

# **Chapter 7**

## **Prevention and Cessation Interventions**



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## Interventions for Smokeless Tobacco Use

Public health efforts to reduce the overall prevalence of tobacco use must focus on both prevention and cessation of all tobacco products. Although cigarettes continue to be the primary tobacco products used, as of 2012, high prevalence rates of smokeless tobacco (ST) use are being reported among males and females, both youth and adults, in a significant number of countries, varying widely by region and area (see chapter 2). Even in countries that currently have low rates of ST use, vigilance is necessary because tobacco companies adapt their products and marketing approaches in response to greater tobacco control restrictions and reduced smoking prevalence. For example, tobacco companies promote ST as a way to adapt to concerns about the health effects of exposure to secondhand smoke in public places.<sup>1</sup> In addition, cigarette companies are introducing novel ST products, including “spit-free” forms, and the marketing of these products may increase use by young people and by smokers responding to environmental restrictions (chapter 6).

This chapter reviews a wide variety of available interventions to prevent and reduce the use of ST, ranging from intensive clinical interventions to high-reach, low-intensity public health programs. The chapter focuses first on prevention, emphasizing its importance especially among youth. Although by far the most research on youth tobacco use centers on smoking, there is an increasing awareness of the potential increased use of smokeless tobacco by youth and young adults. Because resources and cultures vary across countries, examples of interventions from a range of available countries are provided. Most of the current research, however, concentrates on high-income countries and school-based interventions. Several studies use the term *point prevalence* to mean self-report of abstinence from use of any tobacco product for the past 7 days or the past 30 days. Although some studies use *continuous abstinence*, most give the point prevalence estimate both at the end of the study and for follow-up periods. Two different measures of dependence have been used: the modified Fagerstrom scale and the Severson Smokeless Tobacco Dependence Scale (SSTDS).<sup>2</sup>

## Interventions to Prevent Smokeless Tobacco Use Among Young People

To date, only limited efforts have been made to prevent ST use among children and adolescents in the United States and other countries. Compared to the extensive research on prevention of smoking, few publications have reported on empirical evaluations of ST prevention interventions. Considering the effects of ST, its health consequences, and its impact on public health, it is clear that more tobacco control efforts and interventions are necessary. Available prevention studies are described in Table 7-1, and community, school, and individualized (targeted to specific populations) interventions are reviewed.

Table 7-1. Smokeless tobacco prevention interventions

Study*	Intervention	Design	Outcomes
<b>Community Level</b> Arora, Stigler et al. 2010 (16)	Project ACTIVITY (2 years of intervention) Community intervention: Training workshops, community-based cessation camps, interactive activities, and enforcement of prohibition on sales to minors. Films, street plays, rallies, pamphlets, comic books, roleplaying, and stickers. Change agents were trained youth leaders and action groups.	Cluster-RCT 14 low socioeconomic status communities in Delhi, India Subjects: adolescents ages 10–19 Control group received no intervention	Not available. Qualitative results show community interventions denormalize ST use.
Arora, Tewari et al. 2010 (15)	Community intervention: Interactive activities, pretested posters, audio recordings, films, lectures, street plays, and knowledge enhancement using pictorial handouts, booklets, and pamphlets. Awareness rally to reach the masses and positively influence tobacco use norms in the community.	Cluster-RCT 2 low-income communities (Delhi, India): one treated as intervention and the other as control Subjects: adolescents ages 10–19 Saliva cotinine used for verification in 25% of sample	Significant difference in current tobacco use between study groups: intervention group—reduction in use, control—increase in use. After intervention, significantly lower uptake of tobacco use in intervention group compared with control group. No significant change found for quit rates across conditions.
Biglan et al. 2000 (4)	Project SixTeen Community intervention: Media advocacy, youth anti-tobacco module, family communication activities, and youth access campaigns. School-based intervention: curriculum titled Programs to Advance Teen Health (PATH).	Cluster-RCT 16 communities in Oregon Controls received school-based curriculum	Significant intervention effect on reducing ST use among 9th grade males at 1-year follow-up but not among 7th grade males. Prevalence of ST decreased significantly in community intervention.

Study*	Intervention	Design	Outcomes
<b>School-Level Behavioral</b>			
Dent et al. 1995 (23)	<p>Project TNT</p> <p>The same treatment conditions as used in the report of 1-year outcome data (see Sussman et al., 1993):</p> <ol style="list-style-type: none"> <li>(1) Countering normative social influences</li> <li>(2) Countering informational social influences</li> <li>(3) Changing misperceptions about physical consequences of tobacco use</li> <li>(4) A combined condition to counteract both social influences and perceptions of physical consequences.</li> </ol> <p>A "booster session" related to the original curriculum was delivered to the 8th grade cohort.</p>	<p>Cluster-RCT</p> <p>Subjects: 7th grade students at 48 junior high schools (California)</p> <p>Assigned to one of four program conditions or to a control group which received usual care.</p>	<p>(2-year outcome data)</p> <p>Data suggested that:</p> <ol style="list-style-type: none"> <li>(1) Effects in the combined and physical-consequences conditions were maintained 2 years after the program (that is, physical-consequences curriculum was successful in attenuating increases in adolescent ST use).</li> <li>(2) A comprehensive program with all 3 components was necessary to attenuate increases in weekly use of both forms of tobacco.</li> </ol>
Elder et al. 1993 (21)	<p>Project SHOUT</p> <p>A psychosocial intervention combining refusal skills training, contingency management, and other tobacco use prevention methodologies such as telephone and mail boosters. College undergraduates served as change agents for both the classroom and booster interventions. A booster intervention was delivered in 9th grade.</p>	<p>Cluster-RCT</p> <p>Subjects: 7th grade students at 22 California middle schools; schools matched for size and tobacco use prevalence.</p> <p>Controls received no intervention</p>	<p>(3-year outcome data)</p> <p>Prevalence of tobacco use was significantly lower among intervention students compared to controls.</p>

Study*	Intervention	Design	Outcomes
Perry et al. 2008 (24) Perry et al. 2009 (25)	Project MYTRI Purpose: To prevent and reduce many forms of tobacco use (ST, cigarettes, and bids) among youth in India. Two-year, school-based, multicomponent, peer-led, tobacco intervention. Included classroom curriculum, school posters, parent postcards, and peer-led health activism. Underlying theory: social cognitive theory and other theories of youth health promotion.	Cluster-RCT Subjects: Students in grades 6–9 received the intervention (two cohorts studied: grade 6 and grade 8) in 32 private and government schools in Delhi and Chennai, India Schools stratified by city, gender (male, female, or coed), and type (government or private) and randomized into intervention and delayed-program control groups	(At 2-year follow-up) Students in the intervention group were significantly less likely than students in the control group to have increased their cigarette or bidi smoking over the 2-year study period. ST use was not reduced, but students were less likely to intend to smoke or chew tobacco in the future.
Severson et al. 1991 (20)	Multicomponent intervention delivered by classroom teachers and same-age peer leaders. Seven class sessions with emphasis on refusal skills. Two sessions on ST.	Cluster-RCT 13 middle schools and 9 high schools in Oregon matched, stratified, and randomly assigned Control group received only the usual 7th grade health education classes or 9th grade science classes, both including materials and lectures on tobacco All groups assessed before intervention and 1 year after intervention via questionnaires and collected expired carbon monoxide (CO) and saliva	Significant effects for reducing ST use by 7th grade boys but marginal effects on the rate of ST use for 9th grade boys.
Sussman et al. 1993 (22)	Project TNT Four curricula were developed, tested, and each was used in a treatment condition, which consisted of activities to counteract: (1) Normative social influences (2) Informational social influence (3) Misperceptions about physical consequences of tobacco use (4) A combined condition to counteract both social influences and perceptions of physical consequences.	RCT (a 5-group randomized block design) Subjects: Students at 48 middle schools from 27 southern California districts over a 5-year period Questionnaire at baseline and 1 and 2 years postintervention, along with a saliva or breath sample	(1-year outcome data) Combined intervention most effective overall in reducing initial and weekly use of cigarettes and ST. Each program component effectively decreased both the initial and weekly use of cigarettes (except for the social curriculum, in which refusal skills were taught) and initial use of ST (except for the curriculum for correcting social misperceptions).



Study*	Intervention	Design	Outcomes
<p><b>Individual-Level Behavioral</b></p> <p>D'Onofrio et al. 2002 (32)</p>	<p>A set of five experience-based modules led by teams of trained adult volunteers and older 4-H youth delivered at monthly club meetings. Sessions plus activities to be completed between meetings. Subjects received illustrated, self-guided booklets reviewing the five club sessions, instructions and worksheets for activities. Other materials: leader's manual, pamphlets for parents identifying ways they could help, guides for clubs and members who wanted to form a Project 4-Health Action Team. Examples of Action Team projects: creating tobacco use policy for the 4-H club, conducting a tobacco survey at schools, and organizing a poster display and contest.</p>	<p>Cluster-RCT</p> <p>Subjects: 4-H club members aged 10–14</p> <p>72 California 4-H clubs were matched and randomized, N = 1,438</p> <p>Controls received no intervention</p>	<p>(At 1 year)</p> <p>Short-term effects were found on 7 of 24 outcome measures, indicating changes in knowledge, attitudes, and behavioral intention, but not changes in social influence variables or behaviors.</p> <p>None of the short-term program benefits were sustained 2 years after program completion.</p>
<p>Schinke et al. 2000 (31)</p>	<p>Two intervention conditions:</p> <p>Skills intervention alone: Cognitive and behavioral skills for substance abuse prevention.</p> <p>Skills plus community intervention: Local community residents were also engaged in community activities to raise awareness.</p>	<p>Cluster-RCT</p> <p>Subjects: 1,396 Native American 3rd–5th graders from 27 elementary schools</p> <p>2 treatment groups and 1 control in North Dakota, South Dakota, Idaho, Montana, and Oklahoma</p>	<p>At 30- and 42-month follow-ups, ST use significantly lower for subjects assigned to the skills-based treatment condition, but community-based components did not demonstrate any added benefit.</p>

\*Numbers in parentheses correspond to full citations in the References at the end of this chapter.  
 Abbreviations: Project Activity = Advancing Cessation of Tobacco in Vulnerable Indian Tobacco Consuming Youth; Project MYTRI = Mobilizing Youth for Tobacco-Related Initiatives in India; Project TNT = Towards No Tobacco Use; Project SHOUT = Students Helping Others Understand Tobacco; RCT = randomized controlled trial; ST = smokeless tobacco.

### Community- and Health Care–Based Prevention

Community-based efforts—which use a comprehensive approach that includes schools, media, family, advocacy, and public policy—may be effective in helping to prevent ST use by youth. The fact that community interventions can reach young people who may not be attending school is an advantage, because school dropouts and non-attending youth may have higher tobacco use rates than youth who are attending school.<sup>3</sup> Project SixTeen,<sup>4</sup> a randomized controlled trial (RCT) conducted in the United States (Oregon), tested whether a comprehensive communitywide effort to prevent teen tobacco use was a better deterrent than a school-based tobacco prevention program alone. The community intervention included media advocacy, a youth anti-tobacco module, family communication activities, and a youth-access campaign. The school-only intervention consisted of an evidence-based curriculum called Programs to Advance Teen Health. The study found that the community intervention had a significant effect on the prevalence of ST use by males after one intervention year, which suggests that a multicomponent community-based intervention can have stronger preventive effects than a school-based program alone, which was not as effective at preventing smoking initiation and future increases in smoking prevalence.

Despite a relative lack of specific ST prevention efforts in the United States, studies have documented an overall decline in adolescent ST use since the late 1990s and an increase in the percentage of 8th, 10th, and 12th graders who perceive regular ST use as harmful.<sup>5</sup> However, the most recent national survey data suggest that during the past 10 years, ST use among high school students has remained flat; perceptions of ST harm among 8th, 10th, and 12th graders also were constant through 2010, but as of 2012, perceived risk of ST use has decreased among 8th and 10th graders.<sup>6,7</sup> Temporary improvement of ST perceptions may have been the result of the extensive anti-tobacco efforts targeted toward young people throughout the United States in the 1990s, although these efforts focused primarily on cigarette smoking.<sup>5</sup> For example, in 1993, the Massachusetts Tobacco Control Program began a statewide comprehensive youth tobacco (ST and cigarette) prevention campaign in communities and schools and through the media. An analysis of school survey data between 1993 and 1996 found a greater decline in the state than had occurred nationally, suggesting the program was effective in preventing ST use.<sup>8</sup> This decline had continued as of 2005.<sup>9</sup>

Visits with oral health care providers offer a natural opportunity to deliver a brief ST intervention because these providers are in a unique position to identify the oral consequences of ST use. Although dental settings have been a venue for several cessation studies in the United States that have demonstrated efficacy in ST cessation,<sup>10–12</sup> they have not been evaluated for providing preventive interventions. Pediatricians might be in a similarly advantageous position to provide brief counseling to young people about avoiding tobacco use, as indicated in Indian health care settings,<sup>13</sup> but the only study evaluating this approach, which took place in the United States, did not find that counseling by pediatricians significantly prevented ST use.<sup>14</sup>

Few evaluations of U.S. programs to prevent young people from starting to use ST or preventing their continued use have been focused on interventions in communities, families, or health care settings. The results reported by Project SixTeen<sup>4</sup> are encouraging, but additional research is needed to determine effective ways to educate both children and parents about the health risks of ST use. The dental office setting offers a unique and timely opportunity to provide preventive education, but studies in this

setting to date have focused on cessation; there are no published evaluations of prevention efforts in dental settings.

In low- and middle-income countries, community-based interventions may have significant potential for reducing ST use. A study with 10- to 19-year-olds in two low-income communities in Delhi, India, compared a community that received the intervention with another community that served as the control. A significant difference in current tobacco use was observed between the study groups, with the intervention group showing a reduction in ST use and the control group showing an increase in use. Postintervention, there were significantly fewer new tobacco users in the intervention group compared with the control group. No significant differences were observed in tobacco quit rates between the two groups.<sup>15</sup>

Based on the success of this demonstration study, a group RCT called Project ACTIVITY (Advancing Cessation of Tobacco in Vulnerable Indian Tobacco Consuming Youth) was implemented to reduce tobacco use among disadvantaged youth (aged 10–19 years) in 14 low-income communities in Delhi. The study was conducted in collaboration with Health-Related Information Dissemination Amongst Youth (HRIDAY) and the University of Texas in the United States. In 2009, seven communities were randomly assigned to receive a 2-year intervention, and another seven served as controls.<sup>16</sup> The 2-year intervention targeted intrapersonal and socio-environmental risk factors to prevent initiation of smoking and ST use, and to promote tobacco cessation.<sup>17</sup> Four intervention strategies—training workshops, community-based cessation camps, interactive activities, and policy enforcement—were used, with an emphasis on leadership education and enforcement of tobacco control laws. Although final quantitative outcome data for this study are not available, preliminary qualitative results show that community-based interventions can be effective in preventing adolescents from starting tobacco use in a low-resource setting such as India, in changing community norms around tobacco use and denormalizing ST use among all community members.<sup>18</sup>

### School Curriculum Interventions

Most interventions to prevent tobacco use have been school based because schools provide access to young people, and many interventions are designed to teach youth to resist peer pressure in relation to using tobacco products.<sup>19</sup> Some promising school-based programs are reviewed below and summarized in Table 7-1.

One study conducted in the United States evaluated a classroom-based social influences program delivered by teachers and peer leaders in randomly assigned schools. The goal of the intervention was to sensitize students to overt and covert pressures to use tobacco. Even though only two of the seven class periods focused on ST-specific content, the intervention resulted in diminished ST use among males (the predominant users of ST) in the 7th and 9th grades. The program had a significant effect on reducing ST use among the boys in the 7th grade.<sup>20</sup>

Another example of a successful school-based program, Project SHOUT, evaluated an intervention delivered to 7th grade students in 22 California middle schools. Directed toward grades 5 through 9, the Project SHOUT program combined education, social activism, behavioral strategies, and telephone support from an older peer. At the 3-year follow-up, results showed a significant decrease in cigarette

use (OR = 0.77), ST use (OR = 0.47), and combined cigarette and ST use (OR = 0.71) at the school level within the past month.<sup>21</sup>

A California school tobacco prevention curriculum, Project Towards No Tobacco Use,<sup>22,23</sup> also showed promising results for ST prevention. This program corrected misperceptions about ST use, taught about the physical consequences of use, and tested the effectiveness of refusal skills. Although the combined curriculum was effective in reducing initial and weekly use of ST, the results of a 2-year follow-up showed that only the physical consequences curriculum sustained its benefit over the long term, which suggests that teaching students about the physical consequences of ST use in personally relevant ways can be important to preventing ST use.

School- and community-based intervention and prevention efforts in high-income countries have shown promising results, but prevention programs that target both substance use and tobacco may not offer enough information to have a significant impact on ST initiation. Most tobacco prevention programs focus on smoking and give little attention to ST in their curricula or activities.

School curricula targeting prevention of tobacco use, including ST, in some low- to middle-income countries (such as India) have been tested and also show promising results. Project MYTRI (Mobilizing Youth for Tobacco-Related Initiatives) was a multicomponent intervention aimed at reducing tobacco use among adolescents in schools in Delhi and Chennai, India. Students from 32 schools in the two cities were randomly assigned to either an intervention group or a control group. Baseline, intermediate, and outcome data were collected from two cohorts of 6th and 8th graders beginning in 2004; from 2004 to 2006, 14,063 students completed surveys. The Project MYTRI intervention is based on social cognitive theory and existing evidence-based smoking prevention programs which were appropriately translated to match the needs of adolescents in India.<sup>24,25</sup> The intervention consisted of behavioral classroom curricula, school posters, a parental involvement component, and peer-led activism. Classroom activities were based on a graded curriculum, and multiple sessions were implemented each year. In both years of interventions, high participation rates were achieved for classroom interactive activities. The peer-led component involved training a large number of students as peer leaders, while training teachers to supervise and assist the peer leaders in conducting classroom activities.<sup>25</sup> The control group received only a diet and physical activity intervention.

Over the 2 years of the MYTRI intervention, significant differences were noted between the intervention and control groups in the trajectories of cigarette smoking and bidi smoking, but no significant between-group difference was seen in trends in ST use behavior.<sup>26</sup> However, there were significant differences between groups in students' intentions to use ST and their social susceptibility to ST, suggesting that the intervention had some positive impact.

Project MYTRI's baseline data indicated that the prevalence rate for ever-use of ST for girls and boys was 12% and 16%, respectively.<sup>27</sup> In the intervention schools, ST adoption for girls decreased marginally over time compared to initiation of ST use by girls in control schools, where there was no change.<sup>25</sup>

### Individualized Preventive Interventions

Among youth in the United States and other high-income countries, ST use is considerably lower than cigarette smoking, although higher rates of ST use occur in certain subgroups. Smokeless tobacco use is much more common in boys than in girls,<sup>28</sup> and the highest rates of use in the United States are observed among Native Americans and Alaska Natives, in the Southern states, and in rural areas of low socioeconomic status.<sup>29</sup> Smokeless tobacco is also more common among young male players of certain sports, such as baseball.<sup>30</sup> Some prevention programs concentrate on these subgroups.

One study that focused on Native American youth<sup>31</sup> developed and tested a skills- and community-based approach to preventing substance abuse, including ST use. The program was carefully tailored to the cultural values and everyday realities of Native American youth in the targeted western reservations. The study found follow-up rates of ST use were lower for youths who received the skills intervention than for those in the control group, which did not receive an intervention.

Although not a special population of users, youth aged 10–14 years were targeted by a program that was implemented in 4-H clubs throughout California. This program focused on education about tobacco use in general, not specifically ST use. A youth development organization, 4-H is popular in rural areas and small towns in agricultural regions, and these voluntary clubs provided a unique opportunity to reach young people. Seventy-two 4-H clubs (with a total of 1,438 members) were matched and randomly assigned to an intervention (tobacco education delivered by volunteers in five successive monthly club meetings) or to a no-treatment control.<sup>32</sup> At a 1-year follow-up, club members in the intervention group showed significant effects in improved knowledge of the harmful effects of tobacco. Seven of 24 program effects were significant at 1 year in increasing knowledge, improving perceptions, and decreasing intentions to smoke, but no significant effect on reducing tobacco use was seen at the 2-year follow-up.

Studies conducted in the United States have documented that high school males frequently use ST when playing or watching a sport,<sup>33–35</sup> and the greater their athletic involvement, the more likely they are to use smokeless tobacco.<sup>36</sup> A behavioral intervention targeting male high school baseball athletes<sup>37</sup> was designed to discourage ST initiation and promote cessation. The intervention included an interactive peer-led component and a dental component with an oral cancer screening exam. Although the intervention was effective in promoting ST cessation, it was ineffective in preventing initiation. One predictor of ST initiation was that young people perceived that most of their teammates used ST (OR = 4.73), suggesting that correcting this overestimation would be an important component of an effective ST prevention program.

### Smokeless Tobacco Prevention Among Youth—Summary

The studies conducted in India and the United States strongly suggest that communitywide programs can significantly reduce intentions to use smokeless tobacco. The cultural adaptations made in Project ACTIVITY also demonstrate that community interventions can succeed in challenging environments such as very poor neighborhoods of Delhi, but more studies are still needed in other countries.

Some well-designed school-based interventions tested in the United States have also shown positive results in preventing ST use, but the number of ST interventions is much lower than the number of

smoking prevention interventions conducted in the United States in recent years. School-based prevention programs that focus specifically on the negative health and physical effects of ST and combine educational strategies with social activism can significantly reduce the likelihood that young men will start to use smokeless tobacco. Since ST use is especially high in some special populations, it is encouraging that interventions have been targeted toward these groups. Recent comprehensive reviews and meta-analyses confirm that school-based drug interventions can be successful provided they: (1) are interactive, (2) engage peer facilitators, (3) involve parents and other segments of the community, (4) are theory based and follow the social influences model, (5) adequately train teachers and support health-promoting school policies, and (6) are provided in multiple years, starting with age of initiation.<sup>3,38,39</sup> School-based interventions in India did not successfully reduce ST rates, although they changed intentions, attitudes, and knowledge of health risks. In conclusion, although there is a need to address ST use through curricula and school-based programs that target ST use by adolescents, broad community-based interventions appear to have more effect than school-based programs alone. However, school-based programs containing the six components listed above can produce at least short-term effects and reduce the prevalence of tobacco use among school-aged youth, particularly when they are implemented in combination with other initiatives such as mass media campaigns and state and community programs.<sup>40</sup>

## Smokeless Tobacco Cessation

Abstinence is the most effective way to prevent the morbidity and mortality associated with ST use. Evaluations of behavioral and pharmacologic interventions to treat ST use have shown that these interventions have had varying degrees of success, as measured by short- and long-term ( $\geq 6$  months) tobacco abstinence rates. In addition to promoting ST cessation, these interventions can be effective in treating tobacco craving and nicotine withdrawal symptoms. Most published RCTs evaluating interventions for ST use were conducted in the United States and may have employed slightly different measures of cessation, making it difficult to generalize the findings to other nations with different types and patterns of ST use. However, results of these trials can form a foundation upon which to construct interventions specifically tailored to regionally or culturally driven patterns of ST use. Table 7-2 lists ST cessation interventions that have been conducted at the community, organizational, and individual levels.

Table 7-2. Smokeless tobacco cessation interventions

Study*	Intervention	Design	Outcomes
<b>Community Level</b>			
Anantha et al. 1995 (46)	A 2-year community-based health education program aimed at preventing people from initiating any form of tobacco use or helping them quit use. Components included films, exhibits, and display of photographs of ST's harmful effects.	Cohort study	Evaluated through changes in prevalence, quit and initiation rates. Follow-up surveys after 2 and 3 years. In intervention cohort, the quit rate for ST use = 30.2% in males and 36.7% in females. Significantly higher proportion of men quit tobacco chewing (30.2%) than quit smoking (20.4%).
Gupta et al. 1986 (44)	Baseline and annual exams to detect oral cancer or lesions over 5 years. Personal education and mass media communication promoting tobacco cessation. Five-year intervention.	Cohort study in Ernakulam District, Kerala state, India 12,212 intervention subjects Comparison group received no education	Intervention significantly increased abstinence from tobacco (9.4% in the intervention group vs. 3.2% in the control) and reduced incidence of leukoplakia lesions.
Kyaing et al. 2003 (43)	176 facilitators were trained in 11 communities. Program included roundtable community discussions; advocacy talks with community leaders; Information, Education, and Communication (IEC) materials; disseminating tobacco-control messages during festivals; monthly meetings between facilitators and quitters; billboard postings.	Community demonstration. 11 communities in Myanmar	Quit rate of betel quid users in one community was 11%.
Murthy and Saddichha 2010 (48)	Tobacco Cessation Clinics (TCCs) in cancer, surgical, and cardiology clinics; and in nongovernmental organization settings. TCCs provide behavioral therapy, education, tips to quit, motivation to change, and relapse prevention counseling.	Cohort study 23,320 cases from the first 5 years of operations of TCCs in India Comparison group received counseling only	Counseling and medication (bupropion) significantly increased tobacco abstinence rates compared to counseling alone.
<b>Organization-Level Behavioral</b>			
<b>Youth Cessation</b>			
Burton et al. 2009 (60)	Addiction group Psychosocial dependency group Groups met for 5 sessions in 1 month, where they watched video clips and discussed tobacco use, and ST users were encouraged to use oral substitutes.	Schools randomly selected 337 subjects from 16 schools in Illinois and California Controls received no intervention	Intervention significantly increased abstinence among ST users compared with smokers.

Study*	Intervention	Design	Outcomes
D'Onofrio et al. 2002 (32)	Tobacco education delivered by volunteers in 5 successive monthly club meetings.	Cluster-RCT Subjects: 1,438 4-H club members from 72 clubs in California Controls attended regular meetings	Intervention significantly improved knowledge but not abstinence (see Individual-Level Behavioral table for more information on study outcomes).
Gansky et al. 2005 (58)	Intervention consisted of: (1) 3-hour videoconference training for athletic trainers/dentists/hygienists; follow-up newsletter for athletic trainers (2) Oral cancer screening by dentists/hygienists (3) Athletic trainer follow-up and referral with follow-up by trainer on quit date, plus 3 booster sessions 1 week apart (4) Peer-led component with education meeting (50–60 minutes).	Cluster-RCT Subjects: 1,585 collegiate baseball players from 52 California schools Control group received anti-tobacco education	Intervention did not increase ST abstinence but significantly reduced initiation of use.
Walsh et al. 1999 (56)	Team-based program including oral exam with feedback, photos of ST effects, advice to quit, self-help manual, optional brief counseling (15–20 minutes, about quit date, triggers, tobacco withdrawal); optional nicotine gum, optional phone counseling.	Cluster-RCT Subjects: 360 athletes from 16 California colleges Controls received oral exam only	Intervention significantly increased ST abstinence.
Walsh et al. 2003 (37)	Peer-led component: Interactive, peer-led team directing education with videotape and brief discussion, slide show, and small-group discussion on tobacco industry advertising. Dental component with oral cancer screening exam by a dentist or hygienist. Included advice to quit, a self-help guide, tobacco cessation counseling in small groups, and a phone call on the quit date.	Cluster-RCT Subjects: baseball athletes from 44 rural California high schools (516 subjects in 22 intervention schools, and 568 subjects in 22 control schools) Control group received no intervention	Cessation prevalence for intervention group was significantly higher than for controls.



Study*	Intervention	Design	Outcomes
Walsh et al. 2010 (59)	Peer-led educational session, oral exam with feedback, and three nurse-led group cessation counseling sessions. Peer-led sessions included video/slide presentation and discussion about the presentations and how the tobacco industry targets young males. Oral exam included feedback about any tobacco-related lesions, advice to quit using ST, assessing of readiness to quit. The three nurse-led counseling sessions were non-compulsory.	Cluster-RCT Subjects: 4,731 male students at 41 schools in rural California counties Controls received no intervention	At 1-year follow-up, non-smoking ST users in the intervention group were significantly more likely to stop using ST (62%) than those in the no-intervention group (36%).
<b>Adult Cessation</b>			
Kiesges et al. 2006 (63)	Discussion of positive changes since quitting ST use, information on negative consequences of ST use including visual depiction of health risks, encouragement to use oral substitutes (non-nicotine and non-tobacco herbal chew), and discussion of the progression from ST to other tobacco products.	RCT Subjects: 33,215 U.S. military recruits who quit using ST on entering basic training Controls received general health education	Intervention significantly increased abstinence from ST.
Severson et al. 1998 (12)	Usual dental care and office intervention with an oral exam, advice to quit, quit date setting; self-help materials including pamphlets, oral replacement, video; one phone support call.	Cluster-RCT with stratification 633 subjects from 75 dental clinics in Oregon Controls received usual dental care	Intervention significantly increased ST abstinence.
<b>Individual-Level Behavioral</b>			
<b>Youth Cessation</b>			
Fisher et al. 2001 (68)	Interactive computer program called Chewers Choice, which used a baseball interactive format.	Cohort study 50 subjects, mostly males	85% of users made a quit attempt, and 58% reported quitting.
Gala et al. 2008 (51)	Interactive, multiple-contact Internet ST cessation program.	Cohort study 18 collegiate baseball players from California (6 lost to follow-up)	As a result of this intervention there was a 26% self-reported reduction in ST use after 1 month, along with increases in motivation and confidence to quit.
Severson et al. 2011 (69)	An evaluation of Web-based cessation programs for ST users ages 14–25: one basic text-based website and one enhanced interactive site.	RCT 1,718 subjects	Intervention did not significantly increase ST abstinence.

Study*	Intervention	Design	Outcomes
<b>Adult Cessation</b>			
Boyle et al. 2008 (73)	A self-help manual plus proactive phone-based cessation counseling. Phone-based treatment included up to 4 calls in support of quitting and personalized cognitive and behavioral tobacco treatment strategies (e.g., setting a quit date, examining use patterns, developing stress-reduction skills, avoiding known triggers to use).	RCT 406 subjects from Minnesota Controls received usual care (i.e., self-help manual only)	Intervention significantly increased abstinence from tobacco. Significantly higher abstinence at 3 months in the intervention group (30.9%) than the control (6.8%), and at 6 months (intervention, 30.9% vs. control, 9.8%).
Cigrang et al. 2002 (65)	Program using motivational interviewing consisted of a treatment manual, video, and two supportive phone calls from a cessation counselor.	RCT Subjects: 60 military personnel from Texas Controls received usual care	Intervention significantly increased abstinence from ST at 3 months but not at 6 months.
Severson et al. 2000 (72)	Assisted self-help including: (1) Phone support (two calls, 10–15 minutes, with quit date setting and tobacco withdrawal management) (2) Self-help manual (60 pages) (3) Self-help videos (20 minutes).	RCT 1,069 subjects in Oregon, Washington, Idaho, Montana, and Alaska Controls received a self-help manual	Intervention significantly increased tobacco abstinence.
Severson et al. 2008 (74)	Enhanced website including personal quitting assistant (guided, interactive program), printable resources, links to other sites, two Web forums, plan-to-quit module, staying-quit module.	RCT Subjects: 2,523 ST users from 49 U.S. states Controls received a static textual website	Intervention significantly increased abstinence from tobacco. At 3 months, quit rate for intervention subjects = 12.6; for controls = 7.9%.
Severson et al. 2009 (64)	Telephone counseling by a trained cessation counselor who offered assistance in quitting ST use; a mailed videotape and self-help guide tailored for the military.	RCT Subjects: 785 military personnel across the United States Controls received usual care	Intervention significantly increased abstinence from tobacco. Repeated point prevalence at 3 and 6 months showed abstinence from all tobacco: intervention subjects, 25% vs. controls, 7.6%. Abstinence from ST at 6 months: intervention subjects, 16.8% vs. controls, 6.4%.

Study*	Intervention	Design	Outcomes
Stevens et al. 1995 (66)	Oral exam with feedback, advice to quit from hygienist and dentist, self-help manual, quit kit, video, phone call from counselor, free helpline, six newsletters.	RCT Subjects: 518 ST users in the Pacific Northwest	Intervention significantly increased abstinence from ST. Abstinence among intervention subjects at both 3 months and 12 months = 18.4%, compared to 12.5% among controls.
<b>Individual-Level Non-pharmacologic</b>			
Chakravority 1992 (76)	Interventions: (1) herbal mint snuff or (2) nicotine chewing gum	RCT Subjects: 70 male ST users ages 14–18 (Illinois area) Controls received lecture only	Herbal mint snuff users significantly decreased ST use compared to those who used gum or attended lectures.
Hatsukami et al. 2000 (75)	Herbal mint snuff. All subjects received a self-help treatment manual and 10 minutes of individual counseling at 8 clinic visits over 10 weeks.	RCT with a 2x2 design; active vs. placebo patch crossed with herbal mint snuff vs. none 402 subjects from Minnesota	Herbal mint snuff did not increase abstinence rates but significantly reduced tobacco craving and withdrawal.
<b>Individual-Level Pharmacologic</b>			
<b>Nicotine Replacement Therapy: Nicotine Gum</b>			
Hatsukami et al. 1996 (81)	2 mg nicotine gum for 8 weeks starting at 6 pieces per day then tapering, with an option for a third month.	RCT with 2x2 design; intensive counseling vs. minimal contact crossed with nicotine gum vs. placebo Subjects: 210 adult ST users from Minnesota	Gum significantly decreased tobacco withdrawal symptoms but did not increase abstinence from tobacco.
<b>Nicotine Replacement Therapy: Nicotine Lozenge</b>			
Ebbert et al. 2009 (78)	4 mg nicotine lozenge for 12 weeks including tapering period.	RCT 270 subjects from Minnesota and Oregon Controls received a placebo	Lozenge significantly increased self-reported abstinence from all tobacco at 3 months and significantly decreased tobacco craving and withdrawal.

Study*	Intervention	Design	Outcomes
Ebbert et al. 2010 (80)	4 mg nicotine lozenge for 12 weeks mailed to subjects, plus phone support.	RCT 60 subjects from Oregon and Minnesota Controls received a placebo	Nicotine lozenge did not increase abstinence from tobacco but significantly decreased tobacco withdrawal symptoms.
<b>Nicotine Replacement Therapy: Nicotine Patch</b>			
Croucher et al. 2003 (82)	15 mg patch for 4 weeks vs. brief counseling.	Non-randomized study, with pairs matched on age and amount of tobacco use; no placebo Subjects: 130 UK-resident Bangladeshi women who used paan	NRT and brief advice did not significantly increase tobacco abstinence rates compared to brief advice alone.
Ebbert, Dale et al. 2007 (85)	Conditions: (1) 63 mg nicotine patch, (2) 42 mg patch, (3) 21 mg patch, (4) placebo. Patches were given for 8 weeks. All subjects received behavioral counseling.	RCT Subjects: 42 ST users from Minnesota Multidose, placebo-controlled	Statistically significant dose-response relationship, with higher nicotine doses associated with less tobacco withdrawal.
Hatsukami et al. 2000 (75)	21 mg nicotine patch for 10 weeks, including tapering period.	RCT with a 2x2 design; active vs. placebo patch crossed with herbal mint snuff vs. none 402 subjects from Minnesota	Patches significantly increased abstinence from tobacco at 10 and 15 weeks and significantly decreased tobacco craving and tobacco withdrawal symptoms.
Howard-Pitney et al. 1999 (83)	15 mg nicotine patch for 6 weeks. Intervention subjects and controls received self-help materials and phone support.	RCT Subjects: 410 adult ST users in California Controls received a placebo	Patch significantly increased ST abstinence at 3 months.
Stotts et al. 2003 (84)	Conditions: (1) Nicotine patch tailored to baseline cotinine: >150 mg/ml received 21 mg initially, otherwise 14 mg with medication tapering for 6 weeks of treatment (2) Counseling only (6 behavioral intervention classes with NCI materials) (3) Counseling plus placebo patch and phone calls.	RCT Subjects: 303 users ages 14–19 in Arkansas Controls received a placebo	At 1 year, no differences between the placebo and active patch groups, but combined, the two patch groups had significantly higher cessation rate (32.8%) than the counseling-only group (22.9%).

Study*	Intervention	Design	Outcomes
<b>Bupropion</b>			
Dale et al. 2002 (87)	Bupropion SR 150 mg twice a day for 12 weeks.	RCT 68 subjects from Minnesota Controls received a placebo	Bupropion non-significantly increased short-term tobacco abstinence rates and significantly decreased tobacco withdrawal.
Dale et al. 2007 (86)	Bupropion SR 150 mg twice a day for 12 weeks.	RCT 225 subjects from West Virginia and Minnesota Controls received a placebo	Bupropion SR did not increase abstinence from ST but significantly attenuated weight gain and significantly decreased tobacco craving.
<b>Varenicline</b>			
Ebbert et al. 2011 (89)	Varenicline for 12 weeks.	RCT Subjects: 76 ST users in Wisconsin and Minnesota Controls received a placebo	Varenicline significantly decreased tobacco craving, but this study was underpowered to assess abstinence outcomes.
Fagerström et al. 2010 (88)	1 mg varenicline twice/day for 12 weeks.	RCT Subjects: 431 Scandinavian snus users Controls received a placebo	Varenicline significantly increased abstinence from ST at 6 months.

\*Numbers in parentheses correspond to full citations in the References at the end of this chapter. Abbreviations: mg = milligram; ml = milliliter; RCT = randomized controlled trial; ST = smokeless tobacco.

### Community-Level Interventions

Tobacco cessation efforts in low- to middle-income countries are primarily community-level interventions, reflecting, in part, limited resources and a scarcity of professional ST cessation training. For example, the Global Adult Tobacco Survey (GATS), conducted in India during 2009 and 2010, found that 47% of ST users had visited health care providers in the past 12 months, but only 34% of those users were asked about ST use, and only 27% of those who had visited health care providers in the past 12 months were advised to stop tobacco use.<sup>41</sup> These findings support implementing cessation efforts at the community level and offering more cessation training to health care providers.<sup>41,42</sup>

Myanmar and India are implementing tobacco control programs with legislation, community awareness, community mobilization, and/or health promotion activities as main components.

Myanmar piloted a community tobacco use cessation project.<sup>43</sup> In this pilot study, community facilitators in two regional divisions, Yangon and Bago, were selected and trained. Community-based cessation activities included roundtable discussions with the community; advocacy talks with community leaders; Information, Education, and Communication (IEC) materials; dissemination of tobacco control messages during festivals; monthly meetings between facilitators and quitters; and billboard postings. The impact of these cessation activities varied widely in different communities depending on the intensity of the interventions. Among smokers, 11% completely stopped smoking and 15.4% were in the process of quitting; among ST users, one community reported a quit rate of 11%.<sup>43</sup>

A large community-based cessation intervention was also tested in one state in India. The intervention included personal and mass media communications to motivate smokers and ST users to quit, which contributed to significantly more quit attempts among program participants in the intervention group (9.4%) than in the control group (3.2%) after 5 years of intervention.<sup>44</sup> This intervention was effective across all demographic groups but had a greater impact on men, ST users, older people, and those with a shorter duration of tobacco use.<sup>45</sup> The researchers also reported a reduced 5-year age-adjusted incidence rate of leukoplakia (oral lesions) after tobacco cessation.

Another community-based tobacco control education program was implemented in the Kolar district in Karnataka (India). In an effort to prevent individuals from initiating tobacco use in any form and to quit use if already using, this program used health education materials, consisting of films, exhibits, and displays of photographs of harmful effects. Program results were evaluated through changes in prevalence rates, quit rates, and initiation rates, and the effects of 2 years of intervention were assessed by follow-up surveys after the second and third years. In the intervention cohort, the quit rate for ST use was 30.2% among males (vs. approximately 1.15% in the control group). A higher proportion of men had quit ST use (30.2%) than had quit smoking (20.4%).<sup>46</sup>

In 2002, with support from the World Health Organization (WHO), the Government of India, through its Ministry of Health and Family Welfare (2009),<sup>47</sup> established 19 tobacco cessation clinics (TCCs) across the country, primarily in cancer, surgical, and cardiology clinics, and in some nongovernmental organization settings. The TCCs provide behavioral therapy, education, tips for quitting, motivation to change, and relapse prevention counseling.<sup>47</sup> Experiences from the TCCs were pooled, and baseline information was obtained on 23,320 individuals from the first 5 years of the TCCs' operations.

Sixty-nine percent of the individuals received behavioral therapy only, and 31% received both behavioral therapy and pharmacotherapy.<sup>48</sup> Younger men, ST users, and those receiving combination therapies had relatively better outcomes at 3-, 6-, and 9-month follow-ups. Continued follow-up was found to contribute to better outcomes in these clinics. However, more research is needed to determine whether these outcomes are sustainable over the long term. Barriers to ST cessation were low levels of awareness of the harms from ST use and lack of knowledge about the benefits of quitting and methods of quitting.

The tobacco cessation experience in India suggests that clinics have better outcomes with ST users than with smokers. Moreover, the “5 A’s” approach for smoking cessation translates well into ST cessation: (1) Asking all treatment seekers about their tobacco use, (2) Advising them in clear terms about the risks of continuing use and the advantages of stopping, (3) Assessing their readiness to quit, (4) Assisting them in quitting, and (5) Arranging for referral or follow-up. Health professionals and community staff in existing health systems can be trained in using the 5 A’s, which can easily be integrated into health initiatives in various health care settings.<sup>49,50</sup>

### Organization-Level Behavioral Interventions

A variety of behavioral interventions for the treatment of ST use have been evaluated in a broad array of different populations of ST users at the organizational level (e.g., school, clinic, military unit). Successful interventions have used psychosocial education, social support, relapse prevention strategies, and an oral examination with feedback about changes in oral health caused by ST use. Interventions have been based on social influence theory,<sup>32</sup> the health belief model,<sup>51</sup> diffusion of innovation theory,<sup>52</sup> and cognitive social learning theory.<sup>53</sup>

### Youth Cessation

Few researchers have focused on developing efficacious, practical cessation tools for young ST users. The small number of ST interventions designed for youth are usually incorporated as secondary elements of multicomponent ST tobacco use prevention programs. Although school- or community-based programs may help reduce initiation or early use, any effort to reduce prevalence must include a focus on helping young users quit. In the United States, most ST cessation programs for youth focus on high school or college athletes, groups that are known to have higher rates of ST use.<sup>33,36,37</sup> Some interventions designed to reduce the adoption of tobacco use by middle school and high school youth examine program effects on cessation among students who were already using tobacco products, but few programs have included ST-specific cessation components.

Cessation programs for youth often use multisession, multicomponent, cognitive behavioral interventions that include self-monitoring of ST use, education about health risks, and behavioral coping strategies for helping young people quit. These programs face challenges in motivating young users to quit and overcoming high drop-out rates and attrition levels.<sup>29</sup> These programs tend to be more successful for lower level users who use less ST and therefore are probably less dependent.

Group- or organization-level behavioral interventions have been effective in increasing rates of long-term tobacco abstinence among adolescent ST users. One large study,<sup>37</sup> involving 22 treatment schools

and 22 control schools, examined the impact of ST cessation efforts aimed at high school baseball players randomly assigned to treatment or to a control condition. Treatment consisted of discussion of the harmful effects of ST use, refusal skills training, encouragement of cessation by a strong peer opinion leader, a meeting with coaches, a self-help guide to quit, and a dental exam with cessation advice from a dentist. Sustained ST cessation was significantly higher in the treatment compared to the control group (27% vs. 14%, respectively). Results of this intervention were based on self-reports, but the researchers obtained saliva samples from participants to increase the accuracy of self-reports and used the “bogus-pipeline” procedure, in which participants were informed that the samples could be used to ascertain the veracity of the self-reports.<sup>53,54</sup> Using oral health screening exams, brief counseling, and peer-led educational sessions helped to double the quit rate compared to quit rates of students in control schools. Previous cessation research studies with adults have found that oral exams can be significant motivators for ST users to quit.<sup>29,55</sup>

A similar study found that a college-based ST cessation intervention targeting college athletes was more effective than no intervention for increasing long-term tobacco abstinence among these participants.<sup>56</sup> The study was an RCT involving baseball and football athletes at 16 California public colleges, both rural and urban, which were matched on prevalence of ST use. Players completed questionnaires assessing their tobacco use. The intervention was a team-based cessation program based on cognitive social learning theory<sup>57</sup> in which a dentist performed oral soft tissue exams with each team member, advised users to quit, pointed out ST-related tissue changes in their mouths, showed photographs of cancer-related facial disfigurement, provided a self-help cessation guide, and offered users a single 15- to 20-minute session of counseling. Individuals who wanted to quit received 2 mg nicotine gum to treat tobacco withdrawal symptoms. Dental hygienists met with non-users in small groups to discuss the quitting process and encouraged them to support the ST users in quitting. Those trying to quit received two support phone calls. Among the 360 ST users, the intervention significantly increased ST abstinence rates at 1 year compared to the rates for participants in the control groups. On average, the observed self-reported quit rates were 34.5% for intervention schools and 15.9% for control schools. Besides doubling the quit rate, the intervention led to significant reductions in reported tobacco use for those who did not quit.

Another study involved athletic trainers directing an ST cessation program with collegiate baseball players,<sup>58</sup> who are known to be high users of snuff. This study involved 52 California colleges in a stratified, cluster-RCT of an intervention intended to prevent initiation and promote cessation of ST use. Intervention components included videoconference training, newsletters, an oral cancer screening exam, a self-help guide for quitting, and a counseling session for interested players. Those wanting to quit received follow-up support from the athletic trainer on the quit date and three booster sessions 1 week apart. Athlete peer leaders conducted a single 60-minute educational team meeting that included video and slides. Although the program had the significantly positive effect of reducing initiation of ST use at 1-year follow-up, there was no significant difference in cessation between intervention and control groups (95% CI: 0.70–1.27). The authors attribute this lack of effect on cessation to the small number of dependent ST users enrolled in the study.

Walsh and colleagues<sup>59</sup> conducted a randomized study involving male students in 41 rural high schools. The students received an intervention consisting of a peer-led educational session plus an oral exam with



feedback and three nurse-led group cessation counseling sessions, or no intervention. In the peer-led educational session, student peers presented videos and slides and then led a discussion about the 2 videos and 10 slides related to ST use, and about the role of the tobacco industry in targeting young men. A school nurse conducted the oral exam and pointed out any tobacco-associated lesions to the students. The nurses also asked about tobacco use, advised users to quit, assessed users' readiness to quit in the next month, and assisted with the quitting process by offering a self-help guide. The nurse-led counseling consisted of three non-compulsory, 1-hour cessation sessions held after school approximately 1 week apart. Non-smoking ST users in the intervention group were significantly more likely to have stopped using ST at the 1-year follow-up than those in the no-intervention group (62% vs. 36%).

An ST cessation study involving younger users (aged 10–14 years) was conducted in California agricultural youth 4-H clubs (methods described in “Individualized Preventive Interventions” section above). Four months after the intervention, the intervention group showed significantly improved knowledge, attitudes, and behavioral intention; however, no differences in behavior (no increase in cessation or abstinence) were seen at either the 4-month or the 2-year follow-up.<sup>32</sup>

Burton and colleagues<sup>60</sup> reported a school-based study that compared two models of cessation for smokers and ST users in 16 high schools. Students were randomly assigned to an addiction group, a psychosocial dependency group, or a control group. The addiction model focused on psychological aspects of addiction and the effects of nicotine, whereas the psychosocial dependency model focused on social and psychological aspects of tobacco use and on stress management. The majority of the participants were smokers, but the treatment groups shared some components, and the sessions were divided between information presentations and group discussions. Smokeless tobacco users were significantly more likely than smokers to abstain from tobacco use at the 4-month follow-up, when the validated quit rates were 14.3% for ST users and 6.5% for cigarette smokers; the control groups had no subjects reporting ST abstinence and 3.2% reporting cigarette abstinence.

### **Adult Cessation**

Both smoked and smokeless tobacco use rates in the U.S. military are higher than in the rest of the U.S. population.<sup>61,62</sup> Effective interventions focusing on the treatment of ST dependence are critical for reducing adverse health consequences among military personnel. In a study of U.S. military recruits entering basic military training (BMT), during which no tobacco use is allowed, 33,215 subjects were randomly assigned to either a tobacco use intervention, including an ST component, or a health education control group.<sup>63</sup> The ST component included a discussion of the positive changes since quitting (upon entering BMT), information about the negative consequences of ST use, a visual demonstration, encouragement to use oral substitutes (non-nicotine and non-tobacco herbal chews), and discussion of the progression from ST to other tobacco products. Smokeless tobacco users in the intervention group were significantly more likely than ST users in the control group to be continuously abstinent at follow-up.

Dental offices provide a unique and effective point of intervention for ST users. In a study involving 75 U.S. dental offices, 633 ST users were randomly assigned to a behavioral intervention consisting of usual dental care combined with advice to quit, setting a quit date, self-help materials (pamphlets; non-tobacco, non-nicotine oral replacement products; and a specialized video for smokers and ST users),

and phone support. The control group received usual dental care only.<sup>11,12</sup> The intervention was associated with significantly increased 3- and 12-month ST abstinence rates compared to usual dental care (10.2% vs. 3.3%).<sup>11</sup>

Dental setting interventions in both military and civilian populations have been effective in increasing tobacco abstinence rates among ST users. In a study of 24 U.S. military dental clinics, 785 ST users were randomly assigned to usual care or telephone counseling with a trained cessation counselor. Those in the phone counseling group received assistance in quitting ST use (if desired) along with a mailed videotape and military-specific self-help guide.<sup>64</sup> The first phone counseling call occurred about 1 week after a dental visit. Individuals accepting materials were offered two or more calls coinciding with receipt of the mailed materials and their ST quit date. Subjects in the ST cessation program were significantly more likely to be abstinent from all tobacco, as assessed by repeated point prevalence at both 3 and 6 months (25.0%), and were significantly more likely to be abstinent from ST for 6 months as assessed by prolonged abstinence (16.8%) compared with usual care (7.6%, repeated point prevalence; 6.4%, prolonged abstinence).

Another program identified active-duty military ST users during preventive health screenings and provided an intervention consisting of an ST treatment manual, a video, and several supportive phone calls from a cessation counselor.<sup>65</sup> At 3 months, tobacco abstinence rates in the intervention group were double those in the usual care group (41% vs. 17%), but the difference was not significant at 6 months (37% vs. 19%).<sup>65</sup>

The authors of another study cite feedback from oral exams as a key motivational factor for getting patients to try to quit. In a program conducted in 11 dental clinics, 518 ST users were randomly assigned to usual care or a behavioral intervention incorporating an oral exam with feedback, advice to quit from both a hygienist and a dentist, a self-help manual, a video, setting a quit date, telephone support from a counselor, a free helpline, and six newsletters.<sup>66</sup> The behavioral intervention significantly increased long-term abstinence rates; abstinence among the intervention subjects at both 3 and 12 months was 18.4% compared to a rate of 12.5% among those who received usual care.

A 2010 review of behavioral interventions for oral tobacco cessation offered in countries other than the United States suggested that behavioral interventions and components such as telephone counseling and oral examination may particularly enhance abstinence rates.<sup>67</sup>

### **Individual-Level Behavioral Interventions**

Behavioral interventions for ST users conducted at the individual level are described in Table 7-2.

#### **Youth Cessation**

The high prevalence of Internet and computer use among young people suggests that technology-based interventions might offer an innovative opportunity to engage young users in the quitting process. Several studies of these interventions have been conducted in the United States. Fisher and colleagues<sup>68</sup> reported on the use of an interactive computer-mediated intervention designed to help individuals quit using ST, a mode of delivery that is an attractive alternative to school or clinical settings. A small pilot

study was conducted with 50 individuals who accessed a program called Chewer's Choice, which used a baseball field interface to appeal to users, most of whom were male. The authors reported that at the 6-week follow-up, 85% of all subjects had made a quit attempt, and 58% of all subjects reported having quit all tobacco for at least 24 hours.

Another pilot study evaluated an Internet ST cessation program with 18 baseball players at California colleges in 2008. The 26% self-reported reduction in ST use at 1-month follow-up indicates that this may be a feasible program acceptable to users.<sup>51</sup>

A Web-based program designed specifically for young users could be a low-cost alternative for promoting cessation. An RCT evaluating a Web-based cessation program<sup>69</sup> offered to ST users ages 14 to 25 years (described at <http://www.mylastdip.com>) examined the efficacy of two websites designed for young ST users. The "basic" condition provided a text-based site offering an evidence-based cessation program plus information and resources on ST cessation. The "tailored" condition was a customized, interactive site providing video and other engaging activities plus the opportunity to post on "blogs" (Web-based message boards). A unique feature of this study was that no parental consent was required to participate, as previous research has shown that requiring active consent from parents can significantly deter enrollment in cessation or prevention studies.<sup>70,71</sup> Preliminary results showed relatively high self-reported quit rates at 3 months (38% for the basic condition; 41% for the tailored condition). Although there were no differences between conditions at either the 3-month or the 6-month follow-up, both groups had self-reported rates of abstinence comparable to rates for treatments involving more intense in-person interventions.<sup>69</sup>

### **Adult Cessation**

Telephone support from trained counselors along with self-help materials can enhance tobacco abstinence rates among adult ST users. In a study that randomly assigned 1,069 ST users to a self-help manual only (MAN) condition or to assisted self-help (ASH), the ASH intervention resulted in significantly higher ST quit rates (23.4% vs. 18.4%) and rates for quitting all tobacco products (21.1% vs. 16.5%) at 6 months.<sup>72</sup> The ASH condition included an ST intervention manual, a video, and two support phone calls. Since this combination of assisted support, including the video and the phone calls, greatly increased quit rates, it can be considered a key ingredient for improving success in quitting.

In an RCT of a phone-based intervention, 406 adult ST users in the U.S. Midwest were randomly assigned to self-help alone (a manual only) or to a "QL" condition, consisting of a tobacco quit line with self-help combined with proactive phone counseling that emphasized support, problem-solving, use of cognitive-behavioral strategies (such as setting a quit date, examining use patterns, reducing stress, and avoiding known triggers).<sup>73</sup> Prolonged abstinence (after a 30-day grace period) from all tobacco was significantly higher at 3 months for the QL intervention group (QL intervention, 30.9% vs. manual only, 6.8%) and at 6 months for the QL intervention group (QL, 30.9% vs. manual only, 9.8%). Phone counseling again appears to be an important element in increasing quit rates.

Web-based interventions have increased abstinence rates among adult ST users. In a study of Web-based ST interventions, 2,523 U.S. smokeless tobacco users were randomly assigned to an "enhanced" or a "basic" website intervention.<sup>74</sup> The enhanced intervention included personal quitting aids with a guided,

interactive program; printable resources; and links to other websites, Web forums, and education modules. The basic intervention consisted of static text. On the basis of the repeated point prevalence of all tobacco use at 3 and 6 months, the enhanced intervention significantly increased tobacco abstinence rates compared to the basic intervention (12.6% vs. 7.9%, respectively).

### **Non-pharmacologic Therapy**

Herbal chew is a nicotine-free, non-tobacco product available in U.S. convenience stores or on the Internet. A chopped mint or other plant blend product to be placed in the mouth, herbal chew is intended to replace the oral sensation of ST, which may help users achieve abstinence. One study evaluated the efficacy of an herbal chew product (herbal mint snuff) in a 2 x 2 design with 402 subjects randomly assigned to a nicotine patch or a placebo crossed with herbal mint snuff or no herbal mint snuff.<sup>75</sup> Herbal mint snuff did not increase abstinence rates but significantly reduced cravings and symptoms of withdrawal.

Several studies have noted that non-nicotine oral substitutes can help reduce withdrawal and aid in ST cessation. Smokeless tobacco cessation guides suggest a wide range of products, including chewing gum, nuts, sunflower seeds, beef jerky, or cinnamon sticks.<sup>76,77</sup> Chakravorty assigned 70 rural male ST users aged 14 to 18 years, who averaged 1.5 dips/day, to one of three conditions: use of a non-tobacco product (herbal mint snuff), use of nicotine chewing gum, or only attending a lecture (control condition). Subjects in the herbal mint snuff group were significantly more likely to report decreased use of ST than subjects in the other two conditions. Oral substitutes might be an important element in assisting users to quit ST, and a variety of substitutes exist for this purpose.

### **Pharmacotherapy**

Pharmacotherapies evaluated for the treatment of ST users include nicotine replacement therapy (NRT patch, gum, and lozenge), bupropion sustained-release (SR), and varenicline (Table 7-2).

### **Nicotine Replacement Therapy**

Limited evidence is available regarding the efficacy of NRT. Available evidence suggests that NRT does not seem to increase long-term ( $\geq 6$  months) abstinence rates in ST users; however, it does appear to decrease nicotine withdrawal and craving, and some forms of NRT may increase short-term (10–12 weeks) abstinence rates.<sup>78–80</sup> Treating withdrawal is important because ST users experience a constellation of withdrawal symptoms upon cessation (craving, irritability, frustration, anger, difficulty concentrating, restlessness, impatience, increased appetite, and depressed mood).

**Nicotine Gum**—In a study evaluating the efficacy of 2 mg nicotine gum for treatment of ST use, 210 adult users were randomly assigned to 8 weeks of 2 mg gum or a placebo along with either a group behavioral intervention or minimal contact.<sup>81</sup> Nicotine gum did not significantly increase tobacco abstinence rates. However, during the 8-week treatment, 2 mg gum use significantly decreased tobacco craving and nicotine withdrawal compared to placebo.

**Nicotine Lozenge**—In a study evaluating the efficacy of the 4 mg nicotine lozenge for treatment of ST use, 270 subjects were randomly assigned to a 12-week tapering regimen of lozenges or a placebo.<sup>78</sup> Compared to a placebo, at 12 weeks the 4 mg lozenge significantly increased self-reported all-tobacco abstinence (44.1% vs. 29.1%) and self-reported ST abstinence (50.7% vs. 34.32%), although biometrically confirmed tobacco abstinence rates were not significantly different between the placebo and NRT groups. The nicotine lozenge significantly decreased tobacco craving and nicotine withdrawal compared to the placebo. In a small randomized pilot study (N = 60) evaluating the efficacy of mailing the 4 mg lozenge to ST users combined with phone support, the lozenge significantly decreased withdrawal symptoms compared to the placebo.<sup>80</sup>

**Nicotine Patch**—Another study compared the 15 mg nicotine patch with brief counseling advice alone. The 130 subjects were UK-resident Bangladeshi women who volunteered in response to community outreach. These subjects chewed betel quid (i.e., betel leaf, areca nut, slaked lime [calcium hydroxide], and brown powder paste; also known as paan) with tobacco. They were matched on age and amount of ST use. Of the successful quitters at the end of the 4-week study, 22% had received NRT, and 17% had received brief advice and encouragement alone. This pilot study demonstrated that methods used to help smokers quit can be successfully adapted for use with Bangladeshi women who use betel quid.<sup>82</sup>

In a study evaluating the efficacy of the 15 mg/16-hour patch for ST users, 410 adult ST users were randomly assigned to the patch or a placebo plus a behavioral intervention for 6 weeks.<sup>83</sup> All participants received two sessions with a pharmacist at baseline and at 4 weeks, as well as self-help materials and phone support at 48 hours and 10 days after the target quit date. Use of the patch significantly increased abstinence rates at 3 months compared to placebo (31% vs. 25%, respectively); less craving was observed at 48 hours after the target quit date. This program demonstrated the potential of using pharmacists as interventionists; other professional groups could expand the reach of cessation programs.

Another patch study evaluating the 21 mg/day nicotine patch for 6 weeks with a 4-week taper compared to a placebo. Four hundred subjects were randomly assigned to active patch with and without herbal mint snuff or to a placebo patch with or without herbal mint snuff.<sup>75</sup> Compared to placebo, the nicotine patch significantly increased tobacco abstinence rates at 10 weeks (67% vs. 53%) and at 15 weeks (52% vs. 43%). The patch significantly decreased craving and withdrawal symptoms.

Stotts and associates<sup>84</sup> examined whether ST users aged 14 to 19 years were aided in their cessation attempts by using nicotine patches and receiving several follow-up counseling phone calls. Over 300 students were randomly assigned to one of three conditions: (1) counseling only (6 weeks of 50-minute, age-relevant behavioral intervention classes based on materials from the National Cancer Institute); (2) counseling plus an active nicotine patch and phone support; and (3) counseling plus a placebo patch and phone support. Participants in the two groups receiving the patch plus phone support also received seven 15-minute counseling phone calls. Analysis of 1-year follow-up results indicated no differences between the placebo and active patch groups, but when combined, these conditions were significantly more successful in encouraging cessation for ST (32.8%) than the counseling-only condition (22.9%). This study did not find that nicotine replacement was effective long term

(≥6 months), a finding that is consistent with other studies of the efficacy of nicotine replacement for ST cessation with adults.

In a study evaluating high-dose nicotine patch therapy, 42 ST users were randomly assigned to a 63 mg/day patch, a 42 mg/day patch, a 21 mg/day patch, or a placebo.<sup>85</sup> Patches were used for 8 weeks, and all subjects received behavioral counseling. No significant differences were observed in abstinence rates between the four groups at 6 months. However, a statistically significant relationship was observed between higher patch doses and a greater degree of withdrawal symptom relief.

### **Bupropion**

Bupropion has not been demonstrated to increase short- or long-term abstinence rates among ST users, but two studies found that it may decrease tobacco craving and delay postcessation weight gain. In a study evaluating the efficacy of sustained release (SR) bupropion, 225 subjects were randomly assigned to medication or a placebo for 12 weeks.<sup>86</sup> Bupropion SR led to significantly less tobacco craving up to 14 days after the target quit date and less weight gain (1.7±2.9 kg increase for bupropion vs. 3.2±2.7 kg for the placebo). This weight gain attenuation was also observed in a smaller pilot study of bupropion SR for ST users,<sup>87</sup> in which the mean weight change from baseline to the end of treatment was 0.7±1.9 kg for bupropion and 4.4±2.4 kg for placebo (p = .03).

### **Varenicline**

Varenicline, which came on the market in the United States and the European Union in 2006, has been demonstrated to be effective in treating nicotine dependence among cigarette smokers, yet few studies have assessed its effect on ST abstinence. In a study evaluating its efficacy for ST users, 431 Scandinavian snus users were randomly assigned to varenicline at a target dose of 1.0 mg by mouth twice daily for 12 weeks, or to a placebo. Compared to the placebo, varenicline significantly increased continuous tobacco abstinence rates at weeks 9 to 12 (59% vs. 39%; p <.001) and at weeks 9 to 26 (45% vs. 34%; p = .012).<sup>88</sup> A pilot study that randomly assigned 76 U.S. smokeless tobacco users to 12 weeks of varenicline or a placebo found that varenicline significantly decreased tobacco craving,<sup>89</sup> but the study was underpowered to assess abstinence outcomes.

Concerns have been raised about the possibility of adverse effects related to the use of varenicline. The U.S. Food and Drug Administration has required a boxed warning on the varenicline label to alert physicians and subjects to behavior change risks.<sup>90</sup> The labeling warns of the risk of behavioral changes such as depression, hostility, aggression, suicidal thoughts, suicide, and the risks of vehicular crashes. However, available research has not established a clear causal link between the drug and adverse psychiatric events.<sup>91-93</sup> Additional concerns about adverse cardiovascular effects<sup>94</sup> have been raised but remain controversial.<sup>95</sup> The U.S. Food and Drug Administration required the manufacturer of varenicline to conduct a meta-analysis on the cardiovascular effects of varenicline, which revealed a small increase in adverse cardiovascular effects, but the increase was not significant.<sup>96</sup> As with any pharmaceutical intervention, doctors are advised to weigh the benefits and risk of varenicline use and patients should be monitored for treatment responses and adverse effects.

## Gaps and Limitations

While several studies have examined interventions for prevention and cessation among adults and youth, some of the studies reviewed here were conducted at least 10 years ago. Over that time period the types of ST products available and the marketing of those products have changed considerably. Therefore, the information on the interventions presented in this chapter should be examined in the current context to see if the findings can be replicated. In addition, standard definitions for cessation could be adopted or, at least, durations of abstinence should be consistently reported. When possible, biochemical validation of abstinence is also valuable. Finally, when evaluating interventions, additional consideration should be given to the applicability of these findings for low-income countries as well as the sustainability of the programs described.

## Summary and Conclusions

Effective preventive and cessation interventions as well as public policy efforts can reduce ST use.

School-based and community prevention programs produce short-term effects such as reduced rates of prevalence, experimentation, and intention to use ST, as well as some reduction of use among those already using. Youth and parental involvement in planning and executing these programs may be an important component. Most prevention programs focus on younger adolescents (aged 12–15 years) and emphasize understanding social influences and developing the social skills needed to resist the social pressures to use smokeless tobacco. Many programs involve peer leaders rather than adult providers. School programs supplemented by effective family-based or mass media programs can produce larger effects than school-based programs alone. There is potential for young people to become involved in planning prevention programs for youth that are interactive, engage peer facilitators, and involve parents and other segments of the community. These programs may be more effective if they are theory based, continuous, provide adequate training for teachers, and are supported by school policies that promote health and by government tobacco control policies.

Most cessation programs have been evaluated with adult ST users; they show positive results for dental office interventions and clinical interventions involving multiple sessions and counselor support. Phone counseling and feedback on dental exams appear to be key elements in successful cessation programs. Oral health professionals can be further engaged as a “front line” in the prevention and treatment of ST dependence. To better support cessation interventions, oral health professionals can be trained to recognize oral disease caused by ST use and to deliver tobacco use interventions or refer patients who want treatment to physicians or counselors with the necessary training. Models such as “Ask-Advise-Refer” should be adopted and implemented in health care systems. A drawback of dental office interventions is that many high-risk youth and adults do not see a dentist, therefore considering other potential avenues for intervention is important.

The evidence suggests that pharmacologic aids such as nicotine replacement (e.g., patches, gum, or lozenges) can help reduce withdrawal symptoms and cravings in ST users, but so far they have been found to be ineffective for increasing long-term ST abstinence rates. At least one study has shown significant increases in short- and long-term abstinence rates with varenicline in ST users. So far, however, these medication aids have been approved by regulatory agencies for smoking cessation but

not for ST cessation or for reducing symptoms or cravings. Where available, medication may be helpful in reducing symptoms associated with quitting tobacco use and, in the case of varenicline, increasing short-term quit rates. More research is needed to support specific indications for cessation medications in ST users. Additionally, most of the evidence for medication aids comes from high-income countries, and more research is needed to develop and test interventions that can be effective in resource-constrained environments.

Some targeted interventions for youth have demonstrated efficacy, but available studies have shown varying success. A limitation of many of the studies reported is that they are based on self-reported data that is often school-based and concentrated in high-income areas. Additional research is needed on different types of interventions and programs among a diverse range of countries and groups for youth. Interventions for special populations of ST users (such as Native Americans and athletes) have been developed and evaluated and are available for implementation. Cultural adaptations are needed to provide interventions that are appropriate for both the context of ST use and the ST products being used in different regions, especially when translating a program to a region such as India, where a variety of different oral tobacco products are used.

In environments where resources are limited or clinics are inaccessible for ST users needing or wanting treatment (because of distance or lack of transportation) there may be ways to facilitate cessation, such as mailed self-help materials with follow-up telephone contact. Web-based programs may also be an effective alternative in countries that have widespread access to the Internet. Most evaluation studies to date have been carried out in the United States. Additional evaluation of self-help cessation programs is needed in other countries.

Evidence indicates that the detrimental health effects of ST use are not well known in low- and middle-income countries. Educating the populations in low- and middle-income countries about the harmful effects of ST through media and health care systems is essential.



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