of smoking cessation interventions[a]

Intervention	Usual care	Proactive	Difference
Cost: 2016 $US			
Discounted cost of life-time health-care utilization	$155 980	$156 057	$78
Outcome			
Discounted life years	23.603	23.608	0.005
Discounted quality-adjusted life years	19.481	19.486	0.005
Incremental cost effectiveness ratio			
Cost/quality-adjusted life year	$4231		

[a]Due to rounding, values may not add up exactly.

DISCUSSION

The OPT-IN trial demonstrated that population-level, proactive tobacco cessation outreach increases use of pharmacotherapy and telephone counseling as well as population-level cessation at 1 year post-randomization, compared to usual care. In addition to looking at quit rates, the OPT-IN trial originally sought to evaluate health care utilization, costs and QoL during the time of the trial. We found that, on average, health-care spending 1 year post-randomization did not differ significantly between participants in the intervention and usual care groups, with and without adjusting for covariates. As stated previously, QoL among the intervention and usual care group did not differ significantly at the end of the trial. This latter result might be expected because many of the benefits of smoking cessation are realized in future years as costs saved from an improvement in health. Therefore, we concentrated on the effect of the significant difference in quits and modeled the effects of each arm in a state transition model to determine the long-term impact of cessation on QALYs and health-care costs. We found that the proactive outreach intervention was cost-effective compared to usual care. Furthermore, sensitivity analyses favored proactive outreach intervention over usual care at WTP thresholds of $50 000 and $100 000 per QALY.

Our study is consistent with findings from a cost-effectiveness analysis of Project CLIQ (Community Link to Quit), the only published cost-effectiveness analysis of population-level proactive outreach in the extant literature to date [22]. Project CLIQ tested a proactive telephone outreach strategy using interactive voice response (IVR) technology, a computerized telephone outreach platform that connected interested smokers to telephone counseling for smoking cessation, the nicotine patch and community social services [20]. In the Project CLIQ intervention, the cost difference per smoker was $33, the incremental cost per additional quit was $4137 and the incremental cost per additional life-year gained was $7301 [22]. While proactive tobacco treatment with personal telephone outreach was associated with greater additional costs ($84 per smoker), our incremental cost per additional quit of $2766 and ICER of $4231 per QALY gained was more favorable. Taken together, Project CLIQ and OPT-IN demonstrate that population-level proactive tobacco cessation outreach programs are highly cost-effective over the long-term.

Figure 1 Cost-effectiveness acceptability curves. [Colour figure can be viewed at wileyonlinelibrary.com]

Societal perspective

We have assumed the perspective of a Medicaid program because this perspective represents the payer for this program. If, instead, we were to take on a societal perspective, all costs, regardless of who pays for them, would be included in the model. Therefore, in addition to the costs of the intervention itself and downstream health-care cost savings, the costs of transportation, time lost at work to receive health-care and cost of child care while receiving care would also be included. Because these additional costs would be reduced in the proactive care arm (relative to the usual care arm because of its relative effectiveness in avoiding health-care utilization), a societal perspective would probably generate smaller ICERs, signifying that the intervention would be even more cost-effective than under the Medicaid program perspective. In addition, for any additional years of life that would be caused by the proactive intervention, the Second Panel on Cost-effectiveness in Health and Medicine recommends that all consumption costs incurred or earnings accumulated be included in the analysis [36]. Because these costs might either increase or reduce the ICERs, it is not clear how including these societal factors would affect the ICERs. There is, however, a debate regarding whether survivor consumption costs and earnings should be included [37]. Because of the unsettled nature of the recommendations, we have opted not to include a societal perspective analysis in this paper.

In addition, when considering the societal perspective, we should include the benefits and harms of living with a smoker or former smoker. Most of our trial participants lived with other individuals. The harms of second-hand smoke are well described in the literature [38]. Our intervention would have curbed many of these harms, as more people had a sustained quit while on the proactive outreach intervention. Including the benefits of reduced second-hand smoke exposure to those living with people who received the proactive outreach intervention, and adding the harms of second-hand smoke to those living with people who received usual care, would make the effect of proactive outreach intervention higher than our analysis showed.

Limitations

Our study is not without limitations. First, we assumed that the relapse rate 10 years after quitting was the same as the relapse rate in years 6–10. The study that provided these estimates did not follow participants for more than 10 years. Our assumption, however, is conservative and did not overestimate the benefits of proactive outreach intervention. Secondly, there were differential follow-up response rates between the two groups, and participants with missing abstinence outcome data were assumed to be continuing smokers in the state transition model. With respect to baseline demographic measures and smoking history, there were differences between 1-year follow-up respondents and non-respondents, but these differences were generally consistent between the two conditions. Because the intervention group had a lower follow-up rate the intervention group had more participants that were assumed to be continuing smokers, and while this reduced the modeled effectiveness of the intervention, significant effects persisted, indicating that our findings are robust. In addition, this study was conducted in Minnesota, which is one of only nine states whose Medicaid program provided coverage in 2014–15 for all nine recommended smoking cessation treatments [39]. While the study results may have limited generalizability for states with different coverage policies, the proactive outreach intervention may have even greater benefits in states whose Medicaid programs provide less coverage.

Implications

Population-level, proactive tobacco cessation outreach is a cost-effective and evidence-based strategy for increasing population-level quit rates among socio-economically disadvantaged smokers. The potential public health benefits of proactive tobacco cessation outreach are substantial, because the burden of smoking disproportionately affects socio-economically disadvantaged smokers who are far from achieving Healthy People 2020 objectives to reduce smoking prevalence to 12%. There are an estimated 7.9 million smokers enrolled in Medicaid and smoking cessation is the most cost-effective clinical preventive service [8,40]. Therefore, state Medicaid programs and other safety-net health systems should consider implementing proactive outreach cessation strategies, a high-value investment, to enhance engagement in evidence-based smoking cessation treatment and improve population health outcomes.

Clinical trials registration

ClinicalTrials.gov: NCT01123967.

Data sharing

A data set stripped of identifiers will be made available upon reasonable request for sharing under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes; (2) a commitment to securing the data using appropriate computer and server technologies and (3) a commitment to destroying or returning the data after analyses are completed. Depending on the data requested, the data-sharing agreement and the specific

details of the agreement would have to be approved by the Minnesota Department of Human Services.

Declaration of interests

None.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1 Quality of Life Before and After Trial Period By Treatment Arm. No study design adjustments.

Table S2 Quality of Life Before and After Trial Period By Smoking Status. No study design adjustments.

Table S3 Quality of Life By Treatment Arm (Model A) and By Smoking Status (Model B) Adjusted for Baseline EQ-5D and Study Design.