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## **Opinion Article**

## Can You Do Without Risk Reduction In The Fight Against Smoking?

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### Introduction

Cigarette smoking is one of the major risk factors for the development of cancer, cardiovascular and pulmonary diseases. It alone causes more deaths than alcoholism, drugs, car accidents, homicides and suicides combined [1-6].

The World Health Organization (WHO) estimates that over 8 million people die each year worldwide from direct cigarette smoking, while exposure to secondhand smoke causes 1.2 million deaths [7]. In the European Union, 700,000 deaths from this cause are counted each year (8) while in Italy the Ministry of Health estimates 93,000 deaths a year, of which about 43,000 are caused by tumors attributable to cigarette smoking [8-9].

Experts from all over the world and Regulatory authorities are trying to modify such scenario and the main areas of intervention concern bans, regulatory and fiscal aspects, support actions for cessation aimed at smokers and evidence-based guidelines [10-16]. However, despite all this, the smoking problem is far from being stemmed [17].

Based on the data released by the Italian Istituto Superiore di Sanità (ISS) on 31 May 2022 (World No Tobacco Day), the number of smokers in Italy has increased significantly in the last year with an

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increase of around 800 thousand smokers, compared to 2019, although this can be at least partially explained by the increase observed during the COVID-19 pandemic, given that compared to 2021 there was a decrease in smoking prevalence of about 2 percentage points [18].

These data give rise to concern, also considering the objectives of the European Commission which would like to achieve a smoke-free generation by 2040 [19].

### **Policies on Tobacco Use Containments**

Cigarette smoking is a chronic relapsing disease conditioned by nicotine addiction [20]. The US experience of the last 25 years demonstrates that a drug policy based on prohibition and the application of penal sanctions to the use and sale of illegal products has resulted in an exponential increase in the costs related to crimes compared to the costs related to prevention addiction therapy and research. Basically, it has been seen that policies inspired by the bans and marginalization of consumers of addictive substances increase the risks to life and health associated with consumption and also increase social inequalities [21].

In the case of smoking, it has been demonstrated that regulatory intervention policies based on taxation and a ban on consumption are useful for containing the phenomenon but do not resolve the issue of heavy smokers, i.e. those who do not intend to quit smoking or, worse, fail to quit [22].

It is worth noting that, even where the principles of the cessation guidelines are scrupulously applied, the failures consistently outnumber the successes. At the CAF of the S. G. Bosco Hospital in Turin, (one of the Centers monitored by the ISS) an external audit had quantified the three-year cessation rates as 46% [23]. A flattering figure considering the numbers reported in the scientific literature which report abstinence rates at three years ranging between 26.5% (in younger subjects) and 37.3% (in older smokers) [24]. Economic incentives had been also used, trying to support the cessation goal but, apart from small improvements, with unsignificant results regarding this task [25]. Unfortunately, those who fail regularly return to the initial consumption of cigarettes and we must ask ourselves what to do in these cases. For these smokers, according to the indications of most public health bodies, there is no alternative to a new attempt to quit and therefore they remain at the mercy of their addiction, slipping towards a destiny of illnesses and deaths.

# Nicotine, Combustion, Tobacco Harm Reduction and Smoke-free products

It is certain that tobacco combustion products are the main cause of smoking-induced diseases, and nicotine addiction underpins tobacco use [26].

It is well known that combustion is the main cause of tobacco-related diseases, but the reduction of the harm from tobacco combustion still remains a controversial topic. Tobacco harm reduction involves providing tobacco users who are unwilling or unable to quit with less harmful nicotine products for continued use. Skepticism about harm reduction is based in part on a past misconception that low-tar/nicotine cigarettes were assumed to be associated with fewer health risks than regular cigarettes. In recent years there has been a proliferation of products defined as "smoke free" because they are characterized by a strong reduction of combustion products that could potentially serves as a means of reducing the harm of tobacco. Some members of the tobacco control community believe these products have great potential to reduce mortality and morbidity among smokers who switch to them altogether. Others believe that a new form of addiction is being created with these products. Certainly, a consumption of nicotine characterized by a significant reduction in combustion toxicity while not resolving the issue of addiction could be an important aid for inveterate smokers who are unable or unwilling to quit and this switch could rapidly reduce the half million annual deaths associated with cigarette smoking in the United States [27].

Nicotine, in all commercially available forms (gum, transdermal patch, nasal spray, inhaler, and sublingual tablets/lozenges) is currently used to help people attempting to quit smoking. The use of nicotine as a replacement therapy increases the chances of successful quitting and its efficacy is largely independent of the intensity of additional support provided to the individual [28].

Most recently, a Cochrane review featuring a stringent selection of 78 completed studies with 22,052 participants, of which 40 were randomized trials, concluded that there is high-certainty evidence that nicotine-enhanced e-cigarettes increase quit rates compared to dispensed nicotine. Pharmacological while there is definite evidence of moderate certainty that the use of nicotine-free e-cigarettes still increases quit rates. The size of the measured effect still remains to be clarified. The data also demonstrate that in the two-year follow-up (the longest period measured) the consumption of e-cigarettes turned out to be substantially free of adverse events and there was no evidence of serious harm from nicotine taken via electronic device [29].

Supporting the usefulness of nicotine assumption in the absence of combustion, an in-depth review was recently published which found that the health risks associated with the use of Snus, in which nicotine is decoupled from harmful tobacco smoke, are significantly lower than those associated with cigarette smoking. The use of Snus in Sweden has been shown to be effective in reducing the incidence of lung cancer and cardiovascular disease: diseases in which combustion is the main culprit. This review led to calls for a review of the EU ban on the marketing and sale of snus as a kind of harm reduction in heavy smokers with public health benefits [30].

The debate appears to be very heated but the fact remains that cessation is such a difficult goal to achieve that we cannot ignore other ways of aid that can be received by the population of inveterate smokers otherwise destined with absolute certainty to illness and death. In short, where it is not possible to obtain the most important goal which remains cessation, a partial prevention offered through smoke-free devices could save thousands of lives. This is also the position of the Ministry of Health of UK [31-33] and of New Zealand [34].

Even the possibilities that physicians themselves prescribe electronic cigarette in case of adult smokers who are unable to quit have been suggested [35]. In other words, a sort of partial prevention is suggested for the umpteenth time with the aim of containing toxicity by reducing the pathologies linked to burnt tobacco consumption.

The available data indicate that countries with high adoption of alternative nicotine products (e.g. UK, New Zealand, Sweden, Norway, and Japan) have been able to achieve lower smoking rates. The findings suggest that adoption of alternative nicotine products may help in reduce smoking prevalence faster than traditional tobacco control measures solely focused on prevention and cessation [36].

### **Gateway vs Displace Effect**

Many scientists argue that smoke-free products bring young people closer to nicotine addiction by constituting a gateway to smoking. However, it is not likely that it will be possible to demonstrate between vaping and smoking which one really causes the other in a period of adolescent experience. It is no coincidence that since 2015, and subsequently in 2018, a group of experts, commissioned by Public Health England to review the evidence on smoke-free systems, recommended: "we strongly suggest abandoning the gateway terminology until it is clarified how the theory can be scientifically studied in this field" [37].

Perhaps a quantification of the gateway effect could more usefully derive from evaluating the number (which should be substantial) of adolescents who, having reached e.g. 20-year-olds are habitual smokers due to a period of vaping in their adolescence: this could certainly be a worrying outcome. But there is as yet no evidence to support this result. The most recent evidence would seem to indicate that the most frequent adolescent users of e-cigs are those who are already cigarette smokers or would become smokers (displace effect), for whom the use of e-cigs could be as beneficial if not immediate as less in a potential future, as a diversion from cigarette smoking [38-42].

According to data from the National Youth Tobacco Survey (NYTS-USA), the exclusive use of cigarettes among high school students has substantially decreased from 11% in 2012 to 0.5% in 2021, accompanied by an increase of the use of e-cigarettes from 0.5% in 2012 to 9.8% in 2021 [43].

The results of a study conducted on the MTF (Monitoring The Future) cohort of 1,297,362 adolescents aged 13-18 years, in the period 1991-2019, in agreement with two other previous studies, led the Authors to conclude that '' the transition from E-cig to cigarettes (gateway to effect) was not a dominant factor at the population level at least until 2019" [44].

Furthermore, for someone, the safety of new products has not been demonstrated and for others there are doubts about the reduction of toxicity, but very often we forget that the comparison must always be made in relation to the damage and toxicity of burnt smoke: in any case, it is a concept relating to a relative risk compared to the absolute one represented by combustion products. Then there is to consider that electronic cigarettes are a consumer product and not a medical product but the question is whether they constitute only a risk to health or if they could also represent an opportunity for the inveterate smokers [45] as it was the Hon Lik's hope, the Chinese pharmacist who invented electronic cigarette. For any of these topics there are aspects which should be further investigated.

Meanwhile, the initiation in youth and young adults still largely belongs to traditional cigarette smoking. Many questions spontaneously arise: why do young people have access to cigarettes and electronic cigarettes in clear violation of the bans in force? How is it possible that Public Health England (now Office for Health Improvement and Disparities), states that "based on the reviewed evidence, we believe

that the 'at least 95% less harmful' estimate remains broadly accurate, at least over short and medium term periods. However, it might now be more appropriate and unifying to summarize our findings using our other firm statement: that vaping poses only a small fraction of the risks of smoking. As we have also previously stated and reiterate, this does not mean vaping is risk-free, particularly for people who have never smoked"? [33]. Are Britain's experts lying or are those who dispute these data wrong?

### **Conclusion**

Certainly, medical ethics cannot push prudence, which is always appropriate in the health sector, to the point of blocking the action of aid to a large portion of the population who get ill and die as a result of the combustion of tobacco smoke.

We hope that, based on scientific evidences, the time is ripe for a frank reflection on these aspects, bearing in mind that the prevention of initiation into tobacco use has nothing to do with policies to help smokers resistant to cessation. All of this would require a great collective and institutional effort, networking, forming alliances and above all remembering that where healing cannot be guaranteed to the patient, one must intervene by treating and helping. Perhaps the recovery of some values of medical science could help more to address the complex issues of smoking. We think this can happen.

### **Conflict of interest**

The authors have no conflicting interests to declare.

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