

Tobacco Cessation research in the Real World

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Overview

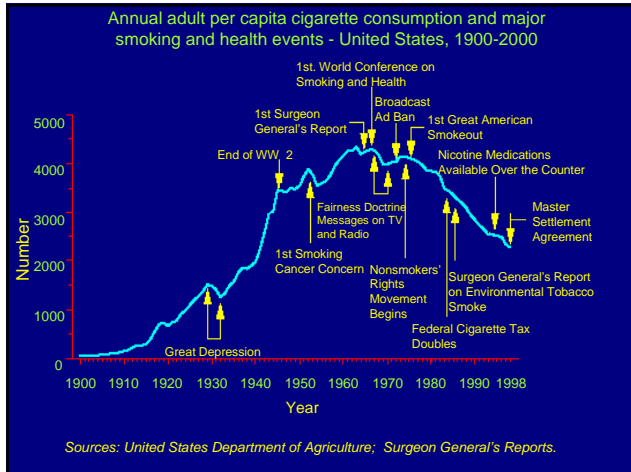
- Burden
- Chronic, relapsing condition
- Opportunities
- What do health care providers do?
- Does it make a difference?
- Where can we make a difference?
- Dissemination
- Future directions

Burden: Tobacco-related impacts and costs

- 45 M (>20%) of US adults smoke
- > 400,000 premature deaths per annum (US)
- Smoking-attributable health care expenditures are estimated at \$96 billion per year in direct medical expenses and \$97 billion in lost productivity
- If all smokers covered by state Medicaid programs quit, the annual savings to Medicaid would be \$9.7 billion after 5 years

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Mokdad et al., JAMA, 2004

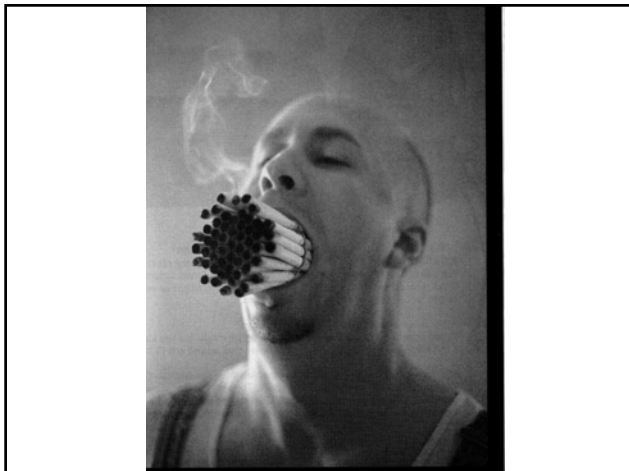


The burden of illness from tobacco use

How do we know that an agent (such as tobacco) can cause disease?

- Temporal relationship
- Reversibility
- Strength of association
- Consistency of effect
- Biological plausibility
- Biological gradient
- Specificity
- Coherence of evidence
- Experimental evidence
- Reasoning by analogy

All criteria have been met for tobacco:lung cancer relationship
Hall, 1965



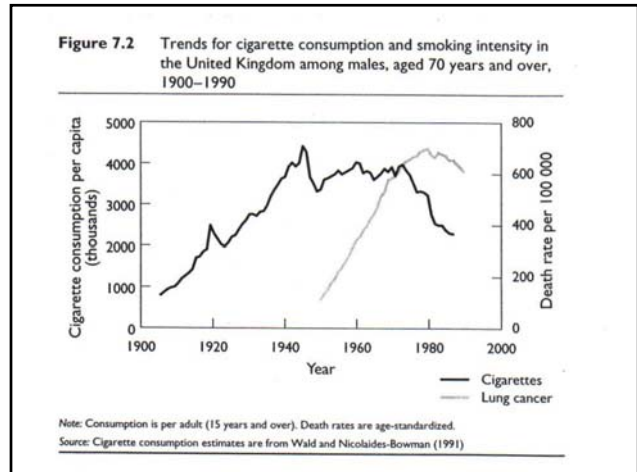
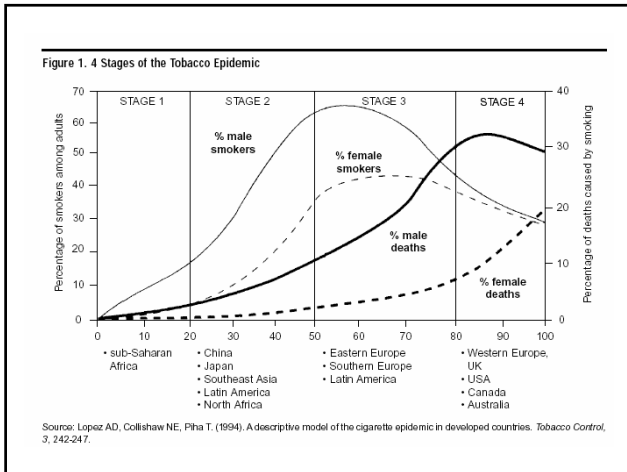
The tobacco epidemic can be characterized as going through four stages:

Stage 1: Men's smoking starts to grow rapidly but very few women smoke. There is very little tobacco caused disease because men have not been smoking long enough for this to occur

Stage 2: An increasing proportion of women smoking begin smoking; male smoking remains high and male tobacco deaths are high. There is very little female tobacco mortality.

Stage 3: Male smoking starts to fall, but male tobacco mortality continues to rise, reflecting previous years' smoking. Female smoking plateaus and there are obvious signs of a rise in female mortality from tobacco use.

Stage 4: Male smoking continues to fall, and male mortality also starts to fall. Female and male smoking rates are about the same, but female mortality continues to rise.



Chronic, relapsing condition

- Only a minority of tobacco users achieve permanent abstinence in an initial quit attempt.
- The majority of users persist in tobacco use for many years and typically cycle through multiple periods of remission and relapse.

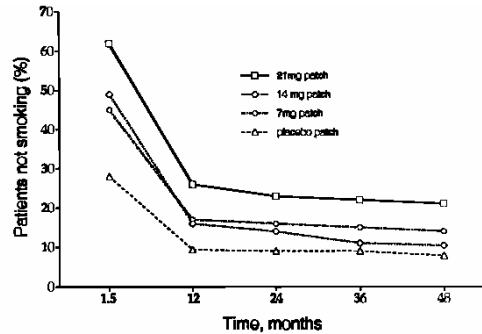
Chronic, relapsing condition: Acute illness model of treatment

- Posits that, like an infection, a course of treatment of some length will be sufficient to "cure" smoking
- Treatment is usually (and quite arbitrarily) 8-12 weeks in duration
- Effects are gauged (somewhat arbitrarily) by outcomes post-treatment at 6 and 12 months

Chronic, relapsing condition:
Acute illness model of treatment

- Does not take into account clinical reality that relapse is the (by far) most probable outcome, even with the most successful treatments currently available
- Does not recognize that forces driving relapse, whether biological, psychological or both, continue to exert their influence well beyond the period of active treatment

Long-term quit rates in patch-treated smokers



Daughton et al., *Prev Med*, 1999

Chronic, relapsing condition:
Acute illness model of treatment

- Implies that there is one treatment that will be effective for virtually all smokers
- Implies that success should be defined only on the basis of permanent abstinence.
- Failure to appreciate the chronic nature of tobacco dependence may undercut clinicians' motivation to treat tobacco use consistently

Chronic, relapsing condition:
Acute illness model of treatment

- A chronic disease model recognizes the long-term nature of the disorder with an expectation that patients may have periods of relapse and remission.
- If tobacco dependence is recognized as a chronic condition, clinicians will better understand the relapsing nature of the ailment and the requirement for ongoing, rather than just acute, care.

Chronic, relapsing condition:
Acute illness model of treatment

- A chronic disease model emphasizes for clinicians the importance of counseling and advice (e.g., counseling OK for diabetes, hypertension or hyperlipidemia, - why not tobacco?)
- Clinicians should be aware that relapse is likely, and that it reflects the chronic nature of dependence, not their personal failure, nor a failure of their patients.

Chronic, relapsing condition:
Acute illness model of treatment

- 70% of smokers say they want to quit
- 44% try to quit each year
- 81% try to quit at least once
- Most quit attempts are unaided
- 4-7% remain quit after one year

Opportunities

- 70% of smokers say they want to quit
- >70% of smokers visit health care settings every year (but only a minority of them leave that clinic visit with evidence-based treatments to help them quit)
- We have more effective tools at our disposal than ever before

Opportunities: Ten Key Guideline Recommendations

1. Tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit. However, effective treatments exist that can significantly increase rates of long-term abstinence.
2. It is essential that clinicians and healthcare delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a healthcare setting.

Opportunities: Ten Key Guideline Recommendations

3. Tobacco dependence treatments are effective across a broad range of populations. Clinicians should encourage every patient willing to make a quit attempt to use the counseling treatments and medications recommended in this Guideline.

Opportunities: Ten Key Guideline Recommendations

4. Brief tobacco dependence treatment is effective. Clinicians should offer every patient who uses tobacco, at least the brief treatments shown to be effective in the Guideline.
5. Individual, group and telephone counseling are effective, and their effectiveness increases with treatment intensity. Two components of counseling are especially effective and clinicians should use these when counseling patients making a quit attempt
 - Practical counseling (problem-solving/skills training)
 - Social support delivered as part of treatment

Opportunities: Ten Key Guideline Recommendations

6. There are numerous effective medications for tobacco dependence and clinicians should encourage their use by all patients attempting to quit smoking, except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers and adolescents).
 - Seven first-line medications (5 nicotine and 2 non-nicotine) reliably increase long-term smoking abstinence rates:
 - Bupropion SR
 - Nicotine gum
 - Nicotine inhaler
 - Nicotine lozenge
 - Nicotine nasal spray
 - Nicotine patch
 - Varenicline
 - Clinicians should also consider the use of certain combinations of medications identified as effective in this Guideline.

Opportunities: Ten Key Guideline Recommendations

7. Counseling and medication are effective when used by themselves for treating tobacco dependence. However, the combination of counseling and medication is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.
8. Telephone quitline counseling is effective with diverse populations and has broad reach. Therefore, clinicians and healthcare delivery systems should both ensure patient access to quitlines and promote quitline use.

Opportunities: Ten Key Guideline Recommendations

9. If a tobacco user is currently unwilling to make a quit attempt, clinicians should use the motivational treatments shown in this Guideline to be effective in increasing future quit attempts.
10. Tobacco dependence treatments are both clinically effective and highly cost-effective relative to interventions for other clinical disorders. Providing coverage for these treatments increases quit rates. Insurers and purchasers should ensure that all insurance plans include the counseling and medication identified as effective in this Guideline as covered benefits.

What do health care providers do?

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Goldstein et al., 1998, Prev Med

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What do health care providers do?

Among a population-based sample of smokers (n=3,037) who had seen a physician during the previous year:

- 51% reported that they were “talked to” about their smoking
- 45.5% were advised to quit
- 14.9% were offered specific assistance
- 3% had a follow-up appointment arranged.

Goldstein et al., 2003, Prev Med

What do health care providers do?

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Thorndike et al., 2007, AJPH

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Does it make a difference?

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Russell et al., 1987, BMJ

Does it make a difference?

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Russell et al., 1988, BMJ

Questions:

Can the PHS guidelines be disseminated in real world settings and, if so, are they effective at helping patients quit smoking?

Can we improve upon the guidelines by adding more intensive counseling?

**An Academic Detailing
Intervention to Disseminate
Physician-Delivered Smoking
Cessation Advice and Counseling:
Smoking Cessation Outcomes of
the Physicians Counseling
Smokers (PCS) Project**

Michael G. Goldstein, M.D., Raymond Niaura, Ph.D., Cynthia Willey, Ph.D., Alessandra Kazura, M.D., William Rakowski, Ph.D., Judith DePue, Ph.D., Elyse Park, Ph.D.
Brown Medical School

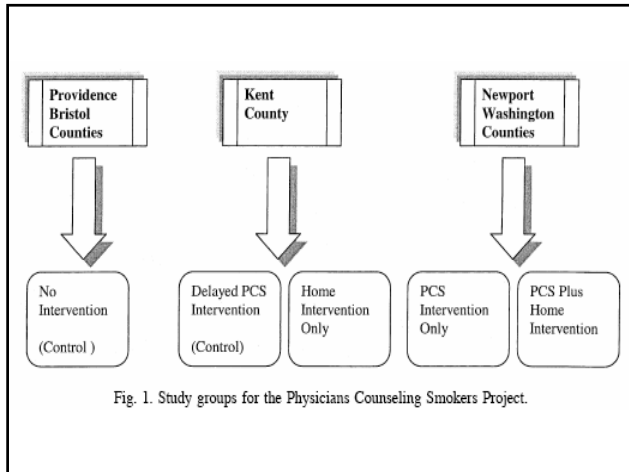
Pr:Goldstein et al., 2003, Prev Med 185-196

•Specific aim: to test the efficacy of a multi-component office-based intervention to increase primary care physicians' adoption, implementation and maintenance of the NCI "4As" smoking cessation strategy.

•Primary outcome of the PCS trial: smoking cessation rates within a population-based sample of Rhode Island smokers.

METHODS

- Test the effectiveness of a physician office-based smoking cessation intervention.
- Community-based samples of both physicians and patients.
- Quasi-experimental design with a delayed intervention arm (at 24 months after baseline assessment) within Rhode Island counties.



Physician Recruitment and Sampling

- Recruit at least eighty percent of eligible primary care physicians within three intervention counties.
- Control group physicians randomly selected from remaining counties matched on gender, specialty, years since graduation.
- Primary care specialty (i.e., family medicine, internal medicine, ob/gyn), primary care \geq 25% patients, post-graduate training, practice state during the study.
- Two-hundred fifty-nine (81%) of eligible physicians were successfully recruited into the study.

Physicians Counseling Smokers Intervention

- Delivered over a one-year period.
- Utilized an "academic detailing" approach based on the NCI "4As." All physicians given NCI manual, How to Help Your Patients Stop Smoking.
- Four to five physician-centered office visits to medical offices to encourage physician adoption of the NCI "4As" approach.

Office procedures to support physician interventions:

- Selecting an office smoking cessation coordinator
- Using a smoker identifier on charts of all smokers
- Maintaining self-help materials
- Creating a smoke free office and assisting with follow-up.
- Patient education resources, materials to identify and track smokers in their practice
- Referral information re. local smoking cessation programs.
- Pocket cards, desk prompts and posters

Smoker Recruitment and Sampling

- Non-institutionalized Rhode Island residents between the ages of 18 and 75 years who lived in a household with a telephone were eligible for the initial random digit dial telephone survey.

- The same number of cigarette smokers in each of three designated geographic areas within the state of Rhode Island

- Smokers could only “benefit” from the physician intervention if they visited a participating physician during the intervention period.

Table 3
Patient report of physician counseling behavior by physician study assignment

Physician study assignment of physician visited during prior 6 months	Assessment								
	12 months			18 months			24 months		
	Talk	Advise	Follow-up	Talk	Advise	Follow-up	Talk	Advise	Follow-up
Physician who was not participating in the study	43.3	45.3	12.4	44.9	47.3	18.7	44.8	44.4	8.1
Control group physician	54.7	56.7	17.8	54.0	55.9	26.8	52.0	52.2	8.9
Experimental group physician	54.2	54.0	17.2	61.2	60.9	35.3	53.2	52.8	10.1
χ^2 , P values	17.6, 0.00	15.6, 0.00	7.5, 0.02	18.4, 0.00	13.8, 0.00	25.0, 0.00	7.1, 0.03	7.9, 0.02	0.69, 0.70

Table 4

Smoking cessation rates at 6, 12, 18, and 24 months by intervention group among patients reporting a visit with an intervention or control group physician during the intervention period, Physicians Counseling Smokers Study

	Percentage quit by intervention group			
	Control/ delay	Physician only	Physician + home intervention	Home intervention
Baseline (n = 962)	0	0	0	0
6 months (n = 932)	7.1	8.4	8.9	7.6
12 months (n = 903)	16.4	17.0	16.9	16.5
18 months (n = 834)	20.0	25.2	19.2	24.8
24 months (n = 820)	22.6	33.3	25.7	26.3

Logistic Regression Predictors of Quit at 24 Months Among Smokers who Reported a Visit with a PCS Physician at 12, 18 or 24 Month Follow-up

INDEPENDENT VARIABLES	OR	p	95% CI
Physician Intervention Counties vs. Control Counties	1.80	.008	1.16–2.75
Received Home Intervention vs. Control Counties	1.26	.313	0.80–1.98
Received Home Intervention and Resided in Physician Intervention Counties vs. Control Counties	1.28	.300	0.80–2.06
Stage of Change at Baseline (Preparation vs. Precontemplation or Contemplation)	2.75	.000	1.89–3.98
Perceived Health at Baseline (Fair/Poor vs. Good, VG, or Excellent)	0.72	.200	0.45–1.19
Gender (F vs. M)	0.94	.740	0.58–1.54
Age (continuous)	1.01	.065	0.99–1.02
Education (highest grade completed)	1.04	.329	0.96–1.13

Conclusions

- Smokers who resided in geographic areas where the experimental PCS office-based academic detailing intervention was delivered were more likely to report that they had quit smoking at 24 months if they had seen an intervention physician than smokers who resided in control areas where there was no PCS office-based intervention.

- PCS intervention enhanced smoking cessation rates by enhancing physicians' adoption of smoking cessation interventions.

Where can we make a difference? : Pockets of prevalence

PHS 2008 Guidelines emphasize the importance of providing interventions to smokers who are at high risk:

e.g., Low SES
Substance Abuse
HIV+
Co-occurring Psychiatric Conditions

Tobacco cessation among low-SES smokers: Motivational enhancement and nicotine patch treatment

Beth C. Bock, Ph.D., George D. Papandonatos Ph.D., Marcel A. de Dios, Ph.D., Michael G. Goldstein, M.D., David B. Abrams, Ph.D., Munawar M. Azam, M.D., Mark Fagan, M.D., Patrick J. Sweeney, M.D., Ph.D., & Raymond Niaura Ph.D.

In press, JCCP

Does intensity of behavioral therapy added to PHS-recommended treatment, including NRT, improve quit rates in an outpatient medical setting?

Current Study:

Adult smokers (n=846) were recruited during routine health care visits at three hospital-based primary care clinics located in separate inner-city hospitals in southern New England.

Inclusion criteria: ≥ 18 years of age; current, regular smoker; speak English or Spanish; be uninsured or Medicaid recipient, and be available for follow-up contact (in-person or by phone).

Exclusion criteria: unstable medical condition which precluded use of the nicotine patch (e.g., unstable angina, uncontrolled hypertension); active skin condition (e.g., psoriasis) or history of skin allergy; currently using smokeless tobacco, NRT or other smoking cessation treatment; pregnant or nursing.

Smokers were identified at patient registration. Recruitment procedures emphasized that patients did not have to quit smoking, or even be interested in quitting smoking, to participate.

After baseline assessment, participants were randomly assigned to: a Standard-of-Care (SC) intervention or a motivation enhanced intervention (ME).

The SC intervention provided smoking cessation assistance following the PHS guidelines (Fiore et al., 2000).

One-hour training sessions for all attending and resident physicians, fellows and interns:

Introduction to the study, its purpose and procedures, educational materials concerning smoking cessation treatment guidelines ("Clinician's Guide") and training in applying the "5 A's" (Ask, Assess, Advise, Assist, Arrange follow-up).

SC condition: subjects were Asked (by their MD) their smoking status, Assessed for nicotine dependence, Advised to quit smoking, and offered Assistance with quitting (NRT, self-help pamphlets and/or program referral) to smokers interested in quitting.

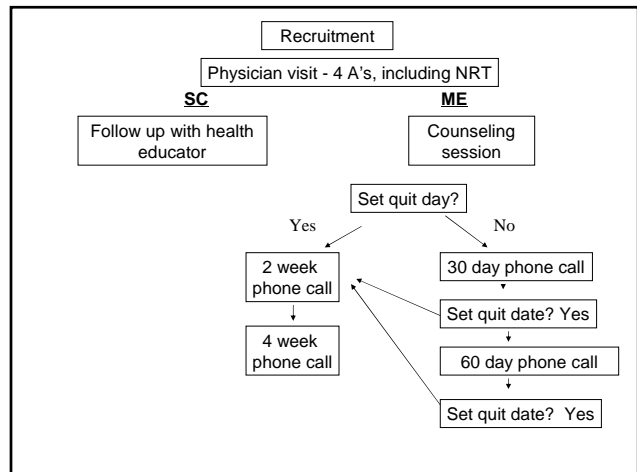
The fifth "A", Arrange follow-up, was handled by the study Health Educator.

ME condition: all components of the SC intervention, plus a 45-minute individual counseling session with a smoking cessation specialist fluent in both English and Spanish.

Counseling included motivational interviewing techniques, and for those ready to quit, included behavioral skills training.

Those who decided to quit: two follow-up telephone counseling calls; one on quit day and another two weeks later.

Those choosing not to quit were telephoned two and four weeks later for follow-up counseling.



Participants interested in quitting were provided with a self-help manual (“Freedom from Smoking”), a list of smoking cessation groups and programs in the local area (“Resource Guide”), and were offered the nicotine patch (8 weeks, tapered dosing) free of charge.

Participants received follow-up assessments at 1, 3, 6 and 12 months following baseline.

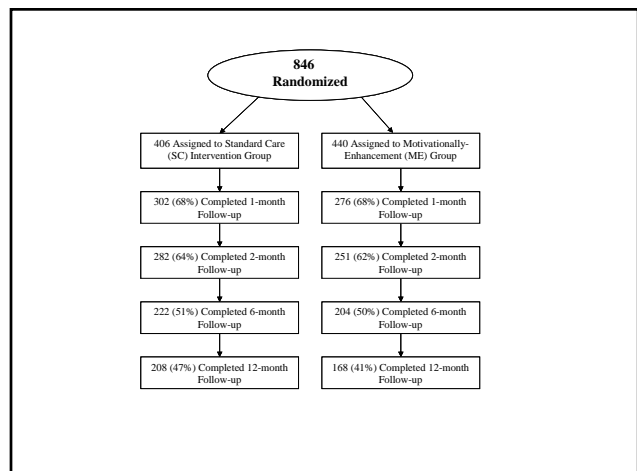


Table 2. Abstinence and Drop-Out Rates by Study Visit

Study Group	Last Visit Attended	Abstinence Rate (%)				Dropout	
		1 month	2 months	6 months	12 months	N	%
ME (N=406)	Baseline					66	16.3
	1-month	37				38	9.4
	2-month	35	32			60	14.8
	6-month	42	37	24		74	18.2
	12-month	38	45	33	29	<i>168</i>	<i>41.4</i>
SC (N=440)	Baseline					71	16.1
	1-month	40				30	6.8
	2-month	38	33			68	15.5
	6-month	37	37	20		63	14.3
	12-month	39	40	30	28	<i>208</i>	<i>47.3</i>

N.B. Figures in italics indicate study completers (N, %) by treatment arm.

Table 4. Logistic Regression Model for 7-Day Point Prevalence Abstinence, Adjusted for Covariates and Corrected for Selection Bias Due to Peri-Randomization Attrition

Model Terms	PE	LCL	UCL	p-value
<i>Odds for referent group:</i>				
1 month	0.28	0.12	0.65	0.003
2 months	0.13	0.05	0.31	<0.001
6 months	0.07	0.03	0.15	<0.001
12 months	0.07	0.03	0.17	<0.001
Less Acculturated Latino/Hispanic	1.99	0.95	4.20	0.070
Highly Acculturated Latino/Hispanic	2.01	0.80	5.06	0.139
Patch Use (weeks): 1m	1.70	1.29	2.24	<0.001
Patch Use (weeks): 2m	1.58	1.33	1.89	<0.001
Patch Use (weeks): 6m	1.19	1.01	1.39	0.042
Patch Use (weeks):12 m	1.14	0.95	1.36	0.180
Number of Telephone Contacts	1.26	0.96	1.66	0.087
Positive Decisional Balance	1.19	1.01	1.39	0.036
Perceived Stress Scale > 8	0.72	0.52	0.99	0.045
Temptation to Smoke (Positive Affect/Habit)	0.83	0.71	0.97	0.021
Temptation to Smoke (Negative Affect)	0.47	0.40	0.55	<0.001
ME Group	0.97	0.36	2.64	0.952
Early Dropout Hazard	0.72	0.37	1.40	0.322
Early Dropout Hazard : ME Group	0.68	0.31	1.48	0.327

Notes: PE = Point Estimate;
LCL = 95% Lower Confidence Limit;
UCL = 95% Upper Confidence Limit

Lessons Learned

PHS-guided intervention works (NRT)

More is not necessarily better (depending on target population)

Interventions (free) are enthusiastically received

Institutional support is needed to maintain interventions

Motivation and Patch Treatment for HIV+ Smokers:
A Randomized Controlled Trial

Elizabeth E. Lloyd-Richardson PhD, Cassandra A. Stanton PhD,
George D. Papandonatos PhD, William G. Shadel PhD, Michael
Stein MD, Karen Tashima MD, Timothy Flanigan MD, Kathleen
Morrow PhD, Charles Neighbors PhD, & Raymond Niaura PhD

In press, Addiction

Rationale

- Smoking prevalence among HIV-positive populations is high, with estimates of 47%-70%;
- Smoking creates a well-known risk for conditions such as cancer, stroke, heart disease, and chronic obstructive pulmonary disease.
- Evidence suggests that smoking poses additional threat to individuals living with HIV/AIDS, including increased risk of developing AIDS-related infections, as well as non-AIDS-related illnesses, cancers, and cardiovascular disease.

- And while findings are inconsistent regarding the relationship between smoking and the course of HIV/AIDS, recent research suggests treatment with highly active antiretroviral therapy (HAART) is less effective for smokers, and that smokers are less likely to adhere to HAART than nonsmokers.
- Some evidence to suggest that smoking is related to increased risk of seroconversion.

- **Population:** HIV+ individuals referred by study physicians for participation in a randomized controlled smoking cessation trial specifically designed for HIV-positive individuals.
- **Sites:** Six outpatient HIV clinics and two primary care medical offices in Southeastern New England.

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- **Inclusion criteria**, as assessed by their physician:
 - (1) 18 years or older;
 - (2) HIV seropositive;
 - (3) not pregnant;
 - (4) no uncontrolled hypertension or skin condition;
 - (5) currently smoking ≥ 5 CPD;
 - (6) willing to speak with a Health Educator and willing to attend up to four intervention sessions

- Patients were compensated for their time and effort.
- Patients were not required to make a quit attempt as a condition of study enrollment.
- All materials and interventions were available in English and Spanish.

- **Measures**
- Sociodemographic Characteristics:
 - age, sex, sexual orientation, marital status, race and ethnicity, language, employment, years of education, and living situation.
 - Participants who self-identified as Hispanic were treated as such, irrespective of race.
 - Remaining participants were classified according to their racial origin, with participants of Asian, Native American or Mixed descent coded as "Other" due to small cell sizes.

- **Measures**
- Smoking Characteristics.
 - Fagerstrom Test for Nicotine Dependence (FTND), a reliable six-item measure of nicotine dependence;
 - daily cigarette consumption (CPD).
 - Motivation to quit smoking via the Contemplation Ladder;
 - Smoking Decisional Balance Scale, used to assess the pros and cons of smoking;
 - Smoking Self-Efficacy Scale, used to assess the degree of temptation to smoke in various situations

- Psychosocial Characteristics.
- Center for Epidemiologic Studies Depression Scale (CES-D) was used to assess depressive symptoms;
- Perceived Stress Scale (PSS) was used to assess participant perceived stress level;
- Multidimensional Quality of Life Questionnaire for HIV/AIDS (MQoL-HIV), a 40-item measure of ten dimensions of quality of life: mental health, physical health, physical functioning, social functioning, social support, cognitive functioning, finances, intimacy, sexual functioning, and medical care.

- **Other Measures:**
- Number of smokers in the household;
- Important People and Activities Instrument (IPA), designed to assess involvement in and support of the social network and activities in the person's smoking and abstinence. Two composite variables were calculated: (a) proportion of social network who smoke and (b) proportion of network who are supportive of quitting.
- Past 30-day alcohol and other substance use was assessed using a 30-day Timeline Follow Back (TLFB)

Intervention

•Patients randomized to receive either a brief, two-session intervention (Standard Care; SC) modeled on PHS guidelines, or a more intensive, four-session motivational counseling intervention (Motivational-Enhancement; ME).

•Participants in both conditions who were willing to set a quit date were also provided 8-weeks of nicotine replacement (patch).

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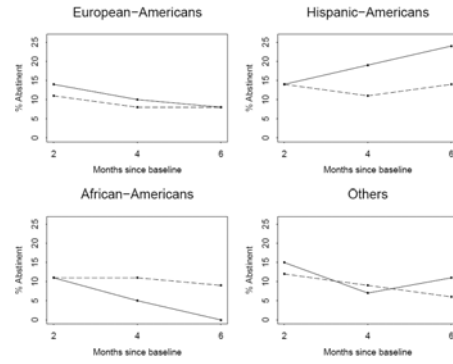
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Results

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Intent-to-Treat (ITT) quit rates over two-month, four-month, and six-month follow-up, by study condition and race/ethnic group.



Note: Standard-Care Treatment = solid line; Motivationally-Enhanced Treatment = broken

Univariate Analysis, 6 Month Outcomes Entire Sample (N=444)

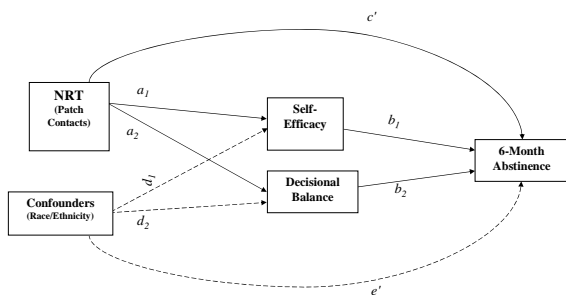
Abstinence	PatchUse	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	Yes	41	12.93	41	12.93
No	Yes	224	70.66	265	83.60
No	No	52	16.40	317	100.00

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- Mediation model
- Dose of NRT intervention:
of NRT-related sessions attended (patch-pick ups)
5.69 ME contacts vs. 5.51 SC contacts
Avg. Minutes per session
31 mins ME vs. 5 minutes SC
- # of NRT contacts significantly predicted the odds of 6-month abstinence.
- Association mediated by self-efficacy and decisional balance?

Multiple Mediation Model



- Abstinence improved significantly with increases in self-efficacy and decisional balance. Association of NRT contacts and abstinence no longer significant (Baron & Kenny, 1986).
- Longer periods of patch compliance may reduce withdrawal and craving symptoms that, in turn, impact the individual's sense of self-efficacy to resist temptations.
- Success experiences (supported by increased time on the patch) contribute to a sense of confidence that translates to behavior change.

- Cost-effectiveness analyses with a subsample of these data (Shepard et al., 2002) indicated the ME condition incurred twice the personnel costs per client compared to SC, \$265 vs. \$130, respectively.
- Even when dose of intervention is accounted for, there was no added benefit to the considerably more time-intensive and expensive ME condition to abstinence.

Conclusions

- 73% of participants set a quit date; 68% used the patch.
- Intent-to-Treat biochemically-verified seven-day point prevalence quit rates were:

	2-Months	4-Months	6-Months
ME	12%	9%,	9%
SC	13%,	10%	10%

- There were no between-group differences.

Conclusions

- Failure to use NRT during the study predicted smoking at six-month follow-up ($p < .05$).
- Significant differences occurred in quit rates by race ($p < .01$).
- There were zero African-American participants in SC who remained quit at 6-Months follow-up.
- Two psychological variables - self-efficacy and decisional balance –mediated the relationship between NRT and 6-month abstinence.

- In sum, brief and frequent contacts focused on NRT were more effective at yielding improved cessation outcomes than a time-intensive motivational counseling approach.
- Culturally-sensitive interventions that target key psychological measures and increase access and compliance with NRT are needed to support smoking cessation efforts among people living with HIV/AIDS.

**Randomized Smoking Cessation Intervention Trials
Among the Methadone-Maintained**

QuickTime™ and a
decompressor
are needed to see this picture.

Addiction, 2006

**Smoking Behaviors Among Methadone-Maintained
Patients**

Over 225,000 persons are enrolled in methadone programs at any given time in the United States of the estimated 900,000 opioid abusers (Mark, 2001). Methadone maintenance treatment program (MMTP) patients have better retention rates than clients in other treatment modalities (National Consensus, 1998). Patients are seen on a daily basis by methadone dispensing staff, and on a less frequent but regular basis by counseling staff, thus providing ample opportunity for recruitment into clinical trials.

**Randomized Smoking Cessation Intervention Trial Among
the Methadone-Maintained**

AIM: To test, in combination with the nicotine patch, the incremental efficacy of a maximal, tailored behavioral treatment over a minimal treatment for smoking cessation.

DESIGN: Randomized clinical trial with 6-month follow-up.

**Randomized Smoking Cessation Intervention Trials
Among the Methadone-Maintained**

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**Randomized Smoking Cessation Intervention Trials
Among the Methadone-Maintained**

PARTICIPANTS: Three hundred and eighty-three methadone-maintained smokers.

**Randomized Smoking Cessation Intervention Trials
Among the Methadone-Maintained**

INTERVENTION: Participants were assigned randomly to nicotine patch (8-12 weeks) plus either (1) a baseline tailored brief motivational intervention, a quit date behavioral skills counseling session and a relapse prevention follow-up session (Max) or (2) brief advice: 4 A's model (Min).

MEASUREMENTS: Carbon monoxide (CO)-confirmed 7-day point smoking cessation prevalence at 3 and 6 months, and self-reported numbers of cigarettes smoked per day.

**Randomized Smoking Cessation Intervention Trials
Among the Methadone-Maintained**

FINDINGS: Participants had a mean age of 40 years, were 53% male, 78% Caucasian, smoked 26.7 (+/- 12.2) cigarettes/day.

At 3 months, 317 (83%) were re-interviewed; at 6 months, 312 (82%) were re-interviewed. The intent-to-treat, 7-day point prevalence estimate of cessation was 5.2% in the Max group and 4.7% in the Min group (P=0.81) at 6 months.

Males were more likely to be abstinent at 3 months (OR 4.67; P=0.003) and 6 months (OR 4.01; P=0.015).

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CONCLUSION: A tailored behavioral intervention did not increase quit rates over patch and minimal treatment. Smoking cessation rates in methadone-maintained smokers are low, with men having greater success.

Association of NRT and Outcomes

OUTCOME: Use of NRT and smoking behaviors during the 180-day follow-up period assessed by the Timeline follow-back method.

FINDINGS: On the day following their quit day, 86.4% of participants used NRT. The percentage of participants using NRT was 52.3%, 27.1%, and 10.4% on day 30, day 60, and day 90, respectively. Participants used NRT on 44.1% of the days through the 90 days of the treatment protocol. The estimated odds of smoking abstinence was 7.1 ($P < .001$) times higher on days when NRT was used than on days when NRT was not used, and cigarettes/day was also significantly lower on NRT days (14.93 vs 4.65; $P < .001$).

Association of NRT and Outcomes

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Association of NRT and Outcomes

CONCLUSION: Nicotine replacement therapy use was inconsistent following an initial quit attempt among methadone-maintained smokers. On days when NRT was used, individuals were likely to smoke at reduced levels or not at all.

Reduction in Smoking

Outcome: longest period of self-reported abstinence during follow-up.

Findings: Longer periods of abstinence in persons reporting at least one 24-hr quit attempt in the year prior to baseline (OR = 1.97, $p = .003$), in those anticipating success in cessation (OR = 1.33, $p = .024$), and in those with a greater percentage of nicotine patch use days (OR = 2.78, $p < .001$).

Smoking Behaviors Among Methadone-Maintained Patients

Smoking prevalence rates of 80-90% have been found among patients in methadone treatment (Clarke 2001; Stark, 1993; Richter, 2001, 2002b; Best, 1998). These high rates are due to the prevalence of smoking among opioid abusers, but methadone itself may also cause increases in smoking (Story, 1991).

The mechanism by which opioid use may increase smoking remains in question: the effects of nicotine and opioids may complement each other; nicotine effects may be attenuated by opioids requiring more cigarette use; opioid administration functions as a discriminative stimulus.

Health Risks of Smoking Among Methadone-Maintained Patients

Methadone maintained smokers are at exceptionally high risk for the negative health effects of smoking.

Among opioid users stable in methadone maintenance treatment, tobacco-related deaths have been well documented (Hser, 2001). After controlling for a wide array of health-risk behaviors, tobacco use, even in a sample of long-term narcotic addicts, was clearly one of the two most distinctive lifestyle markers (the other being disability) strongly correlated with subsequent mortality (Hser, 1994). The death rates were four times that of non-smokers (Hser, 1994).

Motivation to Quit Smoking Smoking Among Methadone-Maintained Patients

Surveys of attitudes in a MMTP population have revealed that methadone users are well aware of the health risks of smoking; a majority of persons are “very interested” in on-site quit programs, and 80% express interest in using nicotine replacement products. (Richter, 2002a; Clemmey, 1997; Sees 1993).

Reduction in Smoking

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Reduction in Smoking

Conclusions: Past quit attempts, self-efficacy, and constant nicotine replacement were associated with duration of abstinence among methadone-maintained smokers.

Reduction in Smoking

Other findings: Overall, mean percent days abstinent was 29.8 during the 180 days follow-up.

By 6-months, 81% of participants reported at least one non-smoking day, and the majority of these participants had multiple quits or at least one day.

Seventeen percent of participants reported contiguous periods of abstinence from 1-6 days; 24% reported periods of abstinence of 7-28 days; and 40% had periods of abstinence of 28 days or more.

Reduction in Smoking

When participants returned to smoking, on the day following a non-smoking day, 55% smoked only one or two cigarettes and 75% smoked fewer than ten.

Only 11% of smokers returned to more than 20 cigarettes (that is, close to their baseline level) on the day following a non-smoking day.

On the day following a low-use day (1-5 cigarettes), 70% of smokers did not smoke at all, again suggesting that a smoking slip most often does appear to be a rapid return to baseline levels.

Reduction in Smoking

Lessons learned:

- 1) excellent follow-up rates are possible with this population;
- 2) a high proportion (>80%) of methadone-maintained smokers set quit days;
- 3) >80% of smokers quit for at least one day and nearly 40% had quits lasting longer than one month;

Overall Conclusions

Quit rates are very low among methadone maintained smokers

NRT use is related to increased periods of abstinence and reduction in smoking

Sustained reductions in smoking are associated with eventual cessation

We must explore newer treatment options including longer treatment regimens and combination treatments, e.g., patch plus fast acting "rescue medications" such as gum, lozenge or spray.

The Effectiveness of Covering Smoking Cessation Services for Medicare Beneficiaries

Geoffrey F. Joyce, Raymond Niaura,
Margaret Maglione,
Jennifer Mongoven, Carrie Larson-Rotter,
James Coan,
Pauline Lapin, and Sally Morton

Health Services Research, 2008

Economic Burden

- ◆ Accounted for \$14.2 billion in Medicare expenditures in 1993, almost 10% of Medicare's total budget (Zhang, et al.)
- ◆ Estimated that smoking-related illnesses will cost Medicare \$800 billion over the next 20 years (Califano, 1995)

Demographic Imperative

- ◆ 12% of Medicare population are current smokers
- ◆ Number of smokers will increase with baby boomers entry into Medicare

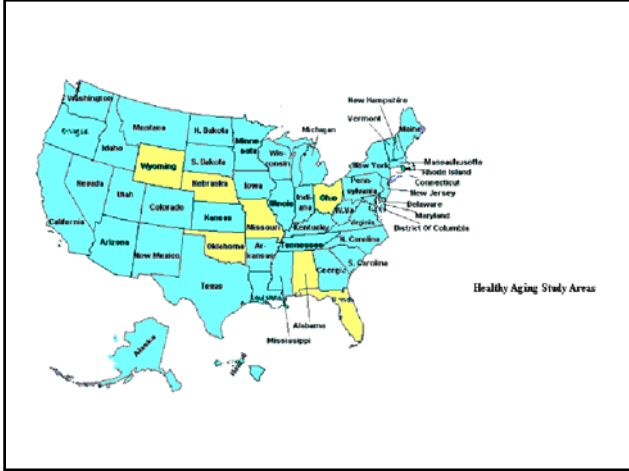
MSSP Goals

To test 4 Medicare smoking cessation benefits for:

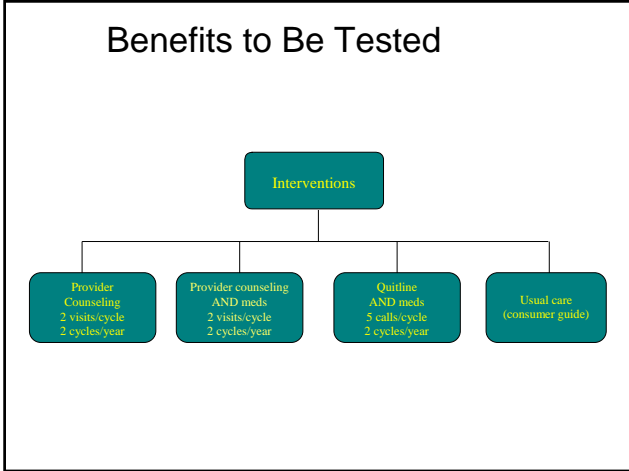
- **Effectiveness**
- **Feasibility**
- **Cost effectiveness**

MSSP Study Design

- ◆ Comparison trial with restricted randomization
- ◆ 7 states (6 study locales)
- ◆ 4 strata in each state; 1 study arm/strata
- ◆ Medicare beneficiaries



- ### State Selection Criteria
- ◆ # of eligible FFS beneficiaries
 - ◆ Smoking Prevalence (≥ 65 yrs)
 - ◆ Absence of pre-existing quit lines
 - ◆ 4 equivalent geographic strata/state
 - ◆ Minimal contiguous borders with other study states
 - ◆ Pooled 7 states: similar to the US



Provider Counseling Benefit

- ◆ Brief counseling, 3-10 minutes
- ◆ 5 A's
- ◆ 2 visits/cycle
- ◆ 2 (12 wk) cycles/year
- ◆ Standard Medicare deductibles and co-payments apply



Provider Counseling and NRT or Bupropion

Provider Counseling and NRT or Bupropion

- Brief counseling
- 2 visits/cycle; 2 cycles/yr
- NRT or bupropion/cycle
- \$5 co-pay on meds



Telephone quitline + NRT

Quitline Benefit

- ◆ Beneficiary calls quitline--menu of options
 - Quit Tips: motivational messages
 - Reactive: live counseling as needed
 - Proactive
- ◆ No Medicare deductible

Quitline Benefit (continued)

- ◆ Proactive:
 - **counselor-initiated calls**
 - **5 calls/cycle; 2 cycles/yr**
 - **NRT with \$5 co-payment**
 - ***Clear Horizons***



Usual Care

Inclusion Criteria

- ◆ Medicare beneficiary with part B
- ◆ ≥ 65 years
- ◆ Current smoker
- ◆ Anticipated residence in the study locale ≥ 9 months
- ◆ Interest in quitting
- ◆ PCP practice and enrollee residence in the same study locale

Measurement

- Baseline registration survey
- Follow-up surveys
 - 6 months
 - 12 months

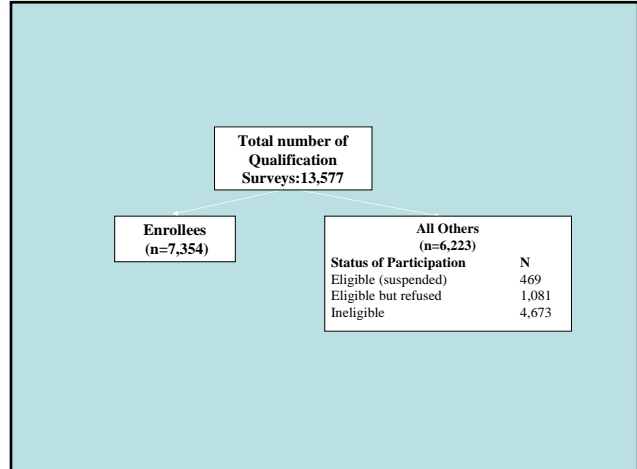


Table 3 Rates of Smoking Cessation at Six and 12 Months (Unadjusted)

MSSP Survey	Usual Care	Provider Counseling	Provider Counseling + Rx	Quitline	Total
Six Months	9.9 (8.7-11.2)	11.9 (9.7-14.2)	15.8 (14.4-17.2)	21.2 (19.2-23.1)	14.8 (14.0-15.6)
Twelve Months	10.2 (9.0-11.5)	14.1 (11.7-16.5)	15.8 (14.4-17.2)	19.3 (17.4-21.2)	14.7 (13.9-15.5)

Notes: Figures reflect the percentage of participants in each intervention arm who reported not having smoked in the last seven days at the time of the six- and 12-month surveys (N=7,354). All survey nonrespondents are assumed to be smoking. 95% confidence intervals in parentheses.

Adjusted quit rates were based on multivariate models that controlled for differences in the characteristics of enrollees in the different intervention arms. Covariates in the model include enrollees' demographic characteristics, smoking history, motivation to quit, health status, other risk factors, state of residence and time of enrollment. Adjusted and unadjusted quit rates were extremely similar.

Conclusions:

- The MSSP attracted a large number of callers and was successful at enrolling a large proportion of eligible patients.
- Each treatment significantly outperformed the Usual Care intervention by 12-months, and increasingly intensive treatments significantly outperformed less-intensive treatments, with the Quitline producing the highest quit rates.

Future Directions

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Colleagues and Collaborators