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Barriers to Tobacco Harm Reduction as a Viable Public Health Strategy: Stakeholder Voices

By Pritika C. Kumar

To reduce the health burden of combustible tobacco products, we should implement science-based policies that acknowledge the risks as well as the benefits of different nicotine products.

Executive Summary

The perils of smoking combustible cigarettes are well documented.[1] Although smoking rates in the United States have dropped from 40 percent at the time of the U.S. Surgeon General's Report in 1964 to 12.5 percent in 2020, the practice is now more concentrated in communities suffering from the greatest economic, health, education and social disparities.[2]

The United States has embraced harm reduction as a public health strategy over the years, ranging from mandating helmets and seat belts to lifting the ban on the use of federal dollars to fund syringe exchange programs, all of which have

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1. Xiaochen Dai et al., "Evolution of the global smoking epidemic over the past half century: strengthening the evidence base for policy action," *Tobacco Control* 31:2 (March 2022), pp.129-137. https://pubmed.ncbi.nlm.nih.gov/35241576.
2. Public Health Service, "Report on Smoking and Health," U.S., Department of Health, Education, and Welfare, 1964; "2014 Surgeon General's Report: The Health Consequences of Smoking—50 Years of Progress," U.S. Centers for Disease Control and Prevention, 2014, p. 944. https://www.cdc.gov/tobacco/sgr/50th-anniversary/index.htm; Monica Cornelius et al., "Tobacco Product Use Among Adults – United States, 2019," *Morbidity and Mortality Weekly Report* 71:11 (March 18, 2022), pp. 397-405. https://pubmed.ncbi.nlm.nih.gov/35298455; Christopher W. Blackwell and Humberto López Castillo, "Use of electronic nicotine delivery systems (ENDS) in lesbian, gay, bisexual, transgender and queer persons: Implications for public health nursing," *Journal of Public Health Nursing* 37:4 (July 2020), pp. 569-580. https://pubmed.ncbi.nlm.nih.gov/32436297.

improved health outcomes at the population level.[3] Harm reduction is a pragmatic public health approach that aims to mitigate the health risks associated with a range of behaviors—rather than expecting individuals to cease engaging in the harmful behavior regardless of their capability or willingness to do so.[4] Despite the acceptance of harm reduction for activities with lower death and disease rates than cigarette smoking, tobacco harm reduction (THR) continues to remain a controversial topic.[5]

To reduce smoking-related disparities, this policy study explores barriers related to the inclusion of tobacco in traditional health care and harm reduction settings by highlighting perspectives from a diverse array of stakeholders. We interviewed 17 experts from harm reduction coalitions, policy, academia, social work, nursing, law enforcement, mental health care and health care, from both rural and urban areas. These conversations resulted in recommendations that could accelerate harm reduction efforts for adult smokers who are unable or unwilling to quit. Two key messages were echoed by interviewees. First, THR should be viewed as an integrated framework that incorporates regulatory, law enforcement, public health and health system policies in equal measure. Second, innovative, reduced-risk nicotine and tobacco products should be made available as viable smoking harm reduction tools.

Introduction

Tobacco use remains the leading cause of preventable death, disability and disease in the United States and worldwide.[6] Based on current estimates from the Centers for Disease Control and Prevention (CDC), roughly 31 million U.S. adults smoke.[7] Of those, close to 500,000 die each year due to smoking-related causes.[8] Smoking also increases the risk of developing cardiovascular disease, cancer, lung disease, diabetes, chronic obstructive pulmonary disease, tuberculosis, erectile dysfunction and more.[9] Although nicotine is the highly addictive substance of combustible smoking products, it is not the primary cause of these dire health consequences—it is the more than 8,000 harmful chemicals inhaled while smoking that leads to disease, disability and premature death.[10]

Traditional smoking-cessation policies and programs present only two options for people who smoke: quit or die. THR strategies, however, have been shown to help reduce the negative effects of tobacco use by taking a different approach. For those who are unable or unwilling to quit smoking, behavioral strategies (such as cutting

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die each year due to smoking-related causes.

3. Mary Hawk et al., "Harm reduction principles for healthcare settings," *Harm Reduction Journal* 14:1 (Oct. 24, 2017), pp. 1-9. https://link.springer.com/article/10.1186/s12954-017-0196-4.
4. "Principles of Harm Reduction," National Harm Reduction Coalition, last accessed June 13, 2022. https://harmreduction.org/about-us/principles-of-harm-reduction.
5. Marc T. Kiviniemi and Lynn T. Kozlowski, "Deficiencies in public understanding about tobacco harm reduction: results from a United States survey," *Harm Reduction Journal* 12:1 (July 5, 2015), pp. 1-7. https://pubmed.ncbi.nlm.nih.gov/26135116.
6. Sebastian T. Lugg et al., "Cigarette smoke exposure and alveolar macrophages: mechanisms for lung disease," *Thorax* 77:1 (May 13, 2021), pp. 94-101. https://thorax.bmj.com/content/thoraxjnl/77/1/94.full.pdf.
7. Monica E. Cornelius et al., "Tobacco product use among adults—United States, 2019," *Morbidity and Mortality Weekly Report* 69:46 (Nov. 20, 2020), pp. 1736-1742. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7676638.
8. Ibid.
9. "2014 Surgeon General's Report: The Health Consequences of Smoking—50 Years of Progress." https://www.cdc.gov/tobacco/sgr/50th-anniversary/index.htm.
10. Neal L. Benowitz and Jack E. Henningfield, "Reducing the nicotine content to make cigarettes less addictive," *Tobacco Control* 22:1 (May 2013), pp. i14-i17. https://tobaccocontrol.bmj.com/content/22/suppl_1/i14; Riccardo Polosa, "Examining the evidence for the health impact of combustion-free products: progress and prospects for tobacco harm reversal and reduction," *Internal and Emergency Medicine* 16:8 (Sept. 15, 2021), pp. 2043-2046. https://link.springer.com/article/10.1007/s11739-021-02837-2.

down the number of cigarettes smoked or delaying the first cigarette of the day) and product-based strategies such as using reduced-risk nicotine products (e.g., nicotine replacement therapy (NRT), low-nitrosamine smokeless tobacco products, e-cigarettes) have been shown to be effective.[11] Unfortunately, despite mounting evidence showing the efficacy of THR products in reducing the negative effects of combustible tobacco products, the use of vape cigarettes and other reduced-risk nicotine products has been met with resistance at various levels.[12]

The following sections provide an overview of the barriers to adopting THR as a natural extension of harm reduction public policy. Feedback garnered from participant interviews was analyzed and stratified into categories that represent systemic-, policy- and product-related barriers. We created policy recommendations within these categories that represent top-down and bottom-up approaches to advancing the inclusion of THR as a viable public health strategy.

Although we have witnessed a dramatic decrease in smoking rates, there continues to be significant disparities in smoking rates among underrepresented racial, ethnic, sexual, socioeconomic and educational groups.

Tobacco-Related Disparities

The United States witnessed a peak in the number of people who self-identified as smokers in the 1960s, with almost 43 percent of the adult population reporting that they smoked.[13] Although we have witnessed a dramatic decrease in smoking rates since then, the decline is not as evident in certain subpopulations.[14] There continues to be significant disparities in smoking rates among underrepresented racial, ethnic, sexual, socioeconomic and educational groups.[15]

It is well documented that those who identify as lesbian, gay, bisexual, transgender or queer (LGBTQ+) have a higher smoking prevalence than the general population.[16] In the 2009-2010 National Adult Tobacco Survey, 32.8 percent of LGBTQ+ individuals reported currently smoking, versus 19.5 percent of heterosexuals.[17] Smoking rates are also disproportionately higher in people living with human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), ranging anywhere between 40 to 70 percent.[18] Studies show similarly high rates in other underserved communities, including people with chronic mental illnesses and people in prisons, who have an excessively high smoking rate compared to the national smoking rate.[19]

11. Nicola Lindson et al., "Smoking reduction interventions for smoking cessation," *Cochrane Database of Systematic Reviews* 9:9 (Sept. 30, 2019). https://pubmed.ncbi.nlm.nih.gov/31565800; Kenneth E. Warner, "How to Think—Not Feel—about Tobacco Harm Reduction," *Nicotine & Tobacco Research* 21:10 (October 2019), pp. 1299-1309. https://academic.oup.com/ntr/article/21/10/1299/4990310.
12. Ibid.
13. "Cancer Prevention & Early Detection: Facts & Figures 2019-2020," American Cancer Society, 2019. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-prevention-and-early-detection-facts-and-figures/cancer-prevention-and-early-detection-facts-and-figures-2019-2020.pdf.
14. Cornelius et al. https://pubmed.ncbi.nlm.nih.gov/33211681; "Health Disparities Related to Commercial Tobacco and Advancing Health Equity," Centers for Disease Control and Prevention, last accessed Nov. 29, 2022. https://www.cdc.gov/tobacco/health-equity/index.htm.
15. Kerith J. Conron et al., "A population-based study of sexual orientation identity and gender differences in adult health," *American Journal of Public Health* 100:10 (October 2010), pp. 1953-1960. https://pubmed.ncbi.nlm.nih.gov/20516373.
16. Francisco O. Buchting et al., "Transgender Use of Cigarettes, Cigars, and E-Cigarettes in a National Study," *American Journal of Preventive Medicine* 53:1 (July 2017), pp. e1-e7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478444.
17. Brian A. King et al., "Current Tobacco Use Among Adults in the United States: Findings From the National Adult Tobacco Survey," *American Journal of Public Health* 102:11 (November 2012), pp. e93-e100. https://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2012.301002.
18. Kathy Petoumenos and Matthew G. Law, "Smoking, alcohol and illicit drug use effects on survival in HIV-positive persons," *Current Opinion in HIV and AIDS* 11:5 (September 2016), pp. 514-520. https://www.ingentaconnect.com/content/wk/coh/2016/00000011/00000005/art00010.
19. Prabhat Jha et al., "21st-Century Hazards of Smoking and Benefits of Cessation in the United States," *The New England Journal of Medicine* 368 (Jan. 24, 2013), pp. 341-350. https://www.nejm.org/doi/full/10.1056/NEJMsa1211128; Sara M. Kennedy et al., "Cigarette Smoking Among Inmates by Race/Ethnicity: Impact of Excluding African American Young Adult Men From National Prevalence Estimates," *Nicotine & Tobacco Research* 18:Suppl 1 (April 2016), pp. S73-S78. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5100810; Karen L. Cropsey et al., "Expired Carbon Monoxide Levels in Self-Reported Smokers and Nonsmokers in Prison," *Nicotine & Tobacco Research* 8:5 (October 2006), pp. 653-659. https://academic.oup.com/ntr/article-abstract/8/5/653/1057954.

Disparities in health-related outcomes resulting from smoking behavior also exists among certain populations. Although Black individuals usually smoke fewer cigarettes and initiate smoking later in life than white Americans, they are more likely to die from smoking-related diseases.[20] Quitting behaviors also reflect disparities based on race. Hispanic and Black adults who smoke have lower smoking rates than non-Hispanic white adults, yet adults from these racial groups who smoke have more difficulty quitting.[21]

In its report on health disparities related to commercial tobacco use, the CDC noted that factors such as the "pressures of discrimination, poverty, other social conditions and barriers to health care and treatment for tobacco use and dependence" contribute to high smoking rates and low cessation rates in minority communities.[22]

Harm Reduction

Given the clear health benefits of quitting combustible products, but the challenges in doing so, an opportunity exists to provide adults who smoke with an option that bridges the gap between abstinence and treatment. That option is harm reduction.

Based on the humane principles of compassion, non-judgement and meeting people where they are, harm reduction is a set of practical strategies that aims to reduce harm to an individual or a society by modifying hazardous behaviors that are difficult, and in some cases impossible, to prevent or cease.[23] The public health community has previously embraced active interventions based on the principles of harm reduction, such as use of helmets on bikes, protective gear in sports, seat belts, traffic lights, food-processing standards and workplace-safety standards.[24] THR can similarly help those who smoke optimize their health.

The ongoing debate around nicotine, a naturally produced chemical in tobacco plants, calls for more clarity on what nicotine is and its impact on people who smoke.[25] Several decades ago, a British scientist noted that people smoke cigarettes for the nicotine, a highly addictive chemical present in tobacco, but die from the byproducts created through the combustion of tobacco, such as tar and toxic gasses.[26] Research shows that roughly 70 percent of adults who smoke want to quit smoking and about 55 percent had attempted quitting in the last year, but only 7.5 percent of people who tried to quit succeeded.[27]

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THR can help those who smoke optimize their health.

Key Term

Tobacco Harm Reduction:

Tobacco harm reduction (THR) refers to substituting lower-risk nicotine and tobacco products, like NRTs, low-nitrosamine smokeless tobacco products and e-cigarettes for the highest-risk tobacco products, like cigarettes and other combustible products, for smokers who otherwise cannot or will not quit using nicotine.

Source: Kenneth Warner, "How to Think—Not Feel—about Tobacco Harm Reduction," *Nicotine & Tobacco Research* 21:10 (October 2019), pp. 1299-1309. https://academic.oup.com/ntr/article/21/10/1299/4990310.

20. Kenneth D. Kochanek et al., "Deaths: Final Data for 2014," *National Vital Statistics Reports* 65:4 (June 30, 2016). https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_04.pdf; Melonie Heron, "Deaths: Leading Causes for 2013," *National Vital Statistics Reports* 65:2 (Feb. 16, 2016). https://stacks.cdc.gov/view/cdc/38214.
21. Jennifer Irvin Vidrine et al., "Tobacco's Role in Cancer Health Disparities," *Current Oncology Reports* 11:6 (November 2009), pp. 475-481. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5031414.
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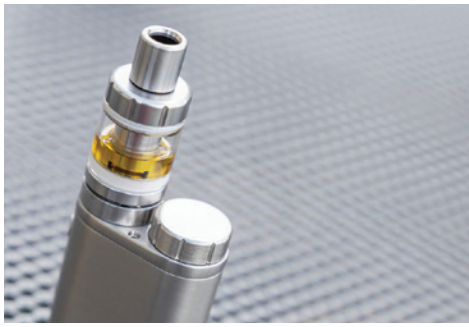
25. Karl Fagerström, "Nicotine: Pharmacology, Toxicity and Therapeutic Use," *Journal of Smoking Cessation* 9:2 (Dec. 12, 2014), pp. 53-59. https://www.cambridge.org/core/journals/journal-of-smoking-cessation/article/nicotine-pharmacology-toxicity-and-therapeutic-use/15D8BBF6393C6093C2076546E6515457.
26. M.A.H. Russell, "Low-tar medium-nicotine cigarettes: a new approach to safer smoking," *British Medical Journal* 1 (1976), pp. 1430-1433. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1640397/pdf/brmedj00520-0014.pdf.
27. "Smoking Cessation. A Report of the Surgeon General," Centers for Disease Control and Prevention, last accessed Oct. 17, 2022. https://www.cdc.gov/tobacco/sgr/2020-smoking-cessation/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Ftobacco%2Fdata_statistics%2Fsgr%2F2020-smoking-cessation%2Findex.html; MeLisa R. Creamer et al., "Tobacco product use and cessation indicators among adults—United States, 2018," *Morbidity and Mortality Weekly Report* 68:45 (2019), pp. 1013. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6855510.

Currently, the U.S. Food and Drug Administration (FDA) has approved NRT for those who wish to quit smoking; this is designed to help those who smoke reduce their use of the product with the goal of cessation. However, NRTs have proven to be minimally effective.[28] Other THR strategies include recommending the use of alternative products that deliver nicotine without the toxic processes of combustion. In the United Kingdom, vaping is the most popular harm reduction tool for people who are unwilling or unable to give up nicotine, and smoking-cessation programs that involved vaping products have been associated with an almost 65 percent success rate compared to 59 percent for those that did not.[29]

In the United States, however, vaping is not recognized as a smoking-cessation tool, and the uptake of this strategy has met with resistance.[30] This is a policy worth changing, as alternative nicotine products are valuable THR tools that meet people where they are to help them shift to less harmful alternatives to combustible products. Studies have found that these products offer people who smoke an opportunity to use nicotine while substantially reducing the risk of death or disease caused by smoking, and thereby reducing overall health care burdens.[31]

U.S. Policy is Worth Changing



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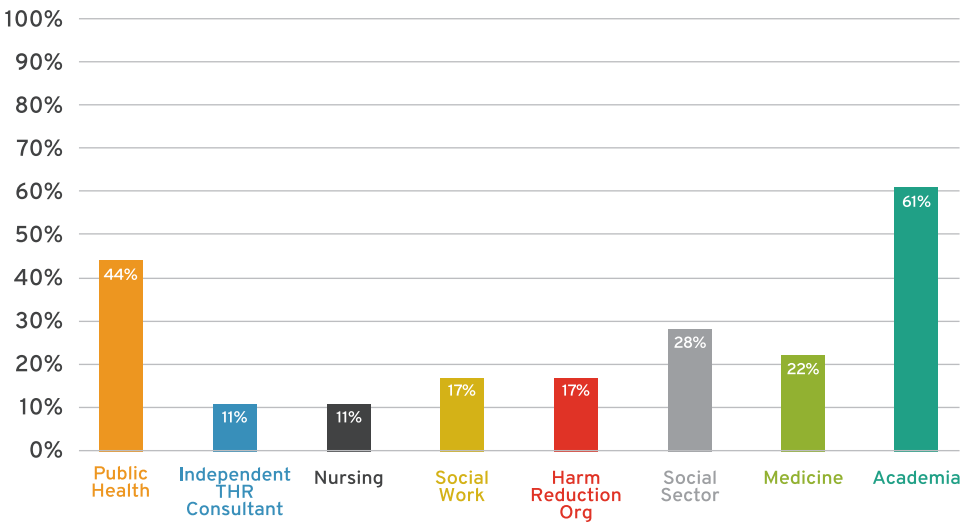
Study Methodology

The objective of our study was to understand the factors influencing the decisions of key stakeholders in their support or opposition in promoting THR measures for the populations they serve. We interviewed 17 stakeholders working in diverse areas related to harm reduction and/or THR. Interviewees included staff from harm reduction coalitions; staff from not-for-profit policy or service organizations serving people with substance use issues, HIV/AIDS or serious mental illness; primary care or addiction medicine physicians or other health care staff; social workers; nurses; academic researchers with published research in harm reduction; and independent THR consultants (Figure 1).

We used a qualitative research method—approved by the Institutional Research Board at Ethical and Independent Review Services—to conduct in-depth interviews with each expert. We used a semi-structured interview guide organized by constructs such as perceived commitment of leadership inside and outside of the organization to advocate for tobacco cessation and harm reduction; perceived THR-related challenges at local, state, or national levels; and recommendations to overcome articulated THR-related barriers.

28. David Moore et al., "Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis," *BMJ* 338 (2009). https://www.bmj.com/content/bmj/338/bmj.b1024.full.pdf.
29. Ann McNeill et al., "Evidence review of e-cigarettes and heated tobacco products 2018: a report commissioned by public health England," *Public Health England*, 2018. https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review/evidence-review-of-e-cigarettes-and-heated-tobacco-products-2018-executive-summary; "Nicotine vaping in England: 2022 evidence update main findings." https://www.gov.uk/government/publications/nicotine-vaping-in-england-2022-evidence-update/nicotine-vaping-in-england-2022-evidence-update-main-findings.
30. "Electronic Cigarettes: What's the Bottom Line?," Centers for Disease Control and Prevention, last accessed Nov. 29, 2022. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/Electronic-Cigarettes-Infographic-p.pdf; Warner. https://academic.oup.com/ntr/article/21/10/1299/4990310.
31. Ann McNeill et al., "E-cigarettes: an evidence update," Public Health England 3:6 (August 2015). https://provap.es/wp-content/uploads/7-cigarrillos-electronicos-una-actualizacion-de-la-evidencia-agosto-2015.pdf.

Figure 1: Distribution of Participant Backgrounds



Stakeholders' Knowledge of THR

Different tobacco products have different levels of harm associated with their use.[32] Stakeholders who were interviewed for this study recognized the harm caused by combustible tobacco products and were aware of the significant burden of disease and death attributable to this habit.[33] Most interviewees—even if not working directly in the tobacco space—seemed aware of the difference between combustible tobacco products and alternative nicotine products such as gums, chews, oral pouches and vapes. All interviewees were aware of NRTs as a measure to help lessen the habit of smoking. While all participants knew about vapes, only about half knew the types of products that are FDA-approved as reduced-risk products and federally approved to be legally sold. Further, nearly half of all interviewees were unaware of the evidence supporting noncombustible tobacco or nicotine products as less-harmful alternatives to cigarettes or the differences between classes of products such as e-cigarettes and heat-not-burn devices.

Nearly half of all interviewees were unaware of the evidence supporting noncombustible tobacco or nicotine products as less-harmful alternatives to cigarettes or the differences between classes of products such as e-cigarettes and heat-not-burn devices.

Over 80 percent of the stakeholders interviewed in this study were aware of the concept of THR. In the conversation with Sheila Vakharia, deputy director of research and engagement at the Drug Policy Alliance, she shared that THR "is like finding ways to get people to get access to nicotine, whether they're physiologically dependent on it or just enjoy it or want to use it recreationally, in safer ways than combustible products."[34] These safer ways could include vaping, gums, patches, pouches, or other "alternative delivery methods" or "different routes of consumption" for people to use nicotine with fewer potential health risks.[35] Jeffrey Kwong, a study interviewee and Professor at the Rutgers School of Nursing's Division of Advanced Nursing Practice,

32. D.J. Nutt et al., "Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach," *European Addiction Research* 20:5 (September 2014), pp. 218-225. https://www.karger.com/Article/Abstract/360220.
33. Pritika Kumar interview with community health organization staff (Virtual), April 7, 2022; Pritika Kumar interview with Kevin McGirr, (Virtual), May 2, 2022; Pritika Kumar interview with Kenneth Michael Cummings, Medical University of South Carolina, (Virtual), April 20, 2022.
34. Pritika Kumar interview with Sheila Vakharia, (Virtual), April 14, 2022.
35. Mitchell Zeller and Dorothy Hatsukami, "The Strategic Dialogue on Tobacco Harm Reduction: a vision and blueprint for the US," *Tobacco Control* 18:4 (August 2009), pp. 324-332. https://pubmed.ncbi.nlm.nih.gov/19240228.

shared that using harm reduction strategies with patients who are unwilling or unable to quit smoking, such as suggesting that they try cutting back from one to three-quarters of a pack a day or delaying their first cigarette of the day by 30 minutes in the morning as small steps to reduce the impact of smoking on their health.[36]

Participants with a background in harm reduction seemed more open to the idea of embracing harm reduction principles for smoking. For example, Kevin McGirr, a clinical professor of community health systems at University of California's School of Nursing, who started his career in substance and mental health research and programs, shared "I embrace the idea that people will make change incrementally, over a long period of time and that they may never get to abstinence," further noting, "I view [THR] as including alternate nicotine delivery devices, teaching and advocating for these to people who smoke and that ultimately it is the person's choice on the device and strategy they want to use."[37] Previous research aligns with this sentiment, as it demonstrates that people who smoke with coexisting substance use disorders were more successful in quitting when using a combination of methods including prayer, distraction, deep breathing, avoidance of triggers and nicotine gum or patches.[38]

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Stakeholder Perspectives on Barriers to the Acceptance of THR

The value of THR for adults who smoke and are unable or unwilling to quit has been debated by those who support and oppose the practice.[39] At the heart of the debate are key differences of opinions that can be loosely grouped into system-level, product-level and policy-related barriers. Our conversations with stakeholders shed light on key barriers within these categories that impede the effective uptake of THR in the United States.

System-Level Barriers

While the following sections articulate feedback from perspectives of health providers and the requisite systems in which they operate, it is important to recognize that leading health authorities in the United States believe there to be insufficient evidence to qualify e-cigarettes as tobacco cessation tools. The U.S. Preventive Services Task force only promotes behavioral interventions for cessation that have received approval by the FDA such as nicotine patches and gums.[40] While the FDA has approved some e-cigarettes through regulatory pathways for tobacco products, it has yet to formally endorse them as tobacco cessation tools. Since the first Surgeon General's Report in 1964, there has been a dramatic decrease in national smoking rates through the implementation of evidence-based policies and interventions by federal, state and local public health authorities.[41] While public health organizations have openly embraced

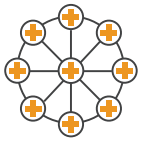
36. Pritika Kumar interview with Jeffrey Kwong, (Virtual), May 12, 2022.
37. Pritika Kumar interview with Kevin McGirr, (Virtual), May 2, 2022.
38. Kimber Paschall Richter et al., "Patients' views on smoking cessation and tobacco harm reduction during drug treatment," *Nicotine & Tobacco Research* 4:Suppl 2 (December 2002), pp. S175-S182. https://academic.oup.com/ntr/article-abstract/4/Suppl_2/S175/1117066.
39. Warner. https://academic.oup.com/ntr/article/21/10/1299/4990310.
40. "Tobacco Smoking Cessation in Adults, Including Pregnant Persons: Interventions," U.S. Preventive Services Task Force, last accessed March 13, 2023. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions.
41. Office of the Surgeon General, "Smoking and Health," United States Public Health Service, 1964. https://profiles.nlm.nih.gov/spotlight/nn/catalog/nlm:nlmuid-101584932X202-doc.

harm reduction in various areas such as transportation, sports and even in socially controversial topics as substance use and sexual health, public health initiatives have dragged their feet on accepting the role of harm reduction in reducing the health impacts of smoking. As one public health researcher in this study shared, their "desired endgame of tobacco was a world without nicotine," even though they acknowledged the role of NRT as a smoking-cessation tool.[42] Other participants were frustrated with the zero-sum approach of some of their public health colleagues.[43] One participant noted that there is a "large population of people who smoke and are dealing with comorbid mental health or substance use conditions," but despite this, they note that "there are some who are dogmatically and unalterably, opposed to even talking in any positive way about the use of alternative products."[44] Certain public health advocate groups have chosen to turn away from the scientific evidence that clearly shows that alternative nicotine delivery system products are significantly less harmful than combustible tobacco products.[45]

Barriers related to health care systems. The stakeholders in this study highlighted various barriers related to health care systems. Participants with a background in health care noted how non-physician health care staff tend to be under-leveraged when engaging with patients who use tobacco. Patricia Cioe, an associate professor of behavioral and social sciences who is affiliated with the Center for Alcohol and Addiction Studies at Brown University, highlighted the need for nurses who specialize in smoking-cessation counseling to whom patients could be referred, similar to the referrals given for diabetes education and treatment.[46] She went on to share, "patients will tell you that nurses are very good listeners and can be trusted more than any other health professionals."[47] A recent Gallup poll supports this position: nurses were ranked as the most-trusted health care professionals for the sixteenth straight year, with over 80 percent of Americans rating them as honest and as having high ethical standards.[48] To better engage nurses in THR work with patients, medical agencies would have to prioritize funding to train nurses in smoking-cessation counseling or find a way to bill their time through third-party payers.

Barriers for patients. Also in alignment with findings from several studies, researchers and health care providers in this study shared that people living with HIV have higher smoking and lower quit rates due to factors such as history of or coexisting substance use, psychiatric diagnoses and socioeconomic challenges.[49] Mark Bigler, professor and department chair of the Department of Social Work

System-Level Barriers for Health Care Systems



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System-Level Barriers for Patients

Researchers and health care providers in this study shared that people living with HIV have higher smoking and lower quit rates.

42. Pritika Kumar interview with a public health researcher, (VirMctual), April 13, 2022.
43. Pritika Kumar interview with Cliff Douglas, (Virtual), Apr 27, 2022; Pritika Kumar interview with Derek Yach, (Virtual), July 1, 2022.
44. Pritika Kumar interview with physician researcher, (Virtual) April 6, 2022.
45. McNeill et al., "E-cigarettes: an evidence update." https://provap.es/wp-content/uploads/7-cigarrillos-electronicos-una-actualizacion-de-la-evidencia-agosto-2015.pdf.
46. Pritika Kumar interview with Patricia Cioe, (Virtual), May 12, 2022.
47. Ibid.
48. Megan Brenan, "Nurses Keep Healthy Lead as Most Honest, Ethical Profession," *Gallup*, Dec. 26, 2017. https://news.gallup.com/poll/224639/nurses-keep-healthy-lead-honest-ethical-profession.aspx?g_source=CATEGORY_SOCIAL_POLICY_ISSUES&g_medium=topic&g_campaign=tiles.
49. Daniel K. Shirley et al., "Factors Associated with Smoking in HIV-Infected Patients and Potential Barriers to Cessation," *AIDS Patient Care and STDs* 27:11 (November 2013), pp. 604-612. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3820122; Pritika Kumar interview with Patricia Cioe, (Virtual), May 12, 2022.

and Gerontology at Weber State University shared that people who have chronic dependence on smoking with multiple health conditions often have a list of childhood traumas and/or behavioral health issues that take precedence over the risk of mortality due to smoking.[50]

Some studies have reported on the cognitive-enhancing effects of nicotine, which may partially explain the higher smoking rates in certain subpopulations. These factors include improving concentration; relieving stress and worry; and coping with depression, anxiety and anger.[51] As an example, Professor Cioe shared, "I have worked with patients with HIV, and there are so many reasons why they won't give up smoking […] they are concerned the nicotine patches will interact with their medications, they don't want to give up one more thing since they have already given up so much, and their confidence in quitting is so low because they have tried so many times before."[52] For individuals like these, having regulated options available to choose from would significantly reduce the health burdens associated with smoking. Kevin McGirr shared that "quitting smoking, just like quitting any other substance or habit, is not a linear process."[53] Hence, offer varying degrees of reduced harm, whether in the form of complete cessation, dual use of smoking and e-cigarettes, or completely switching to reduced-risk nicotine products (including e-cigarettes) allows adults to choose a healthier lifestyle overall.[54]

Barriers related to health care providers. Research shows that while most people may be aware of the dangers of smoking, far fewer people have an accurate perception of the harms related to smokeless tobacco, e-cigarettes and other nicotine/tobacco products.[55] Lane Aiena, a practicing physician in a small college town in Texas shared, "when you read [warning] labels […] how can you convince your patients to use these?"[56] While it is important that the FDA's Center for Tobacco Products invests in public education campaigns to "help educate the public—especially youth—about the dangers of regulated tobacco products," it is as crucial that the public be educated by their healthcare providers about the relative risk of these products along the risk continuum.[57]

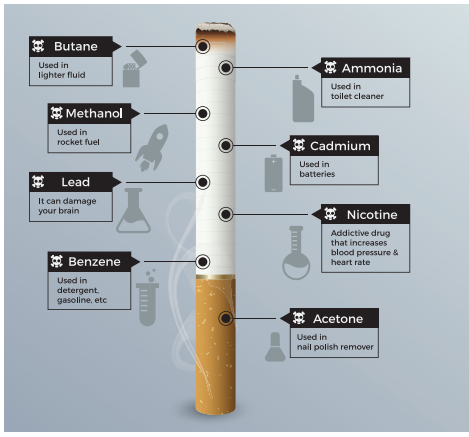
In addition, there are widespread and commonly held misperceptions regarding the harms caused by nicotine versus the harms caused by smoking among physicians: studies have found that over 80 percent of physicians strongly believe that nicotine directly contributes to heart disease, chronic obstructive pulmonary disease

System-Level Barriers for Health Care Providers

There are widespread and commonly held misperceptions regarding the harms caused by nicotine versus the harms caused by smoking among physicians.

50. Pritika Kumar interview with Mark Bigler, (Virtual), April 6, 2022.
51. Jonathan Shuter et al., "Cigarette Smoking Behaviors and Beliefs in Persons Living With HIV/AIDS," *American Journal of Health Behavior* 36:1 (January 2012), pp. 75-85. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3552435; Kristin W. Grover et al., "HIV Symptom Distress and Smoking Outcome Expectancies Among HIV+ Smokers: A Pilot Test," *AIDS Patient Care and STDs* 27:1 (Jan. 10, 2013), pp. 17-21. https://www.liebertpub.com/doi/abs/10.1089/apc.2012.0333.
52. Pritika Kumar interview with Patricia Cioe, (Virtual), May 12, 2022.
53. Pritika Kumar interview with Kevin McGirr, (Virtual), May 2, 2022.
54. Sara Kalkhoran et al.,"Dual use of smokeless tobacco or e-cigarettes with cigarettes and cessation," *American Journal of Health Behavior* 39:2 (2015), pp. 277-284. https://www.ingentaconnect.com/content/png/ajhb/2015/00000039/00000002/art00014.
55. Andrea C. Villanti et al., "Misperceptions of Nicotine and Nicotine Reduction: The Importance of Public Education to Maximize the Benefits of a Nicotine Reduction Standard," *Nicotine & Tobacco Research* 21:Suppl 1 (Dec. 23, 2019), pp. S88-S90. https://academic.oup.com/ntr/article/21/Supplement_1/S88/5684946.
56. Pritika Kumar interview with Lane Aiena, (Virtual), May 12, 2022.
57. "Youth and Tobacco," U.S. Food & Drug Administration, last accessed Nov. 29, 2022. https://www.fda.gov/tobacco-products/public-health-education/youth-and-tobacco; Nicola Lindson et al., "Setting research priorities in tobacco control: a stakeholder engagement project," *Addiction* 112:12 (December 2017), pp. 2257-2271. https://onlinelibrary.wiley.com/doi/full/10.1111/add.13940.

and certain forms of cancer.[58] Cliff Douglass, Director of University of Michigan's Tobacco Research Network and a public health faculty noted, "there is a huge amount of public misperception around the harms of nicotine, directly related to misperceptions held by doctors, influenced by politics and ideology."[59] Nicotine is the highly addictive ingredient that compels people to continue smoking, but most tobacco-related disease is not directly caused by nicotine, but rather by other chemicals present in tobacco or released by combusting tobacco. Despite this well-documented fact, many health care professionals believe that nicotine is the cause for the burden of disease and death associated with smoking.[60]



Despite the well-documented fact that nicotine is not directly related to tobacco-related diseases, many health care professionals believe that nicotine is the cause for the diseases and death associated with smoking.

The stakeholders' most frequently shared health care-related barriers were physicians' lack of time and training with regards to tobacco use. One study participant, a nurse practitioner, explained that patients understand that their care providers wants them to quit smoking, but they do not feel like they are given any effective tools to actually help them stop.[61] Another physician researcher mentioned that physicians are "overwhelmingly busy," so they have to "overlook" the use of cigarettes even though it is the number one cause of preventable death in this country.[62] Research shows that many physicians hesitate to talk about patients' tobacco use due to a variety of factors such as lack of time, perceived communication challenges, lack of confidence speaking about the topic and not wanting to risk the positive physician-patient relationship they have established.[63]

Some of the physicians in our study expressed they did not know enough about vapes to talk to their patients about these alternate nicotine delivery devices. Specifically, there were questions about the safety of such products or where to direct patients to obtain them.[64] Furthermore, in the current health care system, some insurance companies limit the number of quit attempts that they will provide treatment coverage for, which disregards the fact that quitting smoking is difficult but extremely beneficial in the long run.

Barriers related to harm reduction coalitions. Community-led groups such as harm reduction coalitions have played a pivotal role in advocating for the rights of people in underserved and underrepresented communities, such as people who inject drugs and people living with HIV.[65] The work of these harm reduction coalitions is especially important with regard to THR because these groups tend to serve patient populations with higher smoking rates, such as underrepresented racial, ethnic,

System-Level Barriers for Harm Reduction Coalitions

Interviewees working in coalitions unanimously supported THR, but also voiced a shared skepticism around including THR in their programming.

58. Modesta (Maud) Alobawone, "Rutgers-Led National Survey Uncovers Doctors' Misconceptions About Nicotine Risks," Rutgers, Sept. 8, 2020. https://www.rutgers.edu/news/rutgers-led-national-survey-uncovers-doctors-misconceptions-about-nicotine-risks.
59. Pritika Kumar interview with Cliff Douglas, (Virtual), Apr 27, 2022.
60. Michael B. Steinberg et al., "Nicotine Risk Misperception Among US Physicians," *Journal of General Internal Medicine* 36:12 (Sept. 1, 2020), pp. 3888-3890. https://link.springer.com/article/10.1007/s11606-020-06172-8?fbclid=IwAR0GzRkFyYUAUXQOS6Uz1w6UhRK_fnRzm2NEbGTmXjN4AG8mvKRB56FenYw.
61. Pritika Kumar interview with Patricia Cioe, (Virtual), May 12, 2022.
62. Pritika Kumar interview with physician researcher, (Virtual), April 6, 2022.
63. Jamie Bryant et al., "Missed opportunities: general practitioner identification of their patients' smoking status," *BMC Family Practice* 16:8 (Feb. 4, 2015). https://bmcprimcare.biomedcentral.com/articles/10.1186/s12875-015-0228-7; Eva Anne Marije van Eerd et al., "Why do physicians lack engagement with smoking cessation treatment in their COPD patients? A multinational qualitative study," *NPJ Primary Care Respiratory Medicine* 27:1 (June 23, 2017), pp. 1-6. https://www.nature.com/articles/s41533-017-0038-6.
64. Pritika Kumar interview with Lane Aiena, (Virtual), May 12, 2022; Pritika Kumar interview with Aley Kalapila (Virtual), May 4, 2022.
65. L.M. Anderson et al., "Community coalition-driven interventions to reduce health disparities among racial and ethnic minority populations," *Cochrane Database of Systematic Reviews* 6 (2015). https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009905.pub2/pdf/full.

and sexual minorities; incarcerated populations; and people with low education or income levels.[66] Interviewees working in harm reduction coalitions unanimously supported all forms of harm reduction, including THR, but also voiced a shared skepticism around including THR in their programming. The most commonly shared concerns around including THR in their offered services were lack of funding, insufficient staffing and potential negative reactions of donor agencies. Jasmine Benton, director of programs at the Atlanta Harm Reduction Coalition, noted that, "for our grants, we have to answer if we are a tobacco-free community, which always surprised me since most of the people we serve (people who use illicit drugs) also smoke and, many a times, clients pulling up to our syringe exchange program or to get housing are smoking."[67] Such exclusionary policies prevent harm reduction coalitions from even considering adding THR strategies such as handing out reduced-risk tobacco products to their clients who smoke.

Product-Level Barriers

System-Level Barriers
Product-Level Barriers
Policy-Related Barriers

In recent years, novel innovations for nicotine delivery have flooded the marketplace; however, the pace of innovation and the adoption of new products have slowed, and have even been actively impeded by product-level barriers. This is primarily due to concerns regarding product-level features and the appeal and uptake of tobacco among young people. These issues have spurred a polarized debate among academic public health groups and advocacy groups, with significant policy impacts.[68]

Concerns regarding youth use. The use of reduced-risk nicotine products, especially e-cigarettes, has divided public health. Debates are bifurcated between protecting the youth and reducing mortality rates for adults who smoke. When positioned in opposition to one another, as so often is the case, there is little to no room for solutions where the well-being of both groups could be protected.[69] One participant, a public health researcher, expressed their skepticism over e-cigarettes due to "a certain e-cigarette company that could have offered a tremendous smoking-cessation product but got greedy and marketed to kids."[70] Concern over e-cigarette uptake among young people overshadows the positive impact of e-cigarettes for adults who smoke. A study that analyzed published articles in the United States about e-cigarettes found that 70 percent of the articles focused on youth-use concerns, and only approximately 35 percent of the articles noted the potential benefits for adults who smoke.[71] A consequence of such extensive coverage of potential youth uptake is that many adults nationwide consider e-cigarettes to be as or more dangerous than combustible cigarette smoking.[72]

Product-Level Barriers for Youth Use

Debates are bifurcated between protecting the youth and reducing mortality rates for adults who smoke.

66. "Movements that Intersect with Harm Reduction," National Harm Reduction Coalition, last accessed Oct. 27, 2022. https://harmreduction.org/resource-center/harm-reduction-intersects/#intersects5.
67. Pritika Kumar interview with Jasmine Benton, (Virtual), May 12, 2022.
68. Ahmad Besaratinia and Stella Tommasi, "The consequential impact of JUUL on youth vaping and the landscape of tobacco products: The state of play in the COVID-19 era," *Preventive Medicine Reports* 22 (June 2021), p. 101374. https://www.sciencedirect.com/science/article/pii/S2211335521000644.
69. David J.K. Balfour et al., "Balancing consideration of the risks and benefits of e-cigarettes," *American Journal of Public Health* 111:9 (2021), pp. 1661-1672. https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2021.306416.
70. Pritika Kumar interview with a public health researcher, (Virtual), April 13, 2022.
71. Olivia A. Wackowski et al., "From the Deeming Rule to JUUL—US News Coverage of Electronic Cigarettes, 2015–2018," *Nicotine & Tobacco Research* 22:10 (October 2020), pp. 1816-1822. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7542638.
72. Wenxue Lin and Joshua E. Muscat, "Knowledge and Beliefs Regarding Harm From Specific Tobacco Products: Findings From the H.I.N.T. Survey," *American Journal of Health Promotion* 202 (Aug. 2, 2021). https://journals.sagepub.com/doi/abs/10.1177/08901171211026116.

However, as demonstrated by the ban on flavored e-cigarettes in San Francisco, California, while e-cigarette use and nicotine dependency are not ideal, they are preferable to combustible cigarette use and its related health risks. When San Francisco banned flavored e-cigarettes, the city saw a sharp spike in combustible cigarette smoking among young people while youth smoking rates declined in communities without such bans.[73] Sheila Vakharia aptly noted, "emotions and fear and weaponizing children is being used to stifle public health efforts."[74] While youth uptake should certainly be dissuaded, the benefits of e-cigarettes for established adult smokers must be the priority in the development of public health policies.

Most of the stakeholders we interviewed for this study work with people who smoke or who smoke and belong to marginalized communities. Aley Kalapila, a physician working at the Atlanta Harm Reduction Center and the Grady Hospital, pointed out, "my patients might not view smoking as the most pressing issue" and that the "availability of flavors in authorized reduced-risk nicotine products" might provide a "tipping point" for them to "switch from smoking to the reduced-risk nicotine products."[75]

Concerns regarding flavors in reduced-risk nicotine products. An important part of the transition from smoking to reduced-risk nicotine products is flavors. Studies have shown that a substantial proportion of adults who smoke initiate e-cigarette use with the help of non-tobacco flavors and, in some cases, subsequently quit smoking.[76] Helen Redmond, a THR advocate and adjunct faculty at New York University's Silver School of Social Work noted that "we have gone too far with the flavor bans, we have not learned our lesson from the war on drugs, and we are not paying attention to people who smoke, especially the ones who are already marginalized."[77] Sheila Vakharia spoke about the current flavor restriction in e-cigarettes to tobacco flavor only: "you're mandating that this product that has nothing to do with the cigarette must taste like a cigarette."[78] Research supports the point that vaping products with the traditional cigarette flavors of tobacco and menthol lead to continued smoking.[79] Yet discussing flavors in reduced-risk nicotine products invariably leads to vocal concerns about non-tobacco or fruity flavors appealing to youth. Research has shown that the uptake of vaping was not affected by the flavor of the vapes, or by whether they were tobacco or non-tobacco flavors.[80] Furthermore, tobacco flavor in alternative nicotine products could also contribute to users confusing the two products and thinking that e-cigarettes are as harmful as combustible cigarettes.

Product-Level Barriers for Flavors in Reduced-Risk Nicotine Products

Studies have shown that a substantial proportion of adults who smoke initiate e-cigarette use with the help of non-tobacco flavors and, in some cases, subsequently quit smoking.

73. Abigail S. Friedman, "A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California," *JAMA Pediatrics* 175:8 (May 24, 2021), pp. 863-865. https://jamanetwork.com/journals/jamapediatrics/article-abstract/2780248.
74. Pritika Kumar interview with Sheila Vakharia, (Virtual), April 14, 2022.
75. Pritika Kumar interview with Aley Kalapila (Virtual), May 4, 2022; Pritika Kumar interview with physician and public health researcher, (Virtual) April 6, 2022.
76. Christopher Russell et al., "Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA," *Harm Reduction Journal* 15:33 (June 28, 2018). https://link.springer.com/article/10.1186/s12954-018-0238-6.
77. Pritika Kumar interview with Helen Redmond, (Virtual), May 3, 2022.
78. Pritika Kumar interview with Sheila Vakharia, (Virtual), April 14, 2022.
79. Dina M. Jones et al., "Flavored ENDS Use among Adults Who Have Used Cigarettes and ENDS, 2016-2017," *Tobacco Regulatory Science* 5:6 (November 2019), pp. 518-531. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6834350.
80. Abigail S. Friedman and SiQing Xu, "Associations of Flavored E-Cigarette Uptake with Subsequent Smoking Initiation and Cessation," *JAMA Network Open* 3:6 (2020), pp. e203826-e203826. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766787.

Concerns regarding the affordability of reduced-risk nicotine products. Several stakeholders noted that the affordability of reduced-risk nicotine products was a barrier.[81] While higher taxation of combustible cigarettes has been shown to reduce smoking and increase the use of reduced-risk nicotine products such as e-cigarettes, research shows that higher taxation of e-cigarettes increases combustible cigarette smoking rates and reduces the use of e-cigarettes.[82] Helen Redmond raised concerns over increased tax on alternative nicotine delivery system products and how that tax can be "counterproductive to patients with low income."[83] The affordability of reduced exposure and reduced-risk tobacco and nicotine products is directly tied to how these products are taxed. A state-level analysis done by researchers in Minnesota found that approximately 33,000 adults who smoke could have switched from combustible tobacco products to e-cigarettes in the absence of the tax on e-cigarettes.[84] Taxing reduced-risk tobacco and nicotine products at the same rate as combustible cigarettes leads adults who smoke to over-estimate the risk of e-cigarettes relative to cigarettes.[85]

Product-Level Barriers for Affordability of Reduced-Risk Nicotine Products

Research shows that higher taxation of e-cigarettes increases combustible cigarette smoking rates and reduces the use of e-cigarettes.

Policy-Related Barriers

A substantial body of evidence points to the notable differences in risk between smoking and alternative nicotine products. Despite this, there are significant policy-related barriers that, if removed, could improve public health. Specifically, stakeholders in this study expressed concerns about the role of law enforcement and the FDA in tobacco and nicotine policy development and implementation.

System-Level Barriers
Product-Level Barriers
Policy-Related Barriers

The Role of Law Enforcement. The role that law enforcement could play in advancing public safety, public health and public confidence is rarely discussed in the THR realm. Generally, law enforcement tobacco control work is focused on "the issue of bans and the unintended consequences they have on public health issues in our communities."[86] The role of law enforcement in tobacco control is emphasized when federal and state regulations are proposed or implemented to reduce access to select tobacco products. For example, the FDA's recent proposal for a national ban on menthol cigarettes is a prime example of the dependency on law enforcement to carry-out tobacco control regulations. While at face value this may seem reasonable, "the reality is that all 50 states treat unlicensed distribution and sale of banned tobacco products as a crime. In 44 of these states, the crime is classified as a felony. In 37 states, the crime is subject to mandatory minimum sentences and mere possession is treated as a crime.[87]" Diane Goldstein, former lieutenant and current executive director of the non-profit organization, Law

Policy-Related Barriers for the Role of Law Enforcement

All 50 states treat unlicensed distribution and sale of banned tobacco products as a crime.

81. Pritika Kumar interview with Lane Aiena, (Virtual), May 12, 2022; Pritika Kumar interview with Sheila Vakharia, (Virtual), April 14, 2022; Pritika Kumar interview with physician researcher, (Virtual) April 6, 2022.
82. Michael F. Pesko et al., "The Effects of Traditional Cigarette and E-cigarette Tax Rates on Adult Tobacco Product Use," *Journal of Risk and Uncertainty* 60:3 (June 2020), pp. 229-258. https://www.nber.org/system/files/working_papers/w26017/w26017.pdf.
83. Pritika Kumar interview with Helen Redmond, (Virtual), May 3, 2022.
84. Henry Saffer et al., "E-cigarettes and Adult Smoking: Evidence from Minnesota," *Journal of Risk and Uncertainty* 60:3 (June 2020), pp. 207-228. https://www.nber.org/system/files/working_papers/w26589/w26589.pdf.
85. W. Kip Viscusi, "Risk Beliefs and Preferences for E-Cigarettes," Vanderbilt Law and Economics Research Paper No. 15-3 (March 1, 2015), pp. 1-49. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2571489.
86. Pritika Kumar interview with Diane Goldstein, (Virtual), May 9, 2022.
87. Mazen Saleh and Jillian Snider, "R Street Testimony for FDA's Proposed Tobacco Product Standards for Menthol in Cigarettes and Flavored Cigars," R Street Institute, July 18, 2022. https://www.rstreet.org/outreach/r-street-testimony-for-fdas-proposed-tobacco-product-standards-for-menthol-in-cigarettes-and-flavored-cigars.

Enforcement Action Partnership, shared that it would be more efficient if tobacco control agencies such as the FDA "proactively collaborated with law enforcement when working to pass laws such as [the] menthol ban announcement and flavor ban announcements on state levels," but that too often, law enforcement involvement is an afterthought.[88] Unintended consequences of prohibition-based regulatory measures often lead to a proliferation of illicit markets as consumers find a way to access their products.

The role of the FDA. The FDA "evaluates tobacco products based on a public health standard of 'appropriate for the protection of public health,' that considers the risks and benefits of the tobacco product to the population as a whole, including users and nonusers."[89] Since its announcement of the "deeming rule" in May 2016, the FDA has had the authority to regulate all tobacco products, including reduced-risk nicotine products.[90] Through the pre-market tobacco application (PMTA), modified risk tobacco products application (MRTP) and substantial equivalence application pathway, the FDA provides oversight, regulates and decides whether a new or existing product is appropriate for the protection of public health and is marketable. This process has proven to be clunky, time consuming and unfair to all players because of the expensive application process.[91] Cliff Douglass shared "the FDA is really struggling through its PMTA and MRTP application processes, and what it boils down to is that it is lacking a guiding vision."[92] The estimated cost to file for these applications ranges between $117,000 and $466,000, although industry experts believe the actual cost can easily run into the millions.[93] Although the Tobacco Control Act states that the FDA must review PMTA applications and issue final orders within 180 days, the clock does not start until the FDA considers the application complete, and the FDA can also restart the clock whenever the applications are amended or new information is requested or provided by the applicant. As a result, numerous PMTA and MRTP applications in the pipeline are waiting to be reviewed.

Policy-Related Barriers for the Role of the FDA

The FDA provides oversight, regulates and decides whether a new or existing product is appropriate for the protection of public health and is marketable. This process has proven to be clunky, time consuming and unfair to all players because of the expensive application process.

Recommendations

Science-backed policy strategies that support the use of reduced-risk THR products offer an off-ramp from smoking that could help more than 30 million people who smoke reduce their risk of morbidity and mortality.[94]

One overarching recommendation resulting from this study is the need to bring diverse stakeholders together to reflect on and develop strategies to mitigate the risks of smoking. This group would ideally include health care providers (primary

88. Pritika Kumar interview with Diane Goldstein, (Virtual), May 9, 2022.
89. "Rules and Regulations," U.S. Food & Drug Administration, April 28, 2022. https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/rules-and-regulations.
90. "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. Final rule," *Federal Register* 81:90 (May 10, 2016), pp. 28973-29106. https://pubmed.ncbi.nlm.nih.gov/27192730.
91. Eric N. Lindblom, "How Might Manufacturers of E-Cigarettes Get New Product and MRTP Orders from FDA More Quickly and Easily?," *Food and Drug Law Journal* 73 (2018), pp. 624-641. https://www.fdli.org/wp-content/uploads/2018/11/EL-Lindblom-Formatted-Final.pdf.
92. Pritika Kumar interview with Cliff Douglas, (Virtual), April 27, 2022.
93. Guy Bentley, "How the FDA Is Saving the Cigarette," Reason Foundation, Sept. 8, 2020. https://reason.org/commentary/how-the-fda-is-saving-the-cigarette.
94. Warner. https://academic.oup.com/ntr/article/21/10/1299/4990310.

care physicians, nurses, physicians assistants, dentists, social workers, mental health care providers, specialist physicians, etc.); academic researchers/scientists (from various disciplines such as medicine, public health, social work, psychology, health economics, nursing, etc.); regulators and policy makers at local and federal levels; tobacco and synthetic nicotine industry representatives; law enforcement; harm reduction coalitions; health department representatives; parents and educators; and—most importantly—people who previously smoked and who currently smoke. Many of the stakeholders we interviewed for this study pointed out that a health equity lens needs to be used in public health policies and programs to provide the opportunity for everyone to reach their full health potential, regardless of socially determined circumstances.[95]

In addition to the overreaching recommendation to bring a diverse group of stakeholders together, we also gathered recommendations from interviewees specific to each of the key barrier areas discussed above.

System-Level Recommendations

- [x] System-Level Recommendations
- [ ] Product-Level Recommendations
- [ ] Policy-Related Recommendations

The annual estimated cost of smoking-related adverse outcomes is over $300 million. Using a modeling approach, tobacco-control researchers found that if U.S. adults who smoke were to switch to vaping products, from 2013 to 2060, almost 2 million deaths could be prevented and almost 40 million life-years could be saved.[96]

Our study also found that those working in tobacco harm reduction recognize the importance of engaging those who smoke or those who have smoked as peer educators on THR.[97] One interviewee, Helen Redmond, shared:

> In the educational sessions I did with adults who smoke with substance use disorders, I took the help of a friend who had a smoking habit and had transitioned to vaping. The folks in my group looked at him as a peer navigator. It was a great experience for people in the group.[98]

Additionally, research should be designed and current and former smokers should be recruited to help explore barriers that prevent adults from accessing help and switching to lower-risk tobacco products.

Quitting smoking, much like quitting any problematic substance use habit, is not a linear process moving from a use to no-use state. Therefore, making regulated, reduced-risk nicotine products available as THR tools through health care providers and pharmacies would give greater access to those hoping to reduce or quit smoking. Additionally, making reduced-risk products more affordable than combustible cigarettes is a key strategy.[99] The United Kingdom offers an example of

95. Laura Brossart et al., "Best Practices User Guide: Health Equity in Tobacco Prevention and Control," Center for Public Health Systems Science, 2015. https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=1076&context=cphss; Pritika Kumar interview with public health researcher, (Virtual), May 10, 2022.
96. David Levy et al., "Public health implications of vaping in the USA: the smoking and vaping simulation model," *Population Health Metrics* 19:1 (2021), pp.1-18. https://link.springer.com/article/10.1186/s12963-021-00250-7.
97. Pritika Kumar interview with Patricia Cioe, (Virtual), May 12, 2022; Pritika Kumar interview with Helen Redmond, (Virtual), May 3, 2022; Pritika Kumar interview with Kevin McGirr, (Virtual), May 2, 2022.
98. Pritika Kumar interview with Helen Redmond, (Virtual), May 3, 2022.
99. Pritika Kumar interview with Jasmine Benton, (Virtual), April 15, 2022; Pritika Kumar interview with Lane Aiena, (Virtual), May 12, 2022.

this approach, as vaping products are available through the National Health Service at no cost, giving marginalized populations with the highest smoking rates an option to switch to a reduced-risk alternative.[100]

The health care system is central to influencing widespread health-based behavioral changes. Consistently integrating tobacco use screening, diagnosis and counseling in clinical encounters were practices emphasized by health care provider participants of our study.[101] In addition, health care providers could benefit from additional education to counter clinician-level misperceptions around nicotine.[102] For instance, even though NRTs have been available as a tobacco-cessation aids for decades, over 80 percent of health care providers have been found to wrongly believe that nicotine in combustible tobacco products causes cancer and other tobacco-related health issues.[103]

Product-Level Recommendations

System-Level Recommendations
Product-Level Recommendations
Policy-Related Recommendations

With most of the innovation of reduced-risk nicotine products coming from the for-profit industry, it would be helpful to recognize these industries as partners in THR. In addition, there is an opportunity for the FDA to strengthen the enforcement activities to remove unregulated products from the market. Doing so would increase the value of the regulatory pathways, ensure a fair and competitive market, and help prevent youth from accessing illicit products. The tobacco industry has previously invited hostility from the public health community but could work towards tobacco harm reduction.[104] In working together, the pace of innovation could increase for effective, reduced-risk nicotine alternatives.

The stakeholders in this policy study provided us with rich insights into the barriers of implementing THR strategies. A key foundational step in overcoming these barriers is to design and engage in long-term research on the effectiveness and safety of different reduced-risk tobacco/nicotine products, even though sufficient global scientific evidence exists that shows a significant drop in risk when a person switches from smoking combustible tobacco products to using alternative nicotine products.[105] Importantly, despite scientific evidence demonstrating the value of THR strategies, no e-cigarette has been approved by the FDA for use as a harm reduction tool on the grounds of needing more evidence "to understand potential risk and benefits to adults who use tobacco products."[106]

100. Helen Redmond, "U.K. Will Send a Powerful Message by Allowing NHS to Prescribe Vapes," Filter, Nov. 9, 2021. https://filtermag.org/nhs-prescribing-vapes.
101. Pritika Kumar interview with Jeffrey Kwong, (Virtual), May 12, 2022.
102. Pritika Kumar interview with Cliff Douglas, (Virtual), April 27, 2022.
103. Steinberg et al.. https://link.springer.com/article/10.1007/s11606-020-06172-8?fbclid=IwAR0GzRkFyYUAUXQOS6Uz1w6UhRK_fnRzm2NEbGTmXjN4AG8mvKRB56FenYw.
104. Natalie Huet, "WHO's strategy to put Big Tobacco 'out of business,'" *Politico*, May 11, 2016. https://www.politico.eu/article/the-whos-strategy-to-put-big-tobacco-out-of-business-margaret-chan-tax-cigarettes-labeling-rules-trade.
105. David B. Abrams et al., "Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives," *Annual Review of Public Health* 39 (April 2018), pp. 193-213. https://www.annualreviews.org/doi/10.1146/annurev-publhealth-040617-013849.
106. "E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems (ENDS)," U.S. Food & Drug Administration, last accessed Oct. 28, 2022. https://www.fda.gov/tobacco-products/products-ingredients-components/e-cigarettes-vapes-and-other-electronic-nicotine-delivery-systems-ends#:~:text=To%20date%2C%20no%20e%2Dcigarette,adults%20who%20use%20tobacco%20products.

Flavors play a significant role in helping break the association with tobacco-flavored cigarettes and helping individuals who are considering switching from combustible tobacco products to non-combustible products.

Policy-Related Recommendations

Current tobacco policies are designed and implemented with the aim of permanently reducing smoking rates, and, to that end, tend to deploy punitive and prohibitory bans and alarmist public service messaging. Integrating a harm reduction lens would mean recognizing the reduced risk that alternative nicotine products offer for those who want to continue using nicotine. Thus, effective policy development and enforcement is key. The FDA is key in terms of determining how smoking harm reduction is embraced at a population level, including in terms of what reduced-risk nicotine products are available yet to fully achieve a smoke-free United States, the agency will need to align its strategy to other developed nations that have fully adopted e-cigarettes as tobacco cessation tools. Recommendations to achieve these aims include:

- Streamline the FDA's current review and approval processes using a product standards approach based on the risk continuum for the portfolio of nicotine products.
- Reduce the time and cost barriers of the FDA's product application process to allow innovative, reduced-risk nicotine products to enter the competitive marketplace. This may require that the FDA modify its current processes to provide greater transparency around the regulation of reduced-risk nicotine products.
- Make FDA data available from equivalent applications for existing reduced-risk nicotine products that are approved in order to support producers and help save time, effort and cost for similar product applications.
- Work with stakeholders from various groups such as public health, law enforcement, tobacco/nicotine industry, and retailers to prevent counterfeit or unauthorized products from entering the market.
- Undertake education campaigns to remove common nicotine misperceptions held by health care professionals and the public.
- Empower the public to understand the risk continuum of nicotine products (called for by the recent approval of "very low nicotine cigarettes (VLNC)" by the FDA) and the relative risks of using VLNCs relative to other alternative nicotine products such as e-cigarettes or NRTs.[107]
- Support "switch messaging" via FDA channels for products authorized by the FDA that are significantly less harmful than cigarettes on the risk continuum to increase awareness of alternative nicotine products.[108]

107. Andrea C. Villanti et al., "Misperceptions of Nicotine and Nicotine Reduction: The Importance of Public Education to Maximize the Benefits of a Nicotine Reduction Standard," *Nicotine & Tobacco Research* 21:Suppl 1 (December 2019), pp. S88-S90. https://academic.oup.com/ntr/article/21/Supplement_1/S88/5684946.
108. Kenneth Warner et al., "A Proposed Policy Agenda For Electronic Cigarettes In The US: Product, Price, Place, And Promotion," *Health Affairs* 41:9 (September 2022), pp. 1299-1306. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00187.

As previously discussed, laws that prohibit reduced-risk nicotine products or that increase taxation on them have a detrimental impact on smoking rates.[109] Tobacco and nicotine products must be taxed proportionately to the risk that they pose as determined in the FDA's PMTA and MRTP application pathways, which are designed to determine whether a nicotine product is "appropriate for the protection of public health."[110] Proposed legislations could use this metric to exempt nicotine products that have received authorization through the FDA when proposing bans on reduced-risk nicotine products or flavors.[111] This would further encourage companies producing reduced-risk nicotine products to authorize them through the FDA and elevate industry standards.

To reduce the health burden of combustible tobacco products, we should implement science-based policies that acknowledge the risks as well as the benefits of different nicotine products. Such policies can help facilitate individual and population level change.

Less-harmful products are key in improving health outcomes for individuals who smoke, but significant barriers exist around helping individuals transition.

Conclusion

Smoking is undeniably one of the most significant public health issues of the 21st century. We are faced with the uphill challenge of altering the behavior of more than 30 million U.S. adults who currently smoke to either quit smoking altogether or to switch from smoking combustible cigarettes to using less-harmful tobacco/nicotine products.[112] These less-harmful products are key in improving health outcomes for individuals who smoke, but significant barriers exist around helping individuals transition. These barriers are evident at the system-level, product-level and policy-level, as evidenced by this study's findings.

Stakeholders across sectors are united in their call for new measures to make e-cigarettes and other NRT products less appealing and available to youth. At the same time, they reiterate the need to deploy all available resources to help people quit smoking. Both of these goals are achievable with an improved regulatory framework and better-informed consumers, health care providers and policymakers. Applying harm reduction principles to traditional tobacco control approaches may hold the key to a public health breakthrough that could save millions of lives.

109. Michael F. Pesko et al., "The Effect of Potential Electronic Nicotine Delivery System Regulations on Nicotine Product Selection," *Addiction* 111:4 (April 2016), pp. 734-744. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4801654.
110. Scott Gottlieb and Mitchell Zeller, "A Nicotine-Focused Framework for Public Health," *The New England Journal of Medicine* 377:12 (Sept. 21, 2017), pp. 1111-1114. https://www.nejm.org/doi/full/10.1056/NEJMp1707409.
111. Chelsea Boyd, "Risk-Proportionate Tobacco Harm Reduction Legislation," R Street Institute, March 18, 2022. https://www.rstreet.org/2022/03/18/risk-proportionate-tobacco-harm-reduction-legislation.
112. Jyothi Marbin et al., "Health Disparities in Tobacco Use and Exposure: A Structural Competency Approach," *Pediatrics* 147:1 (January 2021). https://publications.aap.org/pediatrics/article/147/1/e2020040253/33415/Health-Disparities-in-Tobacco-Use-and-Exposure-A.

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