

METHODS

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

- Develop a conceptual model (also sometimes called an evidence model or a causal pathway).³⁶
- 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 methodologic and clinical criteria.
- Synthesize the results.

The following are broad categories of interventions that can be used to promote smoking cessation among persons age 65 or older:

- self-help
- counseling
- pharmacotherapy
- education

- financial incentives – provider and patient
- regulatory and legislative interventions
- media campaigns.

These interventions are described below.

Self-help. In self-help interventions, a patient uses provided instructional materials to help himself/herself stop smoking.

Counseling. Counseling can be in person or via telephone, in individual or group therapy.

Providers include peer counselors, social workers, psychologists, and psychiatrists. Medical doctors also often provide brief counseling.

Pharmacotherapy. Nicotine replacement therapy (NRT) can be administered by chewing gum, nasal spray, or transdermal patch. Clonidine, antidepressants, anxiolytics, and mecamylamine have also been prescribed in efforts to curtail patients' smoking.

Education. Patients may be educated in person or through the mail, by pamphlets, peer educators, newsletters, audiovisual materials, computers, or electronic publications. Providers can be educated about smoking cessation interventions by attending workshops, training sessions, or lectures.

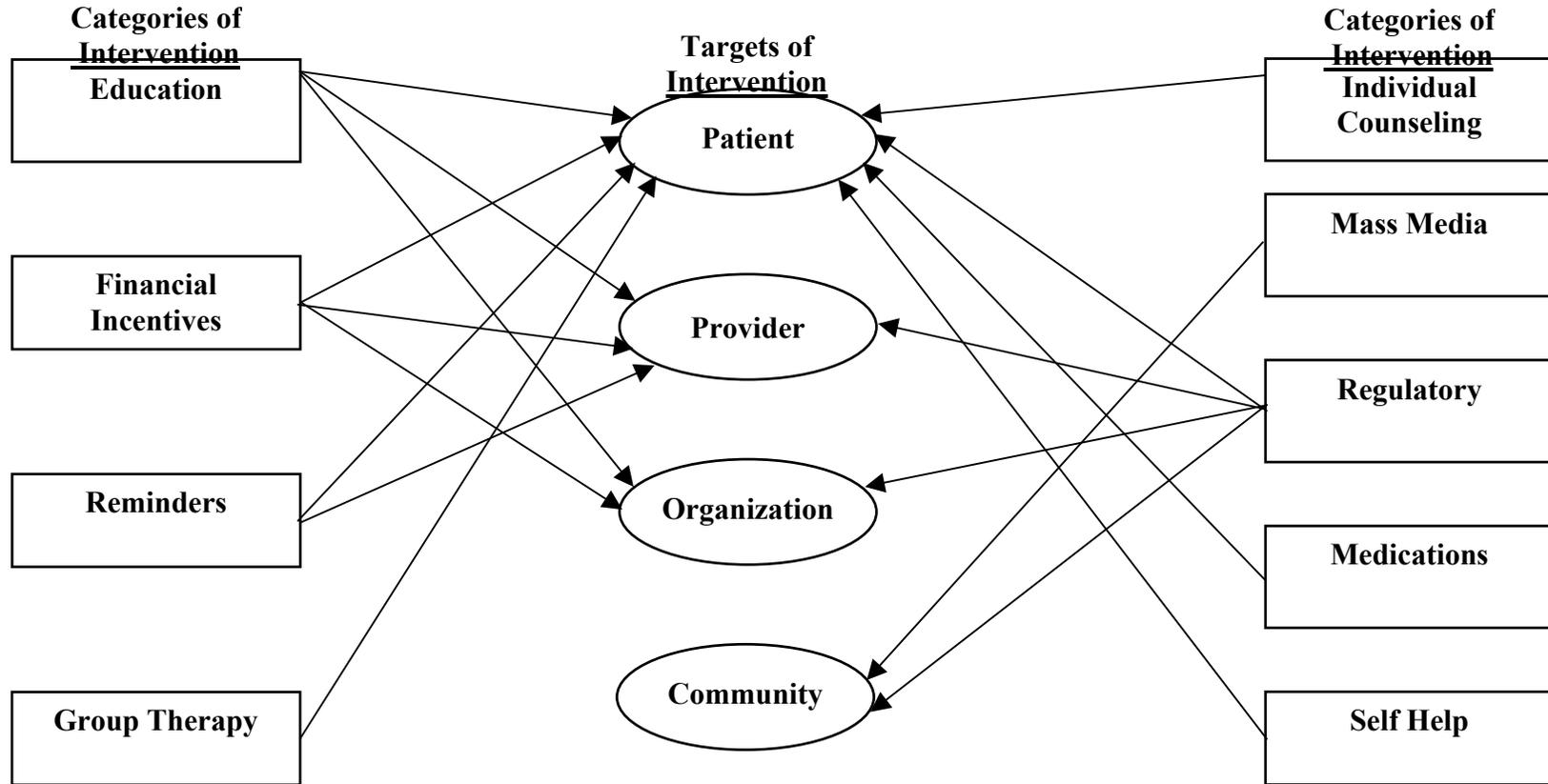
Financial incentives. Direct or indirect financial reward or benefit can be tied to a specific action on the part of a patient or provider. For example, patient insurance payments may be reduced, or gifts can be offered as a reward for biochemical confirmation of abstinence from tobacco.

Regulatory and legislative initiatives. Regulatory and legislative initiatives may operate on the local, state, or national level by creating new incentives or barriers that shape behavior. The most common policy changes include smoke-free workplaces and increased taxes on tobacco products.

Media campaigns. Media campaigns reach great numbers of people, through television, radio, newspapers, and billboards.

The relationships of these broad categories of interventions to the potential targets of smoking cessation interventions (patient, provider, organization, and community) are shown in Figure 1.

Figure 1. Conceptual Model



IDENTIFICATION OF LITERATURE SOURCES

We used the sources described below to identify existing research and potentially relevant evidence for this report.

COCHRANE COLLABORATION

The Cochrane Collaboration is an international organization that helps people make well-informed decisions about health care by preparing, maintaining, and promoting the accessibility of systematic reviews on the effects of health care interventions. The Cochrane Library contains both a database of systematic reviews and a controlled-trials register. The library receives additional material continuously to ensure that reviews are maintained through identification and incorporation of new evidence. The Cochrane Library is available on CD-ROM, by subscription. The Cochrane Tobacco Group maintains a database (held in Reference Manager) of over 2,000 citations on tobacco cessation. About 1,300 report on controlled trials or other types of evaluations of interventions. Other references are held for their potential as background material. The search terms used by the Cochrane Tobacco Group are reproduced in Table 1. (Cochrane Library, 1999).

Table 1. Literature Search Terms Used by the Cochrane Tobacco Group

Medline

SMOKING CESSATION

"SMOKING-CESSATION"/ all subheadings

"TOBACCO-USE-DISORDER"/ all subheadings

"TOBACCO"/ all subheadings

"NICOTINE"/ all subheadings

"TOBACCO,-SMOKELESS"/ all subheadings

"SMOKING"/ prevention-and-control , therapy

(QUIT* or STOP* or CEAS* or GIV*) near SMOKING

#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8

"SMOKING"/ all subheadings

#10 not #9

PT=RANDOMIZED-CONTROLLED-TRIAL

PT=CONTROLLED-CLINICAL-TRIAL

RANDOMIZED-CONTROLLED-TRIALS

RANDOM-ALLOCATION

DOUBLE-BLIND-METHOD

SINGLE-BLIND-METHOD

#12 or #13 or #14 or #15 or #16 or #17

PT=CLINICAL-TRIAL

explode CLINICAL-TRIALS / ALL

(CLIN* near TRIAL*) in TI

(CLIN* near TRIAL*) in AB

PLACEBOS

PLACEBO* in TI

PLACEBO* in AB

RANDOM* in TI

RANDOM* in AB

RESEARCH-DESIGN

(SINGL* or DOUBL* or TREBL* or TRIPL*) near (BLIND* or MASK*)

(#29 in TI) or (#29 in AB)

(VOLUNTEER* or PROSPECTIV*) in TI

(VOLUNTEER* or PROSPECTIV*) in AB

#19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #30 or #32

explode "EVALUATION-STUDIES"/ all subheadings

explode "CROSS-SECTIONAL-STUDIES"/ all subheadings

"PROSPECTIVE-STUDIES"

"RETROSPECTIVE-STUDIES"

"FOLLOW-UP-STUDIES"

#34 or #35 or #36 or #37 or #38

explode "HEALTH-EDUCATION"/ all subheadings

explode "HEALTH-BEHAVIOR"/ all subheadings

explode "COMMUNITY-HEALTH-SERVICES"/ all subheadings

"HEALTH-PROMOTION"/ all subheadings

Table 1 (continued)

explode "BEHAVIOR-THERAPY"/ all subheadings

#40 or #41 or #42 or #43 or #44

#18 or #33 or #39 or #45

(TG=ANIMAL) not ((TG=HUMAN) and (TG=ANIMAL))

#46 not #47

#48 and #9 (First part of search - uses core smoking related terms, for maximum specificity)

#48 and #11 (Second part of search - highly sensitive, low specificity)

An updated search of PsycLIT (Psychological Abstracts - American Psychological Association) was developed and run retrospectively.

Updated PsycLIT search on Silverplatter ASCII3:

#1 SMOKING CESSATION

#2 ANTISMOKING or ANTI-SMOKING

#3 QUIT* or CESSAT*

#4 ABSTIN* or ABSTAIN*

#5 CONTROL* NEAR SMOK*

#6 explode "BEHAVIOR-MODIFICATION"

#7 #2 or #3 or #4 or #5 or #6

#8 PREVENT*

#9 "TOBACCO-SMOKING" OR SMOK* OR CIGAR* OR TOBACCO*

#10 #7 and #9

#11 #8 and #9

#12 #1 or #10 or #11

Dissertation Abstracts Online:

1 SMOKING ADJ CESSATION

2 SMOKING OR CIGARETTE\$1 OR TOBACCO

3 RANDOMISS\$ OR RANDOMIZ\$ OR (RANDOM ADJ ALLOCATS) OR (DOUBLE ADJ
BLIND\$1)

4 PROSPECTIVE ADJ (STUDY OR STUDIES)

5 TRIAL\$1

6 2 AND (3 4 5)

7 1 OR 6

Applied Social Sciences Index & Abstracts (ASSX)

8 SMOKING ADJ CESSATION

9 SMOKING

10 RANDOMISS\$ OR RANDOMIZ\$ OR TRAIL\$1 OR (RANDOM ADJ ALLOCATS)

11 DOUBLE ADJ BLIND

12 PROSPECTIVE ADJ (STUDY OR STUDIES)

13 9 AND (10 11 12)

14 8 OR 13

Social Citations Index (SCI) and Social Science Citations Index (SSCI):

SMOK* & (CESSAT* OR TRIAL* OR RANDOMI* OR PROSPECTIVE OR BLIND)

SMOKING CESSATION GUIDELINES

The Agency for Healthcare Research and Quality (AHRQ, formerly the Agency for Health Care Policy and Research, AHCPR) developed guidelines for smoking cessation in 1996. An advisory panel employed an explicit science-based methodology and expert clinical judgement to develop specific statements on smoking cessation interventions. Critical reviews and syntheses were used to evaluate empirical evidence and outcomes. More recently, the Public Health Service (PHS) has published a document, *Treating Tobacco Use and Dependence*, which evaluates literature from 1975 to 1999.¹⁸ These findings were released in June 2000. We were provided with the list of references used in both analyses, and we ordered the documents not already in our possession. In preparing the Public Health Service clinical practice guideline, more than 50 meta-analyses were performed on type of counseling (phone, individual, group), length of counseling, intensity of program, etc. These analyses were not stratified by age.

PREVIOUS SYSTEMATIC REVIEWS

We identified 10 previously completed systematic reviews relevant to this project from our personal files (see Table 2). Each review discusses one or more interventions aimed at smoking cessation. We retrieved all relevant documents referenced in these publications.

Table 2. Previous Systematic Reviews

- Cepeda-Benito A. Meta-analytical review of the efficacy of nicotine chewing gum in smoking treatment programs. *J Consult Clin Psychol.* 1993;61:822-30.
- Covey LS, Glassman AH. A meta-analysis of double-blind placebo-controlled trials of clonidine for smoking cessation. *Br J Addict.* 1991;86:991-8.
- Curry SJ. Self-help interventions for smoking cessation. *J Consult Clin Psychol.* 1993;61:790-803.
- Fiore MC, Smith SS, Jorenby DE, Baker TB. The effectiveness of the nicotine patch for smoking cessation. A meta-analysis. *JAMA.* 1994;271:1940-7.
- Fisher EB Jr., Lichtenstein E, Haire-Joshu D, Morgan GD, Rehberg HR. Methods, successes, and failures of smoking cessation programs. *Annu Rev Med.* 1993;44:481-513.
- Kottke TE, Battista RN, DeFries GH, Brekke ML. Attributes of successful smoking cessation interventions in medical practice. A meta-analysis of 39 controlled trials. *JAMA.* 1988;259:2883-9.
- Pederson LL. Compliance with physician advice to quit smoking: A review of the literature. *Prev Med.* 1982;11:71-84.
- Silagy C, Mant D, Fowler G, Lodge M. Meta-analysis on efficacy of nicotine replacement therapies in smoking cessation. *Lancet.* 1994;343:139-42.

Skaar KL, Tsoh JY, McClure JB, et al. Smoking cessation. 1: An overview of research. *Behav Med.* 1997;23:5-13.

Ward KD, Klesges RC, Halpern MT. Predictors of smoking cessation and state of the art smoking interventions. *The Journal of Social Issues.* 1997;53:129-45.

HEALTH CARE QUALITY IMPROVEMENT PROJECTS (HCQIP)

Each U.S. state and territory is associated with a Medicare Peer Review Organization (PRO) that conducts various research projects. HCFA maintains a database with a narrative description of each research project, called a Narrative Project Document (NPD). An NPD includes the aims, background, quality indicators, collaborators, sampling methods, interventions, measurement, and results of a project. We searched the NPD database for studies on smoking cessation. This search retrieved only two NPDs, reflecting the lack of smoking intervention trials in the Medicare population.

SUPPLEMENTAL LIBRARY SEARCH

The Cochrane Library database contains records of studies published up to June 1997. We conducted a search of literature published since that date, using the terms used by the Cochrane Tobacco Group (Table 1), and we acquired copies of all relevant articles not already obtained through the sources mentioned above.

EVALUATION OF POTENTIAL EVIDENCE

We reviewed the articles retrieved from the literature sources against exclusion criteria to determine whether to include them in the evidence synthesis. We created a one-page screening review form that contains a series of yes/no questions (Figure 2). After evaluation against this

checklist, each article was either accepted for further review or rejected. A physician and a psychologist, each trained in the critical analysis of scientific literature, independently reviewed each study, abstracted data, and resolved disagreements by consensus. Dr. Erin Stone (the co-principal investigator of this study) resolved any disagreements that remained unresolved after discussions between the reviewers. Project staff entered data from the checklists into an electronic database that was used to track all studies through the screening process.

While we were searching primarily for data relevant to the Medicare population, we included studies containing data on populations under age 65 to avoid loss of potentially useful data. (We did exclude studies on adolescents and pregnant women, for obvious reasons.) The studies had to measure quit rates at least five months after the start of the intervention. To be accepted at this stage, a study had to use one of the following study designs: randomized controlled trial, controlled clinical trial, controlled before and after study, or interrupted time series with adequate data points. We defined the study types according to the criteria described below.

Randomized controlled trial (RCT). A trial in which the participants (or other units) are definitely assigned prospectively to one or two (or more) alternative forms of health care, using a process of random allocation (e.g., random number generation, coin flips).

Controlled clinical trial (CCT). A trial in which participants (or other units) are either:

- a) Definitely assigned prospectively to one or two (or more) alternative forms of health care using a quasi-random allocation method (e.g., alternation, date of birth, patient identifier),

OR

- b) Possibly assigned prospectively to one or two (or more) alternative forms of health care using a process of random or quasi-random allocation.

Controlled before and after study (CBA). A study in which the intervention and control groups become involved in the study in a way other than by random process and in which the baseline period of assessment is included in the main outcomes. We used two minimum criteria for inclusion of CBAs in the review:

- a) Contemporaneous data collection – data on the pre- and post-intervention periods for the study and control sites are the same,
- b) Appropriate choice of control sites – the study and control sites are comparable with respect to dominant reimbursement system, level of care, setting of care, and academic status.

Interrupted time series (ITS). An ITS study examines data trends and attributes a change in trend to an intervention. Such studies can be either retrospective or prospective. We used two minimum criteria for inclusion of ITS designs in the reviews:

- a) A clearly defined point in time at which the intervention occurred.
- b) At least three data points before and three data points after the intervention.

Following these restrictions on study design, we excluded studies that employed a simple pre/post design (i.e., a study design in which an intervention is administered to providers, patients, or communities, and the proportion of persons receiving the service is recorded once before and once after the intervention). Such a study design has no control group; therefore, it cannot account for temporal effects unrelated to the intervention.

Figure 2. Screening Form
Topic = SMOKING CESSATION
HCFA - Healthy Aging Evidence Report #2

1. Article ID _____ Topic : _____
 2. First Author _____
 (First 8 character of first author's last name)

3. Reviewer _____

4. Subject of article:
 Smoking cessation 1
 Other 9

(IF OTHER, REJECT - STOP)

5. Study Design:
 RCT 1
 CCT 2
 CBA 3
 ITS 4
 Other 9

(IF OTHER, REJECT - STOP)

6. Age:
 65 years and over only 1
 Under 65 and over 65 2
 Adults under 65 only 3
 Not adult (e.g. teenager) 4
 Other (specify: _____).... 9

(IF OTHER OR NOT ADULT, REJECT - STOP)

7. If under 65 and over 65:
 Are the results split out by these age groups?
 Yes 1
 No 2

8. Country of subjects:
 USA 1
 Other 9

9. Was smoking cessation assessed by:
 Patient report..... 1
 Biochemical confirmation
 (e.g. thiocyanate,
 cotinine, nicotine,
 carboxyhemoglobin
 levels) 2
 3rd party 3
 Other (specify: _____) .. 9

10. Number of months after treatment that LAST follow-up occurred:
 Less than one month 0
 One 1
 Two 2
 Three 3
 Four 4
 Five 5
 Six 6
 Seven 7
 Eight 8
 Nine 9
 Ten 10
 Eleven 11
 Twelve 12
 More than 12 (specify:
 _____ months)

Reject Code

EXTRACTION OF STUDY-LEVEL VARIABLES AND RESULTS

We abstracted data from the relevant articles on a specialized form (see Figure 3). The form contains questions about the study design; the number and characteristics of the patients; the setting, location, and target of the intervention; the intensity of the intervention; the types of outcome measures; the time from intervention until outcome measurement; and the results. We selected the variables for abstraction with input from the project's technical experts. A physician and a psychologist, working independently, extracted data in duplicate and resolved disagreements by consensus. A senior physician resolved any disagreements not resolved by consensus.

To evaluate the quality of the study, we collected information on the study design (with the hierarchy of internal validity being RCT, CCT, CBA, and ITS), withdrawal/dropout rate, and agreement between the unit of randomization and the unit of analysis. We did not use blinding and concealment of allocation,³⁷ because those techniques were not feasible in many studies of smoking cessation interventions. The primary outcome consisted of the proportion of clients who quit smoking in the control and intervention groups. Many studies confirmed quit rates biochemically by measuring breath carbon monoxide, saliva cotinine, or serum thiocyanate. If confirmed numbers were unavailable, we extracted self-report data.

**Figure 3. Abstraction Form
Smoking - HCFA-Healthy Aging - Evidence Report #2**

1.	Article ID: _____	ID 1-5
2.	Study number within ID: _____	SUBID 6-7
	Describe: _____	CARD 01
3.	First Author: _____	10-17
4.	Reviewer: _____	
5.	Date of publication: 19____	18-19

6.	Are any vulnerable populations specifically included?			
		Yes	No	
	Persons 85 and older.....	1	2	20
	African-Americans.....	1	2	21
	Hispanic.....	1	2	22
	Other minority populations.....	1	2	23
	Low-income populations.....	1	2	24
	Nursing home.....	1	2	25
	Pregnant women.....	1	2	26
	Other (specify:_____)	1	2	27
7.	Target of the intervention:			
		Yes	No	
	Patients.....	1	2	28
	Providers.....	1	2	29
	Organizations.....	1	2	30
	Community			
	other geographic area.....	1	2	31
8.	If PROVIDER is targeted, what best characterizes the provider type?			
		Yes	No	
	Physicians.....	1	2	32
	Nurses.....	1	2	33
	Dentist.....	1	2	34
	Pharmacist.....	1	2	35
	Psychologist.....	1	2	36
	Counselor.....	1	2	37
	Social Worker.....	1	2	38
	Other (specify:_____)	1	2	39
	Provider is not target.....	1		40

9.	What is the setting of the intervention?			
	Academic setting.....	1		
	Non-academic setting.....	2		
	Both academic and			
	Non-academic setting.....	3		
	Not sure.....	4		
10.	What is the geographic setting of the intervention?			
	Mainly rural.....	1		
	Mainly urban/suburban.....	2		
	Mixed rural/urban/suburban.....	3		
	Not sure.....	4		
11.	In what health-care practice settings did the intervention occur?			
	Hospital.....	1		
	Outpatient, clinic/program.....	2		
	Outpatient, w/primary-care physician.....	3		
	Outpatient, not P-C physician.....	4		
	Outpatient, other (specify _____).....	5		
	Both hospital and outpatient.....	6		
	Nursing home.....	7		
	Not applicable.....	9		
12.	What best describes the reimbursement system of the care in which the intervention occurred?			
	Fee-for-service.....	1		
	HMO.....	2		
	Managed care, not HMO.....	3		
	Mixed reimbursement			
	systems.....	4		
	Other (specify:_____)	5		
	Not applicable.....	9		
13.	Comorbid conditions/other cessation-affecting factors:			
		Included	Excluded	Neither
	High nicotine dependence.....	1	2	3
	Proximity to other smokers.....	1	2	3
	High stress level.....	1	2	3
	Concern about weight gain.....	1	2	3
	Psychiatric comorbidity.....	1	2	3
	Other (specify:_____)	1	2	3

Figure 3: Abstraction Form (continued)
Smoking - HCFA-Healthy Aging Evidence Report #2

14. What was the unit of allocation?	51	17. Was there a sample-size justification or power calculation?	54
Patient	1	Yes	1
Provider	2	No	2
Organization	3	18. What outcomes were measured?	55
Community or		Proportions/percents	1
geographic area	4	Other	2 (If Other, give to Erin)
Not applicable	9	19. When were the outcomes last measured relative to after the start	
15. What was the unit of analysis?	52	of the intervention?	56-58
Patient	1	_____ weeks	
Provider	2	20. Were costs analyzed?	59
Organization	3	Yes	1 (If Yes, give to Erin)
Community or		No	2
geographic area	4	21. Is this a crossover study?	60
Not applicable	9	Yes	1
16. If the unit of allocation and the unit of analysis are not the same,		No	2
was any statistical correction made for clustering?	53		
Yes	1		
No	2		
Not applicable	9		

Figure 3: Abstraction Form (continued)
Smoking - HCFA-Healthy Aging Evidence Report #2

GROUP 1 / 2 / 3 / 4 / 5 (Complete this page for each intervention arm)

Description of group (optional): _____

23. What best characterizes the intervention for this group?

Description of Intervention	X	Intensity	Duration	# Times	Medium	Content
01 Control/Usual Care/No intervention						
02 Education without detailing/outreach						
A Patient						
B Provider						
03 Detailing						
04 Provider feedback						
05 Financial/administrative intervention						
A Patient						
B Provider						
C Organization						
06 Reminders						
A Patient						
B Provider						
07 Group therapy/counseling						
A Leader trained						
B Leader not trained						
08 Individual counseling						
09 Mass media/community intervention						
10 Regulatory						
A Patient						
B Provider						
C Organization						
11 Medications		Dose (mg)	Duration days	Times/Day		
A Nicotine Replacement						
1 Gum						
2 Patch						
3 Nasal spray						
B Clonidine						
C Antidepressants						
D Anxiolytics						
E Mecamylamine						
F Other drug ()						
12 Self-help						
13 Organizational (process) change						

ID 1-5
SUBID 6-7
CARD 02

24. Does the intervention include any of the following?

	Yes	No	
Social influence.....	1.....2		10
Marketing/Outreach.....	1.....2		11
High visual appeal/clarity.....	1.....2		12
Collaboration, teamwork.....	1.....2		13
Design based on needs, barriers, incentives, assessments, or theory.....	1.....2		14
Top management support.....	1.....2		15
Active learning strategies.....	1.....2		16

25. How many patients were...

Enrolled _____, _____ 17-22

Followed _____, _____ 23-28

Figure 3: Abstraction Form (continued)
Smoking - HCFA-Healthy Aging Evidence Report #2

Describe the outcomes:

SMOKING CESSATION

Group	Percent not smoking before intervention	Percent not smoking after intervention	Sign (<=>)	p-value	Comparison group
1	_____ . ____	_____ . ____	___	___ . _____	___
			___	___ . _____	___
2	_____ . ____	_____ . ____	___	___ . _____	___
			___	___ . _____	___
3	_____ . ____	_____ . ____	___	___ . _____	___
			___	___ . _____	___
4	_____ . ____	_____ . ____	___	___ . _____	___
			___	___ . _____	___
5	_____ . ____	_____ . ____	___	___ . _____	___
			___	___ . _____	___

ID 1-5
SUBID 6-7
CARD 07

10-24

25-31

32-46

47-53

54-68

69-75

76-90

91-97

98-112

113-119

Figure 3: Abstraction Form (continued)
Smoking - HCFA-Healthy Aging Evidence Report #2

ADDITIONAL INSTRUCTIONS

Intensity: Length of time in minutes for each unit of intervention, e.g. 60 minute educational session, 1 minute TV spot, 5 minute counseling session.

Duration: Length of time in days from start of intervention to end of intervention. E.g. TV spots ran for 15 days, educational session occurred only once (1 day), nicotine replacement therapy given for 4 weeks (28 days).

Number of units of intervention: Number of times the intervention occurred for each target. E.g. 1 counseling session each week for 5 weeks for each patient (5 units), 2 reminders sent to each patient (2 units), 1 brochure given to each patient (1 unit).

Medium/Delivery vehicle of intervention. Write down number(s) from list below (3 numbers max):

1. In person
2. By telephone
3. In group
4. Radio
5. Broadcast TV
6. Billboard
7. Electronic
8. Video
9. Internet (web site)
10. Poster
11. Mail
12. Other
13. Printed material (e.g. newsprint, brochure, computer printout)
14. Other Visual Display

Content: Was there mention that the content was tailored to the audience (e.g. ethnically sensitive billboard)? Write **Y** for Yes and **N** for No.

EXPERT PANEL REVIEW OF EVIDENCE REPORT

We presented the draft evidence report to a panel of experts (Table 3) for feedback and discussion on October 21, 1999. During this meeting, we reviewed our methods and preliminary results. We also presented draft models for smoking cessation demonstration projects in fee-for-service and managed-care settings. Feedback from the expert panel was useful in fine-tuning both our analysis and our proposed intervention demonstration projects.

Table 3. Expert Panel

Susan Curry, Ph.D.

Associate Director
Center for Health Studies
Group Health Cooperative of Puget Sound

Michael Fiore, M.D., M.P.H.

Professor of Medicine
Director, Center for Tobacco Research and Intervention
University of Wisconsin

Expert Panel Chair

Jessie Gruman, Ph.D.

Executive Director
Center for the Advancement of Health

Jack Henningfield, Ph.D.

Vice President for Research and Health Policy
Pinney Associates

Jack Hollis, Ph.D.

Program Director
Epidemiology and Disease Prevention
Kaiser Permanente Center for Health Research

Richard Hurt, M.D.

Director
Nicotine Dependence Center
Mayo Clinic

Corrine Husten, M.D., M.P.H.

Medical Officer
Office of Smoking and Health
Center for Disease Control and Prevention

Carlos Roberto Jaen, M.D., Ph.D.

Associate Professor and Director
Center for Urban Research in Primary Care
Department of Family Medicine and Department of
Social and Preventive Medicine
State University of New York at Buffalo

Robert Kaplan, Ph.D.

Professor
Family and Preventive Medicine
University of California, San Diego

Frederick Kviz, Ph.D.

University of Illinois at Chicago
School of Public Health

William Lawrence, M.D., M.S.

Director, Lombardi Cancer Clinical and
Economics Outcomes Core
Georgetown University

Glenn Morgan, Ph.D.

Clinical Psychologist, Tobacco Control Research
National Cancer Institute

Deborah Ossip-Klein, Ph.D.

Director, Smoking Research Program
University of Rochester Cancer Center

Helen Halpin Schauffler, Ph.D.

Associate Professor of Health Policy
University of California, Berkeley
School of Public Health

Maxine Stitzer, Ph.D.

Professor, Department of Psychiatry and
Behavioral Sciences
John Hopkins/Bayview Medical Center
Behavioral Biology Research Center

Victor Strecher, Ph.D.

Professor
Director, Department of Health
Behavior and Health Education
University of Michigan
Comprehensive Cancer Center

Kenneth Warner, Ph.D.

Professor
University of Michigan
Department of Public Health Policy and
Administration, School of Public Health

Disclaimer: Participation as an Expert Panelist does not indicate consensus with the recommendations of this evidence report

STATISTICAL METHODS

Prior to our analysis, we entered all data on outcomes and interventions into the statistical program SAS.³⁸ In the analysis itself, we sought to answer a variety of 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. How useful is provider training?
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 leading the 2000 Public Health Service (PHS) clinical practice guideline on smoking cessation guidelines. However, the focus of this report was to draw inferences for Medicare programs and policies for an insurance benefit. Here we present the PHS analyses where applicable.¹⁸

Our summary of the evidence is both qualitative and quantitative. For many of the specific questions listed above, the evidence was too sparse and/or heterogeneous to support statistical pooling. In these cases, our summary of evidence is qualitative. For those questions that had sufficient information to support statistical pooling, we used meta-regression.

META-REGRESSION ANALYSIS

We first retrieved all studies that assessed the effects of an intervention or interventions relative to either a group that received usual care or a control group. We then fit a series of meta-regressions to these studies.³⁹ The basic data matrix for the meta-regressions was as follows. Each study with a single intervention arm contributed four observations corresponding to the cells of a two-by-two table of treatment by outcome (control and intervention cases that received the preventive or screening service; control and intervention cases that did not) to a weighted logistic regression that predicted cessation of smoking or no cessation. An observation's weight was equal to the number of individuals belonging to the corresponding cell. Studies that had more than one intervention contributed an additional pair of observations (those who did not and those who did receive the service in the intervention group, respectively) for each additional intervention. For example, a study that had three intervention arms contributed eight

observations to the meta-regression: two for the control group, two for the first intervention, two for the second intervention, and two for the third intervention.

To assess the statistical significance of each type of intervention, or of the interaction between treatment and a particular covariate of interest—for example, whether intervening worked better for particular subpopulations—we constructed specific models that contained both an intervention component indicator or specific covariate-by-treatment interaction indicator and indicator variables for each study. The inclusion of study indicators controlled for all measured study characteristics and all unmeasured ones and is akin to fitting a fixed-effects model. Each model produced odds ratios versus control or usual care for covariate-by-treatment interactions that are adjusted for all measured and unmeasured study-level differences.

COST EFFECTIVENESS

To assess the cost-effectiveness of the interventions, we first determined whether the studies included cost data. We chose to summarize these studies qualitatively because of heterogeneity.

