SHARED DECISION MAKING IN ELECTIVE COLORECTAL SURGERY:  
COST UTILITY ANALYSIS OF SMOKING CESSATION PROGRAMS  
A Thesis in  
Public Health Sciences  
by  
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ABSTRACT

Smoking is a behavior that involves many underlying psychological, physiological, and socioeconomic drivers. In patients undergoing elective procedures, such as colon resections, this population is more prone to a variety of postoperative complications. This study incorporates a known driver of increased healthcare costs—tobacco smoking—with the current limitations of the available therapies for smoking cessation, in order to determine whether uniform adoption of a particular smoking cessation strategy represents a cost-effective decision in the preoperative optimization of patients requiring elective colectomy. The therapies considered within the model include bupropion, nicotine replacement therapy, varenicline, and no therapy. After considering this model from a provider perspective, the base case analysis suggests that bupropion is cost-effective with an incremental cost-effectiveness ratio of approximately $75,000 per quality-adjusted life year. One-way and two-way sensitivity analyses established ranges for which of the three medications were either cost-effective or dominant compared to the baseline strategy of no uniform therapy. These results give providers objective estimates by which healthcare organizations can make decisions on whether the use of particular therapies represent good value for patients and providers.
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Chapter 1

Introduction

Elective colon resections are relatively common procedures, with an estimated 110,000 cases performed annually in the United States. Previous studies suggest that approximately 20% of this population are current tobacco smokers, and a similar proportion are former smokers. This population is more prone to a variety of postoperative complications, ranging from hypercoagulability with venous thromboembolic events to surgical site occurrences and anastomotic leaks. Smoking is a behavior that involves many underlying psychological, physiological, and socioeconomic drivers. While the mechanisms behind the initiation and cessation of this behavior are complex, the physiologic benefits of cessation have been clearly documented. These benefits have been shown specifically with regard to surgical outcomes, in reducing postoperative morbidity after a variety of surgical procedures. Since the literature indicates that a significant proportion of the population continues to engage in this behavior around the time of an elective surgery, implementing cessation strategies that target this at-risk cohort is imperative.

It has been estimated that a mere 10% decrease in the prevalence of smoking within the United States would result in savings to the healthcare systems in excess of $60 billion. Accordingly, several studies from various countries—including the United States—have utilized Markov modeling to determine the cost effectiveness of smoking cessation pharmaceutical agents, including varenicline, bupropion, and nicotine.
replacement therapy (NRT).\textsuperscript{9,11} By assessing lifetime risks of various smoking-related diseases, such as lung cancer, chronic obstructive pulmonary disease, coronary heart disease, and stroke, these analyses aimed to determine whether uniform administration of these treatments to all current smokers signifies an efficient use of healthcare dollars over a patient’s lifetime. These studies consistently conclude that these therapies are indeed cost-effective, and sometimes even dominant, when compared to strategies that do not uniformly provide pharmacologic cessation aids for current smokers. Despite these findings, third-party coverage for these pharmaceutical strategies remains either unavailable or substantially limited within the United States,\textsuperscript{10} precluding their use among a large subset of the target population.

To address the limited applicability of these studies, we endeavored to evaluate whether uniformly providing pharmacologic smoking cessation strategies to a subgroup of patients at particularly increased risk, preoperative colectomy patients, is an efficient use of healthcare resources. We adopted a provider perspective for our model, in order to simulate a healthcare delivery system by which the provider can decide to bear the costs of the intervention, with the hope that reductions in complications also translate into overall cost savings. Because our model aims to estimate the comparative effectiveness of smoking cessation interventions relative to postoperative risk within a short, defined time period, we utilized a decision tree structure rather than the Markov model frequently utilized in other studies. This analysis incorporates a known source of increased healthcare costs—tobacco smoking—with the current limitations of the available therapies for smoking cessation, in order to determine whether uniform adoption of a
particular smoking cessation strategy represents a cost-effective decision in the preoperative optimization of patients requiring elective colectomy.
Chapter 2

Methods

In this study, cost-effectiveness analysis (CEA) was used to estimate the relative value of health care intervention over a one-year postoperative time horizon. In the case of preoperative smoking cessation, the question of value is whether the incrementally higher risk of postoperative complications is worth the costlier approach of providing standardized preoperative smoking cessation programs. We estimated the incremental cost-effectiveness ratio (ICER), which comprises the fundamental metric of CEA, for providing uniform smoking cessation programs to all patients undergoing elective colorectal procedures versus providing no standardized plans. A provider perspective was adopted for this model.

Model Structure

The decision tree (Figure 1) was constructed using TreeAge Pro software (TreeAge Software, Inc., Williamstown, MA, USA). The initial decision node in the model represents the provider’s decision to provide either NRT, bupropion, varenicline, or no smoking cessation strategy to all patients who are current smokers presenting for elective colectomy.
Figure 1: Decision model structure.
Model Parameters

Model parameters and references are listed in Table 1.

Table 1: Model parameters.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Sensitivity Analysis</th>
<th>Reference</th>
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<tbody>
<tr>
<td></td>
<td>Estimate</td>
<td>Lower</td>
</tr>
<tr>
<td><strong>Probabilities</strong></td>
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<td></td>
</tr>
<tr>
<td><strong>Probability of Cessation</strong></td>
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<td></td>
</tr>
<tr>
<td>No Medication</td>
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<td>Bupropion</td>
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<td>0</td>
</tr>
<tr>
<td>Nicotine Replacement Therapy</td>
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<td>0</td>
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<tr>
<td>Varenicline</td>
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<td>0</td>
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<td><strong>Probability of Complication</strong></td>
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<td></td>
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<tr>
<td>Current Smoker</td>
<td>0.145</td>
<td>0.05</td>
</tr>
<tr>
<td>Former Smoker</td>
<td>0.126</td>
<td>0.02</td>
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<tr>
<td><strong>Probability of Mortality</strong></td>
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<td></td>
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<tr>
<td>Current Smoker</td>
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<td>0</td>
</tr>
<tr>
<td>Former Smoker</td>
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<td>0</td>
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<td></td>
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<td>Bupropion</td>
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<td>4</td>
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<td>4</td>
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<tr>
<td>Varenicline</td>
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<td>4</td>
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<td><strong>Annual Costs</strong></td>
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<td>Baseline</td>
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<td>Complication in Current Smoker</td>
<td>$46,811</td>
<td>$15,000</td>
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<tr>
<td>Complication in Former Smoker</td>
<td>$46,538</td>
<td>$15,000</td>
</tr>
<tr>
<td>In-hospital Mortality</td>
<td>$117,892</td>
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<td><strong>Utilities</strong></td>
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<td></td>
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<tr>
<td>Complicated Postoperative Course</td>
<td>0.897</td>
<td>0</td>
</tr>
<tr>
<td>Uncomplicated Postoperative Course</td>
<td>0.938</td>
<td>0</td>
</tr>
<tr>
<td>In-hospital Mortality</td>
<td>0</td>
<td>n/a</td>
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</table>
**Probabilities**

In order to parameterize the model, estimates for the rates of smoking cessation for each of the four therapeutic strategies (including placebo) were obtained from a recent large, prospective trial comparing the strategies.\(^{12}\) “Effective” cessation was defined as continuous abstinence of tobacco use during weeks 9-12 after initiation of therapy (regardless of whether full compliance with the treatment regimen was achieved), and is based upon the results of this study. Probabilities associated with complication rates required comparisons between current smokers and former smokers, rather than non-smokers; risk-adjusted estimates were obtained from a large retrospective study of patients undergoing colectomy.\(^{2}\)

**Utilities**

To estimate the utility of both complicated and uncomplicated postoperative courses after colectomy, results from a study measuring utilities using the Short Form 6D (SF-6D) in post-colectomy patients were used (Table 1).\(^{13}\) The values were then used to estimate the quality-adjusted life years (QALYs) associated with the four intervention arms.

**Costs**

Due to limited data within the literature regarding one-year costs after colectomy for patients either with or without postoperative complications, institutional data was
utilized to estimate cost parameters. Patients undergoing colectomy procedures over a four-year period (July 2012 and June 2015) at our academic center were identified through Diagnosis Related Group (DRG) codes indicating colectomy without complications (DRG 331), colectomy with minor complications (DRG 330), and colectomy with major complications (DRG 329). Emergent procedures were identified as those with charges for emergency department services, and were excluded from analysis. Total costs for both current and former smokers were then calculated based on the weighted average of the probability of minor and major complications observed in these two populations. Lastly, patients who died during the index hospitalization formed a separate cohort in order to estimate healthcare costs associated with in-hospital mortality. Total costs were adjusted to 2016 dollars using records from the first half of 2016 dollars from the medical care component of the Consumer Price Index (CPI).

Analysis

The ICER was calculated for the base case scenario, and then recalculated based upon strategies that were excluded based on extended dominance. The willingness-to-pay (WTP) threshold was set at $150,000 per QALY. One-way sensitivity analyses were performed to estimate the values of the parameters at which the ICER fell below the accepted WTP threshold. The primary one-way sensitivity analyses were focused around the cost and clinical effectiveness of the pharmaceutical agents, the utilities associated with complicated and uncomplicated postoperative courses, as well as the probabilities
associated with experiencing a postoperative complication. Two-way sensitivity analyses were performed to identify the dominant strategy by varying the estimates for two parameters simultaneously. For the two medications that were not eliminated by extended dominance, bupropion and varenicline, the probabilities of quitting using either medication the costs associated with each were varied. Additionally, the costs associated with complication profiles in both current and former smokers were varied in the sensitivity analyses.
Chapter 3

Results

Costs

A total of 1,438 patients were identified who underwent colon resections with subsequent hospitalizations; of these, 440 patients had uncomplicated postoperative courses, 773 patients experienced minor complications, 214 patients experienced major complications, and 10 patients experienced in-hospital mortality. After determining costs using institutional data, patients whose hospitalizations involved either minor complications or major complications had significantly higher costs, both for the index hospitalization as well as for the year following the procedure. Initial costs for hospitalization for uncomplicated courses was $14,914 (95% confidence interval [CI] $14,380 to $15,448), for courses with minor complications was $21,093 (95% CI $20,140 to $22,046), for courses with major complications was $48,070 (95% CI $42,093 to $54,047), and for patients who experienced in-hospital mortality was $117,348 (95% CI $61,574 to $173,122). Regarding annual cost, which were used to parameter this one-year time horizon decision model, the annual cost for colectomy patients who had uncomplicated courses was $34,199 (95% confidence interval [CI] $29,903 to $38,496), for courses with minor complications was $59,027 (95% CI $54,099 to $63,954), and for courses with major complications was $109,360 (95% CI $93,282 to $125,438).
In the base case, the bupropion strategy was more costly but also more effective than not providing a standardized pharmaceutical smoking cessation strategy (Table 2). However, the incremental cost-effectiveness ratio (ICER) was $74,255.23 per QALY; therefore, at the widely accepted willingness-to-pay (WTP) threshold of $150,000 per QALY, this intervention would be considered cost effective. The next most costly strategy, NRT, was only $12 more costly than bupropion, but was associated with such a small marginal effectiveness that its ICER compared to bupropion was $936,096.28. The ICER between the most costly strategy, varenicline, and NRT was also high ($897,265.39), but less so than that of the previous pairing (NRT versus bupropion); therefore, the NRT strategy was eliminated due to the extended dominance of the bupropion and varenicline strategies. As a result, the ICER that remains between varenicline and bupropion was computed and was $898,244.32 (Table 2), which remains above the acceptable WTP threshold.
Table 2. Base-case analysis.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Cost</th>
<th>Marginal Cost</th>
<th>Effectiveness</th>
<th>Marginal Effectiveness</th>
<th>ICER ($/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>None</td>
<td>$41,819.40</td>
<td></td>
<td>0.92035</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bupropion</td>
<td>$41,858.02</td>
<td>$38.62</td>
<td>0.92087</td>
<td>0.00052</td>
<td>$74,255.23</td>
</tr>
<tr>
<td>NRT</td>
<td>$41,869.69</td>
<td>$11.67</td>
<td>0.92088</td>
<td>0.00001</td>
<td>$936,096.28</td>
</tr>
<tr>
<td>Varenicline</td>
<td>$42,306.56</td>
<td>$436.87</td>
<td>0.92137</td>
<td>0.00049</td>
<td>$897,265.39</td>
</tr>
<tr>
<td>Non-Dominated Strategies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>$41,819.40</td>
<td></td>
<td>0.92035</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bupropion</td>
<td>$41,858.02</td>
<td>$38.62</td>
<td>0.92087</td>
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<td>$74,255.23</td>
</tr>
<tr>
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<td>$42,306.56</td>
<td>$448.54</td>
<td>0.92137</td>
<td>0.00050</td>
<td>$898,244.32</td>
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</table>

Sensitivity Analyses

One-Way: Probability of Quitting with Medications

When comparing bupropion to no therapy, the use of bupropion becomes cost-effective when the probability of quitting is slightly below 25% (Figure 2). Comparing
NRT to no therapy, this value is 25%; comparing varenicline to no therapy, it is approximately 55%.

Figure 2: One-way sensitivity analysis of probability of quitting with medications
One-Way: Cost of Medications

Costs of the pharmaceutical agents were then varied to determine values for which each agent became cost-effective relative to using no therapy (Figure 3). For bupropion, the associated cost was $220, and for NRT was $225, both of which are higher than the current retail costs of these pharmaceutical agents. For varenicline, the cost at which this medication becomes cost-effective relative to no therapy was approximately $440, which is lower than the current retail costs of this strategy.

Figure 3: One-way sensitivity analysis of cost of medications
One-Way: Probability of Complications in Current and Former Smokers

For both current smokers and former smokers, the probability of experiencing a postoperative complication was varied across a 20% range (Figure 4). For current smokers, bupropion is cost-effective once the probability of a complication exceeds 14%, and varenicline is cost-effective once it exceeds 20.5%. In former smokers, bupropion is only cost-effective if the probability of complications remains below 13.1%, and varenicline is cost-effective if it becomes below 6.5%.

![Figure 4](image.png)

Figure 4: One-way sensitivity analysis of probability of complications in current and former smokers. Bup=bupropion, NRT=nicotine replacement therapy, Var=varenicline.

One-Way: Utilities Associated with Complicated and Uncomplicated Hospitalizations

The utilities associated with the states of experiencing postoperative complications and having uncomplicated postoperative courses were varied over a range
of 0 to 1 (Figure 5). Regardless of the utility associated with having a complicated postoperative course, bupropion remains below the WTP threshold for all utility values from 0 to 1, suggesting that this analysis is robust to variation within this parameter. For uncomplicated postoperative courses, bupropion is cost-effective for all values over 0.84; for all values below 0.70, all three pharmaceutical regimens are dominated, involving higher costs and less effectiveness than the strategy involving no medications.

Figure 5: One-way sensitivity analysis of utilities associated with complicated and uncomplicated hospitalizations. Bup=bupropion, NRT=nicotine replacement therapy, Var=varenicline.

**Two-Way: Probability of Quitting with Bupropion and Varenicline**

At probabilities of quitting with bupropion above 29.4%, this strategy dominates no therapy; while at probabilities of quitting with varenicline above 79.6% varenicline dominates no therapy (Figure 6).
Figure 6: Two-way sensitivity analysis of probability of quitting with bupropion and varenicline.

**Two-Way: Costs of Bupropion and Varenicline**

At costs below $145 for a course of therapy, the bupropion strategy dominates no therapy, and at costs of varenicline below $285, varenicline dominates no therapy (Figure
If the cost of varenicline was reduced to below $143 for a course of therapy, then varenicline would be overall less costly and more effective than both the bupropion and no standardized therapy strategies.

Figure 7: Two-way sensitivity analysis of costs of bupropion and varenicline.
Costs of Complications in Current and Former Smokers

At increasingly higher annual costs for current smokers and lower costs for former smokers, bupropion becomes the dominant strategy, followed by varenicline therapy (Figure 8).

Figure 8: Two-way sensitivity analysis of costs of complications in current and former smokers.
Discussion

Because of the significant potential for reduction in postoperative morbidity and even mortality, an increased focus on preoperative smoking cessation warrants careful consideration for clinicians. Our analysis suggests that a pharmaceutical agent that is currently available—bupropion—may provide a cost-effective strategy in establishing a uniform preoperative smoking cessation program, costing approximately $75,000 for each QALYS gained. Although varenicline is a more clinically effective agent in providing both short-term and durable tobacco cessation rates, its substantially higher costs relative to bupropion result in a marginal ICER of almost $900,000, exceeding any commonly accepted willingness-to-pay thresholds. This analysis provides a provider perspective on the cost-effectiveness of routine preoperative smoking cessation, which—in a time where insurance coverage and reimbursements are tenuous and rapidly changing—providers and their associated health care organization must increasingly look toward internal costs to evaluate which programs represent good value.

Our sensitivity analyses aimed to evaluate the two facets of smoking cessation therapies that are most relevant to their clinical applicability, and that both represent potential targets for improvement: costs and effectiveness. If more clinically effective drugs become available, as shown in the sensitivity analyses, then pharmaceutical strategies would not only fall below the accepted WTP threshold, but would actually become less costly and more effective than the strategy involving no standardized
intervention. Thus, continuing efforts towards pharmaceutical development remain important, to reduce the proportion of patients who take the medications without benefit. Similarly, reducing the costs associated with the medications—particularly varenicline, to prices below $143—can achieve lower overall costs for providers while allowing patients to enjoy more quality-adjusted life years. Since this model was constructed primarily to reflect a provider perspective, the results of the two-way sensitivity analyses may be more informative to health care providers who are considering implementing standardized tobacco cessation programs; these analyses identify points at which uniform use of a particular medication becomes less costly to the healthcare organization, without requiring that organization to assign a maximum threshold that it is willing to pay to improve patient quality of life. Until more clinically effective medications are available, our results may provide objective data to allow providers to establish target costs when negotiating with pharmaceutical companies.

Although there are multiple previous cost-effectiveness analyses of smoking cessation products, there has not been widespread implementation regarding funding or insurance coverage for these products by payers or providers within the United States. While this discrepancy is largely multifactorial, an important feature of these prior studies is that the costs and benefits are measured over the lifetime of the individual patients. Therefore, the providers and/or payers that are bearing the initial costs may not be the same parties that receive the eventual benefits. This observation limits the applicability of the findings from these studies, as providers and payers may be reticent to accept the costs associated with providing the initial therapy without an assurance of eventual benefit. Additionally, these other studies frequently utilize a one-year quit rate to
define former smokers, which may not be a reasonable timeframe in our population, given that delaying colectomy for a year may not be feasible in the majority of indications. Our study provides a focused and relevant model for the implementation of smoking cessation in a specific subgroup of patients, in order to identify a cohort of patients for which universal implementation may be attempted.

Another issue that is relevant in any study of smoking cessation, particularly in those examining long-term outcomes such as the aforementioned studies, is recidivism. For patients who successfully engage in tobacco cessation efforts preoperatively, recidivism may occur in the majority of patients, as little as 3 months following the procedure. Some patients find that engaging in preoperative smoking cessation therapies, however, does enable them to achieve long-term cessation, as shown in a meta-analysis by Berlin and colleagues. Ideally, improvements in health behaviors that are encouraged preoperatively—such as smoking cessation and weight loss—would translate into durable behavioral changes. Our study is unique in that it is not designed to rely on lifelong smoking cessation in order to observe the eventual benefits. Thus, these results quantify the benefits of short-term cessation for a specific subgroup of patients, and complement the previous cost-effectiveness studies that evaluate the long-term benefits of these strategies.

Another issue that has been a matter of considerable debate within the perioperative smoking cessation literature is the question of timing—how late is too late? There was a previous misconception that smoking cessation less than 8 weeks before surgery is associated with increased postoperative complications, but this has since been debunked, and other studies have shown that cessation as little as 4 weeks prior to
surgery can still lead to a decrease in postoperative complications.\textsuperscript{7,18} Although the magnitude of benefit may not be optimized with shorter durations of cessation,\textsuperscript{5} the results of our one-way sensitivity analyses (Figure 4), suggest that even a small differential in complication rates between current and former smokers—approximately 14\% and 13.1\%, respectively—is adequate for bupropion to fall below the WTP threshold of $150,000 per QALY.

An additional consideration in modeling strategies for smoking cessation is patient compliance. Our model is parameterized with results from a randomized controlled trial analyzed with intention-to-treat principles, in which documented compliance (both partial and full compliance) only reached 80\%.\textsuperscript{12} Therefore, the model accounts for suboptimal compliance that may be expected in the real-world setting. Moreover, evidence from a simulation model suggested that full smoking cessation therapy coverage within US-based health plan caused the baseline quit rate to increase by 9\%.\textsuperscript{19} These data suggest that the financial barriers to obtaining these pharmaceutical agents are not inconsequential, and that physicians have an important opportunity to bridge this gap among this population, resulting in benefits for both patients and providers.

One limitation of the present study is that it does not account for the importance of behavioral therapy in successful smoking cessation, which has been shown to increase cessation rates beyond pharmaceutical therapies alone.\textsuperscript{20,21} Establishing routine preoperative behavioral therapy for current tobacco smokers requires more than financial input; it requires additional personnel and potentially infrastructure changes to a practice. However, there is likely substantial variability regarding the type and extent to which
different providers can implement these changes. Moreover, previous studies have indicated that even with minimal professional support, pharmaceutical agents can still provide short-term smoking cessation, although its long-term effectiveness is less clear.\textsuperscript{20-22} The current model was parameterized with cessation rates that did not utilize behavioral therapy—rather, it only used smoking cessation counseling of no more than 10 minutes—in order to estimate the potential benefits that could be gained from the provision of medications alone.\textsuperscript{12} Establishing concomitant standardized behavioral therapy would be ideal for providers to maximize the effectiveness of cessation regimens, but infeasibility of this adjunct does not preclude providers from pursuing cost-effective changes to preoperative practices.

The present study has several other limitations. There have been concerns regarding the neuropsychiatric safety of both bupropion and varenicline, which could have a substantial influence on the utilities associated with the use of the medications in our decision model. These concerns, however, were not borne out in a recent large randomized controlled trial of patients, both with and without previous neuropsychiatric comorbidities. The cost data used to parameterize the model are derived from a single institution, and may not represent the healthcare costs for various providers nationally. Lastly, the utilities used in the model did not distinguish between major and minor complications, nor the duration of complication effects throughout the postoperative year.

While an extremely complex issue in the decision-making that surrounds preoperative planning, smoking cessation represents just one area of potential optimization. Although this issue has a large behavioral component, for which patients have to bear the majority of the emotional costs, it is the duty of providers to determine
cost-effective strategies in sharing some of this burden to improve patients’ health and outcomes. Further studies to determine whether there are subgroups of patients who would particularly benefit from this strategy are warranted.
References