Youth Smoking Cessation Interventions: Treatments, Barriers and Recommendations for Virginia

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Executive Summary

Tobacco use is the leading cause of preventable death in the United States. This life-threatening addiction usually begins in childhood; 80-90% of adult smokers begin smoking between ages 12 and 14. If current tobacco use patterns persist, an estimated 6.4 million youth who smoke will eventually die prematurely from a smoking-related disease. In Virginia specifically, approximately 15.5% of high school students smoke, and it is projected that of all Virginian children currently under 18, approximately 152,000 will die prematurely from smoking.

Adolescents who smoke cigarettes also put themselves at greater risk for reduced lung function, slowed growth of lung function, cough with phlegm or blood, shortness of breath, and poorer overall health, fitness, and endurance. Importantly, most adolescent smokers want to quit smoking but are unable to do so. These findings highlight the critical need for efficacious, cost-effective, and acceptable youth smoking cessation interventions.

In addition to tobacco control policies, youth smoking cessation interventions can include both pharmacotherapy (medications) and behavioral approaches. Medications for smoking cessation include nicotine replacement therapy (NRT), bupropion (BUP), and varenicline. Seven medications are FDA-approved for adult smoking cessation; however, no medications are recommended for use with adolescents because there is insufficient evidence of their efficacy with this population. In fact, only seven studies have been published on smoking cessation pharmacotherapy for adolescents, and these have not shown consistently positive results. However, across these trials, NRT and BUP were found to be safe and well-tolerated in adolescents. Current Public Health Service (PHS) Clinical Practice Guidelines recommend referral to behavioral intervention as the most appropriate intervention for adolescent smokers.

Recent reviews on behavioral approaches to adolescent smoking cessation have concluded that there is now sufficient evidence to recommend these programs to help youth quit smoking. Behavioral approaches can use a number of different theoretical foci; cognitive behavioral, stages of change and contingency management theories show some advantages over others. Effective treatments include behavioral programs that have at least 5 sessions, certain programs conducted in primary care settings, and counseling via telephone quit lines. Newer approaches that use web-based techniques show promise. Also, behavioral approaches benefit from both efficacy and effectiveness evaluation, cost-effectiveness evaluation, and successful program dissemination and adoption.

In Virginia, several smoking cessation programs are available for funding by the Virginia Foundation for Healthy Youth: Not-On-Tobacco, Project Ex, Helping Teens Stop Using Tobacco (TAP), Intervening with Teen Tobacco Users (TEG), and Ending Nicotine Dependence (END). Several reviews identify Project EX and N-O-T as the only two programs that are evidence-based. Funding for these programs varies from year to year, and programs have limited availability. In addition, some, but not all pharmacotherapies are covered by Medicaid and insurance plans for state employees,

and counseling for youth is generally not covered. Last, the Virginia quit line does not provide counseling for youth younger than age 18.

Overall, barriers to effective smoking cessation interventions for adolescents include a lack of sufficient research on pharmacotherapy, insufficient coverage for treatment, and lack of funding and resources for intervention dissemination. Further, healthcare providers often lack adequate awareness and training in youth tobacco cessation interventions. Many behavioral programs have limited availability due to a scarcity of funding. In addition, recruitment and retention of youth can be challenging, and parental consent can increase the difficulty of recruiting and retaining youth in treatment. Finally, few programs are sufficiently evaluated, disseminated, and adopted.

Recommendations to overcome these barriers include:

- Supporting additional research on pharmacotherapy
- Referring adolescents to effective behavioral programs
- Advocating for increased behaviorally-based tobacco cessation treatment coverage via Medicaid and insurance plans
- Expanding tobacco cessation education and training for Virginia healthcare providers
- Broadening the availability of behavioral approaches, including a statewide youth quit line in Virginia
- Conducting cost-effectiveness analyses on existing behavioral programs
- Improving recruitment and retention strategies for adolescents in cessation treatment
- Supporting both efficacy and effectiveness evaluations for behavioral programs
- Funding only evidence-based programs
- Increasing the dissemination and adoption of effective programs
- Creating and sustaining a *Research, Policy and Practice Advisory Board* to develop consistent and universal guidelines for programs and projects funded by the Virginia Foundation for Healthy Youth
- Promoting a statewide campaign in Virginia to promote the adoption of tobacco-free school policies

Introduction

Overview of Adolescent Smoking and Smoking Cessation

Prevalence and Harm Caused by Youth Smoking

Tobacco use is the leading cause of preventable death in the United States,[1,2] and 80-90% of adult smokers begin smoking during adolescence.[3,4,5] Although overall rates have declined in recent years, 10% of middle school and 23-26% of high school students are current smokers.[6] If current tobacco use patterns persist, an estimated 6.4 million youth who smoke will eventually die prematurely from a smoking-related diseases.[7] Importantly, not all negative effects of adolescent cigarette smoking occur in the distant future. Adolescents who smoke cigarettes put themselves at greater risk for a number of immediate health effects, like reduced lung function, slowed growth of lung function,[8] cough with phlegm or blood, shortness of breath, and poorer overall health, fitness, and endurance.[9]

In Virginia, approximately 15.5% of high school students smoke, and 62% percent of Virginia youth smokers reported planning to quit in the next year.[10] It is projected that of all Virginian children currently under the age of 18, approximately 152,000 will die prematurely from smoking.[11]

Persistence of Smoking into Adulthood

The typical course of adolescent substance use behaviors, including that of alcohol, marijuana, and other illicit drug use, peaks in young adulthood and declines sharply thereafter [12]. These are referred to as "developmentally-limited" behaviors, that is, behaviors associated with a particular developmental stage. Cigarette smoking is distinct in that it tends to persist into adulthood. The earlier an adolescent begins to smoke, the greater the likelihood that he/she will continue to smoke as an adult. The relationship between early smoking initiation and reduced odds of quitting smoking is partially explained by greater nicotine dependence levels found among early initiators.[13] Essentially, adolescents who begin smoking early also smoke at higher rates (i.e., more cigarettes per day) and have higher levels of nicotine dependence, and in turn have more difficulty quitting smoking.

Motivation versus Success among Adolescents

Most adolescents fail in their quit attempts, but not for lack of trying. Several studies have shown that the majority (two-thirds or more) of adolescent smokers want to quit smoking, and most report having tried to quit during the past year.[14-16] Unfortunately, when adolescent smokers try to quit smoking without assistance, they almost always fail. The relapse rate has been estimated at 90-95%[17-19] with most returning to smoking within a month of the quit attempt.[20-22] Adolescents who quit smoking while taking part in a cessation program do fare somewhat better, yet relapse rates are still quite high (88% on average at 3-6 months post-treatment).[19] Thus, identifying treatments that have the potential to increase cessation success among adolescents is a critical issue.

Overview of Types of Smoking Cessation Interventions

Smoking interventions for adolescents have included pharmacotherapy, behavioral approaches (such as school and community-based programs), and tobacco control policies; these interventions have had mixed results (for reviews, see [19, 23, 24, 25]). Detailed information about pharmacotherapies is available in Chapter 1, and detailed information about behavioral approaches is included in Chapter 2. While tobacco control policies are not the focus of this report, they are reviewed briefly in this section.

Tobacco Control Policies and Media Campaigns

Tobacco control policies can include education, controlling youth access, increasing taxes, advertising bans, and smoking bans,[26] including tobacco-free school policies. These control policies can prevent the initiation of youth smoking, and can also serve as an impetus for youth tobacco cessation. For example, adolescent and young adult quit rates are increased by higher cigarette prices,[27, 28, 29] worksite public smoking restrictions[29] and other policies such as age restrictions, packaging, limits on free distribution, and point-of-sale checks using underage buyers to enforce retail outlets' compliance with tobacco laws.[30] Strong enforcement of these anti-tobacco policies discourages the use of tobacco products. Further, communication of these policies and consequences of violating them is important for reducing use.[18] For these reasons, advocating tobacco control policies is critical in the fight to promote youth tobacco cessation.

Tobacco-free school (TFS) policies have also been shown to reduce youth smoking, and students who attend schools with enforced TFS policies are less likely to use tobacco.[31,32] An example of a comprehensive TFS policy is the prohibition of any tobacco use by students, staff, and visitors on school grounds or at school events. Students who violate TFS policies face penalties such as warnings, parent conferences, suspension, conducting community services, and/or educational alternatives to suspension.[31] Resources are available for alternative education programs including the American Lung Association's four-week program "Alternative to Suspension" that is used in schools throughout the country. However, none of these alternative programs has been adequately tested for effectiveness.

One state (North Carolina) has developed a statewide campaign to promote the adoption of TFS policies, and developed a model policy for schools to use.[31] Support for school districts in North Carolina includes training, consultation and technical assistance, a peer network, TFS signs, and other resources. Currently, all 115 North Carolina school districts have a tobacco-free school policy in place (http://nctobaccofreeschools.com).

Media campaigns can also reduce youth smoking by preventing smoking initiation and/or increasing cessation rates. While a number of studies have assessed the impact of media campaigns on prevention of adolescent smoking, few studies have focused on the effect on adolescent smoking *cessation* specifically. In one study, researchers examining a 3-year anti-smoking media campaign in South Carolina, Florida, Texas, and Wisconsin found that adolescent smokers exposed to the campaign

were slightly less likely to report 30-day smoking than those in the control condition. In another study, adolescent exposure to a media campaign for a quit-smoking website was assessed. Results showed that one quarter of the adolescents surveyed were aware of the site, were interested in quitting, and visited the site. However, data on actual quit rates was not available.[34] Finally, in a survey of youths exposed to several antismoking advertisements, results showed that younger adolescents (aged 12-13) who had seen or heard antismoking advertisements were less likely to become established, regular smokers (although this effect did not exist for adolescents aged 14-15[35]). Overall, media campaigns can reduce youth smoking, although the extent to which they help youth actually quit is not clear.

Tobacco Control Policies and Media Campaigns in Virginia

In Virginia, a number of tobacco control policies exist, including several laws that aim to reduce the sale of tobacco to minors and to restrict tobacco use in certain environments. For example, proprietors must post signs indicating that the sale of tobacco products to those under 18 is prohibited by law; employees must be trained in tobacco control laws; and internet sales of tobacco products to minors are prohibited. In addition, smoking is prohibited in certain areas: the interior of elementary, middle, and high schools and school buses, childcare centers that are not designated as residences, hospital emergency rooms, public restrooms of healthcare facilities, restaurants, health departments, state buildings and state vehicles (Virginia Code §§ 15.2-2820 to 15.2-2833; § 18.2-371.2). However, there is no license suspension for the sale of tobacco products to minors, and the Virginia tax rate is only 30 cents per pack (§ 58.1-1001). Virginia's tax rate is comparably low—the state is 49th in the nation for tobacco taxes.[36]

Virginia schools also have policies on student use and possession of tobacco and other drugs, although each school division develops their own specific policies and consequences for violation. The Virginia Department of Education provides school districts with guidance and sample policies,[37] although these example policies are limited in their scope. Further, data on the exact types of policies, and extent to which these policies are in use and enforced in Virginia is not currently available.

Since 2002, Virginia has conducted several antismoking media campaigns, including television and radio advertisements, as well as street and internet marketing. Notably, research conducted every 6 months on the "ydouthink" campaign has shown that, since 2003, most adolescents (75-79%) are aware of the campaign.[38] While no causal relationship can be made between marketing and youth smoking prevalence, smoking rates among high school students in Virginia have decreased from 21.9% in 2003 to 15.5% in 2008.[10]

Overall, although Virginia has conducted impressive antismoking media campaigns, the state's tobacco control policies are limited relative to many other states.

Purpose, Scope, and Organization of this Report

The purpose of this report is to provide an overview of youth smoking cessation interventions, including pharmacotherapies and psychosocial/behavioral interventions. Interventions and services available in Virginia will also be reviewed. In addition, barriers to these youth smoking cessation interventions will be discussed. Finally, recommendations will be made about how Virginia can best use its resources to improve smoking cessation interventions for youth.

Specifically, Chapter 1 provides an overview of pharmacotherapy for adolescent smoking cessation, and covers the existing literature in this area. Chapter 2 reviews behavioral approaches to adolescent smoking, including two evidence-based programs. Chapter 3 describes interventions and services in Virginia, including behavioral programs, insurance coverage, and the state quit line. Recommendations for future actions are presented in Chapter 4.

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Chapter 1

Pharmacotherapy for Adolescent Smoking Cessation

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Pharmacotherapy for Adolescent Smoking Cessation

--- Summary ---

- Although there are seven FDA-approved medications for adult smoking cessation, no medications can yet be recommended for use with adolescents based on insufficient evidence of their efficacy in adolescents.

- Over 100 randomized clinical trials of nicotine replacement therapy (NRT) and bupropion (BUP) have been conducted with adults; only 4 randomized clinical trials have been conducted with adolescents, and few are currently in progress.

- NRT for adolescent smoking cessation has been tested in two open-label trials and two randomized trials. The two open-label trials had very low quit rates. One randomized trial had high quit rates but no effect of NRT other than reduced craving; the other found that nicotine patch resulted in greater abstinence rates than placebo at the end of treatment and 3-month follow up.

- BUP for adolescent smoking cessation has been tested in one small open-label trial and two randomized control trials. The open-label trial had high abstinence rates but low treatment completion rates. The two randomized trials showed no effect of a 150 mg dose. The one randomized trial that tested a 300 mg dose found it was better than placebo for achieving short-term abstinence.

- Across the seven published trials, NRT and BUP were found to be safe and well-tolerated in adolescents.

- Current PHS Clinical Practice Guidelines recommend referral to psychosocial intervention as the most appropriate intervention for adolescent smokers.

Pharmacotherapy for Adolescent Smoking Cessation

Background Information on Pharmacotherapy for Adolescent Smoking Cessation

Introduction to the Extant Literature and Clinical Recommendations

The large majority of randomized cessation trials with adolescent smokers have tested psychosocial interventions. More recently, initial trials testing the effects of pharmacotherapy on adolescent smoking cessation have begun to appear in the research literature. Compared with other areas of smoking cessation research (e.g., adolescent psychosocial treatment research; adult pharmacotherapy and psychosocial treatment research) the amount of research to date devoted to testing pharmacotherapies with adolescent smokers is minimal, consisting of only seven published studies. This small set of studies varies in terms of type and dose of pharmacotherapy tested, research design used, and characteristics of the samples. Further, results from these trials have been largely disappointing.

Reflecting the state of the research literature, current federal clinical practice guidelines caution that there is "insufficient evidence" at this time to recommend pharmacotherapies for the treatment of adolescent smoking [1]. Rather, the guidelines recommend referral to appropriate psychosocial interventions (e.g., school- or community-based, individual counseling) as the most appropriate front-line treatment for adolescent smokers.

Purpose of this Chapter

The purpose of this chapter is two-fold. First, it is to provide more detailed information about the current state of knowledge related to pharmacotherapies for adolescent smoking cessation, including preliminary information about their safety, acceptability, and efficacy. Second, it is to make some recommendations regarding the use of pharmacotherapies for adolescent smoking cessation. Additional recommendations regarding future directions in this area are included in Chapter 4.

Pharmacotherapies Tested with Adolescents: Evidence from Adult Trials

Although there are seven FDA-approved first-line medication treatments for adult smoking cessation (five different forms of nicotine replacement therapy, bupropion, and varenicline), none of these is currently recommended for treatment of adolescent smokers based on insufficient evidence. Tests of medications in adolescent smokers have been limited to nicotine replacement therapy and bupropion. Below, these medications are briefly described and the rationale for their use in adult smokers is summarized.

Nicotine Replacement Therapy (NRT)

Nicotine is the addictive ingredient in cigarettes; when smokers stop smoking, they commonly experience nicotine withdrawal which can involve craving, irritability, depression, sleep disturbance, hunger and weight gain, and difficulty concentrating. These symptoms subside when an individual returns to smoking, so experiencing withdrawal symptoms presents a significant risk for relapse to smoking. NRT is designed to reduce or prevent withdrawal symptoms by delivering a steady dose of nicotine (without the carcinogens and toxic carbon monoxide involved in smoking) to individuals while they are trying to quit. It is available over-the-counter without a prescription.

The efficacy of NRT for adult smoking cessation has been documented in over 90 clinical trials and is associated with approximately doubling the odds of achieving long-term abstinence compared with treatment with placebo.[1-3] There are five forms of NRT that are considered first-line treatments for adult smoking cessation. These include: nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, and nicotine patch. There is some evidence that combinations of different NRT forms may be more effective than using a single form of NRT. Only two forms of NRT (patch and gum) have been tested with adolescents, and no combinations of NRT have been tested with adolescents.

Bupropion SR (Sustained Release)

Bupropion SR (BUP) is another medication that is considered a first-line treatment for adult smokers. In adults, BUP, a dopamine and norepinephrine reuptake inhibitor and nicotine receptor antagonist, produces robust abstinence rates relative to placebo. It is a non-nicotine antidepressant prescription medication sold under the name Zyban for smoking cessation and sold under the name Wellbutrin for treatment of depression. However, the efficacy of BUP for smoking cessation does not appear to be due to its antidepressant effects. Rather, BUP may also reduce the severity of nicotine withdrawal symptoms, making it easier for smokers to maintain abstinence during a quit attempt. Like NRT, BUP has been widely tested (24 trials in adults) and found to roughly double long-term abstinence rates compared to placebo. Evidence from early BUP trials suggested that it may be superior to nicotine patch for adult smoking cessation.[4, 5] Most adult trials have tested a 300 mg dose of BUP, a few have tested 150 mg. BUP can also be used in combination with NRT, although it is not clear whether the combination is more effective than either alone.[1] In adolescents, both BUP alone and BUP combined with NRT have been tested.

Rationale for using Pharmacotherapies with Adolescent Smokers

Because NRT and BUP appear to work primarily by reducing or preventing withdrawal symptoms, the application of these treatment approaches to adolescent smoking cessation presumes that adolescents smoke at a level that results in dependence on nicotine, and that smoking cessation produces withdrawal symptoms in adolescence.

There is considerable debate about the nature and course of nicotine dependence during adolescence[6-8]. Compared with smoking behavior among adults, adolescent smoking tends to be lighter on average and less regular; it is more likely to be non-daily than adult smoking, and it may be more situation-specific than adult smoking.[9] This lighter/less regular pattern of smoking, coupled with emerging concerns about the neurotoxic effects of nicotine on the adolescent brain, have given some researchers and clinicians reservations about treating adolescents with pharmacotherapy in general and NRT in particular.

However, an early comprehensive review[10] of studies involving adolescent smokers concluded that between 20% and 60% of adolescent smokers meet clinical criteria for nicotine dependence, with the higher proportions found in studies of daily and/or heavy adolescent smokers. More pertinent to the issue of pharmacotherapy, across studies, a large majority of adolescent smokers (two-thirds or more) report experiencing withdrawal symptoms when they stop or try to reduce their smoking. Though this early evidence was limited by the fact that it relied on retrospective self-reports of withdrawal symptoms, more recent carefully controlled laboratory studies confirm that adolescent smokers reliably experience withdrawal symptoms, craving, and increased negative mood when they stop smoking,[11-13]and that returning to smoking eliminates the symptoms.[14,15]

In sum, the combination of: 1) low quitting success among adolescent smokers; 2) evidence for dependence and withdrawal among daily and relatively heavy adolescent smokers; and 3) the doubling of long-term abstinence rates associated with pharmacotherapy in adult smokers provide the basis for exploring the potential efficacy of pharmacotherapy among adolescent daily/heavy smokers.

Pharmacotherapy for Adolescent Smoking Cessation: Review of the Evidence

Adolescent Cessation Trials Testing NRT: Open-Label Trials

The first pharmacotherapy trial conducted with adolescents[16] was a relatively small NRT trial, which enrolled 22 adolescents (68% female) between the ages of 13 and 17. Participants were heavy daily smokers, smoking 20 or more cigarettes per day at baseline. This trial was a non-randomized open-label trial, meaning all participants received active NRT; there was no control group that received a placebo. The NRT regimen consisted of a 22 mg nicotine patch daily for 6 weeks followed by an 11 mg patch daily for 2 weeks. In addition, all participants received relatively intensive psychosocial treatment, including weekly individual behavioral counseling and group support for 8 weeks. The rate of treatment completion was high (86.4%) but the abstinence rates (verified by exhaled carbon monoxide levels) were disappointing: 13.6% at the end of treatment, 4.5% at 3-month follow up, and 4.5% at 6-month follow up.

A subsequent, larger, open-label trial was conducted by the same research group[17]. This trial enrolled 101 adolescents (41% female) between the ages of 13 and 17; participants were again daily smokers but only required to smoke 10 or more cigarettes per day (the average cigarettes smoked per day was 20). NRT consisted of a

15 mg nicotine patch daily for 6 weeks, with participants instructed to remove the patch overnight. In an attempt to isolate the effects of the patch alone on smoking behavior, additional treatment was minimal consisting only of 10-15 minutes of brief counseling if the adolescent requested it. Despite the procedural differences in this study, the outcomes were strikingly similar: the large majority of participants (70.3%) completed treatment but only 10.9% were confirmed abstinent at the end of treatment, and only 5% were abstinent at 3- and 6-month follow ups. In sum, abstinence rates at follow up in the first two trials approximated rates obtained during unassisted quit attempts in adolescent smokers.

Adolescent Cessation Trials Testing NRT: Randomized Trials

Two randomized NRT trials have since been reported. The first of these[18] enrolled 100 adolescent daily smokers (57% female) between the ages of 13 and 19; participants smoked at least 10 cigarettes per day. In this trial, smokers were randomly assigned to receive either nicotine patch or placebo patch. Patch treatment lasted for 10 weeks; those in the nicotine condition received 14 or 21 mg per day for the first 6 weeks and 7 or 14 mg per day for the next 4 weeks, with doses depending on cigarettes per day. This was a double-blind study meaning neither the participants nor the investigators knew who was getting a nicotine patch and who was getting the placebo until the blind was broken at the end of the study. In addition to the patch, all participants received intensive cognitive behavioral therapy plus incentives for smoking abstinence using a voucher-based contingency management procedure.

Unfortunately, despite all of its methodological and clinical strengths, this study was challenged by low adherence rates; only 53% of the adolescents completed treatment. At the end of treatment, the abstinence rates were encouraging with 28% of those assigned to the nicotine patch group confirmed abstinent versus 24% of those in the placebo group, but the difference between the groups was not statistically significant. Because follow-up rates were so low at 3-month and 6-month follow up (26% and 20%, respectively), the data were not reported.

The second randomized NRT trial[19] involved 120 adolescent daily smokers (70% female) between the ages of 13 and 17 who smoked 10 or more cigarettes per day. In addition, smokers in this trial were required to meet standardized criteria for substantial nicotine dependence. Three-quarters of these participants incidentally had one or more psychiatric diagnoses, reflecting the high rate of co-occurring disorders that characterizes the population of adolescent heavy smokers. The nicotine patch regimen consisted of a 21 mg patch per day for 12 weeks. In the nicotine gum group, heavier smokers (24 or more cigarettes per day) received 4 mg gum for 12 weeks; those who smoked less than 24 cigarettes daily received 2 mg gum. All participants received cognitive-behavioral group therapy weekly throughout the 12-week trial.

Like the earlier trial, this one suffered from high attrition, with only 44% completing treatment. Because treatment completion rates were so low, the investigators analyzed quit rates 2 weeks into the treatment trial when most participants were still in the trial. These analyses found abstinence in the patch group (18%) to be significantly higher than in the placebo group (2.5%). Abstinence in the

gum group (6.5%) did not differ from the two other groups. At the end of treatment, and again at 3-month follow up, 20.6% of those assigned to patch were confirmed abstinent compared with 8.7% in the gum group and 5% in the placebo group. At these time points, the difference between the effect of patch versus placebo was borderline significant.

NRT: Summary of Efficacy Data

In sum, the smoking cessation outcomes for NRT have been mostly disappointing to date. The two open-label trials had high compliance but very low quit rates that were about the same as quit rates attained when adolescents quit unassisted. The first randomized trial had high quit rates but nicotine patch did not differ from placebo and adherence was low. The second randomized trial showed significantly better quit rates for nicotine patch two weeks into the 12-week treatment trial, and a borderline effect favoring patch over placebo at end of treatment and 3-month follow up. No effects of nicotine gum were found. This trial too had low treatment adherence and study completion rates.

When interpreting the efficacy data, it is important to consider that the adolescents enrolled in these trials are not typical adolescent smokers; they are uncharacteristically heavy daily smokers who would be expected to have the highest failure rates within the larger population of adolescent smokers.

NRT: Other Reported Effects

The four NRT trials varied in the extent to which they measured and evaluated other potential effects of NRT. The two open-label trials noted that the adolescent smokers on nicotine patch did report significantly fewer cigarettes per day,[16,17] lower cotinine levels,[17] and less severe withdrawal symptoms[16,17] over the course of the study. Without a placebo control, it is not possible to attribute these effects to the medication. In the first placebo-controlled trial[18], nicotine patch resulted in significantly less severe craving and withdrawal symptoms than placebo patch. This is in contrast to an earlier pre-clinical study,[19] in which nicotine patch was no better than placebo in reducing craving or withdrawal in abstaining adolescent smokers. The second placebo-controlled trial[20] did not report effects on withdrawal; in this trial, adolescents in all groups reported fewer cigarettes per day over the course of the study but there were no differences between the groups in the amount of reduction. Biochemical reductions (i.e., CO and saliva thiocyanate concentrations) were not significant.

NRT: Data on Safety and Tolerability

Data from the four NRT trials provide support for the safety and tolerability of this medication in adolescents who are heavy daily smokers (at least half a pack of cigarettes daily). Information on side effects is presented slightly differently in each paper, so it is not possible to calculate the average prevalence of each side effect reported across studies. However, it is clear based on the information presented that, although side effects are reported at relatively high rates (40-70%), they tend to be mild. In three of the four studies, none of the participants dropped out due to side

effects. In the remaining study,[17] 5% of participants dropped out due to adverse events but it is unclear that it was due to side effects of the medication (there was a high rate of upper respiratory infections in the study sample).

In the two open-label studies,[16,17] it is not possible to attribute side effects reports to the active patch since there was no placebo comparison. In the first randomized trial[18] the only side effect to differ between nicotine patch and placebo was headaches, which were significantly more likely to be reported in the placebo group. This raises the possibility that headache may be part of the withdrawal syndrome successfully reduced by nicotine patch; this possibility warrants further exploration but must be considered conjecture at this point. In the second randomized trial[20] side effects due to nicotine patch and gum were significantly worse in the nicotine groups than the placebo group, but they tended to be mild and specific to the mode of drug administration (i.e., nicotine patch, applied to the upper arm, produced skin reaction, arm/shoulder pain, and itch; nicotine gum produced itch, sore throat and hiccups). It is noteworthy that this trail used a higher dose (21 mg) patch for all participants, in contrast to the first randomized trial which tailored nicotine dose to the number of cigarettes smoked per day.

Adolescent Cessation Trials Testing Bupropion

The three remaining pharmacotherapy trials with adolescent smokers involved BUP. The first of these was an open-label pilot study,[21] involving 16 adolescent smokers (37.5% female) between the ages of 12 and 19, 11 of whom also had an ADHD diagnosis. Adolescents were required to smoke 5 or more cigarettes daily to be eligible for the study; on average, participants were smoking a pack of cigarettes per day. As in most adult trials, a 300 mg dose of BUP was used (150 mg BUP SR twice daily). The medication phase lasted for 6 weeks and included weekly outpatient visits and two sessions of brief counseling. Only 31% completed 6 weeks of treatment, so the investigators chose to analyze BUP effects after 4 weeks of treatment when 56% of participants were still in the trial. After 4 weeks, 5 of 16 participants (31%) were confirmed abstinent. Cigarettes per day, exhaled CO levels, and craving decreased over the course of the trial; depression and ADHD symptoms remained level.

In a large randomized clinical trial of BUP for adolescent smoking cessation,[22] 312 adolescents (46% female) between the ages of 14 and 17 were enrolled. Inclusion criteria were stringent relative to prior trials: participants had to smoke 6 or more cigarettes daily, have a baseline exhaled CO level of 10 parts per million or more, report two or more prior unsuccessful quit attempts, and could not meet criteria for a concurrent psychiatric diagnosis. In this 6-week treatment trial, smokers were randomly assigned to receive BUP SR 150 mg per day, 300 mg per day, or placebo; all received brief counseling.

Treatment completion rates in this trial were excellent (higher than 80% in all three conditions; 84% overall). At the end of the treatment phase, smokers in the 300 mg group had higher rates of confirmed abstinence (29%) than those in the placebo group (16%); abstinence rates for the 150 mg group (23%) did not differ from placebo. During the medication trial, 300 mg BUP was associated with higher confirmed

abstinence rates than placebo in 4 of the 6 weeks while 150 mg BUP never differed from placebo.

The rates of abstinence above[22] were confirmed using exhaled CO levels; this is the standard method of confirmation used in most adolescent smoking cessation trials. In this trial, self-reported abstinence was also confirmed by urinary cotinine levels (a more sensitive biomarker with a longer half-life than CO) at 6 weeks; these rates of abstinence are markedly lower than the ones confirmed by CO (14% for 300 mg BUP, 11% for 150 mg BUP, and 6% for placebo) but still demonstrate a significant effect of 300 mg BUP over placebo. Differences in abstinence were no longer significant a week later, nor at follow up (week 26). The trial demonstrates efficacy of BUP SR 300 mg for increasing short-term abstinence, an effect that opens the door to testing a number of potential treatment enhancements, such as the addition of more intensive psychosocial intervention, and extension of the medication trial over a longer period of time.

Combining NRT with BUP

The final pharmacotherapy trial published to date with adolescent smokers[23] is a trial in which all participants received nicotine patch and were also randomly assigned to receive either 150 mg BUP SR or placebo. This double-blind trial enrolled 211 adolescent smokers (31% female) between the ages of 15 and 18. Participants had to smoke 10 or more cigarettes daily, have 1 or more prior unsuccessful quit attempts, meet criteria for nicotine dependence, and could not meet criteria for current major depressive disorder. The treatment phase of this trial lasted for 10 weeks during which time all participants received group skills training weekly. The dose of nicotine patch varied depending on participants' daily smoking rate. Treatment completion rates were high (81-87%) but no effect of BUP was found. At the end of treatment, confirmed abstinence rates were 23% for NRT + BUP and 28% for NRT + placebo; 16 weeks later, confirmed abstinence rates were 8% and 7% respectively.

This well-designed trial highlighted methodological and clinical points that warrant further attention in this field. First, high treatment completion rates can obscure important information about actual treatment adherence. In this trial, attendance at the weekly sessions (including the skills training sessions) was good, yet compliance with medication was poor; only 29% of smokers reported using all of their nicotine patches during at least 5 weeks, and only 22% reported taking BUP for at least 6 weeks. End-of-treatment abstinence was predicted by skills training participation ($p=.05$) and nicotine patch use ($p=.06$), but not by BUP metabolite levels. These findings highlight the importance of assessing and explicitly reporting completion and adherence rates separately in pharmacotherapy trials and of measuring their relationship to cessation outcomes. Such analyses may lead to a more complete understanding of the relative effects of medication and psychosocial treatment elements.

BUP: Summary of Efficacy Data

As with NRT, the research base for BUP is simply insufficient to yield firm conclusions. Here we provide preliminary observations that require further corroboration. Of the two BUP doses tested to date, 300 mg shows more promise than 150 mg; neither trial that tested 150 mg showed significant effect of BUP at that dose. The open-label trial[21] with 300 mg BUP enrolled a sample with high rates of co-occurring mental health and psychosocial challenges; in this sample treatment completion was low, but rates of abstinence were promising for those who adhered to treatment. Conclusions are limited by the lack of a placebo control, but this initial trial showed sufficient acceptability and promise of BUP to warrant more research. A subsequent randomized trial[22] supported the efficacy of 300 mg BUP for short-term abstinence in a sample of heavy daily smoking adolescents who did not have co-occurring psychiatric disorders.

As before, it is important to be mindful of the selective nature of the study samples in this area. Smoking quantity and frequency are among the strongest predictors of cessation failure, and adolescents enrolled in these trials conservatively fall within the top quartile of adolescent smoking rates.

BUP: Other Reported Effects

The researchers also evaluated medication effects on other clinically-relevant outcomes. In the initial open-label trial,[21] cigarettes per day, exhaled CO levels, and craving decreased significantly over the course of the trial; levels of depression and ADHD symptoms remained level. Without a placebo control, these effects could not be attributed specifically to BUP. In the combined NRT BUP randomized trial[23] self-reported craving, cigarettes per day and depression all declined during the study but not differentially between groups. In the randomized trial that compared 300 mg BUP to 150 mg and placebo, many other outcomes were also assessed, but medication effects on these outcomes have not yet been published.

BUP: Data on Safety and Tolerability

In general, BUP has been well-tolerated in these trials. Three participants dropped out of the open label 300 mg trial due to side effects, though the characteristics of this small sample were clinically complicated (that is, participants had multiple issues, such as co-occurring psychiatric disorders). No participants dropped out of the combined NRT/BUP trial with the 150 mg dose of BUP. In the randomized trial comparing 300 mg BUP to 150 mg and placebo, 4% of participants dropped out due to side effects. However, in this trial, only two side effects (headache and cough) differed significantly between the medication and the placebo groups, and in both cases the side effects were *worse* in the placebo group than in the medication group. Therefore, we conclude that BUP is safe and well-tolerated in adolescent smokers of 5 or more cigarettes per day.

Conclusions

The field of pharmacotherapy research for adolescent smoking cessation is extremely limited, particularly when compared to pharmacotherapy research for adult smoking cessation. Among adults, many more trials have been conducted per medication type, a broader range of medications has been tested, and more combinations of medications have been tested. In adolescents, a total of three open-label trials and four randomized trials have been published.

End-of-treatment abstinence rates, while encouraging in several cases, are often difficult to attribute to the medication being tested, either because there was no placebo control, or because the medication effects were difficult to disentangle from intensive background treatment, or because adolescents tend to take the medication at low rates. Average quit rates at follow up tend to fall below those obtained in psychosocial treatment trials with adolescents. Psychosocial treatments have added advantages in that they can include a broader diversity of adolescent smokers and tend to have better treatment retention than pharmacotherapy trials.

On the other hand, adolescents enrolled in pharmacotherapy trials are specifically selected to smoke more frequently and more heavily and to be more dependent on nicotine than those in psychosocial trials, so direct comparisons of quit rates are potentially misleading. Further, as illustrated by several trials described in this review, heavier smoking adolescents may have more co-occurring mental health problems and psychosocial issues compared with lighter-smoking adolescents on average, and these issues can present serious challenges for treatment completion and achieving long-term abstinence. It is important for clinical outcomes in pharmacotherapy trials to be evaluated in the context of the population being treated.

Adolescent smoker quit rates in pharmacotherapy trials also fall well below adult quit rates. There are several factors that may be implicated in the lower quit rates in adolescents. First, the adolescent trials are hindered by more difficulties in recruiting, consenting, and retaining participants. As a result, even well-designed trials tend to be statistically under-powered, potentially failing to detect small to medium effects of medication. Second, medication compliance tends to be poor, further limiting researchers' ability to evaluate actual medication effects. Third, the length of medication treatment tends to be briefer in adolescent trials compared with adult trials (e.g., 6-10 weeks rather than 12 weeks). While these decisions are likely influenced by feasibility and acceptability concerns, an inadequate course of medication should not be expected to result in lasting behavior change. Fourth, self-report in adolescent smoking cessation trials tends to be less accurate than in adult trials. As highlighted in the randomized BUP trial described above[22], the standard use of CO for biochemical verification probably does not detect a substantial amount of misreporting in these trials. If misreporting is equal across treatment groups, it contributes to measurement error and can obscure actual medication effects. In sum, to accurately interpret findings from adolescent cessation trials, consumers of this research should recognize these limitations. Institutions that fund such trials should prioritize larger sample sizes, more

sensitive and specific biomarkers, and precise measures of medication dose (e.g., blood levels of BUP[23]).

Even if adequate enrollment, medication compliance, and verification are achieved, pharmacotherapies designed and approved for adults may just not work as well with adolescents. For one thing, adult medications can have different and even opposite effects on children and adolescents[24] and the tendency to move directly from adult to adolescent randomized clinical trials often omits important pre-clinical dose-response studies of medication effects in adolescents.

Second, some research suggests that adolescence is characterized by heightened emotional reactivity, sensation seeking, and reward sensitivity, while the ability to regulate one's behavior develops relatively late in adolescence.[25,26] This could mean that adolescents find it more difficult than adults to keep from smoking, even under minimally tempting circumstances, which could undermine the efficacy of treatment approaches generally.

Another factor may be that the mechanisms underlying smoking may not be the same for adolescents and adults. For example, several studies have reported that even adolescent daily smokers experience fewer or less intense symptoms of nicotine dependence than adults[10, 27] (although the opposite has also been found[28]). If adolescent smoking is influenced less by internal factors such as nicotine dependence and more by external factors like smoking by peers and family members, the potential efficacy of pharmacotherapies might be reduced in adolescents.

Finally, the experience of smoking abstinence in adolescents may differ from adults. In adults, NRT[29,30] and bupropion[31,32] appear to work, at least in part, by reducing nicotine withdrawal. Even if adolescents experience withdrawal symptoms that are similar to those experienced by adults, the degree to which these symptoms precipitate smoking relapse is unclear. If withdrawal symptoms are less closely linked to relapse in adolescents compared with adults, the efficacy of medications designed to address withdrawal in adolescents would be expected to be limited. In sum, until we better understand the unique experiences of adolescent smokers and create developmentally-appropriate interventions for adolescents, it is likely that treatments effects will remain limited.

Consistent with recent reviews and PHS Clinical Practice Guidelines[1], we conclude that there is currently insufficient evidence to recommend the use of pharmacotherapy for adolescent smoking cessation. According to the clinical practice guidelines, referral to appropriate psychosocial intervention (e.g., school- or community-based, group or individual counseling) is the most appropriate front-line treatment for adolescent smokers. Although these interventions produce relatively low overall quit rates,[33] they do significantly increase the odds of quitting over no treatment.

While pharmacotherapies may be considered, they should be prescribed only with close monitoring and after careful consideration of the adolescent's smoking rate, history of failed quit attempts, and current motivation to quit smoking.[34] The inconclusive results from adolescent pharmacotherapy trials suggest the limitations of off-label prescription of these medications to adolescents. These findings should also

raise concerns about possible off-label prescribing of newer medications, such as varenicline, that are untested among adolescents.

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Chapter 2

Behavioral Approaches to Adolescent Smoking

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Behavioral Approaches to Adolescent Smoking

--- Summary ---

- Recent reviews have concluded that *there is now sufficient evidence to recommend behaviorally-based programs* to help youths quit smoking.

- Although behavioral programs are based on various theoretical approaches, several approaches show some advantages over others: cognitive behavioral, stages of change, and contingency management.

- Effective programs have several important characteristics, including treatment intensity--effective behavioral programs *tend to have at least five sessions*.

- Effective treatment can also be provided in medical settings. However, numerous studies indicate that while health care providers ask adolescents about tobacco use, few providers offer counseling and follow-up. When interventions in medical settings are delivered, several studies have shown positive results.

- Telephone counseling is easy to access and can effectively overcome some barriers to the delivery of youth smoking cessation services. Some US quit lines (35 of 52) offer counseling to some or all youth callers.

- Both effectiveness and efficacy trials are important to evaluate behavioral programs, and there can be significant value in using both approaches.

- A cost-effectiveness analysis is an important part of a comprehensive evaluation.

- Program dissemination and adoption of effective programs is critical.

- Research has identified two evidence-based behavioral programs - Project EX and Not-On-Tobacco (N-O-T).

Behavioral Approaches to Adolescent Smoking

Evidence for Adolescent Smoking Cessation

The public health burden of youth smoking has led to a number of reviews of adolescent smoking cessation programs over the years.[1-7] Recent reviews have taken on a different character than those in the past by concluding that *there is now sufficient evidence to recommend behaviorally-based programs* to help youths quit smoking.[1, 6-8] Two recent meta-analyses of high-quality adolescent smoking cessation studies provide additional guidance. Meta-analytic studies synthesize the results or outcomes of multiple studies that focus on a particular topic or related set of research hypotheses, and their purpose is to determine the effect size (treatment effect) of these studies, taken together. Sussman, Sun, & Dent[8] conducted the first formal meta-analysis of adolescent smoking cessation programs. They searched electronic databases and unpublished manuscripts from 1970 to 2003, resulting in 48 experimental and quasi-experimental studies across broad range of behavioral interventions for use in the analysis. Overall, they found that cessation programs offered smokers a 2.9% absolute advantage in quitting over control conditions and increased the likelihood of quitting by 46%. In general, group-based behavioral cessation programs showed the greatest success, and only two federally-recognized, evidence-based behavioral programs were identified – Project EX[9] and the American Lung Association's (ALA) Not On Tobacco (N-O-T) program.[10, 11] The second meta-analysis was conducted by the Cochrane Collaboration.[1] This study used stringent criteria to identify 15 studies for review, and found that tobacco cessation treatment significantly increased the likelihood of cessation over control conditions. This review identified N-O-T as the only program of promise based on the number and outcome of evaluation studies. Both of these meta-analytic studies are outstanding resources, and both are highly recommended. Recently, Sue Curry and colleagues published another exceptional review of adolescent smoking cessation,[6] which is also highly recommended. Among other findings, this review also reported that behavioral smoking cessation interventions for adolescents can be effective.

The Youth Tobacco Cessation Collaborative (YTCC) Blueprint[12] complements the above literature by providing implementation guidance for cessation programming. YTCC guidance includes suggestions such as (1) promoting a variety of science- and theory-based cessation strategies; (2) using interventions that are flexible and easily implemented in a variety of settings; (3) using interventions that can be replicated; (4) using quality control processes and mechanisms for standardization or accreditation; (5) including the intervention as part of comprehensive school- or community-based programming; (6) building on school- and community-based tobacco prevention and control mandates; (7) advocating for financial support via the government's Master Settlement Agreement with the tobacco industry; (8) developing consistent evaluation criteria; (9) developing best practice dissemination methods and criteria; (10) identifying promising implementation settings (e.g., schools, alternative settings,

churches, clinics, etc.); and (11) establishing a network for technical assistance, training, incentives, and widespread access.[11,12,13] Both behavioral approaches and related issues such as implementation are discussed in this chapter.

Purpose of this Chapter

This chapter provides a brief review of the literature on behavioral approaches to smoking cessation in order to provide some guidance to the state of Virginia in articulating its youth smoking cessation efforts. The chapter discusses a variety of behavioral approaches to youth tobacco cessation, and also covers innovative approaches, challenges, and key areas for future research. The chapter does not attempt to replicate the outstanding reviews cited above that are already available in the literature. Instead, it highlights information from those reviews that may be of assistance to Virginia researchers, practitioners, and policy makers as they collaborate to enhance the state's youth smoking cessation efforts.

This chapter also provides discussions of three specific topics/approaches that may also be helpful to Virginia decision makers. First, only two behavioral programs have achieved a sufficient evidence base: Project EX[14] and Not on Tobacco (N-O-T;[11,15)]. Both programs are offered in Virginia; thus, an overview of each is provided. Second, recent research has found that medical settings may hold promise for smoking cessation delivery to adolescents,[8] and thus a discussion of smoking cessation interventions in primary healthcare settings is presented. Third, smoking cessation quit lines have shown much promise with adult populations. Although there is only limited research with youth, the approach is viable enough for inclusion in this chapter.

Helpful Theoretical Approaches

Recently, Sussman and Sun[7] conducted a review of sixty-four cessation studies; they discovered five different theoretical foci in these studies. These include (1) social influence, (2) cognitive behavioral, (3) motivational, (4) medical, and (5) other approaches. Importantly, many programs used bits and pieces of different theories. *Social influence* approaches are designed to counteract the social forces that support smoking behavior.[7] *Cognitive behavioral* efforts address the characteristics of a adolescent's smoking behavior such as reasons for smoking (e.g., stress), smoking triggers (e.g., hanging out with friends), and self monitoring. Cognitive-behavioral approaches also provide adolescents with guidance on how to manage the urges and cravings associated with quitting, life stress, problem solving, and engage in healthy lifestyle behaviors such as improved nutrition and enhanced physical activity.[7, 16] As the name suggests, *motivation enhancement* approaches highlight the desire and benefits of changing to a smoke-free lifestyle. Motivational interviewing is a counseling technique used to promote behavior change.[17] It assumes that the responsibility for change lies within the person/client; the interventionist creates the conditions that promote motivation and confidence to change. Motivational interviewing techniques may be used to help the adolescent smoker address his or her ambivalence about

quitting[18]. Motivational approaches can also include contingency management or response-contingent reinforcement. These approaches attempt to decrease smoking by pairing reinforcement with quitting or reduction behaviors.[19] Finally, motivational approaches may also include the use of stages of change techniques.[7] *Medical approaches* include pharmacological adjuncts and recovery from addiction.

Sussman and Sun concluded that cognitive behavioral, stages of change, and contingency management theories showed some advantages over others. Three other studies reached similar conclusions about useful theoretical approaches for adolescent smoking cessation.[1,6,8] Combination approaches that involve stages of change and social influence also show promise. It is important to note that these same approaches are also effective with adults.[6] However, there exists no single theory of adolescent smoking cessation which suggests how social context, smoking history, and level of addiction may work together to influence key predictors of cessation (e.g., stages of change, motivation) and cessation itself.

Although the field has no unifying theory to inform adolescent smoking cessation, a variety of epidemiological studies have examined and identified psychosocial predictors of smoking cessation.[20-25] Some key predictors of cessation include smoking history, frequency of smoking, level of nicotine dependence, age of first cigarette use, [25-27] presence of family members or peers who smoke [20,28,29] motivation for quitting, and confidence in cessation.[25,30,31] Branstetter et al.[32] describe some of the uncertainty that still remains. For example, some studies have found no differences between quitters and non-quitters on psychosocial factors[29] or motivational variables.[33] Moreover, gender may influence the influence of individual, historical and contextual variables on cessation.[28]

One of the larger challenges in youth smoking cessation research involves the measurement of adolescent smoking behavior, [22,34-36] and specifically, of defining smoking abstinence in youths. Studies show that adolescent smoking patterns may be less regular than those of adults who do not have restrictions based on school and home environments. Adolescents may also define their quit status differently than do adults. For example, adolescents may not consider themselves quitters even after prolonged periods of abstinence.[2,35,36] We also know very little about how adolescents change their smoking patterns over time and how psychosocial and contextual factors may be related to changes in those patterns and to cessation outcomes.

Characteristics of Effective Treatments and Settings

In addition to research on theoretical approaches, there are a number of studies that have examined the characteristics of effective treatments. The next section summarizes findings from these studies. The information presented below may be helpful in determining intervention priorities for Virginia adolescent smokers.

Program intensity

Sussman and colleagues found that program (treatment) intensity was an important factor in determining the effectiveness of cessation programs. Specifically, they found that effective behavioral programs tended to have at least five sessions. This suggests that youth require multiple meetings in order to gain the benefit of a cessation intervention. Dino, Horn, and colleagues also found some interesting findings related to program intensity. These researchers found that an intensive cessation program (i.e., N-O-T) was equally effective for adolescents with a range of nicotine dependence[27] and initial stages of change.[30] In contrast, a brief 20-minute intervention was effective only with adolescents who had low levels of dependence and were moderately or highly motivated to quit.

Influence of Treatment Setting: Interventions in Primary Care

Most youth smoking cessation interventions are done in school settings, such as classrooms or school clinics. However, other settings have also been tested; these include medical clinics, community-based organizations, shopping malls, markets, worksites, and grocery stores. Sussman, Sun, and Dent[8] examined the influence of treatment setting. They found significant effects for school classrooms and school-based clinics, but not for medical clinics. However, in a more recent review, Sussman and Sun[7] found that medical settings did show a significant effect. Since 62% of adolescents see primary care physicians each year,[37] the delivery of smoking cessation interventions in health care settings provides excellent access to youth smokers. Healthcare providers have the opportunity to both ask about tobacco use, and when appropriate, provide treatment. National guidelines on smoking cessation recommend that healthcare providers address the issue of tobacco use with their patients by offering a simple and flexible set of strategies to help youth overcome a powerful addiction (also known as the "5 As"). Specifically, clinicians are advised to:1) ASK: Identify tobacco users and document their status; 2) ADVISE: Strongly urge all smokers to quit; 3) ASSESS: Identify the smokers who are willing to make a quit attempt; 4) ASSIST: Assist smokers to quit by helping with a quit plan, offering advice, and providing supplementary information; and 5) ARRANGE: Arrange the intervention and schedule a follow-up visit.[38]

Recommendations and guidelines for healthcare providers are provided for both brief (less than 10 minutes) or intensive (potentially multiple visits, provided by potentially multiple clinicians;[38]) counseling. Guidelines for addressing tobacco use during adolescent health care visits have also been developed by several professional organizations such as the American Medical Association and the American Academy of Pediatrics.[2] However, numerous studies indicate that while health care providers ask adolescents about tobacco use, few provide counseling and follow-up.[2,39,40,41] For example, data from the National Youth Tobacco Survey shows that only 33% of adolescents reported that they were told by a physician or dentist about the dangers of tobacco use.[42] Other research shows that young adult smokers are less likely to have received information from health care providers than from others.[43]

When medical or clinic-based interventions are delivered, several studies have shown positive results. For example, one study examined the use of an interactive computer program ("Pathways to Change") and brief motivational counseling during primary care visits. Results showed a 24% quit rate at two years.[44] Another study compared an intervention in a pediatric primary care setting to a usual care control condition, and results showed that smokers in the intervention condition were more likely to be abstinent at 6 months than those in the control condition.[45] In another study, smokers were identified during emergency room visits, at outpatient clinics, or at inpatient units, and were randomly assigned to receive brief advice or motivational interviewing. After three months, 20% of the motivational interviewing group had quit smoking while only 10% of those with brief intervention had quit.[46] One other study reported a reduction in smoking among adolescents who received motivational interviewing in hospital clinics or emergency room departments, although the reductions in smoking were small.[47] Barriers to more extensive use of effective smoking cessation interventions within primary care are discussed in Chapter 4.

Finally, very few physicians prescribe nicotine replacement therapy (NRT) to their adolescent patients—one study reported that only 17% of physicians were prescribing NRT.[48] This is not surprising, as current clinical guidelines do not recommend the use of pharmacotherapy for smoking cessation in adolescents.[38] For further information on the use of pharmacotherapies in adolescents, see Chapter 1.

Influence of Treatment Setting: Quit Lines

Telephone counseling is easy to access and can effectively overcome some barriers for youth smoking cessation. For instance, transportation isn't a problem; adolescents might share concerns more readily than in a face-to-face interview; counseling is delivered on an individual basis; counselors can adjust to each individual caller; and a structured protocol is possible.[49, 50] The resulting intervention is brief, focused, and personalized.

Few studies have examined the effectiveness of quit lines and/or telephone counseling for adolescents. In one study, researchers assessed the availability of services to youth under age 18 for all quit lines in the United States.[51] Results showed that 29 of 52 U.S. quit lines offer some form of counseling or specialized materials to youth callers. Of those, 28 U.S. quit lines were studied extensively to assess available services. Findings revealed that the resources provided by quit lines vary. For example, 16 of the 28 quit lines offered counseling services to those under 18. Of those that provide counseling services, the number of counseling sessions varies as does the need for parental consent. In addition, some quit lines that provide counseling for youth (46%) promote their services, and 43% used more than one type of promotion.[51]

While one study comparing telephone counseling with a self-help condition found no differences,[49] some states have been able to create and fund particularly effective quit lines, such as the California Smokers' Helpline (CSH). The CSH was extensively evaluated with more than 1,400 adolescents randomly assigned to an intervention group or a control group. Participants in the intervention group received telephone counseling and written cessation materials; participants in the control group received

only written materials. Results showed that more clients in the telephone counseling group than in the control group quit and remained abstinent for six months.[50]

Adolescence is a time when youth seek out adult behaviors. As such, the counseling protocol of the CSH framed quitting – not smoking – as the adult behavior.[50] Researchers also learned that a counselor's age is less important than his or her skill and enthusiasm in working with young people, and that striking an appropriate balance between empowering the adolescents and providing accountability is important. Also, researchers studying the CSH found that a flexible protocol allowed for discussion of topics interesting to adolescents, which builds trust and rapport with the counselor. CSH researchers concluded that there is an obvious need for adolescent quit lines, although it is unclear whether proactive counseling is the most cost-efficient way to provide the intervention.

Free & Clear, Inc. also provides state quit line services for adults and youth. One of the first youth quit lines to be established in the US by Free & Clear, Inc. is the Utah Youth Quit Line. This service has assisted thousands of adolescents, aged 19 and younger, and has a secondary target audience of the parents of those adolescents. The components of this youth quit line intervention are motivational interviewing and cognitive-behavioral therapy techniques, personal treatment from a highly skilled tobacco cessation specialist, non-judgmental support, and a flexible call schedule with the next call negotiated at the end of the intervention. With services from Free & Clear, Inc., youth can receive a single call or multiple calls, referrals to local resources for support, incentives for call completion, as well as written materials.

Newer approaches for intervention delivery

Both the Sussman and Sun[7] and Curry et al.[6] reviews provide summaries of novel approaches to youth smoking cessation. They identify promising channels such as internet, PC-based expert systems. For instance, both reviews cite a study by Mermelstein & Turner[52] that found a marginally higher 3-month quit rate when telephone calls and a website were paired with the N-O-T program than when the program was used alone. In addition, contingency management approaches show some promise. To illustrate, Tevyaw et al.[18] found that contingency management provides some short-term benefit for reducing smoking among college students. However, in general, both reviews conclude that there is insufficient evidence at this time to recommend any specific approach with confidence.

Other Important Issues for Behavioral Approaches

Decision makers should consider several additional issues regarding the selection and implementation of behavioral youth smoking cessation programs. Several of these are presented next.

Efficacy vs. effectiveness

Public health experts and youth tobacco cessation researchers recommend two types of program evaluation for behavioral interventions - effectiveness and efficacy

trials.[35] In *efficacy research,* program implementation is tightly controlled by scientific investigators. Highly controlled, randomized trials have been the gold standard for evaluating smoking cessation programs. However, critics argue that these highly controlled trials may not identify what programs will be effective in "real-world" settings. Thus, effectiveness research studies the intervention in real-world school or community settings, with less researcher involvement. The common assertion is that efficacy evaluation is high in internal validity, but may be less generalizable, whereas effectiveness evaluation is higher in external validity at the expense of rigor and control. It is not surprising that researchers traditionally favor efficacy, whereas practitioners prefer effectiveness.

There can be significant value in using both approaches. For instance, the developers of the N-O-T program took a two-pronged approach to evaluation.[11] They used both efficacy and effectiveness studies in order to provide information from both rigorous and real-world perspectives. Over the past 10 years, the N-O-T developers, in collaboration with the National Office of the ALA, local ALAs, schools, and communities across the US, conducted both efficacy and effectiveness studies with N-O-T. The N-O-T evaluation approach is also based on considerations of dissemination, adoption by practitioners, and long-term sustainability in multiple settings.

Cost-effectiveness

Scarce resources for tobacco control are the rule rather than the exception. As a result, public health decision makers at school, community, and state levels must try to maximize positive public health outcomes with the most efficient expenditure of resources possible; that is, achieving the best "bang for the buck."[53] One method for accomplishing this is to consider the cost-effectiveness of different intervention options.[54] Unfortunately, there has been very little research that examines the cost-effectiveness of youth tobacco cessation interventions. One exception is a paper describing a cost-effectiveness analysis (CEA) of the N-O-T program.[55] This study compared the cost effectiveness of N-O-T to that of a brief 20-minute intervention when used in school settings. The findings from this research indicated that adolescents who completed the N-O-T program were predicted to have an increased life expectancy of about 7 years more than adolescents who completed the brief intervention. Cost of program administration for each additional year of life expectancy for those completing N-O-T rather than the brief intervention was $442.65. These results suggest that N-O-T was as cost effective as other school-based primary tobacco prevention programs analyzed by others, and potentially more cost-effective than adult tobacco use cessation.

Program Dissemination and Adoption

A program's efficacy is a necessary but not sufficient condition to determine whether a program or strategy would be suitable for widespread dissemination and uptake by organizations (e.g., schools) and practitioners (e.g., health teachers). For instance, a program may promote quitting in a research study but not when it is used in a "real world" setting, such as a school clinic. Other factors must also be considered.

Program adopters must also believe that the program is relevant for and acceptable to adolescents, as well as feasible, practical, and adaptable for their circumstances.[54] The program must be available, cost-effective to use, and provide guidance for program implementation. That is why selecting and implementing effective adolescent smoking cessation strategies for Virginia adolescents will require more than simply identifying what programs are efficacious (i.e., evidence that it "works" in highly controlled research settings).

Evidence-Based Programs

There are numerous behaviorally-based adolescent smoking cessation interventions available today. Among the most visible are Project EX, Not On Tobacco (N-O-T), END, and TEG/TAP. All have been delivered in Virginia. However, systematic reviews consistently identify *only two* behavioral programs as evidenced-based – Project EX and Not on Tobacco (N-O-T). Moreover, these are the only two programs reviewed by the National Registry for Evidence-Based Programs and Practices (NREPP). Notably, both programs are rated highly in NREPP on the quality of research conducted with each program. Each is briefly described below.

Project EX

Project EX is a school-based, smoking cessation program for 14-19 year-old high school youth (for more information, see: http://tnd.usc.edu/ex/index.php?sub_flag=1). The program is delivered in a clinic setting during school hours, in groups of 8-15 participants. Project EX involves activities that are designed to be motivating and enjoyable, and program goals include smoking cessation and smoking reduction. The program addresses motivation, coping skills, and personal commitment. The Project EX curriculum consists of eight 40- to 45-minute sessions that are delivered over 6-weeks. Sessions include topics such as coping with stress, dealing with nicotine withdrawal, and avoiding relapses. The curriculum content also includes social, emotional, environmental, and physiological consequences of tobacco use. Session activities are designed to help participants learn self-control, anger management, mood management, and goal-setting techniques. Motivating activities such as games and yoga are utilized. Project EX can be delivered by highly motivated, non-smoking classroom teachers or health educators, and facilitators are trained by attending a 1 or 2 day class.

Research shows that Project EX is successful with students from diverse ethnic and socioeconomic backgrounds. The effectiveness of Project EX was evaluated using a three-group randomized block design - clinic-only, clinic plus a school-as-community component, and standard care control. At a 3-month follow-up (5 months after the program quit day), 17% of the clinic participants reported that they had quit smoking for at least the last 30 days. In contrast, 8% of the control group reported quitting over the same time period.[56] More information on Project EX can be found at the National Registry for Evidence-Based Programs and Practices (http://nrepp.samhsa.gov/) as well

as the U.S. Office of Juvenile Justice and Delinquency Prevention's guide to model programs (http://www2.dsgonline.com/mpg/)

Not-On-Tobacco (N-O-T)

N-O-T is an evidence-based, theory-driven program, specifically designed for adolescents. The program was developed and evaluated under the direction of a research team from the West Virginia Prevention Research Center (WV PRC). The American Lung Association adopted the program and is responsible for national program training, marketing, dissemination, and implementation. N-O-T takes a total health approach to adolescent smoking cessation and reduction.[16] It incorporates motivational issues; smoking history; nicotine addiction; the physical, psychological, and social consequences of smoking; preparation for quitting; dealing with urges and cravings; relapse prevention; stress management; dealing with family/peer pressure; increasing healthy lifestyle behaviors; and volunteerism. In N-O-T effectiveness studies, participants received 10, 50-minute sessions that occurred once a week for 10 consecutive weeks. Per formative research, N-O-T was delivered with small ($\leq$ 10) same-gender groups by trained same-gender facilitators, in private non-classroom settings during school hours.[16]

With almost a decade of research behind it, N-O-T is demonstrated as cost-effective, adoptable, and suitable for dissemination[11] (an additional summary of research on N-O-T is also located at www.notontobacco.com/pub-reference-list.php). N-O-T has been reviewed by NREPP and has received high ratings, is a National Cancer Institute Research Tested Intervention Program, a PRC Program Adoptable Program, and an Office of Juvenile Justice and Delinquency Prevention (OJJDP) Model Program.[11] The Sussman, Sun and Dent[8] review found a strong evidence-base for N-O-T, with approximately 1 in 5 N-O-T adolescents quitting smoking. Additionally, N-O-T studies between 1998 and 2003 showed end-of-program intent-to-treat quit rates between 15% and 19%,[11] among the highest rates reported in the literature.[54] Moreover, recent research indicated that N-O-T is the most well-researched adolescent smoking cessation program in the world[1] and the most widely disseminated adolescent smoking cessation program in the nation.[57] N-O-T has been demonstrated to be cost-effective, and the program's cost-effectiveness compares favorably to both adolescent smoking prevention and adult cessation programming.[15]

Other versions of N-O-T are also available or under development. For example, N-O-T is also available in Spanish, and a version of N-O-T for Native Americans has been developed; further testing is needed prior to full-scale dissemination. Further, as there is some evidence that physical activity may help promote cessation in adults, N-O-T researchers developed a physical activity module to test whether this may also be the case with adolescents. This module is currently under investigation using a three-armed randomized effectiveness trial. The conditions are: (1) N-O-T plus a physical activity module, (2) N-O-T only, and (3) a 20-minute brief intervention. Results of this project will be available within the next year. More information on N-O-T can be found at the National Registry for Evidence-Based Programs and Practices (http://nrepp.samhsa.gov/).

Although N-O-T is proven effective and available for widespread use, the program is currently not accessible to every adolescent who may want to use it. The American Lung Association (ALA) has an excellent training and dissemination infrastructure to support N-O-T. However, even within the ALA's national training infrastructure, a lack of adequate resources limits program dissemination and utilization. In order to increase program reach, the West Virginia Prevention Research Center (WV PRC), the ALA, and the national Prevention Research Center Program office (PRCPo) at the CDC are working to implement a three-part dissemination approach. The first is the development of a Web-based version of N-O-T. The second is the development and evaluation of a centralized dissemination model for N-O-T; this 5-year product will be the WV PRC's core research project, 2009-2014. The third is the development and evaluation of a dissemination and technical assistance web tool, called NotOnTobacco.com, funded by the PRCPo.

After working with N-O-T facilitators and conducting years of research on the N-O-T program, a Web site was developed to serve the purpose of a technical assistance tool (www.NotOnTobacco.com). The site was created by using best practices of Web site development ("Research-Based Web Design and Usability Guidelines" of the U.S. Department of Health and Human Services). The N-O-T website offers help for all aspects of program delivery, including advertising, recruitment, and implementation. The website is informative, interactive, and useful. The N-O-T website was developed to help users to increase their knowledge of the program and of adolescent smoking cessation, increase the chance of adoption, provide facilitators with tools and resources to implement the program, and encourage networking among program implementers. This internet-based tool aims to provide a "one stop shop" for all basic information on N-O-T. Usability testing is being conducted to ensure the Web site serves all audience types.

Conclusions

There has been increasing interest in, and support for, behavioral approaches to help youths quit smoking. Within the past several years, multiple reviews have concluded that there is *now sufficient evidence to recommend the use of behaviorally-based smoking cessation programs for youths.* Interventions based on cognitive behavioral, stages of change, and contingency management theories showed the most effectiveness. There is also some support for combination approaches including stages of change and social influence. Researchers have also found that program intensity is positively related to program effectiveness; effective interventions seem to have at least five sessions. The most effective treatment settings appear to be school classrooms and clinics, and recent research indicates that medical settings and quit lines can also be settings in which effective smoking cessation interventions to adolescents are delivered.

Two intensive behaviorally-based smoking cessation interventions have been reviewed by NREPP and have received high ratings on research outcomes. This indicates that there is sufficient evidence of (1) program effectiveness and (2) program adoptability. The first is Project EX and the second is Not On Tobacco (N-O-T). Both

programs are currently offered in Virginia. Project EX and N-O-T are both delivered in school settings. N-O-T is also delivered in medical and community settings. Issues regarding efficacy vs. effectiveness, cost-effectiveness, and program dissemination and adoption are also important considerations when selecting and implementing adolescent smoking cessation programs.

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Chapter 3

Smoking Cessation Interventions and Services for Adolescents in Virginia

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-- Summary—

- In Virginia, adolescent tobacco users have several resources to help them quit smoking. These resources include smoking cessation programming (e.g., through schools or community-based organizations), as well as limited access to pharmacotherapies.

- Several smoking cessation intervention programs are available in Virginia through funding from the Virginia Foundation for Healthy Youth (Virginia Tobacco Settlement Foundation Division; VTSF): Not-On Tobacco, Project EX, Intervening with Teen Tobacco Users (TEG), and Ending Nicotine Dependence (END). As Chapter 2 indicates, Project EX and N-O-T are have been reviewed by NREPP and have received high ratings on research outcomes.

- Adolescents who participate in N-O-T show respectable quit rates (an average of 47% at the end of the program). Results are mixed for TEG and END, but are generally not as positive.

- Some, but not all, smoking cessation medication for youth is covered under Virginia's Medicaid program and insurance plan for state employees. Counseling for smoking cessation is provided only for pregnant women under the state Medicaid program, and is not available for youth covered under the health plan offered to state employees. The state quit line does not serve individuals under age 18.

- Overall, youth smokers in Virginia who want to quit smoking have limited resources.

Smoking Cessation Interventions and Services for Adolescents in Virginia

In Virginia, adolescent tobacco users can turn to several resources for help quitting smoking. These resources include behavioral programs for smoking cessation (e.g., through schools or community-based organizations), as well as some pharmacotherapies (to the extent that these are covered under Medicaid, insurance policies, or via state funding).

Purpose of this Chapter

The purpose of this chapter is to describe available information on behavioral programs for adolescents that have been funded by the Virginia Foundation for Healthy Youth (VFHY), as well as insurance coverage for counseling and pharmacotherapy for adolescents in the State of Virginia.

Smoking Cessation Programs for Adolescents

Funding for several designated smoking cessation intervention programs is offered through the VFHY: Not On Tobacco, Project Ex, Helping Teens Stop Using Tobacco (TAP), Intervening with Teen Tobacco Users (TEG), and Ending Nicotine Dependence (END). Funding for these programs is available in one-year and three-year grant cycles (not all programs are funded each cycle). More information about each program is detailed below.

Data on quit rates is limited and inconsistent across programs, and definitions of quit rates are much less stringent than for the pharmacotherapy trials described in Chapter 1. For example, some programs include both pre- and post- program assessments of smoking status, while others do not. Some studies have biochemically validated smoking status, but the majority do not, and rely on self-reported quit rates only. Also, calculations of quit rates differ—some programs include non-completers in the calculations of quit rates, while others do not. In general, no follow-up is conducted. These differences in quit rate calculations and verifications are in sharp contrast to those used in the pharmacotherapy trials described in Chapter 1. Thus, the ability to compare quit rates across studies/types of programs is limited.

Not-On-Tobacco (N-O-T)

The American Lung Association provides N-O-T to youths throughout Virginia. Virginia has consistently been among the top five states that use the N-O-T program. According to the American Lung Association's Virginia Summary Reports, in 2008-2009 alone, 28 Virginia high schools and 50 community sites implemented the N-O-T program. Of these participants, 42% of adolescents stopped smoking and 75% (including those who stopped smoking) reduced the number of cigarettes.

Information about the background and content of N-O-T is included in detail in Chapter 2. In Virginia, the American Lung Association currently runs approximately 100 programs throughout the state at both school and community sites and at faith-based

organizations. Since 2002, the self-reported, end-of-treatment quit rates for N-O-T in Virginia have ranged from 37% to 57%, for an average 47% for students who completed the program. These self-reported quit rates are evaluated through matched pre- and post- tests based on participant initials, and do not include participants who did not finish the sessions (please note that this method differs from the method used for the other cessation programs described in this section, in which pre and post tests are not matched). The number of adolescents who have completed the program began with 324 adolescents in 30 schools in 2002-2003, and has grown to 1,058 adolescents in 28 schools and 50 community sites in 2008-2009. The majority of groups are conducted in the Central Virginia Region while the least number of groups are held in the Southeast Region.

VFHY provides the ALA with funding for a majority of the N-O-T programs across the state, and conducts its own evaluation. During the 2008-2009 school year, 580-669 participants provided pre and/or post-test data. Results showed reductions in the percentage of participants who were current smokers, although these reductions were significant only in one region. Perceived likelihood of quitting and perceived ability to quit increased significantly in some regions, but not in all regions.

N-O-T program facilitators do report difficulties such as recruiting enough students for the groups, getting the groups started, difficulty juggling multiple school responsibilities, lack of youth interest, and little administrative support. However, facilitators report good results once groups are begun.

Project Ex

Information about the background, content, and evidence-base for Project Ex is included in detail in Chapter 2. Currently, no Project Ex programs are funded by the Virginia Foundation for Health Youth.

Intervening with Teen Tobacco Users (TEG) and Helping Teens Stop Using Tobacco (TAP)

Intervening with Teen Tobacco Users, also known as the Tobacco Education Group (TEG) and Helping Teens Stop Using Tobacco (also known as the Tobacco Awareness Program, or TAP) are two other school or community-based, multiple session programs. TEG targets youth who are not currently interested in quitting tobacco. This program is designed to help youth understand the consequences of tobacco use, and has a goal of moving youth along the stages of change continuum[1] to reduce their smoking, quit on their own, or join a program to quit smoking. TEG is often used as an alternative to suspension, or as a diversion from juvenile courts.[2] TAP targets youth who want to quit smoking, and has a goal of providing information about tobacco and motivating youth to quit smoking and supporting them during the quit process.[2]

Only one published paper is available that describes an evaluation of TEG and TAP.[3] In this evaluation, 351 students at six high schools in Southern California, who participate in TEG and TAP, were studied. Results showed that students in both groups significantly reduced their smoking at the end of the programs; saliva cotinine tests

with a subset of the participants confirmed less nicotine intake. Quit rates for participants in the TAP program were 15%, and 9% for TAP participants whose participation was mandatory. Participants who did not complete the program were considered smokers in the calculations of quit rates.

In addition, TAP appeared to move participants along the stages of change continuum more than TEG. Both programs increased students' self-efficacy to resist smoking.[3] Overall, compared to other programs (e.g., N-O-T and Project EX), much less research has been conducted on TAP and TEG. Thus, while results from these programs are promising, they are not considered evidence-based. Further, neither TAP nor TEG is listed in SAMHSA's National Registry of Evidence-based Programs and Practices (NREPP).

In Virginia, only TEG has been used recently. According to data obtained from the Virginia Foundation for Healthy Youth, in 2008-2009, grantees were: the Virginia Wilderness Institute, Fluvanna County Public Schools, Pulaski County Public Schools, Rockbridge County Public Schools, the Giles County Partnerships for Excellence Foundation, Inc., and Planning District I Behavioral Health Services. In total, 179-201 individuals across the state participated in TEG and completed a pre and/or post test. Results from the programs are limited and mixed. For example, data was not available or was insufficient from many programs, probably because of very low enrollment. For other programs, the percent of current smokers was reduced in some programs, but not significantly so. Percentages of students who reported they would "probably" or "definitely" quit smoking in the next 6 months increased in two programs, but decreased in a third (none were significant differences). Percentages of students who agreed or strongly agreed that they could quit using tobacco if they wanted to decreased in the three programs for which pre and post test data were available (none were significant differences).

Ending Nicotine Dependence (END)

Ending Nicotine Dependence (END) is also a school or community-organization based, multi-session program, and is also based on Prochaska and DiClemente's model of the stages of change. Program goals include increasing knowledge about tobacco as well as improving social skills and self-efficacy. END is used for youth interested in quitting smoking, as well as for youth who have violated tobacco laws or policies.[2]

While no peer-reviewed, published research is available on END, an evaluation has been conducted by the state of Utah, with youth who wanted to quit smoking and/or youth who violated Utah tobacco laws. Data from 898 adolescent participants in FY 2008 indicate that end-of treatment quit rates in END were 16.3%, and that 48.9% of adolescents reported reducing smoking.[4] Abstinence was not biochemically validated. END is not currently included in SAMHSA's National Registry of Evidence-based Programs and Practices (NREPP).

In 2008-2009, the Three Rivers Health District (covering areas in Eastern Virginia) used VFHY grant funds to implement the END program with 72-77 youths (number who participated based on those who completed pre and/or post tests). Results from pre and post tests showed that the percent of youths who indicated they

were current smokers was reduced only slightly after the program. Percentages of students who reported they would "probably" or "definitely" quit smoking in the next 6 months decreased slightly, and percentages of students who agreed or strongly agreed that they could quit using tobacco if they wanted to also decreased somewhat. None of these differences were considered significant.

Other Treatments for Smoking Cessation

In Virginia, the state Medicaid program covers several types of nicotine replacement therapy as well as varenicline and bupropion, but not group or individual counseling—counseling is only available for pregnant women.[5] Unfortunately, not providing cessation counseling under Medicaid is common—only about half of other state Medicaid programs in the US provide counseling for tobacco cessation. Further, in Virginia, smoking cessation is not covered in the list of approved services for Block Grant funds (personal communication with Community-Services Board staff, 2008). The state employee health plan covers some forms of nicotine replacement therapy (but not all), as well as varenicline and bupropion, but not group or individual counseling. Intensive phone counseling is available through the Quit for Life program, although only to employees covered under the state employee health plan, their spouses, and their dependents over the age of 18.[5]

Virginia also has a general statewide quit line, but due to limited funding, this quit line does not have resources to serve youth (with the exception of pregnant teens); consequently, the availability of the service is not targeted at youth and few youth utilize the quit line. In fact, demographic data obtained from Free & Clear, the contractual vendor for the Virginia quit line, indicated that only five callers were 17 and under for fiscal year 2008-2009. Six callers did not identify their ages, yet even if they were all youth, the number served is still dismal.

Conclusions

Overall, youth smokers in Virginia who want to quit smoking have some resources to assist them, but these resources are limited. Cessation programs are not available in all areas or at all schools, and depending on an adolescent's insurance plan, counseling may not be a covered service. In addition, youth cannot use the Virginia quit line as a resource for counseling. Finally, the evaluation data on behavioral programs in Virginia includes mixed results, and data is limited for some sites. Recommendations for how to improve services for Virginia youth are included in Chapter 4.

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Chapter 4

Barriers and Recommendations for Virginia

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Barriers and Recommendations

Overview

There are a number of barriers to providing smoking cessation interventions to adolescents. For example, there are barriers to the use of pharmacotherapies, insurance coverage for treatment, and utilization and engagement of healthcare providers. In addition, barriers exist for program availability, accessibility, and cost, as well as for recruitment and retention, for parental involvement, and for evaluation, dissemination, and adoption. Each barrier, along with recommendations for overcoming these barriers, is discussed in more detail below.

Pharmacotherapies for Adolescent Smokers

A major barrier to the use of effective pharmacotherapies for adolescent smokers is a lack of sufficient research demonstrating their effectiveness. With insufficient evidence, pharmacotherapy for adolescent smoking cessation cannot be recommended. Although pharmacotherapies may be considered, they should be prescribed only with close monitoring and after careful consideration of the adolescent's smoking rate, history of failed quit attempts, and current motivation to quit smoking.[1]

Instead, referral to appropriate psychosocial interventions (e.g., school- or community-based, group or individual counseling) is the most appropriate front-line treatment for adolescent smokers. These interventions have been shown to significantly increase the odds of quitting over no treatment, and are the only empirically-supported treatments currently available for adolescents.

Recommendations

- Pharmacotherapy cannot be currently recommended for adolescent smokers. However, referral to effective behavioral programs should be encouraged.

- Additional research on pharmacotherapy for adolescents should be supported (for example, by the Virginia Foundation for Healthy Youth), and could include:

  - Controlled laboratory experiments that can answer basic questions about the physiological, psychological, and behavioral effects of smoking cessation in adolescent smokers, and systematically evaluate the impact of various behavioral and pharmacological interventions on these effects.

  - Basic and clinical research that can evaluate theoretical causal mechanisms proposed to explain smoking and relapse in adolescents. Advances in adolescent smoking cessation treatment depend in part on

evaluating the effects of various treatments on putative mechanisms, and linking these intermediate effects to more distal smoking outcomes like long-term abstinence.

- Preclinical research that can be designed to provide insights into the specific processes involved in smoking, quitting, and relapsing during adolescence. Better understanding the phenomenon of adolescent relapse may help us to develop more specific intervention targets (e.g., increase behavioral self-regulation skills; decrease severity of withdrawal symptoms).

- The development and testing of developmentally-appropriate behavioral and pharmacological interventions (and their combinations). Heavy smoking, nicotine dependent adolescents are highly unlikely to successfully quit smoking on their own. Efficacious treatments are urgently needed to reduce smoking-related illness and premature death in this at-risk population.

Insurance Coverage for Treatment

Insurance coverage for smoking cessation treatment services varies by state, type of service, and plan limits. For example, data from all states from 2007 indicates that most state Medicaid programs cover some form of pharmacotherapy, but, that most require co-payments. About half of state Medicaid programs cover tobacco-cessation counseling services, although some offer counseling only to pregnant women.[2,3] Given that Medicaid recipients are more likely to be smokers,[2-4] smoking cessation coverage for this group is critical. Most insurance plans for state employees also provide little or no coverage for employees—of all 50 states, only six provide comprehensive coverage (all recommended medications, plus individual and group counseling[2]). Uninsured individuals face even more challenges, and are forced to rely on resources such as quit lines or local health department or hospital programs, when these options exists for adolescents.[2]

In general, insurance coverage is inadequate, regardless of source.[2] Even when coverage exists, additional barriers can thwart cessation efforts, such as required co-payments, required prior authorizations, limits on the duration of treatment, annual limits on coverage, lifetime limits on coverage, dollar limits, and “stepped care” therapy.[2,4]

Several states do provide comprehensive services. For example, Oregon’s Medicaid program requires that smoking cessation treatments be covered and that plans provide all medications and options for counseling. Massachusetts’ Medicaid program is also considered a model program.[2]

Recommendations

- As behavioral interventions are the only empirically supported treatment for adolescents, and are not typically covered by insurance, increased funding for behaviorally-based tobacco cessation services should be supported.

- In lieu of increased funding by insurance plans, free or low-cost behavioral programs must continue to be provided to Virginian adolescents, and should be expanded to provide greater access and uniform coverage across the state.

Barriers reported by Healthcare Providers

Physicians report barriers to treating adolescent tobacco users, such as a lack of awareness and training, as well as adolescent concerns about confidentiality.[5,6] Barriers to the treatment of tobacco dependence among adult patients include a lack of patient motivation, limited coverage for interventions, limited reimbursement for physician time, limited time with patients, and limited training.[7] Many of these factors are likely barriers to treating adolescent tobacco users as well. Limited training is a barrier that can be addressed; in fact, training pediatric providers in brief cessation interventions has been shown to be feasible.[8] Further, adolescents cite health as a motivator for quitting smoking;[9] thus, overcoming the barriers that healthcare providers face is especially important, as primary care can be a setting in which adolescent smokers are engaged.

Recommendations

- More training on tobacco and smoking cessation should be provided to healthcare providers in Virginia by integrating education on tobacco and cessation into existing healthcare education programs.

- Training should be fostered with easy-to-access lectures and conferences that provide continuing education credits. Institutions that provide healthcare training should be encouraged to recommend continuing education credits on tobacco screening, brief interventions, and referral.

- Research funding should be provided to identify the most cost-effective and adoptable training and intervention methods for provider-based cessation intervention with adolescents, following the previous work in this area (described in Chapter 2).

Behavioral Approaches: Availability, Accessibility, and Cost

Recently, researchers reviewed 591 tobacco cessation programs across the US.[10,11] Results showed that the majority of cessation programs were in school-based settings, and most were found in urban counties. Fewer programs were found in low-income counties, and some counties (38%) had no programs at all. Youth smoking prevalence or tobacco control expenditures seemed to be unrelated to the number of programs in a county; however, there were significant differences in program availability for counties funded by Master Settlement Agreement funds versus those counties that were not (far fewer programs were found in non-MSA counties).

The primary locations of the group programs were classrooms, school health clinics, or another location at the schools. Groups were also found - though less often - in community centers, community-based health clinics, hospitals, church and religious centers, or drug treatment centers. Programs were started due to organizational initiative (40%), health department or department of education initiative (22%), and teacher initiative (11%). Only 2% of the programs were youth-initiated and less than 1% reported initiation based on parent motivation. One of the reasons for providing cessation opportunities was the need to provide a consequence for those who violated school tobacco use policies.

Of packaged programs used, the American Lung Association's Not On Tobacco (N-O-T) program was most commonly used; 51% of the program administrators reported using N-O-T. Also frequently used were the Tobacco Education Group/Tobacco Awareness Program (TEG/TAP); 16% reported using these. Some program administrators also reported using internally-developed programs (12.7%). Most of these internally-developed programs were found in urban areas, and they more often addressed other substance abuse issues and problem behaviors, as compared to packaged programs.[11]

Although programs may be available in a variety of regions, they are not necessarily accessible to all adolescent smokers. For example, faculty support and allowance for student release time are vital for access to school-based programs. In addition, if the program is after school, transportation can become a barrier to access. Programs that take place during school may make access easier for students, and thus attendance more likely.[12] Also, internet-based programs are only accessible to individuals who can access the internet.

In addition to limited availability and potentially limited accessibility, resources for tobacco control programs are scarce. The median annual budget for surveyed programs was a modest $2,000 per group, and the most commonly cited sources for the program's funding were the federal government, the local government, and community-based, non-profit organizations.[10] Further, organizations that use internally-developed programs may have even less funding available.[11] Program administrators also cite insufficient resources as a barrier to recruitment.[13]

Recommendations

- Greater efforts should be made to make smoking cessation programming for adolescents available throughout the state (including in both urban and rural areas), to youth with different socioeconomic status, and in a variety of settings.

- An emphasis should be placed on making programs accessible for all youth, through encouragement by school faculty, allowing for student release time, and arranging for transportation when needed.

- Access to services should be increased by having a statewide, free youth quit line. Efforts should be made to offer this service in Virginia.

- Cost-effectiveness analyses should be conducted for all behavioral programs offered, thus maximizing public health outcomes. An example of a cost-effectiveness analysis is described in Chapter 2.

Recruitment and Retention Issues

Although multiple studies indicate that youth smokers want to quit, few youths demand treatment. Further, many programs (more than 75% in a recent review) enrolled fewer than 50 youths annually and the most commonly cited challenge was recruiting enough participants.[10, 11]

Few programs have mandatory enrollment (9%), and some have a mixed voluntary and mandatory enrollment.[10] Programs with voluntary enrollment recruited participants through adult encouragement (90%), referrals from an adult (physician, teacher, school nurse – 90%); referrals from other participants (88%), and peer outreach (81%). Peer outreach seemed to be the most effective method of recruitment (27%), followed by referrals from other participants (19%). Not surprisingly, punishment for possession or use of tobacco was the most common enrollment reason for mandatory programs (92%).

Research from Canada shows that when asked, youth smokers report not wanting to join a school-based smoking cessation program (only 13% of occasional and regular smokers who wanted to quit smoking said they were interested in participating;[14]). This discrepancy may be explained by adolescents' concept of being a smoker.[15] Youth need to identify themselves as smokers and to see the cessation message as one that is directed to them. If youth are not self-identifying as smokers, they may not see the need for structured treatment. Also, youth consistently underestimate how much they smoke as well as the dependence-producing power of nicotine. They also perceive a difference between "social smokers" and "real smokers."[12] Frequently, youth smokers report that, though they want to quit, specific

plans for quitting are vague and may be well into the future (e.g., "after college", "when I get married", "when I have children"[16]).

High-risk youths, who are often the target of smoking cessation programs, face additional barriers that could reduce demand for treatment. First, youths must attend school to attend the programming. Low school attendance can therefore become a barrier to recruitment in school-based programs. This is compounded by the finding that low school attendance is associated with high-risk youth behavior.[13] Second, if smoking is a punishable behavior, youth may not seek help if they will suffer negative consequences for doing so.[12]

Finally, some research shows that youth are not aware of cessation programs,[16] and may not perceive them to be useful. More specifically, when asked about the most frequently used strategies to quit smoking, approaches such as groups/classes, websites, help lines, and pharmacotherapies were the least frequently used, and were rated as the least helpful.[17] Also, although older adolescents and young adults use the internet to access health information, they do not seem to use computer-based cessation interventions that are available on the internet,[10] and may not be aware of the availability of these programs.

Recommendations

- Strategies should be used that maximize the recruitment and retention of youth in tobacco cessation programs, including: using peer outreach; using telephone counseling for added privacy, and initiating those calls; assuring adolescents of the privacy of reported information; and creating tailored counseling. Another possibility that has been suggested by researchers is to include all youth (smokers and non-smokers) in cessation programming (when appropriate), so as to not identify smokers individually. [18]

- Other strategies that can maximize retention should also be used, such as mandating participation in programs that are considered alternatives to suspension for students who violated tobacco control policies, offering snacks, class credit, class release time, and scheduling programming during school instead of after school.[12,18-19]

- Research should be conducted to identify the most effective recruitment and retention strategies for Virginia youth specifically.

Parental Involvement

Some smoking cessation interventions require parental notification or consent, and programs that don't require parental notification seem to have less trouble recruiting participants. (Importantly, consent is required for research projects, but may or may not be required for non-research related programming). Nationally, 22% of

cessation programs require parental consent and 34% require parental notification.[10] Requirements for parental consent are generally left to individual schools/community-based organizations where programs take place. Research is conflicting on the extent to which adolescents want or do not want parents involved or informed about their smoking status.

For example, some studies report that some adolescents do not want their parents to know that they are smokers,[13] and this makes recruitment which requires parental consent a challenge. Consent to participate in smoking cessation programs can be passive or active: passive consent requires the parents to notify program staff if they do not want their children involved, while active consent requires the parent to notify program staff in writing if they do want their children to participate. Although recruitment can be successful, active consent may decrease participation.[13]

In contrast, one study reported that adolescents using a telephone help line may not be concerned about notifying their parents. Among this group, most (88%) reported not minding having their parents contacted.[9] Some even used this forum to let their parents know they were smokers. Parental involvement in a smoking cessation attempt can be helpful, as adolescents' accountability for their quit attempt increases when counselors talk with parents. Additionally, parental contact enables the counselors to intervene on behalf of the adolescent, which maximizes parental support and lessens the potential sabotage (nagging, smoking in front of the adolescent). Also, if the parent smokes, this intervention provides a forum for the parent to receive cessation assistance. This benefit is significant in light of studies that show that parental smoking cessation lowers adolescents' likelihood of continuing to smoke.[20]

Recommendations

- School systems/community-based organizations that have required parental consent in the past should be encouraged to change their policy so that parental consent is not required. An alternative approach is to provide interventions so that participation does not identify the individual as a smoker.[18]

- Alternatively, in some situations, involving parents may be helpful. Identifying the contexts in which parental involvement is helpful could increase adolescents' success at quitting smoking.

Evaluation, Dissemination, and Adoption of Effective Programs

As described in Chapter 2, adequate evaluation of programs is critical. This evaluation should include both research on efficacy (implementation in highly controlled settings by scientific investigators) and effectiveness (research in real-world settings). Further, program data should be reported in peer-reviewed, published papers, and/or comprehensive state reports that describe effectiveness research. Inclusion of

empirically supported interventions in national registries such as the National Registry of Evidence-Based Programs and Practices (NREPP) is also recommended.

Dissemination and adoption of effective programs is also key. As described in Chapter 2, programs must be suitable for widespread dissemination and adoption, and program adopters must believe that the program is relevant and acceptable for a population. In addition, programs must be feasible, practical and adaptable as needed. Programs must also provide guidance for implementation.

Recommendations

- Support both efficacy and effectiveness evaluations of smoking cessation programs for adolescents, in particular for those programs that have not been sufficiently evaluated.

- Fund on-going assessments of all cessation programs/projects funded by the Virginia Foundation for Healthy Youth (VFHY), and use evaluation data to drive future program and policy decisions. Evaluations should continue to include pre- and post tests, and should consistently measure actual quit rates.

- Encourage the use of community-based research and participatory evaluation methods to ensure cultural competence and increase the likelihood of community buy-in.

- Fund only evidence-based programs, interventions, and strategies.

- Increase dissemination and adoption of effective programs by being aware of relevance, feasibility, practicality, adaptability, and ease of implementation.

- Provide all VFHY Grantees with guidelines on evidence-based policy and practice.

- Create and sustain a *Research, Policy and Practice Advisory Board* comprised of researchers, policy makers, and program decision makers to develop consistent and universal guidelines for youth cessation programs/projects funded by the Virginia Foundation for Healthy Youth.

- Finally, consider promoting a statewide campaign in Virginia to promote the adoption of tobacco-free school policies.

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