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Whether to push or pull? Nicotine reduction and non-combusted alternatives - Two strategies for reducing smoking and improving public health

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ABSTRACT

Combustible cigarettes remain the most harmful and addictive tobacco product, and reducing the prevalence of smoking continues to be a critical public health goal. While nicotine is the constituent primarily responsible for addiction to cigarettes, most of the harm associated with smoking comes from byproducts of tobacco combustion. Recently, two different approaches for reducing the harms of smoking have emerged, both of which focus on breaking the link between the addiction to nicotine and the harms caused by smoking. First, the addictive potential of cigarettes could be minimized by requiring a large reduction in the nicotine content of cigarettes. Evidence for a nicotine reduction policy thus far shows that the use of very low nicotine content cigarettes results in a reduction in the number of cigarettes people smoke per day and a reduction in cigarette dependence. Second, emerging alternative nicotine delivery systems (ANDS) like electronic cigarettes may provide sufficient nicotine to act as substitutes for cigarettes while delivering much lower levels of toxicants. Evidence suggests that the emergence of ANDS has increased the percentage of smokers who are able to quit. The present paper will briefly review the evidence for each of these approaches, and consider what contemporary reinforcement and addiction theories can tell us about their likely success. We argue that the most effective endgame approach is one that pursues both nicotine reduction and alternative nicotine delivery systems as complementary.

1. Harms associated with burned tobacco

Tobacco use continues to devastate public health, causing an estimated 6 million deaths worldwide annually (World Health Organization, 2015a). The vast majority of the harm from tobacco use is caused by cigarettes and can be traced to the byproducts of combustion and specific constituents in tobacco (The Surgeon General, 2014). Combustion is not necessary for nicotine delivery, although it does facilitate the rapidity with which nicotine is delivered by enabling pulmonary absorption (The Surgeon General, 2014). Nicotine itself, when delivered in cigarette-like doses, is not benign (The Surgeon General, 2014), but is far less toxic than other constituents of tobacco

smoke and hence would likely be less harmful if it was delivered in a non-combusted vehicle (Nutt et al., 2014). Indeed, the harms associated with nicotine and tobacco products may be best viewed as a continuum in which abstinence from all tobacco products would be the least harmful, the use of combusted tobacco products would be the most harmful, and non-combusted tobacco products are somewhere in the middle (Nutt et al., 2014; Sweanor et al., 2007; Zeller et al., 2009; Saitta et al., 2017; Food and Drug Administration, 2017; Kozlowski et al., 2001). The goal of policies and interventions should be to effectively move the population down that continuum of harm in order to improve public health (Zeller et al., 2009).

Unfortunately, cigarettes are highly addictive, engineered over

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decades to maximize the development and maintenance of chronic, dependent smoking (The Surgeon General, 2014; Proctor, 2011; US Department of Health and Human Services, 2010). In the US, only 7.4% of adult smokers are able to quit smoking each year, despite the fact that 68.0% are interested in quitting and 55.4% make a quit attempt (Babb et al., 2017). Since at least 1988 and arguably much longer (US Department of Health and Human Services, 2010; US Department of Health and Human Services, 1988), the addictive properties of cigarettes have been attributed almost exclusively to nicotine. This perspective, that nicotine is the cause of cigarette addiction, has driven smoking cessation medication development and innovation of Alternative Nicotine Delivery Systems (ANDS)—noncombustible nicotine or tobacco products designed to deliver fewer toxicants than cigarettes (Warner and Pollack, 2014; Kunze et al., 1998). ANDS include products like snus, nicotine replacement therapy products, and, in recent years, e-cigarettes. Understanding nicotine as the driving force in cigarette addiction has also provided a rationale for potential tobacco policies such as reducing the nicotine content of combusted tobacco products to render the product less addictive (Benowitz and Henningfield, 1994).

Of course, smoking is about more than nicotine. Other factors such as the sensory stimuli associated with smoking and the act of smoking itself, become potent drivers of use (Rupprecht et al., 2015; Caggiula et al., 2009). Indeed, smoking is interwoven throughout much of smokers' lives, and smokers have strong expectations and feelings about smoking, both positive and negative (Brandon et al., 1996). Smoking also remains embedded in culture. Many tobacco control policies have effectively shifted the cultural norms, although implementation and impact of those policies is quite heterogeneous and smoking remains normative in many parts of the world (Eriksen et al., 2015). Traditional tobacco control efforts have and should continue to address these issues, particularly reshaping cultural norms. Nevertheless, managing how people use nicotine – the constituent that is widely considered to be the central determinant of long-term use – has the potential to greatly improve public health. Currently, some 40 million Americans and over one billion smokers worldwide are using a product developed and aggressively marketed over decades, deeply embedded into the environments in which smoker's live, and integrated into their personal histories, making behavioral change extremely difficult (Eriksen et al., 2015; World Health Organization, 2015b).

2. Two approaches to breaking the link between nicotine and harm

Two approaches to reducing combusted product use have recently received considerable attention. One approach is to encourage smokers to switch to ANDS rather than continue to smoke cigarettes (Abrams, 2014; Henningfield, 2014), and thus to reduce the harms of nicotine delivery among those who are unable or unwilling to quit using nicotine. The other approach focuses on reducing the nicotine content of combusted tobacco products to render them less addictive (Hatsukami et al., 2013a; Hatsukami et al., 2013b; Donny et al., 2014; Donny et al., 2017). The intent is to reduce the harms associated with smoking, not by altering the toxicity of the product, but by reducing the likelihood that someone will start smoking or continue to smoke. Both represent approaches directed at breaking the link between nicotine consumption and the harms associated with inhalation of smoke from combusted tobacco. At the core, both are harm reduction approaches in that neither is particularly concerned with nicotine use per se, but instead focus on reducing exposure to smoke as a delivery vehicle for nicotine. Indeed, when the Food and Drug Administration (FDA) recently announced a new strategy for regulating tobacco products, these two approaches were considered essential and complementary components of a comprehensive FDA strategy (Food and Drug Administration, 2017).

Despite the shared focus on reducing use of combusted products and the two-pronged approach announced by FDA, some have argued that

these two approaches are fundamentally and philosophically opposed. ANDS have been conceptualized as a bottom-up or pull approach, emphasizing that market-driven, consumer-driven approaches will persuade smokers to switch products while still protecting individual rights. ANDS, and policies that favor use of ANDS over cigarettes (e.g., light-touch regulation, differential taxation), might be conceptualized as a “nudging” approach to public health or what Loewenstein has called “asymmetric paternalism” (Loewenstein et al., 2007). Conversely, nicotine reduction has been described as a top-down or push technique, emphasizing the forced nature of product standards that some smokers may not want (Bates, 2015). Kozlowski and Bates have described nicotine reduction as cigarette prohibition (Bates, 2015; Kozlowski, 2016) - more of a shove than a nudge. It is true that reducing nicotine would likely result in a reduction in cigarette sales, but it is important not to confound a reduction in the appeal and addictiveness of cigarettes with the prohibition of nicotine itself. Regardless, nicotine reduction is undeniably a more invasive tobacco control policy, and thus it is important to justify its necessity (Nuffield Council on Bioethics, 2007).

3. Promises, pitfalls, and prognosis of alternative nicotine delivery systems (ANDS)

Proponents of ANDS point to the number of smokers who have quit or reduced their smoking using ANDS (Farsalinos et al., 2016). Evidence of the potential utility for reducing smoking is most clearly observed in surveys focusing on the number of ANDS users who were smokers and have subsequently switched partly or entirely to e-cigarettes. For example, Farsalinos and colleagues estimated that as of 2014, 6.1 and 9.2 million European Union citizens have quit or reduced their smoking with the help of ANDS, respectively (Farsalinos et al., 2016). The evidence seems clear that for some smokers, ANDS may provide a path towards cessation (Brown et al., 2014). Smokers who use e-cigarettes frequently, particularly those using systems that more effectively deliver nicotine, may be more likely to quit smoking (McRobbie et al., 2014; Hitchman et al., 2015; Blank and Eissenberg, 2015; Bullen et al., 2013; Adkison et al., 2013; Carpenter et al., 2017). Furthermore, some data have shown that in 2014 and 2015, when the prevalence of ANDS use rose drastically among adolescents, use of cigarettes in the same population decreased (Jamal et al., 2017), which might suggest that the availability of ANDS reduces the use of combustible cigarettes in youth. In Japan, a class of ANDS known as heat-not-burn products are increasing in prevalence. These products may provide a superior sensory experience to e-cigarettes because they involve heated tobacco rather than nicotine isolated from tobacco and reduced harm in comparison to cigarettes because the tobacco is not combusted (FDA, 2017; Tobacco Meets Technology, 2017). As these products have taken off in Japan, cigarette sales have declined, again suggesting that their availability reduces cigarette use (Fojtik, 2017). Proponents of ANDS argue that these encouraging findings are only the tip of the iceberg because the nicotine delivery and positive subjective effects associated with ANDS products should continue to improve if innovation in this area is encouraged (Bates, 2015).

However, several observations warrant caution with regard to the impact of ANDS on current smokers. First, the vast majority of smokers either have not tried e-cigarettes, have tried them but abandoned them after a short trial period, or continue to use both products (i.e., dual use). In the EU, only an estimated 31.1% of current smokers have ever tried e-cigarettes, with just 4.2% reporting current use (Farsalinos et al., 2016). In the UK, an estimated 45% of e-cigarette users continue to smoke cigarettes, suggesting a sizeable portion of users do not switch completely in the timeframe assessed (Action on Smoking and Health, 2017). Likewise, although population data in England and the U.S. have concluded that e-cigarettes are increasing the rate of smoking cessation (Beard et al., 2016; Zhu et al., 2017), most smokers have not benefitted. For example, in England, an estimated 16,000–28,000 additional long-

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