Considering an Epidemiological Approach

For Achieving an Optimal Success Rate

With Tennessee’s Tobacco Cessation Program

By
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Advisor: Hollie Pavlica

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Second Reader: Ami Mitchell

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Date
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Abstract

In October 2007 the state of Tennessee began enforcement of a workplace smoking ban now known as the “Non-Smoker Protection Act”. In an effort to help local health departments be well positioned to assist individuals with smoking cessation the Department of Health rolled out a patient assessment and treatment program. For best results, this program can take an epidemiological approach. Epidemiology is defined as the study of the distribution of determinants and antecedents of health and disease in human populations, with the goal of identifying their underlying causes and ultimately the application of findings for disease prevention and health promotion (Turnock 387). By understanding some key characteristics of the patients our providers encounter, such as socioeconomic status and nicotine dependence, we can develop cost effective strategies to achieve optimum success with the smoking cessation program.
Introduction

Background

One of public health’s greatest conquests began over forty years ago and the story of the Tobacco Epidemic continues to play out on the world stage. Since the 1964 Report of the Advisory Committee to the Surgeon General, entitled Smoking and Health, there have been twenty-eight other reports issued from the U.S. Public Health Service concerning the health risks associated with Tobacco use (Office on Smoking and Health 1). These twenty-nine reports have described in detail the direct association of smoking with lung and other cancers, chronic obstructive lung disease, respiratory infections, asthma, cardiovascular disease, low birth-weight, and a myriad of other poor health outcomes (CDC 986; EPA 6; Mokdad 1238). There is empirical evidence that smoking is the single largest preventable cause of death and disability in the United States.

Beginning in the 1990s, this overwhelming body of evidence led to several states filing law suits against tobacco companies seeking recovery of costs associated with the treatment of smoking related illnesses. In 1998, the Attorneys General of 46 states signed the Master Settlement Agreement with the four largest tobacco companies (Phillip Morris, RJ Reynolds, Brown and Williamson, and Lorillard) in the United States to settle these law suits (Office on Smoking and Health 2). One of the major effects of this agreement was the establishment of the National Foundation. This non-profit foundation, established by the Executive Committee of the National Association of Attorneys General (NAAG), is the vehicle that delivers funds secured from the settlement to support the prevention of diseases associated with tobacco use (Hermer 1).
Landmark reports and court settlements have paved the road public health professionals are currently taking to prevent tobacco related morbidity and mortality. The goals and objectives related to tobacco control are explicitly described by the U.S. Department of Health and Human Services. National health objectives focused on the year 2010 have been issued by DHHS, referred to as Healthy People 2010. Those objectives target prevalence of tobacco use by designating it as one of the top ten leading health indicators (Turnock 76). Objectives within the focus area of tobacco according to Healthy people 2010 are as follows: target a reduction of the current smoking prevalence among adults to 12%, among students in grades 9-12 to 16%; increase smoking cessation attempts by adults to 75%, increase smoking cessation attempts by adolescents to 64%; increase smoke-free environments of schools and workplaces to 100% (National Center for Health Statistics 1).

**Tennessee Tobacco Control Efforts**

Tobacco control efforts throughout the United States employ a variety of strategies to reach the Healthy People 2010 targets. Effectively diminishing the toll taken by tobacco on the public’s health has been achieved by raising cigarette prices through state excise taxes, establishing social support through telephone counseling, and enacting clean air laws or smoking bans (Chaloupka 62; Maher 65; Heironimus 1). Furthermore, a synergistic effect is clearly demonstrated when multiple control efforts are employed at once (Hopkins 42). Tennessee is an example of one such place where multiple control efforts are being used to close in on the targets set forth in Healthy People 2010. On June 11, 2007, Governor Phil Bredesen signed the “Non-Smoker Protection Act” into law in Tennessee, which makes it illegal to smoke in most places where people work (Tennessee
Department of Health \(^1\). The workplace smoking ban was followed by a tax increase of forty-two cents per pack, only the third in state history, which increased the tax from twenty cents to sixty-two cents per pack.

The local health departments in Tennessee are well-positioned to take advantage of one of the best suited environments to tackle the tobacco problem. With multiple tobacco control efforts firmly in place, a new patient assessment, tobacco use survey, and cessation assistance program was rolled-out with enthusiasm across the state. The smoking status of all patients encountered at the local health departments over the age of thirteen is now being assessed. At each point during a patient’s visit (registration, provider consultation, check-out) they are assessed for potential enrollment into the smoking cessation program. Additionally, consenting patients are referred to the Tennessee Tobacco Quitline. This telephone service provides personalized support for Tennesseans who want to quit smoking by assigning them a quit-coach for one-on-one counseling during quit attempts (Tennessee Department of Health \(^2\)). This free of charge service is available without referral from a provider as well.

For those patients who enroll in the cessation and treatment program, the local health department is providing access to non-prescription nicotine replacement therapy in the form of nicotine gum or lozenges. Chantix, a pharmaceutical therapy that controls the response of nicotine receptors in the brain, is also being made available to patients for whom it is indicated. This requires an evaluation by a physician, or a mid-level provider, and a prescription. A sliding-fee scale is administered to determine the charge to the patient for the services and associated medicines. Figure 1 shows the survey instrument used to collect information and assess patient readiness.
(Figure 1.) Courtesy of the Tennessee Department of Health Bureau of HSA

### Patient Tobacco Survey

<table>
<thead>
<tr>
<th>Question Number</th>
<th>Question Text</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Which tobacco products do you currently use? (Check all that apply)</td>
<td>Cigarettes, cigars, pipes, or other smoking tobacco</td>
</tr>
<tr>
<td>2</td>
<td>Have you smoked at least 100 cigarettes in your entire life? (Check box)</td>
<td>Yes, No, Don't know/Not sure, Refused</td>
</tr>
<tr>
<td>3</td>
<td>Do you now smoke cigarettes everyday, some days, or not at all? (Check box)</td>
<td>Everyday, Some days, Not at all, Refused</td>
</tr>
<tr>
<td>4</td>
<td>How many times during the past 12 months have you stopped smoking for 1 day or longer because you were trying to quit smoking? (Check box)</td>
<td>1 time, 2 times, 3 or 4 times, 5 or 6 times, 6 or more times, 10 or more times, Refused</td>
</tr>
<tr>
<td>5</td>
<td>When you last tried to quit, how long did you stop smoking? (If you try)</td>
<td>Less than 1 day, 1 to 7 days, More than 7 days but less than 40 days, 40 days or more but less than 6 months, 6 months or more but less than 8 months, 8 months or more but less than 1 year, 1 year or more, Refused</td>
</tr>
<tr>
<td>6</td>
<td>Would you like to stop smoking? (Check box)</td>
<td>Yes, No, Don't know/Not sure, Refused</td>
</tr>
</tbody>
</table>

**STOP:** Thank you. Please give this sheet to your health care provider.
During this visit today with the patient, did you as the health care professional provide any of the following services? (For each item circle Y (Yes) if you did, or circle N (No) if you did not)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1. Ask about tobacco use. Advise them to quit. Assess readiness to quit.</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>P2. Refer to a smoking cessation class, program, quit line or other health care professional.</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>P3. Prescribe or recommend a patch, nicotine gum, nasal spray, an inhaler, or pills such as Chantix®</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>P4. Please classify the smoking status of this patient. (Check one box)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Current smoker, <strong>not willing</strong> to quit (NONTQT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Current smoker, <strong>willing</strong> to quit (not in treatment) (WILLQT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Current smoker, starting <strong>treatment</strong> (any combination of the following: smoking cessation program, quit line, tobacco cessation aid such as NRT or Chantix®) (TREAT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Former smoker – Completed Health Department treatment (COMPTX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Former smoker (FORMER)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Never smoked (NEVER)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Unable to determine (NOTDET)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

P5. Provider number (provider who reviewed patient questions 1 – 6 and completed Questions P1 – P4):

**CLINICAL VISIT NOTE:**

[ ] See Progress Note for Details

CC:

PMH:

<table>
<thead>
<tr>
<th>Current</th>
<th>Disease</th>
<th>Y</th>
<th>N</th>
<th>Y</th>
<th>N</th>
<th>Y</th>
<th>N</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>U/M disease</td>
<td>Y</td>
<td>N</td>
<td>Headache</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CV disease</td>
<td>MI</td>
<td>Y</td>
<td>N</td>
<td>MI within 2 weeks</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Arrhythmias</td>
<td>Y</td>
<td>N</td>
<td>Angina</td>
<td>Y</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal disease/renal impairment</td>
<td>Y</td>
<td>N</td>
<td>Breast feeding female</td>
<td>Y</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Current Medications:

**Physical Exam:**

VS, HR, RR, BP, Wt, LMP

U/M:

A/P:

Provider Signature(s):

Date
**Tobacco Epidemiology**

The fundamental perspective linking each of Tennessee’s tobacco control efforts is that of epidemiology. That is the study of the distribution of determinants and antecedents of health and disease in human populations, with the goal of identifying their underlying causes and ultimately the application of findings for disease prevention and health promotion (Turnock 387). Figure 2 provides an epidemiologic model that identifies the agent, host, vector, and environment as they relate to tobacco control (Giovinio 7326).

*Figure 2* From Epidemiology of tobacco use in the United States Gary A Giovino.

Each piece plays a specific role in the chain of events that lead to the outcome of cigarette smoking. They also represent a place or an opportunity to engage the process and reduce the prevalence of the undesired outcome. The agent, tobacco products, is easily described and well understood. As for the environment, the new state cigarette tax increase, non-smoker protection laws, and access to cessation assistance contribute to the current atmosphere of confronting the tobacco use challenge. In consideration of the vector, the tobacco product manufacturers and other users account for smoking initiation
and the development of nicotine addiction. Describing the host requires a closer examination of this specific population in Tennessee.

To best understand how the smoking population in the state of Tennessee compares to the rest of the United States, we can look to information collected by the Centers for Disease Control and Prevention, CDC. The Behavioral Risk Factor Surveillance System, BRFSS, is a state-based system of health surveys, established by the CDC in 1984 that collects information on health risk behaviors such as the prevalence of tobacco use (CDC 1). When the 2005 data were published in April of the following year, a smoking prevalence of 26.7% of the population over age 18 in Tennessee gave them a ranking of 47th, tied with West Virginia, in the U.S. (United Health Foundation 1). This was a full 6.1% higher than the national prevalence of 20.1% and really gave legislators something to reflect upon as the Non-Smoker Protection Act was being prepared for its introduction to the state senate.

The 2006 data from the BRFSS show some change has occurred in the prevalence. Adults who were current smokers in Tennessee made up 22.6% of the population compared to the 20.0% prevalence for the rest of the nation (CDC 1). Figure 3 provides a comparison of the 2006 reported prevalence and the Healthy People 2010 goal. BRFSS also collects specific information related to smoking status.
An even closer examination of the differences between the state and national levels offers crucial evidence for tailoring smoking cessation efforts in Tennessee. Figure 4 represents information about frequency (every day or some days) and history (former smoker or never smoker) of smoking status in 2006. The readily obvious disparity in the four levels of smoking status between Tennessee and the rest of the nation are found among the number of every day smokers. Our state had 3.7% more every day smokers than the rest of the U.S. in 2006 (CDC\(^1\)). On the surface the difference indicates that Tennessee’s population of current smokers has a heavier level of addiction and a potentially lower level of success with cessation.

**Important Variables of Smoking Cessation**

To see beyond the surface we must consider the factors involved with nicotine addiction and quitting smoking successfully. Various studies and surveys have examined an array of variables that are thought to determine the likelihood of individual success with smoking cessation. Among the “core predictor values” that have been explored
regarding cessation success are socioeconomic status, or SES, and other demographic factors such as race and gender (Keiko 375). There are the motivational concepts and belief systems that have been linked to both addiction and cessation. These include self efficacy, outcome expectancy, worries about health and quality of life, and overall attitudes about smoking. Past quitting histories and nicotine dependence variables have been given a statistical analysis as well (A Hyland 85). Researchers have also considered conditions that may be sources of unsuccessful quit attempts like emotional distress and alcohol use (Erik 549).

For an exploration of the association between Socioeconomic Status, or SES, and smoking cessation a description of the SES measure in epidemiologic studies is incumbent upon the journey. Seventy six studies reported in the American Journal of Epidemiology in 1982 and 1985 were examined by researchers to see how many considered social class a variable related to a chronic disease outcome. Nearly 40 percent of those studies looked for the effect of social class upon health outcomes and could be more specifically detailed as follows: 42% considered SES to be a potential confounder, 32% viewed SES as a risk factor, and 26% of these studies used SES as a variable descriptive of the study sample (Liberatos 87).

Since many of the patients encountered at the local health department tend to have lower socioeconomic status, or SES, it is possible that certain trends exist within this population. Higher levels of nicotine dependence, having low self-efficacy to quit, and having no intention to quit are correlated with both low SES and low likelihood of success with smoking cessation (Siahpush 71). The tobacco survey and assessment tool can be used to make this information immediately available to our healthcare providers.
Additionally, some studies show that this social gradient is not limited to the prevalence of smoking, but also differs among smokers between socioeconomic groups, suggesting that individuals of lower SES don’t just smoke, they smoke more intensely (Bobak 311). Even though these critical factors most likely form a continuum along which our patients exist, it is important to recognize how each one can impact the final outcome.

**Information for Action**

Understanding the links between the key characteristics of Tennessee’s smoking population, specifically the patients encountered at the local health departments, and the Healthy People 2010 target prevalence can help us yield actionable information. One other benefit will be the ability to develop clever strategies and innovative tactics with limited financial resources while implementing the smoking cessation program at the local level. Since the local program consists of access to several therapies, two different nicotine replacement therapies and one prescription for a nicotine receptor inhibitor, benefits could be realized from the predictive value of patient characteristics. Inferences from the characteristics can be directed at the most efficacious course of treatment for patients who enroll in the cessation program, thus using the more expensive course of treatment only when indicated as the most effective and taking appropriate steps to better position patients for success.

A discussion if the cost of the program is integral to the development of the approach. Patients who receive this service are charged according to the sliding fee scale. If they have private insurance, the company will be billed for the service. The rate of pay for the uninsured is a function of their reported income. The vast majority of the patients with private insurance or with moderate to high incomes (both indicators of moderate to
high SES) tend to seek smoking cessation therapy with a private primary care provider. Even though the smoking cessation program is available for all who seek assistance, patients encountered at the local health departments are predominantly from the lower SES categories.

When considering the cost of cessation treatment, it is important to note that the full course of therapy is ninety days. A three month supply of nicotine gum costs $139.51, and is the least expensive form of nicotine replacement therapy. For individuals with temporomandibular joint, or TMJ, syndrome and others for whom chewing gum may be contraindicated, a three months supply of lozenges costs $366.03. The third course of treatment requires a prescription. Varenicline (also known as Chantix manufactured by Pfizer) costs $279.92 per three month supply per patient. The twofold increase in the cost of the Chantix compared to the nicotine gum is compounded by the requirement for a prescription. The chewing gum and lozenges can be dispensed by a nurse and do not require written approval by a Physician. Figure 5 summarizes this data. (Figure 5).

![Cost Comparison of Cessation Therapies]

The ultimate goal of this research is the development of a process which leads to a higher percent of patient success with the smoking cessation program at the local health
departments in Tennessee. A fundamental component to developing best practices can be found in the inverse relationship between cigarette consumption and cessation rates. It is well established that cessation rates are much higher among individuals with lowest levels of nicotine consumption. In order to increase cessation rates among those individuals with high levels of nicotine consumption (i.e.; the majority of our patients, based on the correlation of consumption and socioeconomic status,) our program may benefit from interventions that first reduce consumption to lower levels and indirectly boost subsequent cessation rates (A Hyland 92). A review of the existing literature demonstrates a correlation between patient characteristics and cessation which can be used to develop best practices by our providers in prescribing cessation treatment.

Literature Review

Socioeconomic Status (SES) and Smoking Cessation

The establishment of SES as an etiological agent of disease is rather commonplace, however recent literature suggests it is known to be related specifically to smoking cessation. In a 2005 cross-sectional study of smoking initiation and cessation SES was categorized as High Medium and Low with education level of the respondent as the basis. The resulting odds ratios among men of smoking cessation within each level were 1.0 for Low SES, 1.53 for Medium SES and 2.38 for High SES. Results among women were 1.0, 1.44 and 1.79 respectively (A. Jeanne 259).

Some studies set SES levels according to occupation. In a survey of a population sample from Sweden in 1994 the effect of SES on successful smoking cessation was much like the 2005 cross-sectional study. The highest levels of SES were associated with
a twofold increase in smoking cessation. (Lindstrom 201). Figure 6 reports the findings of smoking cessation as it relates to these SES levels.

**Figure 6. Smoking Cessation in Relation to Socioeconomic Variables** (Lindstrom 204).

<table>
<thead>
<tr>
<th>SES levels by occupation</th>
<th>Men Odds Ratio (95%CI)</th>
<th>Women Odds Ratio (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>V Unskilled manual workers</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>IV Skilled manual workers</td>
<td>1.5 (1.1 ± 1.9)</td>
<td>1.3 (0.9 ± 1.8)</td>
</tr>
<tr>
<td>III Low-level non-manual workers</td>
<td>1.8 (1.4 ± 2.4)</td>
<td>1.5 (1.2 ± 1.8)</td>
</tr>
<tr>
<td>II Mid-level non-manual workers</td>
<td>2.0 (1.5 ± 2.5)</td>
<td>1.7 (1.4 ± 2.2)</td>
</tr>
<tr>
<td>I Non-manual workers in leading positions</td>
<td>1.9 (1.4 ± 2.5)</td>
<td>2.0 (1.4 ± 2.7)</td>
</tr>
<tr>
<td>VI Self-employed</td>
<td>1.4 (1.1 ± 1.8)</td>
<td>1.5 (1.1 ± 2.1)</td>
</tr>
<tr>
<td>VII disability pensioners &lt; age 65</td>
<td>1.4 (1.1 ± 1.8)</td>
<td>1.2 (1.0 ± 1.5)</td>
</tr>
<tr>
<td>VIII Unemployed</td>
<td>1.0 (0.8 ± 1.4)</td>
<td>1.2 (0.9 ± 1.7)</td>
</tr>
</tbody>
</table>

In 2003, research that speaks directly to health department patient demographics was conducted using information from the Australia Bureau of Statistics. Data collected in the 1998–99 Household Expenditure Survey allowed researchers to make a connection between SES and the proportion of household income used to purchase tobacco. Not only did the study confirm earlier findings that lower education level, occupational status, living in rented housing, or in disadvantaged areas were associated with higher tobacco expenditure as a percentage of household expenditure, but it also demonstrated that a
social gradient exists where the lower SES group consume more cigarettes and thus are more addicted to nicotine (Siahpush 801).

The effects of higher prevalence of smoking among individuals with lower SES were clearly demonstrated in a study exploring how decreases in cardiovascular mortality were predominantly experienced among the most educated within a cohort. Multiple studies conducted between 1960 and 1993 in Denmark were evaluated to explain how increased social inequality in cardiovascular mortality might be associated with different trends in behavioral cardiovascular risk factors in different educational groups. From 1982 to 1992 the prevalence of smoking decreased mainly among individuals with higher SES, based on education level, and served to widen an existing gap. The increased socioeconomic difference in cardiovascular mortality during the 1980s in Denmark was found to be attributable to the difference in the prevalence of smoking between the different levels of SES (Osler 112).

Analysis of a biological marker for nicotine addiction has provided considerable evidence that the lower socioeconomic groups in society are the heaviest smokers. Data used to monitor trends in cardiovascular diseases in the Czech Republic included observed levels of serum thiocyanate, a biological marker used to determine nicotine intake. The 1999 study found that serum thiocyanate concentrations were inversely associated with education among men. This social gradient was not limited to the prevalence of smoking, but also differed among smokers between groups, suggesting that individuals of lower SES don’t just smoke, they smoke more intensely (Bobak 311).

The correlation between SES and how current smokers become former smokers has been under evaluation for decades. Research in 1987 took data from an ongoing case-
control study that included 3,778 male and 1,486 female ever-smoking patients hospitalized with non-tobacco-related conditions. Patient interviews were conducted between 1977 and 1985. The lifetime quit rate, [no. ex-smokers/no. ever smokers] x 100, was found to increase with increasing educational and occupational level in both male and female patients (Kabat and Wynder 1301). Figure 7 reports findings from the study.

**Figure 7.** (Kabat and Wynder 1302).

<table>
<thead>
<tr>
<th>-Distribution of Ex-Smokers and Present Smokers and Lifetime Quit Rates by Sociodemographic Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
</tr>
<tr>
<td>Ex-Smokers (N = 1828)</td>
</tr>
<tr>
<td>Education</td>
</tr>
<tr>
<td>Grammar School</td>
</tr>
<tr>
<td>High School</td>
</tr>
<tr>
<td>Some College</td>
</tr>
<tr>
<td>College Graduate</td>
</tr>
<tr>
<td>Graduate School</td>
</tr>
<tr>
<td>Occupational Level</td>
</tr>
<tr>
<td>Professional</td>
</tr>
<tr>
<td>Skilled</td>
</tr>
<tr>
<td>Semi-skilled</td>
</tr>
<tr>
<td>Unskilled</td>
</tr>
<tr>
<td>Housewife</td>
</tr>
</tbody>
</table>

*Lifetime Quit Rate = \# Ex-smokers \# Ever Smokers *100%

**Nicotine Dependence and Cessation Success**

A discussion of the measurement nicotine dependence will help develop our understanding of its influence on the outcome of patient success with smoking cessation. The Heaviness of Smoking Index (HSI) is the sum of two categorical measures: number of cigarettes smoked per day (coded: 0: 0–10 cigarettes per day (CPD), 1: 11–20 CPD, 2: 21–30 CPD, 3: 31+ CPD), and time to first cigarette (coded: 0: 61+min, 1: 31–60 min, 2: 6–30 min, 3: 5 min or less). Values for this variable range from 0 to 6. This index is positively associated with nicotine dependence (Heatherton 791). Another method used
to index nicotine dependence is called the Fagerstrom Tolerance Scale. The questionnaire administered to determine nicotine dependence with this method is shown in Figure 8.

Figure 8. (Heatherton 1127).

Fagerstrom Test for Nicotine Dependence *

Is smoking “just a habit” or are you addicted? Take this test and find out your level of dependence on nicotine.

1. How soon after you wake up do you smoke your first cigarette?
   - After 60 minutes (0)
   - 31-60 minutes (1)
   - 6-30 minutes (2)
   - Within 5 minutes (3)

2. Do you find it difficult to refrain from smoking in places where it is forbidden?
   - No (0)
   - Yes (1)

3. Which cigarette would you hate most to give up?
   - The first in the morning (1)
   - Any other (0)

4. How many cigarettes per day do you smoke?
   - 10 or less (0)
   - 11-20 (1)
   - 21-30 (2)
   - 31 or more (3)

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?
   - No (0)
   - Yes (1)

6. Do you smoke even if you are so ill that you are in bed most of the day?
   - No (0)
   - Yes (1)

Your score was: . Your level of dependence on nicotine is: .

0-2 Very low dependence 6-7 High dependence
3-4 Low dependence 8-10 Very high dependence
5 Medium dependence

Beginning in 2002 the United States, Canada, Australia, and the United Kingdom began a prospective cohort study that was aimed at evaluating the behavioral impact of national tobacco control policies. Referred to as the International Tobacco Control Four Country Survey, the study uncovered prominent similarities between the countries with regards to nicotine dependence and smoking cessation. A strong relationship between the percent of smokers in the entire sample that quit and their HSI scores provide evidence that cessation is much more successful at lower levels of nicotine dependence. For
example of the entire sample that made serious quit attempts 14% quit with a HSI of 6, 22% quit with a HSI of 3, and 39% quit with a HSI score of 0 (A. Hyland 88).

Canada’s National Population Health Survey was recently analyzed to determine if statistically significant associations existed between specific HSI levels and success with smoking cessation. The results were found to be immediately relevant to the characteristics of our patients. The study focused on the 2,938 adult respondents who were daily smokers in 1996-97. According to the survey people reporting low levels of nicotine dependence as measured by HSI were most likely to report quitting successfully. Even though some of the smokers with a higher level of nicotine dependence experienced successful quit attempts, they were found to be older wealthier individuals, suggesting that SES is a mediating factor (Chaiton 103).

A recent study conducted to identify individual characteristics that predict successful smoking cessation treatment in African Americans provides solid evidence of the link between nicotine dependence and cessation. Smoking after 30 minutes of waking and smoking fewer cigarettes per day were both found to be statistically significant predictors of cessation. Patients enrolled in the study that reported smoking within 30 minutes of waking were found to have considerably less success with smoking cessation (approximately 60% less success) than those that did not (Harris 498).

In a cohort of Danish men and women, aged 30–60 years at first examination in 1982/1984, smoking behavior was evaluated from questionnaires at baseline and at follow up 10 years later to see how known determinants of successful cessation interacted across varying levels of motivation to stop smoking. The amount of tobacco smoked, a main contributor to HSI scores, was discovered to be strongly associated with
smoking cessation among individuals in the study. The odds ratio of successful cessation dropped from 1 to 0.44 when number of cigarettes smoked per day went from 0-10 to \( \geq 10 \) (Osler 266).

In one of the first studies to prospectively evaluate variables predictive of success in stopping smoking, an index of nicotine dependence was based upon three items from the Fagerstrom Tolerance Scale. Respondents who scored higher on the nicotine dependence index were more likely to have less confidence in their ability to quit and stay off cigarettes, while those who reported smoking more cigarettes daily were less likely to be successful in stopping. The multivariate odds ratio for successful quitting with the variable of *smoking fewer cigarettes daily* was 1.9 (Hellman 84).

**Treatment guidelines for Specific Populations**

There is little scientific evidence available that is currently being used to match individuals with specific forms of smoking cessation therapy. The majority of randomized controlled trials that were employed to explore the efficacy of the various nicotine replacement methods enrolled individuals who were smoking \( >15 \) cigarettes per day. Considering the lower socioeconomic status and higher nicotine dependence of our patient population, Tennessee’s local health departments will likely encounter people who smoke at least as many as 15 cigarettes a day or more. The majority of treatment guidelines have been based upon the rather intuitive concept that level of nicotine dependence and the dose of nicotine prescribed for replacement are directly proportional.

A 2001 international study of the use of nicotine lozenges shows that although highly nicotine dependent smokers were less successful at abstaining when treated with placebo, treatment with the active lozenge eliminated the excess failure due to
dependence and helped high-dependency smokers achieve outcomes comparable to those of low-dependency smokers (Shiffman 1279). Smokers were assigned to a lozenge dose on the basis of nicotine dependence, assessed by time to the first cigarette of the day. Low-dependence smokers were randomized to receive the 2-mg nicotine or placebo lozenge; high-dependence smokers, the 4-mg nicotine or placebo lozenge. Figure 9 contains the detailed observations of the treatment efficacy across nicotine dependence levels.

**Figure 9.** (Shiffman 1271).

<table>
<thead>
<tr>
<th>Time, wk</th>
<th>Low Dependence, % of Participants</th>
<th>High Dependence, % of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Active (n = 450)</td>
<td>Placebo (n = 450)</td>
</tr>
<tr>
<td>6</td>
<td>46.0</td>
<td>29.7</td>
</tr>
<tr>
<td>12</td>
<td>34.4</td>
<td>21.6</td>
</tr>
<tr>
<td>24</td>
<td>24.2</td>
<td>14.4</td>
</tr>
<tr>
<td>52</td>
<td>17.9</td>
<td>9.6</td>
</tr>
</tbody>
</table>

*Low-dependence groups received the 2-mg placebo or active lozenge; high-dependence groups, the 4-mg lozenge. OR indicates odds ratio; CI, confidence interval.

In 2004 researchers were able to demonstrate a difference between smoking abstinence rates for highly nicotine dependent patients and those with low to moderate dependence based upon their assignment to specific nicotine replacement therapies.

Smokers who had low to moderate dependence levels achieved higher abstinence rates with trans-dermal nicotine replacement therapy, whereas smokers who were highly dependent achieved higher abstinence rates with nasal spray. The results from the study suggest that the ability to self-administer nicotine nasal spray when desired and the reinforcing effects of more rapidly delivered nicotine are important factors in facilitating abstinence for more highly dependent smokers (Lerman 431).
With the limited amount of research available to guide decision making when assigning specific cessation therapy to patients, it is important to note the existing guidelines proposed by the U.S. Public Health Service. Even though level of nicotine dependence is not among the factors clinicians are currently considering when selecting a course of treatment, there are other considerations to make. Because of the lack of sufficient data to rank-order cessation therapies, choice of a specific first-line pharmacotherapy must be guided by factors such as clinician familiarity with the medications, contraindications for selected patients, patient preference, previous patient experience with a specific pharmacotherapy [positive or negative], and patient characteristics [e.g., history of depression, concerns about weight gain] (Fiore 26).

Choosing which method to prescribe to whom is only one aspect of developing sound treatment guidelines. Duration of therapy is a significant aspect as well. According to meta-analysis of 21 published, randomized, controlled clinical trials, comparing nicotine replacement therapy [NRT] to placebo the average treatment duration was found to be 145 days. The study found the protective effect of NRT against relapse slowly decreases as a function of time. After stopping NRT, the risk of relapse increases, suggesting it may be more beneficial not to stop NRT after the usual 3-6-month treatment period but to use NRT for longer periods of time (Medioni 247).

Studies on extending the use of prescription Varenicline, also known as Chantix, demonstrate a protective effect by increasing the duration of treatment. Patients that had been treated for 12 weeks with Varenicline and were abstinent during the last week of treatment were enrolled in the trial. Participants were randomly assigned to receive either double-blind Varenicline or placebo for an additional 12 weeks. The continuous
abstinence rate was significantly higher for the Varenicline group than for the placebo group for weeks 13 to 24 with more than twice the number of patients prevented from relapsing (Tonstad 64).

**Development of Best Practices**

**Implications**

The research indicates that the majority of the patients we will encounter at the local health departments in Tennessee are less likely to have success with smoking cessation due to their lower socioeconomic status, or SES. The fact that individuals of lower SES experience a higher level of nicotine addiction accounts for fewer successful quit attempts in this population. While very little scientific evidence exists to match patients with specific smoking cessation therapies, guidelines to treat our population should be developed with these characteristics in mind.

With an assessment tool already in place (see Figure 1) the addition of two simple questions would allow for the enumeration of a patient’s nicotine addiction level. By asking the number of cigarettes smoked per day (coded: 0: 0–10 cigarettes per day (CPD), 1: 11–20 CPD, 2: 21–30 CPD, 3: 31+ CPD), and time to first cigarette (coded: 0: 61+min, 1: 31–60 min, 2: 6–30 min, 3: 5 min or less) a simplified Heaviness of Smoking Index (HSI) score can be assigned and goals can be determined. Patient progress towards a lower score can be tracked during follow-up visits with an ultimate goal of successfully quitting.

I would recommend that patients with an HSI of 5 or 6 begin with the highest level of Nicotine Replacement Therapy, using the gum unless contraindicated since the ability to self administer therapy and the reinforcing effects of more rapidly delivered
nicotine are important factors in facilitating abstinence for more highly dependent smokers (Lerman 431). Based upon the cost of the therapy alone, twice the number of patients with HSI scores of 5 or 6 can be treated with nicotine gum compared to the Chantix (see figure 5). Because patients with lower HSI scores have experienced as much as an 8% higher success rate (A. Hyland 88), the use of Chantix when indicated can be considered for those with an HSI below 5 allows for a targeted approach of the more expensive resource.

The targeting of health department resources by assignment of the Heaviness of Smoking Index score is described in the following flow chart found in Figure 10.

**Figure 10.**

First encounter patients are assessed and given a Heaviness of Smoking Index score

- HSI 5-6 receive nicotine gum or Chantix/lozenges when medically necessary
  - *Prescribe nicotine gum/
    scheduled for follow-up.
  - *Prescribe lozenges when medically necessary

- HSI 0-4 receive nicotine gum or Chantix/lozenges when medically necessary

- HSI 5-6 after follow-up continue NRT/schedule for follow-up exam.

- HSI 0-4 receive nicotine gum or Chantix/scheduled for follow-up.

Final follow-up visit. Dispense or prescribe preferred smoking cessation therapy.

Ensure patient is enrolled with Tennessee Quitline for continued social support and counseling.
This model suggests that for patients presenting with scores of 5 or higher receive appropriate and cost-effective Nicotine Replacement Therapy (NRT) initially. When follow-up visits reveal diminished nicotine dependence (HSI ≤4), then prescribe more NRT or Chantix.

Based upon the clinical guidelines put forth by the U.S. Public Health Service All smokers trying to quit should receive pharmacotherapy for smoking cessation, except in the presence of special circumstances (Fiore 26). Controlled clinical trials and statistical analysis of multiple studies suggest that increasing the average duration of smoking cessation therapy leads to greater success with quit attempts. Because these trials and studies have examined nicotine gum, nicotine lozenges, and Chantix, it is recommended extending the current duration of therapy as far beyond 90 days as resources will allow. The flow chart in Figure 10 was designed with the assumption that 90+ days of therapy will be available. While outside the scope of this paper, future steps should include further research in the efficacy and cost effectiveness of this approach.

**Conclusions**

The Tobacco Cessation Program in Tennessee is one of the most significant attempts to reduce smoking prevalence in the history of our state. The morbidity and mortality of smoking related illness takes a tremendous toll on our population, and has the potential to disproportionately affect those of lower socioeconomic status. The local health departments are in a unique position to provide an essential service by getting the needed smoking cessation therapies to individuals that may not otherwise have access. Characteristics of the patient population should be considered in the design of a treatment protocol.
Making minor adjustments to the assessment tool that provide a Heaviness of Smoking Index score and extending the duration of therapy could lead to more successful quit attempts. Ultimately the program will benefit from interventions that first reduce consumption to lower levels and indirectly boost subsequent cessation rates. The use of an epidemiological approach has primarily considered the relationship of the host and the environment within the scope of our tobacco cessation program. Applying what we know about the host is the fundamental aspect of this approach, and should help us achieve an optimal success rate.

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