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**EVIDENCE REPORT AND
EVIDENCE-BASED
RECOMMENDATIONS:**

**Interventions to Promote
Smoking Cessation in the
Medicare Population**



PREPARED FOR: U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION
7500 Security Blvd.
Baltimore, MD 21244-1850

PREPARED BY: RAND

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EXECUTIVE SUMMARY

INTRODUCTION

Smoking is the single most preventable cause of morbidity and mortality in the United States. Tobacco use causes more than 430,000 deaths and costs the United States between \$50 billion and \$73 billion in medical expenses each year.^{1,2} Fortunately, smoking among adults has decreased: In 1965, approximately 42% of U.S. adults smoked, but in 1994, the number was down to 26%. Still, in 1994, 48 million U.S. adults 18 years of age and older (25.3 million men and 22.7 million women) were current smokers.¹

Today's older smokers grew up in an era in which advertisers, even physicians, promoted smoking; the adverse effects of smoking had not yet been established. The consequences of smoking among this cohort are now evident. In 1990, smoking caused over 287,000 deaths in the United States among persons age 65 and older—about 70% of the U.S. smoking-related deaths that year.³

Smoking is a major risk factor for cardiovascular disease, chronic obstructive pulmonary disease, cancer, hypertension, diabetic complications, and osteoporosis.^{4,5} Zhang and colleagues⁶ estimated that smoking-related illness accounted for about \$14.2 billion in Medicare expenditures in 1993, about 9.4% of Medicare's total budget. More specifically, smoking accounted for 11.4% of hospital care, 11.3% of nursing home care, 5.9% of home health care, and 5.6% of ambulatory care. It is estimated that between 1995 and 2015, tobacco-related diseases will cost Medicare about \$800 million.⁷ This is not surprising, given that in 1994 16%

of Medicare enrollees reported themselves to be current smokers, and another 44% professed to be former smokers.⁸

There are significant benefits to smoking cessation, even after 30 or more years of regular smoking.⁹ Data from the Established Population for the Epidemiological Study of Elderly (EPESE) indicate that smokers who quit have cardiovascular mortality rates similar to those of nonsmokers, and that this benefit is unrelated to age or the time elapsed since cessation.¹⁰ In one study, older smokers who already had coronary artery disease improved their survival and risk of heart attack by quitting.¹¹ In addition, lung function and circulation begin to improve immediately after cessation.¹² A person who smokes more than 20 cigarettes per day and who quits at age 65 can expect to increase his or her life expectancy by 2 to 3 years.¹³ Quitting smoking also greatly increases the quality of life for older adults.

Unfortunately, older smokers may be less likely to perceive the health consequences of smoking. For example, according to a recent survey of members of the American Association of Retired Persons (AARP), 47% of smokers age 50 and over did not believe that quitting could improve their health. In addition, 45% did not believe that continuing to smoke could further damage their health.¹⁴ Still, older smokers are more likely to achieve success in their cessation attempts than younger smokers are.^{15, 16} Thus, although special emphasis needs to be applied in addressing the barriers to quitting among the elderly, age is not a significant obstacle to cessation interventions.

A number of interventions to improve smoking cessation have been studied, and many of these are recommended in clinical practice guidelines promulgated by various organizations.¹⁷ To better understand such interventions in the Medicare population, the Health Care Financing

Administration (HCFA), as part of its Healthy Aging project, commissioned an evidence-based systematic review of smoking cessation, the results of which are detailed in this report.

METHODS

We employed the evidence review and synthesis methods of the Southern California Evidence Based Practice Center, an Agency for Healthcare Research and Quality: the designated center for the systematic review of literature on the evidence on benefits and harms of health care interventions. Our literature review process consisted of the following steps:

- Develop a conceptual model.
- Identify sources of evidence (in this case, sources of scientific literature).
- Identify potential evidence.
- Evaluate potential evidence for methodological quality and relevance.
- Extract study-level variables and results from studies meeting methodological and clinical criteria.
- Synthesize the results.

The interventions used to promote smoking cessation among persons age 65 or older fell into the following broad categories: self-help, counseling, pharmacotherapy, education, financial incentives (provider and patient), regulatory and legislative interventions, and media campaigns. We used several sources to identify existing research and potentially relevant evidence, including the Cochrane Collaboration Tobacco Group database, the draft Public Health Service Report,¹⁸ ten previously completed systematic reviews, and a library search of the computerized databases Medline, PsychLit, Dissertation Abstracts, Applied Social Sciences Index, and Social Science Citations Index.

While we were primarily searching for data relevant to the Medicare population, we included studies on adult populations under age 65 to avoid loss of potentially useful data. To be accepted as evidence, a study had to measure quit rates at least five months from the start of an intervention and use one of the following designs: randomized controlled trial, controlled clinical trial, controlled before and after study, or interrupted time series with adequate data points. From these articles we abstracted data such as the number and characteristics of patients; setting, location, and target of the intervention; intensity of the intervention; types of outcome measures; time from intervention until outcome measurement; and results. In the analysis itself, we sought to answer the following questions specified by HCFA:

1. If Medicare were to offer a smoking cessation benefit, how would providers be reimbursed? For example, by minutes of counseling?
2. Should providers go through a certification process? If so, should Continuing Medical Education (CME) be used?
3. How should provider compliance be measured and monitored?
4. What means could be used to curb overutilization? Cost sharing by patients? Annual caps on services?
5. How effective are patient financial incentives?
6. How effective is telephone counseling?
7. How effective is other counseling?
8. How effective is pharmacotherapy?
9. How effective is self-help?
10. Which practice settings are most effective? Outpatient? Hospital? Free-standing smoking cessation clinics?
11. Who is most effective at delivering smoking cessation interventions? Physicians? Psychologists? Nurses? Dentists?
12. Do certain interventions work better for special populations?
13. What are costs of interventions?
14. Which interventions are most cost-effective?

Some of these questions were similar or even identical to questions being assessed by the team developing the Public Health Service Report Treating Tobacco Use and Dependence.¹⁸

However, the focus of this HCFA report was to draw inferences for Medicare programs and policies for an insurance benefit. With the permission of the principal investigator of the Public Health Service project, we present their analyses where applicable. A panel of experts was convened on October 21, 1999; feedback from the panel was useful in fine-tuning our analysis and recommendations.

RESULTS

Our search yielded 488 articles, 248 of which met our screening criteria. The type of intervention examined in the greatest number of studies, 149, was patient education; we found 118 studies that used individual counseling, 104 studies that used self-help, and 76 studies that used patient financial incentives. (These categories are not mutually exclusive.) Of the 248 selected studies, 40 were randomized or controlled clinical trials.

There were no studies comparing smoking cessation outcomes as a function of different reimbursement schemes (Question 1) or addressing the issue of provider compliance and monitoring (Question 3), and we found no controlled trials of patient financial incentives in smoking cessation interventions (Question 5).

QUESTION 2. SHOULD PROVIDERS GO THROUGH A CERTIFICATION PROCESS?

A recent meta-analysis¹⁹ of nine studies provided data on the effect of provider education on both provider performance and patient smoking cessation rates. Eight of the studies reported the effect of training medical practitioners, while one reported the effect of training dental practitioners. The provider training in all studies was conducted on a group basis, in either a

tutorial or a workshop format. The analysis showed that trained providers were significantly more likely to perform smoking-cessation tasks than untrained providers. Patient outcomes were also affected: Patients who saw trained providers were more likely to stop smoking than those who saw untrained providers (pooled odds ratio=1.48, 95% C.I.=1.20 to 1.83).

QUESTION 4. WHAT MEANS CAN BE USED TO CURB OVERUTILIZATION?

We found one article that reported on the effectiveness and cost-effectiveness of different levels of coverage for both a behavior modification benefit and a nicotine replacement benefit for smoking cessation. This study was performed at a health maintenance organization (HMO) in the Pacific Northwest and involved over 90,000 patients.²⁰ The four benefit strategies are shown in the table below.

Cost-Sharing Plans Analyzed

Plan	Behavior Benefit	Nicotine Replacement Benefit	Cost/Quitter
Full	100%	100%	\$1171
Standard	50%	100%	\$797
Flipped	100%	50%	\$870
Reduced	50%	50%	\$801

The most cost-effective benefit plans (from the health plan perspective) were those in which the patients bore some financial responsibility for the smoking cessation program. However, full coverage of both benefits resulted in more quitters (approximately two to four times as many quitters in the full benefit plan as in the reduced coverage plans).

We found no studies that specifically addressed curbing overutilization or the effect of capitation limits on services. Our expert panel emphasized that overutilization should not be a problem, and that we should concentrate on convincing smokers to engage in cessation interventions.

QUESTION 6 & 7. HOW EFFECTIVE IS COUNSELING?

A number of systematic reviews have examined the effectiveness of counseling for smoking cessation.^{17, 18, 21-23} Preliminary results from the 2000 Public Health Service Report¹⁸ show that all forms of counseling are statistically significantly effective at promoting smoking cessation. In the analysis, individual counseling yielded the highest adjusted odds ratio for success, followed by group counseling, phone counseling, and self help. Individual counseling was statistically significantly superior to self-help (which itself was only marginally statistically different than control). The greater effectiveness of individual counseling over telephone counseling approached statistical significance. There was no statistically significant difference in effectiveness between group counseling and telephone counseling. In another quantitative systematic review that examined only physician counseling,²⁴ 16 trials reported the effect of brief advice on smoking cessation. These trials had a pooled odds ratio of 1.69 (95% C.I.=1.45 to 1.98). Intensive counseling was found to be more effective than minimal advice, with a pooled odds ratio of 1.44 (95% C.I.=1.23 to 1.68).

A recent meta-analysis of five studies²³ found group counseling more effective than no intervention or minimal contact, with a pooled odds ratio of 1.91 (95% C.I.=1.20 to 3.04). In two trials that compared group counseling directly with individual counseling, there were no statistically significant differences between the two interventions.

The 1996 smoking cessation guidelines revealed an apparent dose-response curve between the *amount* of counseling and the smoking cessation rate. For contact less than or equal to three minutes, the adjusted odds ratio was 1.2 (95% C.I.=1.0 to 1.5), and for contact longer than 10 minutes, the adjusted odds ratio increased to 2.4 (95% C.I.=2.1 to 2.7). Counseling lasting between three and 10 minutes had an intermediate adjusted odds ratio of 1.4 (95% C.I.=1.2 to 1.7). Results from the new PHS report show a similar trend.¹⁸

According to the 1996 guidelines, there is a similar relationship for the *duration* of individual counseling. Counseling with a duration of less than two weeks was found to be less effective than counseling that lasted more than eight weeks (adjusted odds ratio of 1.1 versus 2.7).

Counseling lasting between two and eight weeks showed intermediate effectiveness (adjusted odds ratio of 1.6). The *number* of counseling sessions also showed a similar dose-response relationship, with a trend toward increasing smoking cessation rates with increasing number of individual treatment sessions up to seven sessions. Preliminary results from the 2000 PHS Report show an odds ratio of 1.4 (95% C.I.=1.1 to 1.7) for two to three sessions, an odds ratio of 1.9 (95% C.I.=1.6 to 2.2) for four to eight sessions, and an odds ratio of 2.3 (95% C.I.=2.1 to 3.0) for more than eight sessions.

In conclusion, all forms of counseling have statistically significant effects on smoking cessation, with individual counseling appearing to be the most effective method. Dose-response curves are available for length of time spent on each counseling session, number of sessions, and total duration of counseling intervention.

QUESTION 8. HOW EFFECTIVE IS PHARMACOTHERAPY?

In a recent meta-analysis of 91 trials,²⁴ nicotine replacement therapy (NRT) was more effective than the control in smoking cessation, with a pooled odds ratio of 1.72 (95% C.I.=1.60 to 1.84). Different forms of NRT produced moderately different results, shown in the table below. Since the confidence intervals around these estimates of effect overlapped, there was no evidence of a significant difference in the effectiveness of the five types of NRT. The Public Health Service reports a very similar trend in odds ratios.¹⁸

Effectiveness of Nicotine Replacement Therapy versus Control

Delivery Mechanism	Pooled Odds ratio
Gum (49 studies)	1.63
Sublingual tablet (2 studies)	1.73
Patch (32 studies)	1.77
Inhaled nicotine (4 studies)	2.08
Nasal spray (4 studies)	2.27

A quantitative systematic review of four studies that compared bupropion-SR users with a control group²⁵ reported a pooled odds ratio of 2.73 (95% C.I.=1.90 to 3.94). Bupropion-SR is an antidepressant sold as Wellbutrin. It is currently marketed toward smokers under the name Zyban and is currently the only FDA-approved drug for smoking cessation other than NRT. The same review also reported that two studies of nortriptyline (a tricyclic antidepressant) had a pooled odds ratio of 2.83 (95% C.I.=1.59 to 1.03).

Three quantitative systematic reviews on clonidine^{26 17, 27}(which included six studies, seven studies, and 10 studies, respectively) reported pooled odds ratios of 1.89 (95% C.I.=1.30 to 2.74) and 3.0 (95% C.I.=1.5 to 5.9), respectively, for the first two studies, and a quit rate of 5.7% (95% C.I.= -1.3% to 12.7%) in the third study for clonidine, compared with control. There was, however, a high incidence of dose-dependent side effects, particularly sedation and dry mouth. Clonidine is used to treat hypertension; it has not been approved by the FDA for smoking cessation.

Two quantitative systematic reviews^{17, 25} found no effectiveness for anxiolytics such as buspirone, diazepam, or meprobamate.

QUESTION 9. HOW EFFECTIVE IS SELF-HELP?

Two systematic reviews have reported results on self-help interventions.^{17, 22} In the first, a meta-analysis of 25 studies²² reported a pooled odds ratio of 1.23 (95% C.I.=1.01 to 1.51) compared with control. In the second, a meta-analysis of twelve studies¹⁷ reported a pooled odds ratio of 1.2 (95% C.I.=0.97 to 1.6) compared with control. (Similar results were reported in the 2000 Public Health Service Report.¹⁸) These data indicate that self-help materials have a small practical effect on smoking cessation. Studies of helpline/hotline forms of self-help, used alone, had an odds ratio of 1.4 (95% C.I.=of 1.1 to 1.8). There is no evidence that adding self-help materials to individual counseling or NRT improved smoking cessation rates.²²

QUESTION 10. WHAT PRACTICE SETTINGS ARE EFFECTIVE?

Interventions for patients hospitalized with smoking-related illness

Hospitalization gives patients a unique opportunity to quit smoking, as all U.S. hospitals are smoke-free. We found nine studies of interventions with hospitalized patients. We considered conducting a meta-regression on hospital interventions versus usual care in hospitals, but this was not possible for several reasons. First, many studies did not use a pure control group. For example, some studies of NRT for hospitalized patients gave the placebo group counseling, self-help literature, etc. In many cases, the difference between NRT and placebo was insignificant if both groups were provided with counseling and follow-up. Second, the populations studied differed in their reasons for hospitalization. For example, some studies included only cardiac patients, while others excluded cardiac patients. Most important, the interventions used were very heterogeneous.

The highest quit rates were found in two studies of cardiac patients.^{28, 29} The high rates may have occurred because the immediacy of the situation was apparent to the patients; however, the reported rates may be biased upward, and there was no biochemical confirmation of smoking cessation. In studies where cotinine or carbon monoxide was used to verify self-reports (most other studies), cessation rates were far below those reported in the two studies that relied solely on self-reports. In general, interventions with follow-up calls or visits were shown to be more successful than those without, except in one study.³⁰

Free-standing smoking cessation programs

There are very few inpatient or residential programs designed specifically for smoking cessation. In Minnesota, both Hazelden and the Mayo Clinic have such programs, but we found no

controlled studies of them. Thus, we can not make a statement about the effectiveness of such programs. The only study we found of outpatient smoking cessation clinics was a randomized trial, but there was no pure control group.³¹

QUESTION 11. WHO IS MOST EFFECTIVE IN DELIVERING SMOKING CESSATION INTERVENTIONS?

A systematic review of 41 studies¹⁷ comparing nonmedical healthcare providers (social workers, counselors, psychologists), nonphysician medical care providers (pharmacists, nurses, dentists), and physician providers found no statistically significant differences in smoking cessation rates among patients who saw these various providers. The pooled odds ratio was 1.8% (95% C.I.=1.5 to 2.2) for nonmedical providers, 1.4 (95% C.I.=1.1 to 1.8) for nonphysician medical providers, and 1.5 (95% C.I.=1.2 to 1.9) for physicians. However, interventions using multiple providers were found to be more effective than interventions using a single provider (pooled odds ratio=2.8, 95% C.I.=2.6 to 5.6).

In a systematic review of 14 studies specifically focused on nursing interventions,³² smoking cessation rates improved over rates for usual care (odds ratio=1.43, 95% C.I.=1.24 to 1.66). Interventions included cessation advice, counseling, and psychological feedback. In addition, we conducted a meta-regression containing 56 arms comparing an intervention group with a control group. The results are shown in the table below.

Meta-Regression Results by Provider

Provider	Adjusted Odds Ratio	95% C.I.
Physician	3.02	2.62–3.48
Psychiatrist/psychologist	2.68	1.79–4.00
Nurse	2.38	1.87–3.03
Counselor	1.87	1.35–2.61
Unknown	1.41	1.09–1.83
Other (self-help, etc)	1.37	1.15–1.65

The trend indicates that physicians are the most effective intervention providers, compared with control, followed by psychiatrists/psychologists, then nurses. Physicians had a statistically significant advantage over lay counselors, self-help, and interventions where the provider was unknown. Interventions using psychiatrists/psychologists and nurses were shown to be significantly more effective than self-help or interventions with unknown provider type.

QUESTION 12. DO CERTAIN INTERVENTIONS WORK BETTER FOR SPECIAL POPULATIONS?

We found only one controlled trial of smoking cessation interventions designed specifically for Latinos. Unfortunately, only two participants (one in the control group, one in the intervention) demonstrated cotinine-validated abstinence at both post-treatment and 12-month follow-up. More controlled trials of smoking cessation interventions for Latinos are necessary before we can make a statement on effectiveness.

We found five studies on African American populations; only one of which showed statistically significant improvements in smoking cessation. We found no studies that demonstrate reduced

or enhanced effectiveness of generic smoking cessation interventions among different ethnic/racial groups.

QUESTION 13 & 14. COSTS AND COST EFFECTIVENESS OF INTERVENTIONS

This section will discuss the cost and cost-effectiveness of different interventions studied in this review, including counseling, self-help, and mass media. It is important to note that medication costs are sometimes combined with these various interventions. The following table lists the average wholesale cost per dose and cost per day for these medications.³³

Costs of Smoking Cessation Medications

(average wholesale price)

Medication	Cost per Dose	Cost per Day
Nicotine patch	\$3 each	\$3.00
Nicotine inhaler	\$1/10mg	\$1.50
OTC Nicotine gum	\$0.50/piece	\$5.00
Bupropion	\$1.40/150-mg pill	\$2.80
Clonidine*	\$0.25/0.2-mg pill	\$0.50

* not FDA-approved for smoking cessation

The available evidence suggests that smoking cessation interventions are highly cost-effective when compared with other medical treatments and prevention programs.^{18, 34} The widely held view of smoking cessation as the “gold standard” of healthcare cost-effectiveness is underscored by the fact that even the least cost-effective smoking intervention — the use of nicotine gum as an adjunct to physician counseling — is estimated to cost less than half the median cost per life-year saved of nearly 600 life-saving interventions.³⁵

We reviewed 15 published studies examining the cost-effectiveness (C/E) of various smoking cessation programs and three review articles. Eight of the cost-effectiveness analyses (CEA)

were medical practice-based and seven were community-based interventions. In general, community-based programs tended to be less cost-effective than practice-based interventions. Further, practice-based interventions generally applied more rigorous methodologies such as randomized clinical trials. All of the studies reviewed examined adult smokers, yet none solely targeted the elderly.

All of the studies reviewed saved life-years at a cost as low as several hundred dollars to a high of \$14,000, with a median value of about \$5,000 per life year saved. These findings are well below the estimates of most other health interventions. The principal shortcoming of this literature is a lack of evidence on the effectiveness of smoking cessation programs for specific patient subgroups -- such as the elderly -- and their preferences for specific interventions. As Warner³⁴ noted, different interventions are effective for different people. A resource-intensive treatment may be cost effective for smokers who do not respond to less-intensive programs, but may not be successful for smokers attempting to quit for the first time. Further investigation is needed to determine the cost-effectiveness of various smoking cessation interventions on specific patient populations.

LIMITATIONS

The primary limitation of the present systematic review—a limitation that is common to all such reviews—is the quantity and quality of the original studies. The studies we examined are extremely heterogeneous in terms of both the interventions tested and the specific populations or health care systems being studied. Furthermore, many of the study-level variables are highly idiosyncratic and intercorrelated (e.g., a study of patient education with nurses may also be a study of NRT in low-income African Americans). The correlation between intervention-level

variables and population makes the assessment of the effects of the individual components challenging.

In addition, this study assumes that interventions will be as successful when targeted toward adults 65 years of age or older as when targeted toward younger populations. We had insufficient data to empirically test this assumption.

CONCLUSIONS

1. Individual, telephone, and group counseling are all effective, with individual counseling being possibly most effective.
2. There is consistent evidence from multiple analyses that greater intensity of counseling yields higher smoking cessation rates.
3. Nicotine replacement therapy (NRT), clonidine, and bupropion are all effective as pharmacotherapy for smoking cessation, although clonidine is not approved by the FDA for this use.
4. Patients visiting physicians trained in smoking cessation had higher cessation rates than those visiting untrained physicians.
5. Health insurance benefits of 100% for both counseling and NRT produced the greatest number of quitters in a population.
6. There is good evidence that both medical and non-medical providers are effective at delivering smoking cessation services, but conflicting evidence about the relative degree of effectiveness between provider types.

7. Interventions with follow-up calls or visits are more effective than those without.
8. There are insufficient data to support or refute variations on smoking cessation interventions among special populations.

RECOMMENDATIONS

Recommendations based on the evidence were formulated by a panel of experts on smoking cessation, health services research, medicine, and behavior change. The body of the report contains a list of these experts.

1. Smoking cessation interventions should be tested as a Medicare benefit.
2. Any demonstration project should include pharmacotherapy, physician visit, and/or telephone hotline. Group counseling should not be required, as most older smokers will avoid groups.
3. Physicians participating in smoking cessation demonstrations should have training in this area, preferably through Continuing Medical Education (CME).
4. There is no evidence that paying providers for outcomes will work, and there is considerable evidence that it will not. However, providers should be held accountable for their performance in accordance with the Public Health Service Report.¹⁸ The five As (ask, advise, assess, assist, and arrange) should be documented in provider records.
5. As in any demonstration project, sufficient numbers of minorities and women should be included.