Coalition for Evidence-Based Policy

A NONPROFIT, NONPARTISAN ORGANIZATION

Top Tier Evidence Initiative:

Evidence Summary for the Staying Free Smoking Cessation Program

HIGHLIGHTS:

- **Intervention:** A low-cost smoking cessation program for hospitalized smokers who are willing to make a quit attempt.
- **Evaluation Methods:** Four well-conducted randomized controlled trials.
- **Key Findings:** 30% increase in likelihood of confirmed abstinence from smoking approximately one year after patients' discharge from the hospital.

I. The Top Tier initiative's Expert Panel has identified this intervention as *Top Tier*.

The Panel finds that this intervention meets the Congressional Top Tier Evidence standard, defined as: *Interventions shown in well-designed and implemented randomized controlled trials, preferably conducted in typical community settings, to produce sizable, sustained benefits to participants and/or society.*

II. Description of the Intervention:

Staying Free is a smoking cessation program for hospitalized smokers who (i) are willing to make a quit attempt during hospitalization; and (ii) do not have a medical history of substance abuse or psychiatric disorders, and are not pregnant, medically unstable, or cognitively disabled.

Participants first receive a one-minute scripted smoking cessation message from their physician, followed by –

- An intensive counseling session provided at bedside by a nurse case-manager specially trained in smoking cessation (approximately 30-60 minutes); and
- Four to seven telephone counseling sessions – each 5-10 minutes long – provided by the nurse at periodic intervals between 2 and 90 days after discharge.

The bedside session includes (i) education on hazards of smoking personalized to the patient's condition, benefits of quitting, the withdrawal process, and importance of social support; (ii) take-home materials (video, workbook, relaxation tape); and (iii) counseling. The counseling focuses on relapse-prevention – specifically, identifying high-risk situations for smoking relapse and working with the nurse to develop behavioral, cognitive, and social support strategies to remain smoke-free in such situations. The post-discharge phone sessions also focus on relapse prevention. Pharmacotherapy (e.g., nicotine replacement therapy) is provided on an as-needed basis.

The program's cost is $100-$200 per patient (2010 dollars). The program implementation manual is available here; a summary of effective strategies for program dissemination is available here.

III. Evidence of Effectiveness

This summary of the evidence is based on a systematic search of the literature, and correspondence with leading researchers, to identify all well-conducted randomized controlled trials of Staying Free. Our search identified four such trials, three of which are summarized below (a fourth that we reviewed has been submitted for publication and is not summarized here at the author's request). The following summarizes the program's effects on the primary outcome measured in each study – confirmed abstinence from smoking approximately 12 months after the patient's discharge from the hospital.

Overview: In these four trials, the Staying Free group was, on average, 30% more likely to be abstinent than the control group 12 months after the patients' discharge from the hospital.

- Specifically, the average abstinence rate for the Staying Free group in these trials, weighted by sample size, was 32.0%, whereas the average abstinence rate for the control group was 24.6%.

- We also conducted a meta-analysis of the four trials, which found a statistically-significant difference in abstinence rates of similar magnitude (7.5 percentage points, $p < .01$).

Other studies investigating the rate of smoking relapse after 12 months suggest that this effect is likely to endure.[1]

Study 1 (Large Urban Canadian Hospital)

This was a randomized controlled trial of 276 hospitalized smokers with coronary heart disease,[2] in a large urban hospital in western Canada. All sample members were: (i)18 years of age or older and able to speak English; (ii) willing to make a quit attempt and participate in the study; (iii) not pregnant, medically unstable, or cognitively disabled; and without a medical history of substance abuse or psychiatric disorders.

Sample members were randomly assigned to (i) Staying Free, or (ii) a control group that received a minimal intervention (brief nonsmoking advice from their doctor and nurse, and pamphlets on how to quit).

The sample was 83% male and 93% white, averaged 54 years of age, and smoked an average of 21.5 cigarettes per day. 54% had a high school education or less.

Results 12 months after patient discharge from the hospital: The Staying Free group was 54% more likely to be abstinent than the control group.

- Specifically, the Staying Free group's confirmed abstinence rate was 54.1%, whereas the control group's was 35.0%. This difference was statistically significant at the 0.01 level.

[1] Other studies have found a relapse rate after 12 months of approximately 10 percent annually. If this relapse rate affects the Staying Free and control groups equally, the program's sizeable effect on abstinence at 12 months is likely to persist over a number of years. The relapse evidence is carefully reviewed in John R. Hughes, Erica N. Peters, and Shelly Naud, "Relapse To Smoking After 1 Year of Abstinence: A Meta-analysis," *Addictive Behaviors*, 2008, vol. 22, pp. 1516-1520.

[2] Specifically, they were admitted to the hospital for acute myocardial infarction or for coronary artery bypass graft.

- Abstinence was defined as not smoking – not even a puff – over the past seven days, according to self-reports confirmed by a friend or family member.

Discussion of study quality:

- The study had low sample attrition: 10% of the Staying Free group and 11% of the control group withdrew from the study or could not be reached to determine smoking status. In addition, two members from each group died during the study.

- At the start of the study, the Staying Free and control groups were highly similar in their observable characteristics (e.g., demographics, smoking history, health).

- The sample members who withdrew from the study or could not be reached were still included in the study's analysis of the program's effects, and counted as smokers (i.e., the study used an "intention-to-treat" analysis).

- The study verified patients' self-reported claims of abstinence through a phone call with a friend or family member (if not confirmed, the patient was classified as a smoker in the analysis).

- The research staff who interviewed patients (and their friends/family) to determine smoking status were blind as to which patients were in the Staying Free versus control group.

- The study evaluated Staying Free as it is typically implemented in a large urban hospital, thus providing evidence of its effectiveness under real-world conditions.

Study 2 (San Francisco Area Hospitals, All-Female Sample)

This was a randomized controlled trial of 277 female hospitalized smokers with cardiovascular disease or peripheral vascular disease in 10 San Francisco Bay Area hospitals. All sample members were: (i)18 years of age or older and able to speak English; (ii) willing to make a serious quit attempt and participate in the study; and (iii) not medically unstable, or diagnosed with a substance abuse or psychiatric disorder.

Sample members were randomly assigned to (i) Staying Free, or (ii) a control group that received a minimal intervention (brief nonsmoking advice from their doctor, a pamphlet on how to quit, and a list of smoking-cessation programs in their community).

The sample was 100% female and 76% white, averaged 61 years of age, and smoked an average of 18.5 cigarettes per day. 48% had a high school education or less.

Results 12 months after random assignment: The Staying Free group was 14% more likely to be abstinent than the control group; however, this difference was not statistically significant.

- Specifically, the Staying Free group's confirmed abstinence rate was 47.6%, whereas the control group's was 41.7%.

- Abstinence was defined as not smoking over the previous six months, according to self-reports confirmed by either saliva test or a friend or family member.

Discussion of study quality:

- At the start of the study, the Staying Free and control groups were highly similar in their observable characteristics (e.g., demographics, smoking history, health).

- The study measured outcomes for all sample members assigned to the Staying Free group, regardless of whether or how long they actually participated in the program (i.e., the study used an "intention-to-treat" analysis).

- The study verified patients' self-reported claims of abstinence through a saliva test or phone call with a friend or family member (if the claim was contradicted, the patient was classified as a smoker in the analysis).

- The research staff who interviewed patients (and their friends/family) to determine smoking status were blind as to which patients were in the Staying Free versus control group.

- The study evaluated Staying Free as it is typically implemented in a large urban hospital, thus providing evidence regarding its effectiveness under real-world conditions.

- A limitation of this study is sample attrition: At the 12-month follow-up, data on smoking status could not be obtained for 15% of the Staying Free group and 7% of the control group. This difference in attrition conceivably could have caused differences between the two groups, possibly leading to inaccurate estimates of the program's effects.

Study 3 (Kaiser Permanente Medical Centers in the San Francisco Bay Area)

This was a randomized controlled trial of 1551 smokers hospitalized at one of four Kaiser Permanente Medical Centers in San Francisco Bay area. The sample included all smokers hospitalized at the Centers, except those who (i) were admitted to the obstetrical or psychiatric wards; (ii) were unable to speak English; (iii) had a primary diagnosis of alcohol or drug abuse, or an impaired level of consciousness; (iv) were expected to stay in the hospital less than 36 hours, or to move out of the Bay Area during the year; or (v) were unwilling to make a quit attempt or participate in the study. *Unlike studies 1 and 2 above, the sample was not limited to patients with heart or vascular disease.*

Sample members were randomly assigned to (i) Staying Free,[3] or (ii) a control group that received usual care (brief nonsmoking advice from their doctor, a pamphlet on how to quit, and a list of outpatient smoking-cessation programs).[4]

The sample was 52% male and 67% white, averaged 51 years of age, and smoked an average of 20 cigarettes per day. 47% had a high school education or less. 33% were hospitalized primarily for cardiovascular disease.

[3] In this study the Staying Free program, in addition to its usual elements, offered patients who relapsed within 90 days after discharge one additional 30-minute in-person counseling session with the project nurse.

[4] The study also contained a second experimental condition, with a sample of 473 patients, that received a minimal intervention (in-hospital nurse counseling plus only one follow-up phone session). The minimal intervention was found to have no significant effect on smoking cessation.

<u>Results 12 months after patient discharge from the hospital</u>: The Staying Free group was 32% more likely to be abstinent than the control group.

- Specifically, the Staying Free group's confirmed abstinence rate was 26.7%, whereas the control group's was 20.3%. This difference was statistically significant at the 0.01 level.

- Abstinence was defined as not smoking – not even a puff – over the past seven days, according to self-reports confirmed by a blood or saliva test, or a family member.

Discussion of study quality:

- This study had a large sample and low sample attrition: 1551 patients were randomized, and outcome data were obtained for 86% of the Staying Free group and 86% of the control group.

- At the start of the study, the Staying Free and control groups were highly similar in their observable characteristics (e.g., demographics, smoking history, medical conditions).

- The study measured outcomes for all sample members assigned to the Staying Free group, regardless of whether or how long they actually participated in the program (i.e., the study used an "intention-to-treat" analysis).

- The study verified patients' self-reported claims of abstinence through a blood or saliva test or, if not possible, a family member (if the claim was contradicted, the patient was classified as a smoker in the analysis).

- This study evaluated Staying Free as implemented on a large scale for hospitalized smokers with a variety of medical conditions, thus providing evidence of the program's effectiveness in real-world conditions and a diverse population.

<u>Other Studies</u>:

Four other randomized controlled trials of Staying Free have been conducted. Their results are generally consistent with those of the three studies described above. One of these trials has been submitted for publication and is not summarized here at the request of the study author. The other three fall outside our initiative's inclusion criteria (e.g., due to sample attrition, or evaluation of Staying Free as part of a comprehensive fitness intervention, rather than by itself).

IV. Summary of the Intervention's Benefits and Costs:

If taxpayers fund the delivery of this intervention, what benefits to society can they expect to result, and what would be their net cost? The following table provides a summary. This is intended to be a general overview of social benefits in relation to taxpayer cost, rather than a comprehensive benefit-cost analysis. It assigns monetary value to particular benefits and costs only when doing so requires minimal assumptions. The monetary amounts shown are in 2010 dollars.

Benefits To Society

- **A 30% increase in patients' likelihood of confirmed abstinence from smoking, approximately one year after their discharge from the hospital.**

Cost To Taxpayers

- **The program cost approximately $100-200 per patient.**

V. References:

Study 1 – Large Urban Canadian Hospital

- Smith, Patricia M. and Ellen Burgess. "Smoking Cessation Initiated During Hospital Stay for Patients with Coronary Artery Disease: A Randomized Controlled Trial." *Canadian Medical Association Journal*, June 23, 2009, vol. 180, no. 13, pp. 1297-1303.

Study 2 – San Francisco Area Hospitals, All-Female Sample

- Sivarajan Froelicher, Erika S., Nancy Houston Miller, Dianne J. Christopherson, Kirsten Martin, Kathleen M. Parker, Marcy Amonetti, Zhen Lin, Min Sohn, Neal Benowitz, C.B. Taylor, and Peter Bacchetti. "High Rates of Sustained Smoking Cessation in Women Hospitalized with Cardiovascular Disease: The Women's Initiative for Nonsmoking (WINS)." *Circulation*, February 10, 2004, vol., 109, pp. 587-593.

Study 3 – Kaiser Permanente Medical Centers in the San Francisco Bay Area

- Houston Miller, Nancy, Patricia M. Smith, Robert F. DeBusk, David S. Sobel, and C. Barr Taylor. "Smoking Cessation in Hospitalized Patients: Results of a Randomized Trial," *Archives of Internal Medicine*, February 24, 1997, vol. 157, pp. 409-415.

- Taylor, C. Barr, Nancy Houston Miller, Steven Herman, Patricia M. Smith, David Sobel, Lynda Fisher, and Robert F. DeBusk. "A Nurse-Managed Smoking Cessation Program for Hospitalized Smokers," *American Journal of Public Health*, November 1996, vol. 86, no. 11, pp. 1557-1560.

Other studies –

- Smith, Patricia M., Linda Corso, K. Stephen Brown, Roy Cameron, and Doris Winfield. "Results of a Randomized Clinical Trial of an Intensive vs. Brief Inpatient Tobacco Cessation Intervention for Smokers with Medical Co-Morbidities in a Universal Healthcare System." Unpublished manuscript submitted for publication, 2010.

- Feeney, Gerald F. X., A. McPherson, J. P. Connor, A. McAlister, R. M.Young, and P. Garrahy. "Randomized Controlled Trial of Two Cigarette Quit Programmes in Coronary Care Patients after Acute Myocardial Infarction." *Internal Medicine Journal*, 2001, vol. 31, pp.470 - 475.

- DeBusk, Robert F., Nancy Houston Miller, H. Robert Superko, Charles A. Dennis, Randal J. Thomas, Henry T. Lew, Walter E. Berger III, Robert S. Heller, Jonathan Rompf, David Gee, Helena C. Kraemer, Albert Bandura, Ghassan Ghandour, Mia Clark, Raksha V. Shah, Lynda Fisher, and C. Barr Taylor. "Annals of Internal Medicine: A Case-Management System for Coronary Risk Factor Modification after Acute Myocardial Infarction." *Annals of Internal Medicine*, May 1, 1994, vol. 120, no. 9, pp. 721-729.

- Taylor, C. Barr, Nancy Houston-Miller, Joel D. Killen, and Robert F. DeBusk. "Smoking Cessation after Acute Myocardial Infarction: Effects of a Nurse-Managed Intervention." *Annals of Internal Medicine*, 1990, vol. 113, pp. 118-123.

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