Cost-effectiveness of smoking cessation and the implications for COPD

Michele A Faulkner
Tom L Lenz
Julie A Stading
Creighton University School of Pharmacy and Health Professions, Omaha, NE, USA

Abstract: The cost burden of COPD is substantial for patients and families, payers, and society as a whole. Smoking has been known for decades to be the leading cause of the disease. Numerous studies have been completed to address the cost-effectiveness of programs created to aid smokers in their efforts to quit. Because several assumptions must be made in order to conduct such a study, and because differences in study design are numerous, comparison of data is difficult. However, studies have consistently shown that regardless of the perspective from which the study was completed, or the methods used to help smokers abstain, the interventions are cost-effective. Although no study has been conducted specifically to assess the cost-effectiveness of smoking cessation interventions as they relate directly to patients with COPD, based on current data it can be concluded that smoking cessation programs are cost-effective for this population.

Keywords: cost-effectiveness, smoking cessation, COPD

Introduction
Within the next 20 years, it is anticipated that COPD will rank fifth for overall causes of disability worldwide (Murray and Lopez 1996). Year 2000 statistics rank COPD as the fourth most common cause of death in the US (Minino and Smith 2001). When considering smoking burden in the mortality rankings, COPD rises from fourth to third with greater than 25% of all money spent on smoking-related illness consumed as a result (Zaher et al 2004). From a global perspective, COPD is first on the list for worldwide deaths related to smoking. The medical community has been aware of the connection between the use of tobacco and the incidence of COPD for decades. It is estimated that between 1 in 10 and 1 in 20 long-term smokers will develop clinical disease (Strassels 1999). Perhaps even more striking than that, however, is the fact that in comparison with non-smokers, those who abuse tobacco exhibit a mortality rate 12–13 times higher (American Lung Association 2005). Although COPD ranks behind coronary heart disease and stroke when comparing disability-adjusted life years, it has the greatest smoking-related influence since the disease may begin to have an impact on the life and health of a smoker several decades before death. The average smoker loses 8 years of life, and 25% will die before the age of 69 years (Secretary of State for Health and Secretaries of State for Scotland, Wales, and Northern Ireland 1998).

Economic impact of COPD
Establishing the cost burden of COPD is a daunting task. In order to create the most accurate picture, both direct costs (medications and oxygen, services through healthcare providers, inpatient stays, institutional care, diagnostic testing, and visits to the emergency room) and indirect costs (lost wages due to illness that encompass both patients and caregivers, decreased productivity on the job, and travel) must be taken into account. Clearly the former category is the easiest to quantify. Possible variations
such as inaccuracy of diagnostic coding and methods used to estimate future earnings further cloud the issue.

The costs associated with COPD are substantial, and data show that overall healthcare expenditures for patients with COPD are nearly double that of those without (Mapel et al 2000). In 1993 US dollars, COPD was found to cost triple that of asthma on a per capita basis at an average of $1522 annually (Sullivan et al 2000). A study examining the amount of money spent for patients under Medicare found costs to be nearly 2.5 times higher for beneficiaries with COPD than those without ($8482 vs $3511 per capita respectively) (Grasso et al 1998). A study designed to estimate the annual direct medical costs of the disease from a societal perspective (1996 dollars) found that $14.5 billion were expected to be spent on patients with chronic bronchitis or emphysema (Wilson et al 2000). Hospitalizations and medication use accounted for the majority of these projected costs. Indirect costs were not estimated in this study, making those predictions a significant underestimation of the true cost of the disease. Another study that prospectively followed patients at multiple centers for a full year to determine the direct cost of COPD was published in 2003 (Miravitlles et al 2003). Medications and oxygen, costs of physician visits and visits to the emergency room for exacerbations, hospitalizations, admissions to an intensive care unit, and procedure–test costs were included in the data analysis. The mean cost of a single exacerbation was found to be $159, and the global direct yearly per-patient cost was $1876. These figures are again bound to be underestimations because of the exclusion of indirect cost measurement.

Optimization of the care of the COPD patient typically costs a substantial amount of money, and cost-minimization strategies may be in direct opposition to that goal (Sullivan et al 2000). Those individuals charged with deciding policy must take several factors into consideration including the burden of the disease (epidemiology as well as cost), the environment of the setting in question, and the cost-effectiveness of available interventions. Though both the young and the old abuse tobacco, the disease burden is substantially higher in patients over the age of 65 years (National Heart, Lung, and Blood Institute 2000). COPD is relatively rare in persons younger than middle-age (Ward et al 2000). This is an important factor to consider when looking at any intervention that affects the outcomes of patients with COPD since preserved years of life and the quality of those years are primary markers of cost-effectiveness. Disability-adjusted life years, mortality rates, and rates of hospitalization for COPD are greater than are those for coronary heart disease, stroke, and lung cancer (Zaher et al 2004). When examining cost-effectiveness, it is necessary to take all future costs of treatment and disease into account as COPD remains a progressive and incurable disease that will be present for the lifetime of the patient (Ramsey and Sullivan 2003).

Cost-effectiveness analysis

Determining the cost-effectiveness (CE) of an intervention is far from simple. As stated previously, both direct and indirect costs must be included in an analysis in order to consider it complete. However, most CE analyses consider only direct costs. The principal result of a CE analysis is the incremental CE ratio. This ratio takes the amount by which the cost of one intervention exceeds another (the incremental cost), and divides that figure by the amount of money that the use of the intervention in question exceeds the outcome expected by the alternative (the incremental effectiveness) (Garber 1996).

The United States Panel on Cost-effectiveness in Health and Medicine, formed by the United States Public Health Service (USPHS), recommended that certain standards be met by investigators of CE analyses (Ubel et al 2000). A cost utility analysis is designated the gold standard. Such an analysis estimates the number of quality adjusted life years (QALYs) produced when a particular amount of money is used to fund a specific intervention (Boyd et al 1990). QALYs take into account the years that are affected by an illness and weights them of lower value than those during which a patient enjoys good health. A value of 0 is designated for years during which the patient’s quality of life is no better than death, and a value of 1 implies perfect health and the best possible quality of life (Garber 1996). The point at which an intervention stops being cost-effective has been defined in the medical literature as between $20 000 and $50 000 per QALY (Warner 1997; Tengs and Wallace 2000). In the UK, the National Institute for Clinical Excellence has set the benchmark for CE at £20 000 per QALY (Godfrey et al 2005). QALYs are the preferred outcome measure as suggested by the USPHS.

CE analyses can be performed from multiple perspectives including those of society at large (program cost), an insurer, a patient, or an employer. Because the process of CE analysis is neutral politically and economically, public debate about where money should be spent will continue. Though the most appropriate perspective is still being deliberated, the USPHS stipulates that public utility estimates should be the basis for measurements of
the CE of a given intervention (Ubel et al 2000). The argument for this perspective is that CE analysis exists as a tool to determine how scarce resources belonging to a society should be assigned. An individual patient is not shrouded from self-interest, making bias in the assignment of CE a possibility. However, the argument can be made that because society as a whole is blind to the effects of a specific illness, it cannot make informed decisions, and a bias against an illness, particularly an illness such as COPD that is sometimes designated a disease of self-infliction, may cloud the issue. Additionally, society may not look at CE as an issue solely of QALYs, but may favor patients who are severely ill, meaning that fewer QALYs would be gained through an intervention in comparison with interventions aimed at those with a smaller disease burden. The possibility also exists for the geriatric population to be viewed as less valuable because they are felt to have already consumed their resources (Ubel et al 2000). An employer may see the cost of an intervention as excessive since workers may leave the company, making another employer the beneficiary of a person’s improved productivity before the break-even point. Additionally, it has been hypothesized that programs requiring no financial investment on the part of the patient may attract those who are in reality not as motivated to quit, and as such, the overall effectiveness of the program may be diminished (Curry et al 1998).

Discounting is another recommended component of a CE analysis. Simply put, a given amount of money today is worth more than that same amount will be tomorrow. Therefore, when estimating future value, a discount rate should be applied. The amount is controversial, but the USPHS recommends 3%. A sensitivity analysis is often applied to data as well. Because there are large disparities in economic data, it is sometimes necessary to use a “best guess” estimate. All studies examining the CE of smoking cessation require the investigators to employ some amount of modeling (Godfrey et al 2005). For instance, most studies considered long-term extend for a maximum of 1 year; however, smokers may still relapse past that point in time. Because there are limited data beyond 12 months, long-term rates of abstinence from smoking must be estimated (Song et al 2002). The point at which patients can be labeled lifelong quitters has yet to be determined (Ockene et al 2000). Utilization of a sensitivity analysis determines the likelihood that the conclusion of an intervention as cost-effective will be upheld if uncertain values are higher or lower than those used for the original calculations (Garber 1996).

A comparison of CE analyses examined the utilization of the USPHS recommendations (Phillips and Chen 2002). Though discounting was frequently employed, only 22% of studies used the suggested rate of 3%. Less than 1 in 3 reported QALYs as a primary outcome measure. Incremental ratios were used more frequently, but were not a component of 17% of studies. The disparities among study design make comparisons from one to another difficult at best. The population studied and the methods used can significantly change outcomes (Haxby and Baldwin 1996).

Cost-effectiveness of smoking-cessation programs

There are currently no studies examining the CE of smoking cessation as it relates directly to patients with COPD. The difficulty with the administration of such a study is that COPD does not exist in a vacuum. Because patients with COPD tend to be older, there is frequent overlap with other diseases. Many of these, such as coronary heart disease, hypertension, and cancer to name but a few, have their own link to smoking. Therefore, if QALYs are to be used as an outcome measure, it is unlikely that the physiological burden of one disease will be easily separated from that of another. Additionally, the ultimate cause of mortality might be identifiable, but the decline in health leading up to that point may not be attributable to a single illness. The number of years of life saved in studies where disease-specific mortality is estimated is typically smaller than when smokers and quitters are compared for overall mortality rates (Curry et al 1998).

Multiple studies examining the CE of various smoking cessation programs and reporting outcomes in terms of QALYs saved, or more frequently total life-years saved (LYS), have been published (Table 1). Six of these studies were completed to examine overall program (societal) costs. Of these, two reported both QALYs saved and LYS (Javitz et al 2004a; Fennstra et al 2005). The remaining four programs all reported outcome data for LYS alone (Wasley et al 1997; Lennox et al 2001; Tomson et al 2004; Godfrey et al 2005). Three of the studies were done from the perspective of the payer, one reporting cost per QALY saved (Tran et al 2002), and the other two reporting cost per LYS (Curry et al 1998; Gilbert et al 2004). The final study evaluated data from the perspective of an employer over the lifetime of its workforce and reported findings as cost per LYS (Warner et al 1996). These ten studies were very different in design and perspective, and included costs. Most of them included a sensitivity analysis of the data generated,
Several other studies examining CE have been completed, but did not report data per QALY saved or LYS. One such study, an economic model of bupropion and a work-site smoking cessation program, demonstrated the CE of the intervention (Halpern et al 2000). A comparison of

and the majority took background quit rates and likely relapse percentages into account. Despite the inconsistency in study design among the ten, the programs were all deemed cost-effective by the investigators both pre- and post-sensitivity analysis completion.
coverage vs no coverage was employed. The group studied was a cohort of workers and their adult dependants until all had reached the age of retirement (65 years) and death (assumed to be age 85 years). For every dollar spent on a smoking cessation intervention, it was estimated that between $5 and $6.50 was saved when considering both direct and indirect costs. Considering just the money saved on health care, between $4 and $4.70 was saved per dollar spent. Over 20 years, the estimated savings for a managed care organization under this model was between $5.7 and $6.4 million. This study did estimate the number of cases of COPD that could be prevented assuming 100 000 employees and 60 000 dependants were affected. At the end of 20 years, it was expected that 420–670 fewer cases of obstructive lung disease would be seen.

Two bupropion regimens and 2 behavioral interventions were combined in another study examining the CE from an employer’s perspective (Javitz et al 2004b). This trial was open-label and randomized. The primary measure of success was self-reported 7-day abstinence after 12 months. An 11% background quit rate was assumed. The authors concluded that after 5 years, the employer would be expected to realize a benefit of $3735 per non-smoker at a total per-enrollee cost of $119–283 depending on the regimen used. The per-enrollee benefit to the employer was $472–832, making the intervention cost-effective. Benefits were expected to be realized from a decrease in medical expenses of 19%, a decrease in the number of days absent from work (4 days for men and 2 days for women prorated by years post-quit), and a productivity gain of >50%. A sensitivity analysis did not change the CE outcome. It should be noted that this study was completed using Caucasian middle-class subjects who were aware that bupropion would be given, so these data are likely not applicable across all patient groups.

Another study examining a program in terms of cost to the employer using a decision tree analysis found that combinations of 5 weeks of nicotine replacement treatment at an average cost of $128, along with 5 clinic visits ($75) and 5 consultations with a pharmacist ($75) were cost-effective when patients were fully reimbursed (McGhan and Smith 1995). The net benefit per converted non-smoker was found to be $302 for the first year, and $1483 for each additional year after cessation. The authors of yet another analysis concluded that an employer could expect a net benefit of up to $338 per successful quitter in the first year when bupropion and/or nicotine replacement was provided (Neilsen and Fiore 2000). The CE of the intervention remained unaffected after the sensitivity analysis was completed.

The CE of a program administered by family physicians in Australia utilizing special training for the physicians involved demonstrated that the program was cost-effective for all parties (Buck et al 2000). Physicians were trained to gauge the readiness of a patient to quit using the transtheoretical model. Self-reported quit rates at 12 months were verified with carbon monoxide readings of <14 ppm. CE was defined as the cost per quitter believed to have done so as a direct result of the program. The total program cost to the group of smokers who were prepared to quit was $23 429, and $25 734 for the entire group of smokers (1995 dollars). The net quit rate was 7.7% with associated costs of $421 for the organizers, $984 for the physicians, $348 for the smokers, and $1749 for society. Included in the analysis was the cost of the training which makes this study unique, but also makes comparisons with other studies difficult. CE is expected to improve over time as the training is a one time cost and will continue to be spread over a greater number of quitters.

A systematic review of the CE of smoking cessation studies was recently published (Ronckers et al 2005). In an attempt to standardize the studies for comparison, the CE ratios were assessed from the standpoint of the societal perspective. Fourteen studies and 26 overall comparisons were included, and only studies applicable to the non-community setting were used. It was determined that the data analyzing future costs was lacking as only 3 of the studies reported healthcare savings, and a single study reported costs anticipated to be incurred over an expanded lifetime. After recalculation, most of the intervention costs were more expensive than originally reported. The mean increase was more and a double the original estimates. Conversely, effect size decreased after standardization (7%–94%). Relapse rates were not controlled for in many studies (12 for short-term, and 18 for long-term). Unaided quit rates were not incorporated into the data for 16 studies. After standardization was complete, cost per LYS ranged from $490 to $15 280 compared with $220 to $5050 for the original reported data. The incremental CE of counseling with follow-up compared with counseling alone was $500–6000. When the included studies were adjusted with a discount rate, costs nearly doubled. Despite the disparities between the data pre- and post-standardization, the interventions all remained cost-effective.
Cost-effectiveness of relapse prevention

Dependence on tobacco is a chronic disorder, and relapse is extremely common (Percival and Milner 2002). It is estimated that there are 45.7 million former smokers in the US (Centers for Disease Control and Prevention 1999). The 1994 National Health Interview Supplement provided data demonstrating that 46.4% of smokers had engaged in a serious attempt to quit during the previous year (Cinciripini and McClure 1998). Despite that fact, only 5.7% were able to quit for a full month or more. The final annual quit rate was 2.5%. Successful quitters have typically engaged in at least 3 attempts prior to achieving abstinence, and many will unfortunately never succeed in achieving continued abstinence (Curry and McBride 1994; Percival and Milner 2002). The majority of patients who relapse will do so within 7 months of their quit date, and a full 70% will begin using tobacco again within the year (Ockene et al 2000; Brandon et al 2004). Those who have engaged in formal treatment programs are more likely to remain former smokers than self-quitters who have an estimated 1-year relapse rate of 90%. The risk of relapse, though it decreases over time, remains significant even after a year of abstinence. It has been estimated that over a 7-year period, 50% of “successful” quitters will begin to smoke again, meaning that these individuals will not experience the long-term benefits of cessation (Godfrey et al 2005). Of those patients that relapse, up to 38% will attempt to quit again within the following year (Hughes et al 1992). Rates of relapse have the potential to decrease the overall CE of smoking cessation interventions. It has been hypothesized that programs aimed at keeping former smokers from abusing tobacco again may prove more cost-effective than cessation interventions themselves (Brandon et al 2004). Follow-up serves to remind quitters why they stopped smoking in the first place, and contributes to continuing abstinence (Jackson et al 2001).

A study looking at the effect of a program on maintenance of smoking abstinence was published in 2004 (Brandon and DeMichele 2004). Mailings and booklets were mailed out to former smokers in varying combinations and at different frequencies. Questionnaires were given to subjects at 12, 18, and 24 months. A 4% discount rate was employed. For the patients receiving the higher levels of contact, relapse rates were decreased (p<0.05). Dividing the mean cost of the two most intensive interventions with the difference in abstinence rates at 24 months demonstrated that both were cost effective at $186 and $360 respectively. The overall cost of each additional abstainer in the study was $126. It was estimated that a “permanent” quit added an additional 2.25 QALY to the life of a successful abstainer. Limitations of this study include the fact that smokers were only required to have 10 non-smoking weeks behind them when they enrolled, and the fact that the subjects were self-selected, meaning that they were probably motivated to maintain their non-smoking status. Even so, costs compared with most initial cessation interventions were favorable. The provision of relapse prevention programs is therefore likely to be an extremely cost-effective endeavor since repeated use of cessation programs will in many cases be avoided.

Insurance coverage of smoking cessation treatments

It has been demonstrated that the elimination of a co-pay (the amount an insured person is expected to pay out of pocket for medical services) can increase the rate of program utilization 3-fold, and that 1.5 times the number of smokers would quit if full coverage were available (Curry and McBride 1994). Both the Public Health Service (PHS) and the Preventive Services Task Force recommend that benefits for smoking cessation be made available (Department of Health and Human Services 2005). It is further recommended that coverage should be available for a minimum of 2 quit attempts annually, and that co-pays should be minimal or eliminated completely. Included in the benefits should be a minimum of 4 counseling sessions lasting at least 30 minutes, and prescription and over-the-counter medications (bupropion and nicotine replacement). The coverage for over-the-counter products is especially important as some may believe that the availability of these medications to the public somehow relieves the government and insurers from their obligation to help with financial support. Cutting out coverage of medications or decreasing the inventory of medications used in the treatment of smoking is sometimes done because smoking may be viewed as a self-inflicted behavioral health problem instead of as a true chronic addictive disorder with a high risk of relapse (Jonk et al 2005). Additionally, employers have been reluctant to pay for cessation aids as employee turnover negates the certainty that the employer will reap the benefits of the expenditure directly (Warner et al 1996).

Despite the additional success associated with full coverage, a survey completed in 2002 found that managed care organizations (MCOs) cover smoking cessation sporadically (Warner et al 2004). Approximately 1/3 had
no set guidelines for the use of such services. It has been hypothesized that there are several reasons for this lack of consistency in coverage. First, the MCOs may not be convinced of the CE of smoking cessation. Second, there is a limited vocal demand of such services by either patients or employers. Third, similar to the dilemma that employers face with turnover, an MCO may not realize the full benefits of an enrollee transitioning to former-smoker status as they may not stay with the same plan (Curry et al 1998). Results generated from the use of a computer simulation model to assess the effects of an MCO either covering or not covering smoking cessation treatment was recently published (Warner et al 2004). After discounting at the 3% rate, the MCO expenditures were found to be $20.1 million at a cost per coverage-induced quitter of $6791, and a cost per LYS of $3417. It was estimated that over a 30-year period, 19 881 smokers would successfully quit as a direct result of having coverage through the MCO, and that the average gain in life-years would be 7.1. By spending money on cessation the MCO avoids costs related to treatment of smoking-related disease.

In general, studies have shown that smoking cessation programs are highly cost effective when compared with interventions in other areas. It has been estimated that if the UK's National Health Service covered the cost of nicotine patches for quitters, the average cost per LYS would be £392 for those younger than age 55, and £785 for those older (Stapleton et al 1999). This is less expensive than coverage for hip replacement, or screening programs for hyperlipidemia and breast cancer (The Department of Health 1990; Ham 1995). The money spent per benefit user in one study for which patients had full benefit coverage for cessation ($328) is also less than that spent on hypertension treatment ($592) or heart disease ($6941) on an annual basis. This is especially important considering that treatment in these cases extends over the life of the patient (Curry et al 1998).

As smoking cessation is more cost-effective than other interventions which are typically covered by insurance, and because smoking contributes to a plethora of negative health-related outcomes that in turn lead to additional health care expenditures by payers, society, and employers alike, it seems particularly non-sensical that coverage for complete cessation programs is not universal. It is a logical conclusion that spending to help many smokers quit, though increasing expenditures in the short term, would result in a overall decrease in spending in multiple areas across the healthcare continuum. Coverage for smoking cessation should be universal, and co-pays should be low if not eliminated.

Conclusion

Smoking cessation is the most preventable cause of COPD, and in fact is the most preventable known cause of death (Westmaas et al 2000). When examining studies measuring the CE of interventions, it is difficult to generalize the data. Populations differ in terms of economics, education, and motivation, interventions are varied, and the inclusion of indirect and direct costs is inconsistent. CE will vary in accordance with whose perspective is used for the study design. Outcomes are not expressed in a standardized manner.

What has been consistently demonstrated throughout the literature, however, is that even modest rates of abstinence by program users can produce substantial gains in health, and may therefore prevent significant expenditures in healthcare over a lifetime. This is especially true when considering younger smokers who have not yet developed COPD since smokers who quit by the age of 35 years have a life-expectancy no different that those who never abused tobacco (Doll et al 1994).

Healthcare providers are not doing as much as can be done to help smokers quit. Every year 50%–70% of smokers visit either a dentist or a physician (Hayward et al 1989; Anonymous 1993). These practitioners consistently report low levels of smoking intervention behaviors (Smith et al 2003). Although brief opportunistic interventions have the most effect on smokers who use smaller numbers of cigarettes per day, the interaction is still important as that light smoker may transition to heavy smoking over time (West et al 2000). One study found that a maximum of 3 minutes of anti-smoking advice could increase quit rates by over 2% (Westmaas et al 2000). Smokers have consistently reported that advice from healthcare practitioners does help motivate them to attempt to stop.

Regardless of the methods employed, smoking cessation remains among the most cost-effective healthcare interventions. Few interventions in fact have a lower cost per QALY saved (Godfrey and Fowler 2002). For this reason, coverage for cessation therapy should be universal, and programs should be in place for relapse prevention. Comparing the financial burden that COPD places on society to the cost per QALY saved certainly favors this argument.
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