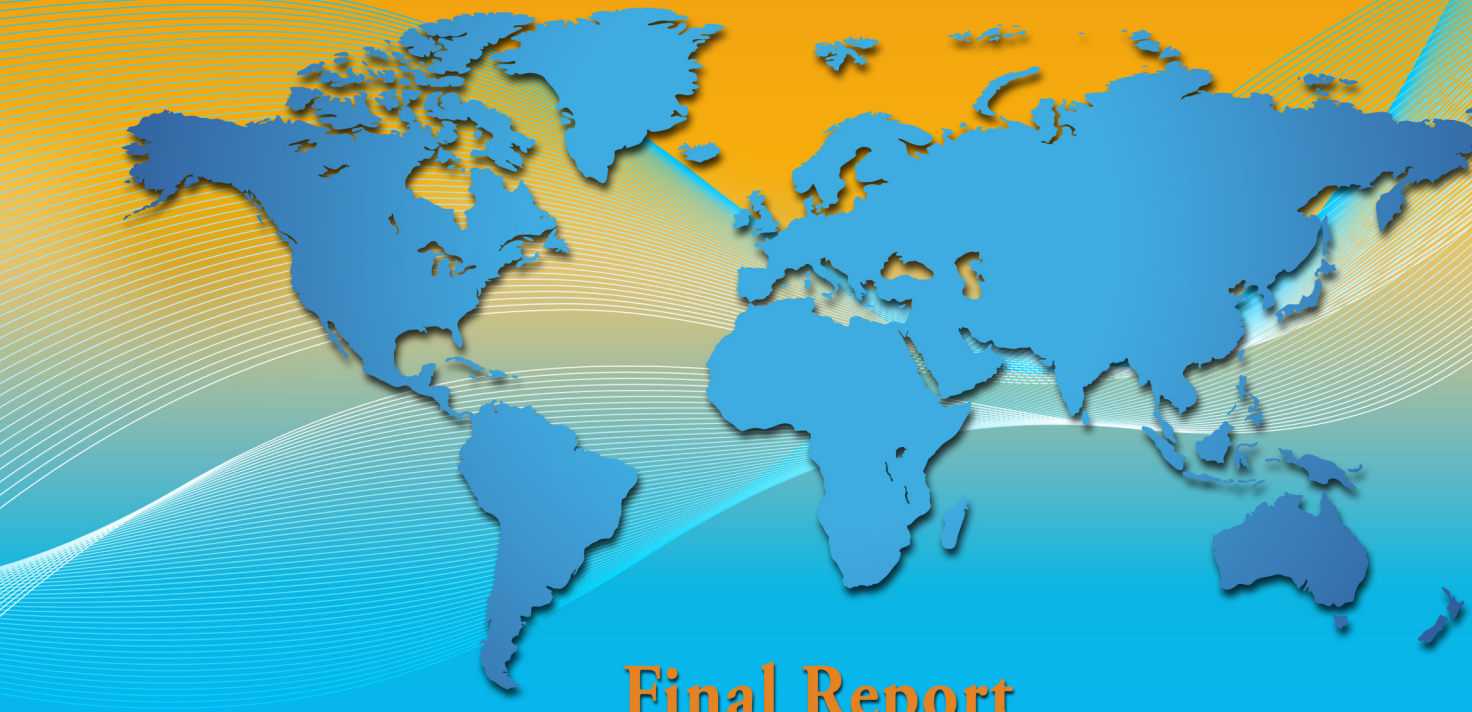
International Smokeless Tobacco Symposium



Final Report

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Sponsored by

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Welcome and Introduction

Mark Parascandola, PhD, MPH

Dr. Parascandola welcomed participants to the International Smokeless Tobacco Symposium and thanked the meeting sponsors—the National Cancer Institute, the Centers for Disease Control and Prevention, the World Health Organization (WHO), and luncheon sponsor Danya International—and the WCTOH Secretariat and organizing committee.

The symposium was a 1-day meeting aimed to understand the characteristics and patterns of use of smokeless tobacco products from regions around the world, particularly where their prevalence is high. Additionally, the meeting aimed to bring together researchers from different regions with the goal of increasing communication and collaboration and developing a global research network around smokeless tobacco.

Meeting Goals

Experts from various regions around the world provided current data on different smokeless tobacco products and their patterns of use. Additionally, presentations highlighted current research and practice needs and potential opportunities for collaboration. Panels addressed the following questions:

- What are the patterns of smokeless tobacco use in different regions, including developing countries?
- What data sources are available or are needed for monitoring smokeless tobacco use in different regions?
- What are the current global smokeless tobacco interventions taking place in different regions? What interventions are working?
- What is the industry currently doing to market smokeless tobacco products in different regions?
- Where do we go from here to continue to enhance communication, collaboration, and development of a global research agenda.

Attendees were encouraged to participate and share knowledge and experience from their own regions throughout the day. This document summarizes the meeting presentations and general discussion and is being distributed to those that attended the session, as well as others in the field of smokeless tobacco use and prevention.

Framing the Smokeless Tobacco Agenda

Mark Parascandola, PhD, MPH

Smokeless tobacco presents a complex and widespread challenge to public health. In many regions of the world, smokeless tobacco use is more common than is use of smoked tobacco, particularly among youth. The Global Youth Tobacco Survey of students aged 13-15, showed that 1 in 9 (11.2%) currently used tobacco products other than cigarettes.

In many regions of the world there are no comprehensive surveillance methods to track use of smokeless tobacco. Moreover, a very wide variety of products—including chewing tobacco, snuff, gutka, snus, toombak, paan masala, and others—are found worldwide and there is no systematic analysis of ingredients, patterns of use, or prevalence in different populations.

The tobacco industry is aggressively marketing new smokeless tobacco products to new users. For example, new products are being promoted for use by smokers in situations where cigarette smoking is not permitted, which may counteract public health gains made through smoke-free legislation.

Recent data released by the Substance Abuse and Mental Health Services Administration (SAMHSA) show that the United States has 8 million smokeless tobacco users age 12 and older; further, past month smokeless tobacco use by males ages 12 to 17 increased from 3.4 percent in 2002 to 4.4 percent in 2007. In addition, 52 percent of past month smokeless tobacco users also smoked cigarettes in the past month. SAMHSA data also show that American teens who use spit tobacco are more likely to become smokers than are teens who do not use this product. During 2005, tobacco manufacturers spent $250 million promoting smokeless tobacco.

In 2002, the International Conference on Smokeless Tobacco in Stockholm produced eight key recommendations:

- Develop a lexicon that brings standardized terminology to the variety of smokeless tobacco products in use around the world.
- Develop standard biomarkers and survey questions.
- Develop a global smokeless research agenda.
- Develop efficient worldwide access to research information.
- Develop well-organized global communication.
- Establish an ongoing forum for scientific exchanges of information.
- Expand efforts for capacity building.
- Develop mechanisms to communicate scientific and public health findings to policymakers and business and community leaders.

The first NIH State of the Science Conference on Tobacco Use: Prevention, Cessation and Control, held in 2006, highlighted the need to expand research on smokeless tobacco, and the National Cancer Institute issued a request for applications for projects to help reach that goal. Responses to that solicitation are now being reviewed. The symposium was viewed as an opportunity to help address some of these research and communication needs.

WHO Recommendations on Smokeless Tobacco Products

Gemma Vestal, JD, MPH, MBA, BSN

WHO established the Tobacco Free Initiative (TFI) in 1998 to focus international attention on the public health threat posed by tobacco. The Initiative calls for regulation of all tobacco products, not only smoked products. One of the ways that TFI works to advance the WHO Framework Convention on Tobacco Control (FCTC) is through the WHO Study Group on Tobacco Product Regulation (TobReg), the WHO Tobacco Laboratory Network, and the WHO Network of tobacco regulators and regulatory agencies, wherein TFI supports the advancement of FCTC tobacco product regulation provisions: Article 9, a requirement to test content and emissions of tobacco products; Article 10, which bears on disclosure of test results; and Article 11, which deals with product packaging and labeling.

WHO attempts to explicitly incorporate smokeless tobacco in TFI activities. Specifically, the WHO Scientific Advisory Committee's 2003 "Recommendation on Nicotine and the Regulation in Tobacco and Non-Tobacco Products" notes that health claims regarding safety of smokeless tobacco should not be permitted and that countries should require that smokeless tobacco products meet all regulatory requirements.

WHO's TobReg Technical Report Series (WHO Technical Report Series 951—The Scientific Basis of Tobacco Product Regulation [second report], 2008) notes that all smokeless tobacco products are hazardous and addictive, and that any claims made for harm reduction should not be permitted unless they are supported by evidence of reduced risk. In many countries there is a "regulatory vacuum" in which smokeless tobacco is marketed as an acceptable option where smoking has been banned, as a reduced risk product, or as a smoking cessation method. WHO TobReg is working on scientific recommendations to support product standards for all nicotine delivery products, including smokeless tobacco. While such standards represent an important step forward, they apply only to products that are manufactured and distributed through conventional marketing and distribution. Additional work will be needed to reduce production and use of home-made or "cottage industry" products that account for a significant proportion of smokeless tobacco use worldwide.

Health Effects of Smokeless Tobacco: Overview of the Science

Dr. Pankaj Chaturvedi

The diversity in smokeless tobacco products and patterns of use represent a "tale of three continents"—North America, Northern Europe, and South Asia—with highly different experiences. There also are vast differences among products; for example nitrosamine levels range from 0.2 ppm for Arriva smokeless "pellets" to 8.0 ppm for Skoal Long Cut smokeless tobacco. Even within regions there are differences that make it difficult to develop systematic approaches to assess the severity of risks posed by smokeless tobacco products. In India alone there are 27 independent cultures, each with a different perception of tobacco use. The tobacco industry understands India's regional, cultural, and community characteristics and is able to produce the right products for each.

Tobacco contains nicotine plus at least 30 carcinogens, including tobacco specific nitrosamines. In 1984, the IARC reported an association between snuff and cancer; in 1986, the U.S. Surgeon General's Report linked snuff use with cancer of the cheek as well as other oral disease, vascular and circulatory diseases. Smokeless tobacco sales are increasing despite growing evidence of short and long term health risks. Claims for harm reduction are based on small and narrowly defined studies that show limited reductions in narrowly defined populations. Larger scale research involving smokeless tobacco documents vast oral and dental harm including, in India, specific hypopharyngeal cancers.

Other studies in India show significant risks for esophageal and gastric cancers among smokeless tobacco users. An oral cancer study in Bhopal found an attributable risk of 84 percent for chewed tobacco. Smokeless tobacco use is associated with harm throughout the entire oral cavity, and different preferences and styles of tobacco use are linked to different health effects. Prevalence of smokeless tobacco use is high among youth in India and leads to lifelong use; as a result, population attributable risk of disease (the proportion of disease that could be eliminated by preventing smokeless tobacco use) exceeds 50 percent in two Indian studies. The tobacco industry is marketing smokeless tobacco aggressively on a global scale, and the severe health risks seen in India should be considered a warning of widespread public health impact of smokeless tobacco. Given the evidence of actual harm attributable to smokeless tobacco, it is important that the public health community confront the claims of harm reduction made for smokeless tobacco by citing studies that show that smokers who switch to smokeless tobacco have higher mortality due to oral and pharyngeal cancer and greater risk of lung cancer than do smokers who quit.

Discussion

Participants discussed the difficulty associated with trying to develop uniform standards for evaluation and regulation for products as widely diverse as those used in India. Some, such as paan masala, may or may not contain tobacco and could be considered as a food product. Industry can evade regulation by changing ingredients, in effect continually creating new products to replace those threatened by specifically written regulations. Health risks are often masked through misinformation; for example, gutka is seen as a breath freshener.

Taxes and other imposed price increases may have limited effect on smokeless tobacco use; the per dose cost is very low, even for commercial products, and many smokeless products are manufactured through small scale or cottage industries that are difficult to regulate.

Regional Profiles

Smokeless Tobacco Use in South Africa

Lekan Ayo-Yusuf, BDS, MPH, PhD

The use of smokeless tobacco, as snuff, has strong cultural significance in South Africa, much as it does in India. Snuff used in wedding ceremonies, for example, is homemade—a mixture of tobacco and charred aloe plant material.

Tobacco use by men in South Africa declined as a result of mandated package warnings in 1993, but use of non-conventional cigarettes is increasing among non-white South Africans. Snuff use is higher among black South Africans than any other group; roughly 11 percent of women and one percent of men use snuff. Women are twice as likely to use snuff as to smoke. Overall, tobacco use rates have flattened, but there is concern about use in vulnerable groups: 10 percent of pregnant women and 14.5 percent of children use snuff. Recent studies suggest increased risk of hypertension and chronic bronchitis among women who use tobacco: risks for chronic bronchitis for those who use snuff more than eight times per day are roughly the same as for those women who smoke more than four cigarettes per day.

The recent entry of Swedish Match products into the South African market appears to be associated with an observed slowing of the declining rates of snuff use. The Taxi brand product manufactured by Swedish Match is a moist snuff with a pH of 10, yielding 97.8 percent free base nicotine—the highest nicotine dosing capability ever recorded for a commercial product. Preliminary analysis of an adolescent cohort study shows that users of Taxi were more likely to be daily users and more likely to be concurrently smoking. Although South African law since 1995 has required health warning labels on snuff products, the industry has challenged this requirement, claiming that Swedish research supports harm reduction and decreased smoking claims for snuff. Internet marketing of smokeless tobacco products intended for the South African market (e.g. Taxi) does not include any health warning, and British American Tobacco's entry into the smokeless tobacco market in South Africa directly courts dual use by giving a snuff brand the same name as the most popular cigarette sold in South Africa.

Discussion

Participants discussed the increasing use of smokeless tobacco—primarily snuff—among male and female teens in Ghana. The increased use may be driven in part by claims that snuff has aphrodisiac properties. Moreover, teens may not correctly understand that snuff is in fact a tobacco product, and therefore discount its potential harm. Participants agreed that enhanced regulation is essential but is going to be difficult to develop because of the wide variety of products with a varied (and easily changed) list of ingredients.

Smokeless Tobacco Burden in India

Dr. Karthik Subbaraman

Tobacco use has a strong cultural component in India. Paan (betel quid) chewing is considered one of the eight Hindu pleasures, and its use dates back roughly 2,000 years. When tobacco was introduced into India around 400 years ago, it was incorporated into paan and hence paan with tobacco became the most important form of smokeless tobacco use in India. India is the world's second largest producer of tobacco and tobacco products and the third largest consumer of tobacco. The tobacco industry is a highly integrated sector, ranging from local farmers to sophisticated manufacturing facilities. It represents a complex target for policy development, regulation, and control.

India produces and consumes a wide variety of smokeless tobacco products and the patterns of use differ among various regions and cultures. In general, however, smokeless tobacco use is higher in regions of low income than in areas of higher income. The areas of highest use also are the most populous regions of India and consequently have greater electoral representation in government than do the regions with lower tobacco consumption. This creates political pressure that acts against policies to restrict tobacco use.

India's National Family Health Survey shows an overall smokeless tobacco prevalence rate of 36.5 percent for males and 8.4 percent for females, with the highest prevalence among those older than age 30. Rural rates are half again as high as urban rates for both men (31.3 percent rural, 20.8 percent urban) and women (13.8 percent rural, 8.8 percent urban). Among Indian children ages 13 through 15 years, rates are 14.6 percent for boys and 8.3 percent for girls; this represents roughly 10 million children at risk for addiction and serious health consequences.

A recent study of pregnant women in Mumbai found that those who used smokeless tobacco five times a day had a 50-percent greater risk of giving birth to a low birth weight baby than did nonusers. The risk doubled for women who used tobacco 10 or more times per day. Daily use of mishri—the most common type of smokeless tobacco—is linked to a range of adverse reproductive outcomes. India has some of the world's highest incidence rates of oral and pharyngeal cancers. The estimated Age Standardized (World) Rate for these cancers in 2002 for males in all of India was 12.8 per 100,000 and that for females 7.5 per 100,000. These cancers are highly related to tobacco use. In addition, compared with nonusers, smokeless tobacco users are at higher risk for early death, and at higher risk for cardiovascular disease.

Despite the risks associated with smokeless tobacco use, advertising for these products is routinely seen in public spaces, such as on public transportation; mass media also tacitly or overtly promote use either tacitly or overtly.

Discussion

Participants discussed tobacco products used as dentifrices, a practice that is prevalent in some Indian regions and cultures. Tooth cleaning powders that contain tobacco are given to children by their mothers. In related misconceptions about the medicinal effects of tobacco, some products are believed by the public to relieve depression.

Smokeless Tobacco in Pakistan: The Habit and its Health Risks

Khalif Bile Mohamud, MD, PhD

Smokeless tobacco use is widespread in Pakistan. Products are typically locally produced betel quid, gutka, and naswar. Men are more likely than women to use tobacco in either smoked or smokeless form, but smokeless use by women is culturally and traditionally accepted. Studies show the relative risk of oral cancer varies by tobacco habit among men in Pakistan, with the highest risk in men who use both betel quid and smoked tobacco. Hospital data show clear associations of tobacco use with a variety of cancers, notably oropharyngeal cancers which are second only to breast cancer and more common in Pakistan than are lung cancers, accounting for nearly 1 in 10 cancers reported in five major hospitals throughout the country: Studies of gender distribution show 15.4 percent of all cancers in men are oropharyngeal cancer, a rate that is nearly half again as high as the 10.7 rate among women. Men are twice as likely to be diagnosed with oropharyngeal cancer as with lung cancer. Rates for these cancers are in Pakistan are at least five times those experienced in Lebanon, Jordan, Kuwait, and Iran, where use of smokeless tobacco is much lower than in Pakistan. Oropharyngeal cancers account for more than 12 percent of cancers in Pakistanis older than age 24, and 15.1 percent of cancers for those ages 45 to 54. There is a regional distribution within Pakistan of various cancers and the pattern is directly related to the pattern of use of various tobacco products. Accurate assessment of the actual risk of tobacco use is difficult, as not all hospitals gather data on tobacco use habits among cancer patients.

Recently instituted public health advertising campaigns use graphic images to link tobacco use with cancer. Separate campaigns are aimed at smokeless tobacco products (specifically paan, naswar, gutka, and supari), linking them with cancer of the mouth, and smoked tobacco, which is associated with lung cancer. These posters are the first solid efforts made to help Pakistanis understand the dangers of tobacco use. Another campaign used a video presentation to document the unhygienic and unsafe conditions of naswar production in regional and village-based facilities that are difficult to regulate or control.

Swedish Snus – Traditional Oral Smokeless Tobacco

Hans Gilljam, MD

Smokeless tobacco use in Northern Europe originated in Sweden, where snus is the traditional tobacco product. Snus also is used in Norway, inhaled snuff is used in Alpine Europe, and smokeless tobacco has come to the United Kingdom by way of India and Pakistan.

Use of smokeless tobacco began in Sweden in the 1820s and use, up until the 1960s, was limited to men in blue collar occupations. The product was "re-invented" as snus in the mid 20th century. Daily nicotine consumption in Sweden now is now higher among males than females, though cigarette use among males is lower than that among women. Data for 2007 show that 12 percent of males and 16 percent of females are daily smokers and that 19 percent of males and 4 percent of females are daily snus users.

Snus consumption doubled between 1970 and 1993, increased roughly 4 percent per year from 1993 to 2004, and dropped to 1 percent in 2005. One in five 9th grade boys report monthly snus use; among girls the rate is roughly 1 in 20. Binge drinking among Swedish youth increases in proportion to tobacco use; 70 percent of youth who use cigarettes and snus report binge drinking more than once a month. The BROMS study tracked a cohort of more than 3,000 Swedish youth ages 11 to 19, surveying them annually on tobacco behaviors from 1997 to 2005. Rates of cigarette use by girls and snus use by boys rose at similar rates as the cohort aged; rates of smoking among boys and snus use among girls remained lower and relatively constant, although girls were likely to report "testing" snus.

Adverse health effects of snus include strong nicotine dependence, reversible and irreversible oral lesions, an increased likelihood of fatal heart attack (though no increased risk of heart attack), and adverse pre-natal effects. Strategies used to quit snus use include cold turkey cessation and counselor-assisted attempts. Use of snus as an aid to smoking cessation is rarely successful and likely to increase nicotine dependence and chronic snus use.

Smokeless Tobacco Interventions in Developing Countries

Mira B. Aghi, PhD

In India, 28.4 percent of men and 12.4 percent of women regularly use smokeless tobacco. Gutka is the most widely used product; other forms of smokeless tobacco include khaini, mawa, paan masala or betel quid, and dental products such as mishri and creamy snuff. Manufactured forms of gutka now are marketed heavily, with colorful packaging and a "hip" image that has led to increased use among men and young professionals.

In an effort to reduce the public health impact of smokeless tobacco use the Tata Institute developed an intervention to help reduce or discontinue smokeless tobacco use. Researchers interviewed 36,000 tobacco users age 15 and older to determine reasons for initiating and continuing tobacco use, perceived health implications of continued use, and possible reasons for discontinuing use. Then they developed a series of communications tools and educational materials to deliver information tailored to personal motivation and goals. This information was delivered through personal communication using a pictorial booklet; mass media approaches such as newspaper articles, radio programs, or folk drama; and cessation camps. Formative research and feedback were used to evaluate approaches and implement mid-course corrections if necessary.

The project demonstrated that primary intervention is not only feasible but practical and effective: the intervention outcomes included reduction (by 50 percent or more) of baseline tobacco use and regression of tobacco-related oral lesions. Success was the result of:

- **Approach:** All strategies were user-driven—users were treated with respect, their opinions were taken into account, and if a particular element of the intervention was ineffective it was seen as a shortcoming of the material, not the tobacco user.
- **Rationale:** The user is aware of the dangers of tobacco, understands its personal impact, makes concrete steps to discontinue use, evaluates reasons for failure and starts again, and acts as an example for others when cessation has been achieved.
- **Philosophy:** Six-stage philosophy user characteristics. 1. establish knowledge of link between tobacco and oral lesions and cancer; 2. strengthen understanding with graphic visual reinforcement and deliberate introduction of fear; 3. convey knowledge of health and other benefits of cessation; 4. select most appropriate intervention method; 5. explain withdrawal symptoms and their time-course; and 6. provide support through praise and encouragement.

Discussion

Participants discussed the importance of identifying and implementing user-driven strategies for cessation that are built upon a foundation of respect for the user rather than adherence to a specific process. The most important question to keep in mind is "what could make you give up his/her tobacco this habit?" and the answer should drive intervention.

Smokeless Tobacco: Constituent Analysis and Application of Biomarkers

Stephen S. Hecht, PhD
Dorothy K. Hatsukami, PhD

The hazardous constituents of smokeless tobacco include nicotine, nitrosamines, polycyclic aromatic hydrocarbons (PAH), aldehydes, metals, and inorganic salts.

Nicotine content and delivery potential (depending in part on pH) varies dramatically among smokeless tobacco products. Free nicotine expressed as mg/g dry weight ranges from less than 2 mg/g for Marlboro Rich snus to more than 7 mg/g for Copenhagen Long Cut and General snus.

Tobacco-specific nitrosamines (NNM and NNK) are not found in green tobacco. They are formed during curing and processing of tobacco. The concentrations found in smokeless tobacco are arbitrary: it is possible to reduce concentrations, but this is not done. In manufactured snus and cut tobacco smokeless products, concentrations are typically less than 4 µg/g. Among products available in South Asia, concentrations may be much higher: 30 to 80 µg/g in khaini, for example. As a rule, products with the highest concentration are the most popular. Industry claims for "low nitrosamine"—and therefore reduced risk—aresmokeless products is a marketing deception.

PAHs, produced through incomplete combustion, are found in smokeless tobacco as the result of curing processes, pollution, or other sources. PAHs are causative agents for cancers associated with cigarette smoking and some occupational exposure. Smokeless tobacco contains a range of PAHs at varying concentrations. In manufactured products sold in the U.S., phenanthrene is found at levels ranging from 41 ng/g dry weight in Camel snus Original to 2,310 ng/g in Skoal Long Cut.

Smokeless tobacco also contains carcinogenic metals such as chromium, nickel, and cadmium, nitrates and nitrites, and chloride in the form of salt in dry weight fractions as high as 15 percent.

There is a need for established analytical standards that use biomarkers to characterize the risks of smokeless tobacco. Nitrosamines (NNK) and their metabolites, expressed as "total NNAL," serve as the best biomarkers for carcinogenicity of smokeless tobacco.

These biomarkers allow an examination of human exposure to toxicants and can help to address several critical questions. Does the use of lower toxicant products among smokeless tobacco users lead to significant reductions in exposure levels of these toxicants? One study switched Copenhagen users to General Snus, which contains lower NNK, or nicotine patch. The results showed a significant reduction in total NNAL in both these conditions, with greater reductions observed with the nicotine patch (because medicinal nicotine does not contain carcinogens).

Does use of reduced nicotine product reduce exposure levels altering tobacco use behavior? In a study that involved smokeless tobacco users "stepping down" through a series of successively lower nicotine products, significant reductions were observed in total NNAL, due to reduced product use and reduced toxicants in the product. In addition, 26 percent of participants achieved abstinence although the study was not designed to lead to cessation.

Do smokers who switch to oral tobacco products reduce their exposure to toxicants? A study involving smokers compared Commit medicinal lozenges with Exalt tobacco "packets" and with Ariva lozenges—non-medicinal products marketed as a stop-gap ("when you can't light up") source of nicotine. Both smokeless products resulted in lower total NNAL exposure compared with cigarettes, but neither produced exposure as low as that of the medicinal product.

These results suggest that use of smokeless products with lower tobacco specific nitrosamine levels may actually lower exposure to toxicants, but medicinal nicotine products leads to the greatest reduction. These results lead to the conclusion that we need performance standards to reduce the levels of toxicants in smokeless tobacco products, consideration should be given in reducing nicotine levels of products, and while smokeless tobacco may lead to less exposure to toxicants than cigarette smoking, cessation with medicinal nicotine is best.

Discussion

Participants discussed the possibility that WHO is relying on underestimated exposure data when relying on information derived in part from industry market share data, as such data may not account for home-made or "cottage industry" products.

In some regions of Tanzania, waste from tobacco production is used as an agricultural pesticide on vegetable crops. This may represent a secondary route of exposure to NNAL.

Participants emphasized the need to require manufacturers to reduce levels of known carcinogens, such as tobacco specific nitrosamines. The presence of these compounds, which can be removed, would be intolerable in any other product. It is important that the tobacco industry not be allowed to label their products as reduced risk, even if there is a reduction of nitrosamines. Participants discussed the risks associated with promotion of smokeless tobacco products as a substitute for medicinal products, which are proven effective and known to be safe. Clinicians should never recommend tobacco products as a method of achieving abstinence from smoking.

Applying the FCTC to Smokeless Tobacco

Cecily S. Ray

Gutka is available throughout India at street stalls and grocery stores. Tobacco regulation is authorized through the provision: the Cigarettes and Other Tobacco Products Act (COTPA). The Consumer Protection Act (CPA) is available to consumers to redress their complaints and seek compensation.

These Indian legal provisions track with some articles of the WHO Framework Convention on Tobacco Control (FCTC) that apply to smokeless tobacco: Article 6: Price and Taxation; Article 9: Regulation of Contents; Article 10: Regulation of Product Disclosures; Article 11: Packaging; Article 12: Public Awareness; Article 13: Advertising; Article 16: Sale to and by Minors; Article 17: Support for Alternative Livelihoods; Article 18: Protection of the Environment and Health; and Article 19: Liability. Of these provisions, only those covering FCTC Articles 12 (Packaging and Labeling), 13 (Advertising), and 16 (Sale to and by Minors) have officially gone into effect, under COTPA. Taxation of tobacco products is covered separatately under yearly Finance Bills.

These provisions have had mixed success. Small, incremental tax increases are enacted, but they are difficult to enforce on products sold in varied markets. Moreover, prices of tobacco products are so low that increased cost does little to discourage use. The tobacco industry has mounted legal challenges to many advertising and labeling provisions, which delays implementation. Content regulation under COTPA has not yet entered into force. Under temporary State level bans of gutka, some manufacturers manipulated contents and product names to circumvent regulation. "Spit free" laws have been used successfully in Viet Nam and Thailand, but they require large sustained public campaigns, which have not been used in Mumbai or other Indian cities, where bans are in place. There are no serious efforts underway to identify or promote production of alternative crops as yet, although some alternative uses for areca nut have been identified.

The variety of smokeless tobacco products that are widely used in India represents a serious challenge to effective regulation. These products include raw tobacco leaf, as well as home-made and vendor-made products, and products assembled on a small scale or at village level. These products are manufactured and sold, unlabeled, beyond the reach of taxation or regulatory accountability. Tobacco manufacturers are currently hampering and evading regulation by lodging legal challenges to regulatory efforts

such as advertising rules, labeling, or the ban of sales near schools. Despite bans, smokeless tobacco is advertised extensively at the point of sale through its bright packaging and, through the use of "surrogates," on television, the internet, and billboards. Under India's Consumer Protection Act, citizens could get protection from unfair trade practices that involve selling goods that are hazardous to health and false representations about product safety. This provision have not yet been used to control the marketing of smokeless tobacco. Meanwhile, the value of tobacco products is increasing: export of smokeless tobacco products increased 10-fold from 2000 to 2008.

Discussion

Participants discussed the experience of trying to regulate use of Indian gutka in Tanzania; the product is increasingly being used by school age children. The government banned its use, but perhaps because it is highly profitable, the law is not enforced.

Cigarette Industry Entry into the Smokeless Tobacco Market Worldwide

Gregory N. Connolly, DMD, MPH

The Framework Convention on Tobacco Control is built on a Western cigarette-based model. The expansion of tobacco industry, however, is in the developing world and increasingly involves emphasis smokeless tobacco products. In the United States, for example, a 2-percent decline in cigarette sales has been matched by a 6-percent rise in snuff sales. Profit per unit sale of snuff is twice as high as cigarettes, and the federal tax on smokeless products is one-tenth that on cigarettes. Industry sees smokeless tobacco as a low cost and highly profitable vehicle for creating dual users, whose polyaddiction makes cessation very difficult.

Consolidation of the tobacco industry is creating very powerful market and lobbying forces. Although industry encourages a "harm reduction" aura for smokeless products, their real intent is made clear in a Philip Morris document describing smokeless tobacco as an "adjacency product." U.S. Smokeless Tobacco Company has developed a graduated strategy to move young smokeless tobacco users through a cycle of products that maximizes potential for addiction. Arguments put forth to advocate smokeless tobacco as a harm reduction tool are based on insufficient data and extrapolation from the "Swedish experience", which accounts for less than one-fifth of 1 percent of global tobacco use. Manufacturers are developing a range of smokeless delivery systems that will encourage dual use and maximize addiction, rather than replace cigarettes. A market analysis by Citigroup Investment Research states that "snus products not expected to hurt cigarette volumes." In addition to intensive conventional advertising, manufacturers are supporting "viral" advertising on social networking sites such as Facebook and through YouTube videos.

The increased use of smokeless tobacco products represents an increasing threat to the developing world in particular. It also raises the likelihood of increasing the rate of dual use—smokers who use smokeless products along with cigarettes. The only proven "harm reduction" product is nicotine replacement, which already is widely used and is successful in promoting smoking cessation. Clinicians who recommend the use of smokeless tobacco when a safe and effective medication such as nicotine replacement therapy exists may be violating the oath to do no harm.

Discussion

Participants discussed the importance of resisting pressures that may result in the European Union opening its doors to sale of snus and other smokeless products. Arguments based on experience in Sweden are irrelevant; the Swedish experience is not transferable to other countries. One participant urged that a statement on the ethical responsibility of physicians to not recommend any tobacco product be made a part of the public record of the Symposium. A participant urged that all public health advocates stop "peddling the false message of harm reduction" associated with smokeless tobacco.

Closing Discussion

It is important that international tobacco control efforts be strengthened and modified to prevent the spread of smokeless tobacco use to regions and countries where it is not currently available. It is important to remember that the Framework Convention on Tobacco Control (FCTC) discusses "tobacco," not "cigarettes," and to strengthen efforts to restrict and reduce all tobacco use. However, current FCTC efforts are focused on cigarettes as the representative standardized product. Yet smokeless tobacco is available in an extensive variety of nonstandardized products, and the FCTC therefore misses the basic dangers of smokeless tobacco products. What's needed is a balanced debate and an FCTC process to develop legal and policy instruments focused around smokeless tobacco. These efforts must incorporate each country's smokeless tobacco experience, as products and patterns of use vary widely across borders. This will steer policy development toward non-commercial products and will be less reliant on a Eurocentric scientific approach.

The low price of smokeless tobacco products in developing countries makes them appealing to users and difficult to regulate. Smokeless tobacco products are easy to make and can be sold for prices that make the cost of a unit dose of nicotine one-third that of cigarettes.

In India and other developing countries, new products target young first-time users. In these countries the availability of non-uniform home- or village-made products makes regulation virtually impossible. Most smokeless tobacco products contain a variety of ingredients, and these additives themselves carry unknown health risks.

The public health community needs better independent intelligence regarding industry research, product development, and marketing strategies. Industry-funded marketing and public relations efforts are designed to create a bias toward favorable consideration of snus and other smokeless tobacco as harm reduction products.

Tobacco use and addiction are increasing worldwide; that alone should justify efforts to block and resist further global expansion by tobacco companies. The public health harm will be felt in every country. Success of tobacco control efforts in the United States is causing industry to shift attention to new delivery mechanisms and new markets. The tobacco control community should keep in mind the lessons learned from historical experience with "light" cigarettes, where tobacco companies marketed their products in ways that led consumers to believe they were less harmful. In fact, "light" cigarettes did not reduce disease risks for tobacco users and may have increased harm by adversely affecting cessation efforts.

The public health community must maintain focus on the harm done by all forms of tobacco. Medical schools, particularly those in developing countries, must teach doctors the dangers of all forms of tobacco and the importance of opposing its use. Governments must stand up to industry in working to end tobacco use.

The tobacco control community must expand public awareness of deadly risks of smokeless tobacco and should work toward creating a smokeless tobacco equivalent of the "smoke free" concept.

Participants discussed the need to develop a resolution or other statement of purpose that incorporates the lessons presented during this smokeless tobacco symposium. Information about the risks of smokeless tobacco should also be incorporated into every article of the FCTC.

Closing Summary

Dr. Parascandola thanked all the participants for their interest and contributions. He said a summary report of the day's presentations would be circulated to all participants and expressed a hope that the ideas discussed could be developed into recommendations or policy statements. Dr. Parascandola said the conversation about smokeless tobacco would continue through an interactive forum such as GlobaLink. The day's presentations represent a strong consensus that smokeless tobacco is a serious problem globally and a problem that is increasing around the world in many regions. It includes a diverse range of products and there is a lot we need to know about the properties of these products and who is using them. Smokeless tobacco is not getting the attention it requires from decision makers in the policy arena or from researchers and clinicians.

Conclusions

Symposium participants agreed that

- Smokeless tobacco use adversely affects all countries and regions.
- Increasing use and industry promotion of smokeless tobacco represents an increasing threat to public health worldwide.
- All forms of smokeless tobacco have an adverse impact on health.
- Smokeless tobacco should not be promoted as a harm reduction product.
- Smokeless tobacco poses substantial challenges to regulatory and control efforts because of the wide variety of products and production methods in use, including individual point-of-use production, home- and village-based production, as well as manufacture by international corporations.
- Smokeless tobacco has not received adequate attention from researchers and policy makers, including the WHO Framework Convention on Tobacco Control.
- The FCTC Secretariat should consider establishing a work group to study ways in which smokeless tobacco can be explicitly incorporated into every FCTC Article in recognition of the global problem posed by smokeless tobacco.
- Future World Conferences should include substantial coverage of research and activities focused on smokeless tobacco products. A conference resolution should be put forth focused on smokeless tobacco products and their public health impact.
- There needs to be an increase in attention to smokeless tobacco in all parts of the world.

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