

Smokeless Tobacco: the Epidemiology and Politics of Harm

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Smokeless Tobacco: the Epidemiology and Politics of Harm

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Abstract

The health burden from tobacco smoking results almost entirely from inhalation of the components of smoke, though this is not widely known. The primary benefit of smoking is nicotine delivery, but nicotine can be obtained without combustion. Thus there is potential for tobacco harm reduction (THR), the substitution of lower-risk nicotine products for smoking. Epidemiologic evidence suggests that smokeless tobacco causes about 1/100th the health risk of smoking. Despite the practice of harm reduction being widely accepted in public health, however, THR has faced fierce opposition from anti-tobacco activists. These activists have effectively misled the public about what aspect of smoking cigarettes causes the harm, convincing them that nicotine and tobacco themselves are harmful, ignoring the smoke. In the interests of promoting public health and rescuing science from politics, experts on inhalation hazards and health could play an important role in educating the public and policy makers about THR.

Keywords (3-6):

Smoking, tobacco harm reduction, smokeless tobacco, health ethics

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The health burden of smoking

The prevalence of smoking remains high despite well-funded smoking cessation interventions over the course of four decades. Dramatic decreases in the prevalence of smoking in North America and parts of Europe from the 1960s to the 1980s resulted almost entirely from rational decisions resulting from increased knowledge of its health risks. Since then, reductions in the prevalence of smoking have slowed or stopped. Despite increasingly draconian anti-smoking efforts, smoking prevalence remains at more than 20% in North America and more than 30% in the European Union (E.U). The European prevalence might eventually fall to the North American level in response to ongoing policy initiatives, but all the available evidence suggests that once tobacco use becomes readily available to a population about 1/5th of them will find it worth consuming, even in the face of major health costs (which virtually everyone is aware of and, indeed, usually overestimate). The costs of smoking include high taxes, time and place restrictions, and social demonization. In many communities elsewhere in the world, particularly where wealth is increasing, the prevalence of smoking is higher and increasing; policies of the sort that might substantially reduce smoking prevalence are not currently being implemented.

Smoking is the most popular form of nicotine and tobacco use by far, and has sensory, social, and time-and-motion characteristics that are difficult to replicate with a different product. But the primary appeal, delivery of nicotine, can be replicated using non-combustion products. This represents huge potential health benefits because smoking is, also by far, the most harmful way of getting nicotine. Inhaling concentrated smoke is an extremely unhealthy behavior. But many of the current smokers in North America, Europe, and elsewhere are unlikely to quit using nicotine or tobacco entirely; many have no interest in quitting, while others have tried the well-known smoking cessation methods but failed.

From a health perspective, smoking is, above all else, a voluntary exposure to very bad air pollution. Tobacco users' exposure solely to nicotine and the unburned tobacco plant itself produces minimal negative health consequences. Cigarette smoke also produces involuntary aesthetic and health externalities that are completely absent with non-combustion nicotine delivery. The health risks of environmental tobacco smoke (ETS) or "second hand smoke" have been wildly exaggerated by smoking ban activists, making it difficult to sort out what the science really says (Siegel 2007). But since some of the epidemiology suggests measurable effects, and ETS exposure is physically similar to low-intensity smoking and similar in some ways to outdoor combustion-sourced air pollution (though at a higher concentration), it seems safe to conclude that it causes disease to some degree.

Tobacco harm reduction

Harm reduction is an uncontroversial approach in public health. It is widely accepted that for many behaviors and other exposures, it is unreasonable (impossible, too costly, foregone benefits are too great, etc.) to try to eradicate the exposure and thus all the harm it causes. We therefore try to improve technology and education to minimize the harm in spite of the continuing exposure. Examples range from reducing risks from everyday, mainstream behaviors (e.g., seatbelts and other methods for making transport safer) to politically more difficult help for those with fringe behaviors (e.g., providing injection drug users with clean needles). Public health

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researchers and practitioners overwhelmingly support harm reduction across this spectrum, even as some political actors oppose some of it to further their social-engineering goals.

Existing smoking cessation methods (e.g., counselling, with or without drugs; sheer desire and willpower; short term use of pharmaceutical nicotine) are effective for some smokers but the vast majority of attempts to quit fail. And no matter how effective nicotine cessation methods are, they will not appeal to smokers who do not want to give up the benefits they get from nicotine. The evidence clearly shows that many nicotine users are not going to choose to quit, and there is no serious possibility that smoking prohibition will be enacted. Thus smoking falls into the category of behaviors that are unreasonable to try to eliminate completely, but where it is possible to provide less harmful variations.

Tobacco Harm Reduction (THR) is the substitution of less harmful nicotine products for cigarettes (see TobaccoHarmReduction.org for more details). Reduced risk alternatives include Western smokeless tobacco (ST) and pharmaceutical nicotine products. THR does not require eradication of tobacco or nicotine use, and thus is similar to other harm reduction strategies: promoting condoms does not require that people give up sex and promoting seatbelts does not require that people give up cars. The major difference between THR and typical public health interventions, however, is that the former has the potential to reduce harm to a vastly greater extent than the latter. ST and other non-combustion nicotine products appear to have only about 1%, or perhaps 2%, of the risk of smoking (Phillips, Rabiou, Rodu. 2006).

This comparative risk estimate of about 1/100th that from smoking is based on the epidemiology of ST, and can be extrapolated to possible long-term use of pharmaceutical nicotine products. There is currently no evidence to support the claims that different non-combustion nicotine products (either different modern Western ST products or pharmaceutical products) pose different levels of risk; such claims are purely speculative. Presumably risks differ somewhat, but the risks from any of these products are so small relative to those of smoking that the differences among various non-combustion nicotine products are inconsequential for purposes of public health policy. It is not yet clear whether novel products, such as inhalers that mimic cigarettes but deliver smoke-free nicotine, pose an equally low risk, though there is little doubt they are much less harmful than smoking.

The dramatic risk reduction of THR is due to the elimination of smoke inhalation. This is largely unrecognized, in part because many anti-tobacco activists misleadingly use the word "tobacco" as if it were an exposure, or "nicotine" as if the health effects of using it were independent of the delivery method. Tobacco is a plant, not an exposure; nicotine is a drug which the evidence shows has health effects similar to those from coffee (including substantial benefits). Inhaling concentrated smoke is an exposure, and a very risky one. Much understanding could be gained by replacing the highly misleading use of the shorthand "tobacco" to mean "tobacco smoking," a shorthand that is ubiquitous in the anti-tobacco propaganda and far too common in even the health science literature, with the more appropriate shorthand, "smoking."

Eliminate the smoke, minimize the risk

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Though it was not widely understood in the mid-20th century, when epidemiologists first widely documented the health effects of smoking, it should be clear to anyone in health science today that smoke is the likely cause of diseases from smoking. Inhaling smoke (regardless of the source) exposes the airway and lungs, and thus the bloodstream and much of the rest of the body to thousands of different chemicals. The products of combustion that are inhaled are similar (e.g., carbon monoxide, nitrogen oxides, polycyclic aromatic hydrocarbons, formaldehyde and acetaldehyde), regardless of whether the substance being burned is tobacco, wood, dung or other solid fuel, candles or incense. In short, smoking is an effective method for the extraction and delivery of the nicotine from tobacco, but it exposes the user to many chemicals other than nicotine, and (unlike other nicotine delivery methods) has created a major health hazard.

In addition to the ample epidemiologic evidence that shows the major health consequences of smoking, there is ample evidence that ST is much less harmful than cigarettes. Use of ST does not affect the lungs (thereby apparently eliminating the risk of lung cancer and other lung disorders), and any risk of oral, pharyngeal, laryngeal, stomach or pancreatic cancer is so small that it cannot be reliably measured (and thus is clearly much less than those risks from smoking). Nicotine, like other mild stimulants, causes an acute blood pressure increase and so we would expect some increase in risk for triggering incipient cardiovascular events such as heart attack and stroke. However, this cardiovascular disease risk is minimal in comparison to that from smoke inhalation. Indeed, the epidemiology fails to convincingly show ST causes a risk for *any* fatal disease, though it seems most appropriate for policy making to assume there is some small mortality risk from all nicotine use.

Tobacco harm reduction in the world today

Extensive data on the efficacy of THR comes from Sweden where *snus* (the Swedish word for moist snuff) has replaced cigarettes as the predominant form of tobacco use. Sweden is the only country to reduce smoking rates substantially below 1/5th of the population, and the only country where smoking prevalence is lower among men than women. Many males in Sweden use snus rather than cigarettes (27% use snus, 2% smoke and use snus, 9% smoke) (Stegmayr 2005). However, snus use is increasingly popular among female nicotine users (fairly recent data show 9% use snus, 2% smoke and use snus, 16% smoke) (Stegmayr 2005). Although Sweden has a prevalence of *tobacco* use that is greater than many other Western countries, it has lower rates of tobacco-caused (i.e., smoking-caused) diseases (Rodu & Cole 2004). Unfortunately, this great public health improvement has been able to expand only to Norway (a neighbor of Sweden, and not a member of the E.U.) because the ST products that appear most promising for harm reduction (snus and other moist snuff) are banned in the rest of the E.U., which includes Sweden's other geographic and cultural neighbors. There is an increasing interest in THR in the U.S., but the limited influence of Swedish culture means that THR has to be built up largely from scratch there.

Moist snuff products are particularly promising THR alternatives (Phillips 2007a) because: 1) like chewing tobacco and pharmaceutical nicotine, they are estimated to be about 99% less harmful than smoking; 2) unlike widely-available pharmaceutical products (patches, gum, etc.) which deliver a low and slow dose, the nicotine delivery is reasonably rapid (though not as rapid

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as smoking) and the peak dose is similar to that from smoking; 3) they are considered more socially acceptable than chewing tobacco, particularly the increasingly available teabag-like sachet products which are easy for smokers to start using and do not require spitting; 4) unlike products that are marketed and delivered like medicine, snuff offers some of the appeal of cigarettes that goes beyond nicotine (e.g., a sense of personal choice, flavor, brand identity, some social connection); and 5) there is evidence of demand for the product, including a potential for society-wide shift as witnessed in Sweden. Our research has show that smokers are interested in and willing to switch to a “hypothetical” oral nicotine product, where the description was really that of sachet-style ST (Geertsema et al., under review; Heavner et al., under review). In addition, a recent study shows that many Americans switched to ST to quit smoking even before ST was promoted as a very-low-risk alternative and cessation method (Rodu and Phillips, 2008).

The potential for THR is currently probably greatest in North America, where there is a long history of ST use, all forms of ST are legal, smokers are interested in reduced harm products, and new Swedish-style products have been introduced in addition to the already popular U.S.-style snuff and chewing tobacco. Sachet-style ST (and the currently more popular loose tobacco) have been widely available in the U.S., produced primarily by specialty ST companies, the largest of which is U.S. Smokeless Tobacco (which was recently acquired by a major cigarette company), the maker of Copenhagen and Skoal. In addition to acquiring existing ST companies, the major cigarette companies have demonstrated their interest in low risk substitutes for cigarettes by introducing new ST products, marketed as "snus," under their major cigarette brand names (Camel and Marlboro).

The snus product introduced by Imperial Tobacco Canada (ITC) (du Maurier, the name of one of their major cigarette brands) in 2007 is, to our knowledge, the only one in North America that the manufacturer is actively marketing as a reduced harm alternative to cigarettes. (The conventional wisdom is that the U.S. companies fear the litigiousness of private attorneys and local governments in the U.S., which when coupled with powerful anti-THR activists make it too risky to try to educate consumers about comparative risks.) However, it appears that ITC will be prohibited from continuing to communicate the THR message to their customers. If that occurs then Canada – which momentarily appeared like it might lead the non-Scandinavian world in THR -- will probably only experience THR after it becomes popular in the U.S. and then spreads. THR depends on education and the U.S. has the advantage that free-speech laws protect those who want to educate the public about the comparative risks of different tobacco products (though the manufacturers appear to not believe they are at liberty to provide such education). In Canada, anti-tobacco activists, who are focused on attacking tobacco rather than helping people, have succeeded in pressuring the government to increasingly censor communication about THR, and the censorship appears to extend beyond corporate marketing to include scientists and educators.

THR in Europe has great potential due to the proximate influence of Sweden and Norway, but the snus ban prevents almost all progress. If a change in E.U. policy occurred, THR could spread quite rapidly. Elsewhere in the world there has been little headway in promoting THR, and attempts to market snus in Africa and Japan have had very limited success. It is not clear

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whether THR could be successfully promoted elsewhere in the world until it is led by U.S. or European cultural influences.

An additional potential avenue for THR comes from novel products that use pharmaceutical nicotine (which is extracted from tobacco and attached to an alternative chemical substrate). The well-known nicotine patch and gum products, which are typically known as "nicotine replacement therapy" are designed to not provide a satisfying dose of nicotine, so are a poor substitute for smoking or ST, though some nicotine users who are happy to have a very low dose are long-term users. They are ostensibly designed to help wean heavy nicotine users off of nicotine entirely, though they have proven to be of limited value for that also. But new products could potentially turn extracted nicotine into a much better substitute for smoking than it has been. For example, several small companies have started to promote imitation-cigarette inhaler devices, which might prove appealing as a THR alternative to smokers (though research is warranted to assess whether re-introducing aerosols and lung involvement in a THR product might cause greater negative health effects than purely oral products). Unfortunately, the pharmaceutical companies that have a stake in their existing cessation products and possible future THR products, and who have already effectively lobbied and funded anti-tobacco organizations to discourage the use of ST in THR, are likely to lobby for the closure of less-regulated competitors who sell non-tobacco nicotine products.

Why hasn't there been widespread adoption of THR?

Notwithstanding the E.U.'s ban and restrictions on THR promotion in Canada, THR can be implemented by educated individuals, or promoted by governments at any jurisdictional level or by non-governmental public health organizations. Thus we must ask why there has been so little progress on THR outside of Scandinavia. Part of the explanation is that smoking has appeal that no alternative product has matched. But it seems difficult to believe that most smokers would prefer getting those benefits to acquiring nicotine from another source and eliminating almost all the health risks. The extremely low adoption of THR in North America, and probably elsewhere, is largely due to misperceptions of tobacco, nicotine, smoking and THR. In Canada, the situation is exacerbated by the prohibition on dissemination of accurate information to correct these misperceptions. Some of the common misperceptions are that: something other than smoke is the source of most of the health risks from smoking; ST is as risky as, or even more risky than smoking; ST is more likely to cause oral cancer compared to smoking; nicotine causes cancer; and ST products require spitting (Tenorio et al. 2008; Bergen et al. 2008; Phillips, Bergen, Guenzel 2006; Geertsema et al., under review; Heavner et al., under review). These misperceptions are attributable to an active disinformation campaign by anti-tobacco activists, supported by many ostensible experts and ostensibly public-interest health organizations, both private and governmental. Manufacturers are unable to dispel these myths due to limitations on advertising and the content of their communication, while independent experts in the science lack the resources for major communications efforts and are drowned out by vocal and well-funded activist groups as well as medical and public health organizations whose tobacco policies are controlled by anti-tobacco (rather than pro-health) advocates.

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To a degree that is difficult to imagine occurring in other areas of public health, "education" efforts related to tobacco use seem to be characterized by many activists saying whatever they think might discourage people from using tobacco, regardless of whether the claims are accurate or honest (Phillips et al. 2005, Phillips, Bergen, Guenzel 2006; Enstrom 2007; Siegel 2007; Phillips 2007b; Phillips 2008). This appears largely due to the shift of anti-tobacco advocacy from the goal of promoting health to trying to enforce an illiberal "purity of behavior" ethic, coupled with an unwillingness to admit that existing anti-smoking efforts have largely run their course, as well as a desire to punish tobacco companies because of the industry's previous transgressions. Only by recognizing the dominance of other motives over genuine public health concerns is it possible to understand why the opportunity to eliminate 99% of the harm caused by nicotine use provokes such fierce opposition and disregard for accepted ethics.

Anti-tobacco (smoked and smokeless) activism has proven a threat to the integrity of epidemiologic research (Phillips, 2007b). Epidemiology has many inherent limitations that are not widely understood by non-experts (which includes almost all clinicians and health policy makers), making it easy for those with an unscientific agenda to manipulate what is claimed. Focused attempts to "prove" ST causes major health risks exploit – and exacerbate – the weaknesses of the science of epidemiology. The tactics include widespread "publication bias *in situ*" (PBIS) (Phillips 2004), the picking-and-choosing of which statistical model to run (choices of which covariates to include, where to dichotomize continuous variables, etc.) and which analyses to report the results from. A less subtle tactic consists of emphasizing outlier results in the literature (as there will inevitably be in epidemiology) as if they were representative best estimates. The latter of these was long common practice for the claim that ST causes a substantial risk for oral cancer, which was based on a single outlier study (sometimes coupled with a biased interpretation of a second study) that has long-since been recognized as not representing the true risk. As awareness grew that modern Western ST does not seem to cause a measurable level of risk for oral cancer, the focus shifted to pancreatic cancer. That claim is based on picking out three reported results from studies that evidence a variety of questionable characteristics, including failure to control for a potentially major confounder and PBIS (Heavner et al. 2008).

Anti-THR activism also tends to diminish the quality of health science by denying the importance of epidemiology when its findings are politically inconvenient. Epidemiology is, by definition, the one science that can assess the effects of actual exposures on actual health outcomes. Chemistry, experiments on non-human animals, and other techniques can answer many questions, but obviously cannot provide evidence of actual human health consequences of real-world exposures. Nevertheless, anti-THR activists have tried to emphasize particular chemicals that are present in tobacco (and mostly common in many other plants), some of which have (in isolation from the rest of the ST, in very high doses, and in only some of the experiments conducted) caused cancer in non-human animals. This is often presented in ways that explicitly distract people from the dangers of inhaling smoke, an attempt to convince the public that the risks of cigarette smoking are from the tobacco plant rather than the fact that it is on fire.

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Thus, a combination of political activity, disinformation, and abuse of science has created formidable barriers to assisting smokers who want to reduce their risk from tobacco use. It would be difficult to ethically defend these actions given that the leading tenet of modern health ethics is that individuals are entitled to make informed autonomous decisions about their own health. It would appear that those who might condemn the anti-THR actions on ethical grounds, are kept mute by the effectiveness of the disinformation – few know enough to realize that an ethical issue exists. Fortunately, the promotion of THR does not actually require stopping unethical actions or arbitrating ethical debates: Every time a smoker learns that the harm from smoking comes overwhelmingly from smoke, they have the opportunity to act on that knowledge (at least in most of the world, where low risk nicotine products are legal). So how will they learn?

Restoring the focus on health and legitimate science

Scientists have some duty to try to correct the misconceptions about THR. Because science has been used (or abused) in the disinformation campaign that impedes the adoption of THR, it becomes the role of scientists to respond with accurate information. In particular, experts on inhalation hazards could make major contributions by explaining the importance of inhaling smoke. The anti-tobacco and anti-industry rhetoric has led to a failure to understand this. This, in turn, has led to an increase in the use of "organic" or "natural" cigarettes and hookah pipes among younger smokers, based on the mistaken impression that smoking something other than typical cigarettes makes a substantial difference in the health effects. Communication from experts about what constitutes the actual hazard could minimize such costly mistakes.

Scientists, particularly epidemiologists, need to focus on rescuing health science from becoming more of a junk science that serves primarily as a political foil. Scientists also need to escape from the naïve assumption that everyone wants to quit smoking, as well as refining our understanding of what benefits smokers derive from smoking. Instead of engaging in vilification of smokers and the tobacco industry, interested researchers should engage in multi-lateral communication and support the industry's investment of time and resources into the development and promotion of safer products (as is done with nearly every other industry).

A partnership between the studies of aerosols and biomarkers and public health can refocus attention on the greatest risk factor. We can educate the public about the health risks of inhaling combustion products (regardless of the source). More objective and accurate quantifications of the health risks of ETS are also desperately needed. Hopefully this information will persuade those who cannot or do not want to quit using nicotine to adopt safer ways to use it and thereby reduce the morbidity and mortality attributable to nicotine and tobacco use.

Acknowledgments / Conflicts of Interest

The authors focus much of their work on assessing and promoting the potential of tobacco harm reduction (reducing the morbidity and mortality caused by tobacco use by encouraging smokers to switch to smokeless tobacco or other low-risk sources of nicotine). As such, we have an

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interest in discouraging exaggerated claims of the risks from smokeless tobacco and other low-risk sources of nicotine, and encouraging others to take up the cause. A history of fierce attacks on our academic freedom and our careers by anti-tobacco extremists -- including by the administration of the University of Alberta School of Public Health -- likely influence our work and worldview (Phillips 2007b, 2008). We favor an approach to research and health promotion that includes constructively working with stakeholders – smokers and the smokeless tobacco industry, but doing this is politically difficult in the present political climate, creating conflicts of interest (which is to say, political pressures force us to decide what research and writing we consider to be worth the harassment, rather than being able to make our decisions based entirely on the scientific merit). The authors' research is partially supported by an unrestricted (completely hands-off) grant to the University of Alberta from U.S. Smokeless Tobacco Company. Dr. Phillips has consulted for U.S. Smokeless Tobacco Company in the context of product liability litigation. Subsequent to the presentation and drafting of this work, Dr. Phillips became a member of British American Tobacco's External Science Panel that deals with developing reduced harm products.

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