Heart Care Foundation of India Consensus Statement on Tobacco Harm Reduction and Vaping

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It is a well-known fact that tobacco products, primarily combustible cigarettes, are the single greatest cause of tobacco-related diseases and kill about 7 million people worldwide each year. The tobacco epidemic in India has also reached alarming levels. As per the latest estimates, there are nearly 106 million people in India who smoke tobacco and 32 million who smoke as well as chew tobacco. There are ~270 million people who use tobacco in India. India is home to roughly 11.2% of the smokers in the world and 1.35 million people in the country die every year due to tobacco-related illnesses.

The indirect and direct costs of tobacco-related illnesses and deaths in India are also staggering. As per a Report by the Ministry of Health and Family Welfare, Government of India, the total economic costs attributable to tobacco usage related diseases in India, in the year 2011 for people aged between 35-69, was Rs. 1,04,500 crores (around US \$22.4 billion). In recent times, many smokers have transitioned to vaping products in their efforts to quit combustible smoking or reduce harm created by the same. Vaping products contain heated nicotine extracted from tobacco, as well as a variety of flavorings and other additives.

It is important to note here that vaping is not the same as smoking as there is no combustion that is taking place. Combustion from smoking generates significant level of tar, carbon monoxide and other chemicals out of which 69 are known carcinogens. Combustible cigarettes accelerate cancer caused by the released chemicals. Second-hand smoking or passive smoking from combustion not only increases the risk of coronary heart disease by 25-40% (almost the same level as a smoker), but also causes numerous

health problems in infants and children, including more frequent and severe asthma attacks, respiratory infections, ear infections and sudden infant death syndrome. Vaping products, on the other hand, do not result in combustion that results in nicotine delivery and as a result do not generate harmful chemicals to the level of conventional cigarettes.

SCIENTIFIC SUMMARY

There is significant scientific evidence that suggests that vaping products seem to be a reduced harm alternative to combustible cigarettes.

- In its independent evidentiary review, Public Health England (PHE) has categorically concluded that "Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. The previous estimate that, based on current knowledge, vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping." It has further observed that "To date, the levels of metals identified in e-cigarette aerosol do not give rise to any significant safety concerns, but metal emissions, however small, are unnecessary." On assessment of exposure to harmful constituents, PHE has observed that "biomarkers of exposure assessed to date are consistent with significant reductions in harmful constituents and for a few biomarkers assessed... similar levels to smokers abstaining from smoking or nonsmokers were observed."
- **The Royal College of Physicians** has also opined that "Toxin levels inhaled from vaping products under

- normal conditions are likely to be well below prescribed threshold limit for occupational exposure, which make the probability of significant long-term harm unlikely."
- The National Academies of Sciences, Engineering and Medicine (NASEM) has concluded in relevant part that "there is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicant and carcinogens present in combustible tobacco cigarettes" and there is substantial evidence that completely switching from regular use of combustible tobacco products to vaping results in reduced short-term adverse health outcomes in several organ systems."

As such, NASEM has concluded that "e-cigarettes pose less risk to an individual than combustible tobacco cigarettes" and "complete switching from combustible tobacco cigarettes to e-cigarettes would be expected to reduce tobacco-related health risk." Lead authors of the NASEM report on vaping, Dr Eaton and St Helen, also published a follow-on Evidence to Practice article, which recommended that, "if a smoker's initial treatment has failed or not been tolerated, or if the smoker refuses to use approved medications and counseling and wishes to use e-cigarettes to aid quitting, physician should encourage the smoker to switch completely to e-cigarettes. We agree with PHE that behavioral support should be provided to smokers who want to use e-cigarettes to help them quit smoking, and that health professionals should receive education and training in use of e-cigarettes in quit attempts."

- statement that stipulates basis the available scientific evidence that the use of vaping is less harmful than smoking cigarettes. It has further observed that despite clinical advice, many smokers "...will not attempt to quit smoking cigarettes and will not use FDA approved cessation medications. These individuals should be encouraged to switch to the least harmful form of tobacco product possible; switching to the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products."
- **The American Heart Association* has observed that "E-cigarettes either do not contain or have lower levels of several tobacco-derived harmful and potentially harmful constituents compared with cigarettes and smokeless tobacco. In comparison with nicotine replacement therapies (NRTs), e-cigarette use has increased at an unprecedented rate, which presents an opportunity for harm reduction if smokers use them as substitutes for cigarettes."

Public Health, New York University, writes in the April 2018 issue of Annual Review of Public Health: "A diverse class of alternative nicotine delivery systems (ANDS) has recently been developed that do not combust tobacco and are substantially less harmful than cigarettes. ANDS have the potential to disrupt the 120-year dominance of the cigarette and challenge the field on how the tobacco pandemic could be reversed if nicotine is decoupled from lethal inhaled smoke. ANDS may provide a means to compete with, and even replace, combusted cigarette use, saves more lives more rapidly than previously possible."

Based on currently available evidence, using current generation vaping products is less harmful than smoking cigarettes, but the health effects of long-term use are not known. The Heart Care Foundation of India (HCFI) and undersigned medical practitioners recognize their responsibility to continue monitoring and evaluation of emerging scientific evidence in relation to vaping products and will always strive to promptly inform policy makers, public and medical practitioners of these findings.

CLINICAL RECOMMENDATIONS

The undersigned medical practitioners and HCFI have always supported smokers in their efforts to quit smoking regardless of the approach giving paramount importance to their health and well-being. To help smokers quit, HCFI and the undersigned medical practitioners recommend clinicians to advise their patients to use available smoking cessation products coupled with behavioral counseling.

However, we also note that many smokers are increasingly using vaping products to quit smoking or reduce the harm caused by combustible smoking. To this end, we recommend that the best option is to quit smoking altogether but if a smoker finds it tough, they should use vaping products. It is important to note here that all individuals/patients should be consistently advised to quit using any form of tobacco products or related products completely. We further caution against the concurrent use of vaping products and combustible cigarettes.

POLICY RECOMMENDATIONS

The undersigned medical practitioners and HCFI would encourage the Government of India to frame policies and regulations of vaping products that addresses:

Marketing and Advertisement

- Youth access: Such products should only be available to smokers above the age of 21
- Safeguarding pregnant women from initiation and use through awareness campaigns
- Labeling
- Quality control over manufacturing
- Standards for contaminants.

Further, such regulations should allow adults to access quality-controlled products in their efforts to stop the use of combustible smoking with the objective to reduce harm.

It is also recommended that the Government of India should allocate funds for independent and continued research on the health effects of vaping products and guide their policies from time to time basis such evidence. There should be consistent guidance from regulatory authorities on product and ingredient standards with a view to further reduce toxicity and addictiveness of any tobacco product and related harm reduction products. Importantly, with respect to vaping products, manufacturers should be disallowed from making any unproven health claims unless the same has been approved by a relevant authority of the Ministry of Health and Family Welfare, Government of India.

It is our strongest recommendation to refrain from initiation of consumption of any tobacco product and related harm reduction product. However, transitioning to a related harm reduction product presents an important and critical public health opportunity for existing smokers and must be encouraged through appropriate regulations and support from clinicians.

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