

# Italians are still loyal to conventional cigarettes, despite novel tobacco products

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## Abstract

**Introduction.** Over the last few decades in Italy, we observed a substantial reduction in conventional tobacco cigarette consumption, the introduction of electronic cigarettes (e-cigarettes) in 2010, and the launch of heated tobacco products (HTP) in 2015.

**Methods.** We investigated novel products, i.e. e-cigarettes and HTP, use in Italy in 2018-2021 using data from the cross-sectional annual PASSI (Progressi delle Aziende Sanitarie per la Salute in Italia) survey conducted in representative samples of adults aged 18-69 (overall n = 101,458). We compared characteristics of conventional cigarette smokers with those of novel product users.

**Results.** A stall in e-cigarette use at around 2.4% and a three-fold increase in HTP use from 0.5% in 2018 to 2.5% in 2021 were recorded, with around 60% of e-cigarette users and 70% of HTP users who kept on smoking conventional cigarettes. Around 86% of smokers did not use novel products at all. Novel products use among former smokers was more likely in younger e-cigarette with no nicotine users, whereas older users of both novel products were less able to completely shift to an exclusive use.

**Conclusions.** After 10 years from the introduction of e-cigarettes and 5 years from that of HTP, the majority of smokers in Italy were still loyal to conventional tobacco cigarettes, and more than half of novel product users kept on smoking conventional cigarettes.

## Key words

- smoking prevalence
- tobacco
- ENDS
- e-cigarette
- heated tobacco products
- heat-not-burn tobacco
- Italy

## INTRODUCTION

Tobacco smoking was the second leading risk factor for premature death and disability worldwide in 2019 accounting for 8.71 million deaths [1]. However, the last decades have seen a substantial expansion and strengthening of tobacco control initiatives, following articles outlined in the World Health Organization Framework Convention on Tobacco Control (WHO-FCTC) and the 25×25 non-communicable disease (NCD) targets. As a result, a substantial reduction in tobacco use was recorded over the last few decades, at least in high-income countries [1]. Recently, novel products have been introduced into the market, including electronic cigarettes (e-cigarettes) and heated tobacco products (HTP). Their popularity and use grew rapidly worldwide [2], also thanks to their aggressive promotion, with claims that they were less harmful than conventional cigarettes [3].

Long-term health consequences of these novel products are still largely unknown [3]. Recently, an Australian report highlighted the lack of evidence to conclude that e-cigarettes are not dangerous [4]. Moreover, a recent article suggested that combining smoking with e-cigarette use did not reduce cardiovascular events [5]. However, there is still a huge debate in the scientific community as to whether e-cigarettes can be considered a technology to help smokers to quit and provide a safer alternative to cigarettes [3], or a tool that will allow the tobacco industry to subvert policies, renormalize smoking and new smokers [6, 7]. Notwithstanding that the debate is not over, Australia from October 2021 banned e-cigarettes because of the significant increase in young people.

Due to the alleged reduced harm, novel products obtained fiscal and regulatory benefits compared to

conventional cigarettes in most high-income countries [6]. In 2014, however, the European Union introduced the Tobacco Products Directive, which included restrictions to advertising and mandatory warnings on e-cigarette products containing nicotine [8]. In addition, in 2018, the eighth session of Conference of the Parties stated that HTP meet the definition of tobacco products under FCTC, thus the full range of policy and regulatory measures contained in the WHO-FCTC apply to HTP [9].

E-cigarettes have been introduced into the Italian market in 2010 and HTP since the end of 2015. Data from a series of cross-sectional surveys conducted annually on representative samples of around 3,000 Italians aged >14 years showed that e-cigarette users increased from 1.2% in 2013 to 2.1% in 2017-2019, while HTP users were 1.1% in 2019 [10]. Moreover, data from the ongoing Italian behavioural risk factor surveillance system PASSI (Progressi delle Aziende Sanitarie per la Salute in Italia) showed the use of e-cigarettes as a quitting tool, with one out of ten smokers who attempted to quit in 2014-2015 using e-cigarettes [11].

The aim of this study is to use PASSI data to provide updated estimates of e-cigarette and HTP use in Italy in 2018-2021 and to compare characteristics of conventional cigarette smokers with those of novel product users.

## METHODS

The PASSI surveillance system is a cross-sectional survey carried out annually on a sample of the Italian population aged 18-69 years. A random sample is extracted from the lists of residents in each Local Health Unit (LHU), stratified by sex and age group (18-34, 35-49, 50-69 years) based on the proportion of population in each stratum, obtaining annual estimates of the main variables at LHUs level with an acceptable precision. The survey collects information on a wide variety of health-related and behavioural topics along with demographic and socio-economic data. Informed consent was obtained from all participants. More details on methodological issues related to PASSI data collection have been described elsewhere [12].

For the present analysis we included data from the 2018-2021 PASSI surveys, comprising 139 Italian LHUs and 101,458 interviews (around 31,600 per year in 2018-2019, 16,361 in 2020 and 22,000 in 2021). We collected information on e-cigarettes, HTP and conventional tobacco cigarettes use, together with demographic and socio-economic characteristics.

We defined current e-cigarette users or current HTP users as respondents who declared to use nicotine or non-nicotine e-cigarettes or HTP on the date of the interview, respectively; current cigarette smokers as respondents who smoked at least 100 cigarettes in their lifetime and smoked in the last 30 days; former smokers as respondents who smoked at least 100 cigarettes in their lifetime but were not current smokers; never smokers as those who smoked less than 100 cigarettes in their lifetime; dual users as respondents who used e-cigarettes or HTP and kept on smoking conventional cigarettes. The present analysis included 24,508 current smokers, 17,779 former, and 59,092 never smokers.

Proportions were estimated by taking into account for the survey design using the Taylor series method for variance estimation and by assigning each record a probability weight equal to the inverse of the sampling fraction in each LHU stratum [12]. A Poisson regression model with robust variance was used for estimating prevalence ratios (PR) of e-cigarette or HTP use according to selected demographic, socio-economic and smoking characteristics. Interactions between age and economic status, smoking status and education were evaluated.

All the analyses were carried out using Stata 17 software.

## RESULTS

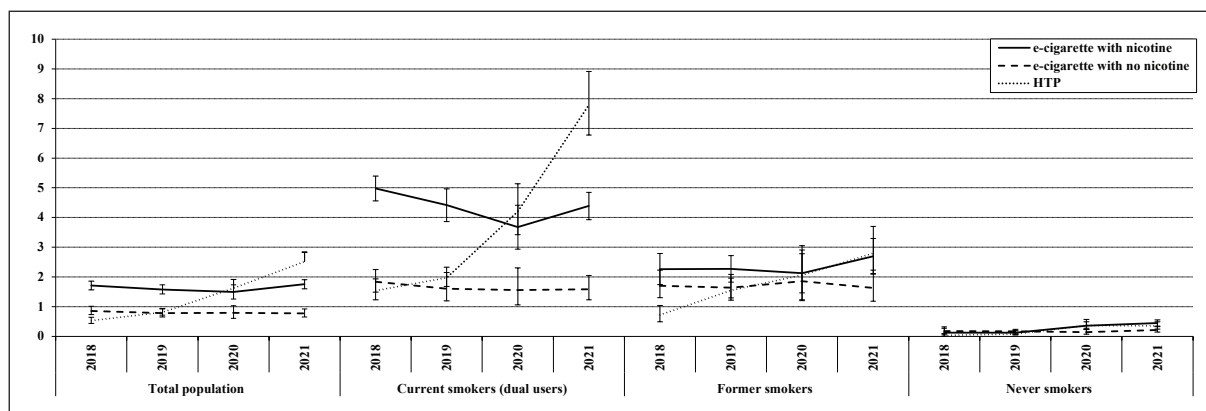
In 2018-2021, e-cigarette users (with or without nicotine) stalled around 2.4% in the overall population and 4.0% among former smokers. Among current smokers, nicotine and non-nicotine e-cigarette users stalled respectively around 4.4% and 1.7%, with a slight increase from 2020 to 2021 in nicotine e-cigarette. On the other hand, among never smokers e-cigarette with nicotine increased from 0.1% in 2018 to 0.4% in 2021, and HTP users increased from 0.5% to 2.5% among total population, from 1.5% to 7.8% among current smokers, from 0.7% to 2.8% among former smokers, and from 0.0% to 0.3% among never smokers (*Figure 1*).

Most novel product users were dual users: in 2021 the proportion of dual users was 59.4% (=1.0% / [1.0% + 0.7%]) among nicotine e-cigarette users, 48.7% among non-nicotine users (= 0.4% / [0.4% + 0.4%]), and 73.4% among HTP users (= 1.8% / [1.8% + 0.7%]). Moreover, most smokers (in 2021 86.3% = 20.5% / [20.5% + 1.0% + 0.4% + 1.8%]) kept on exclusively smoking conventional cigarettes (*Figure 2*). Interestingly, e-cigarette (non-nicotine and nicotine) and HTP users among never smokers increased from 6.1% in 2018 to 12.0% in 2021.

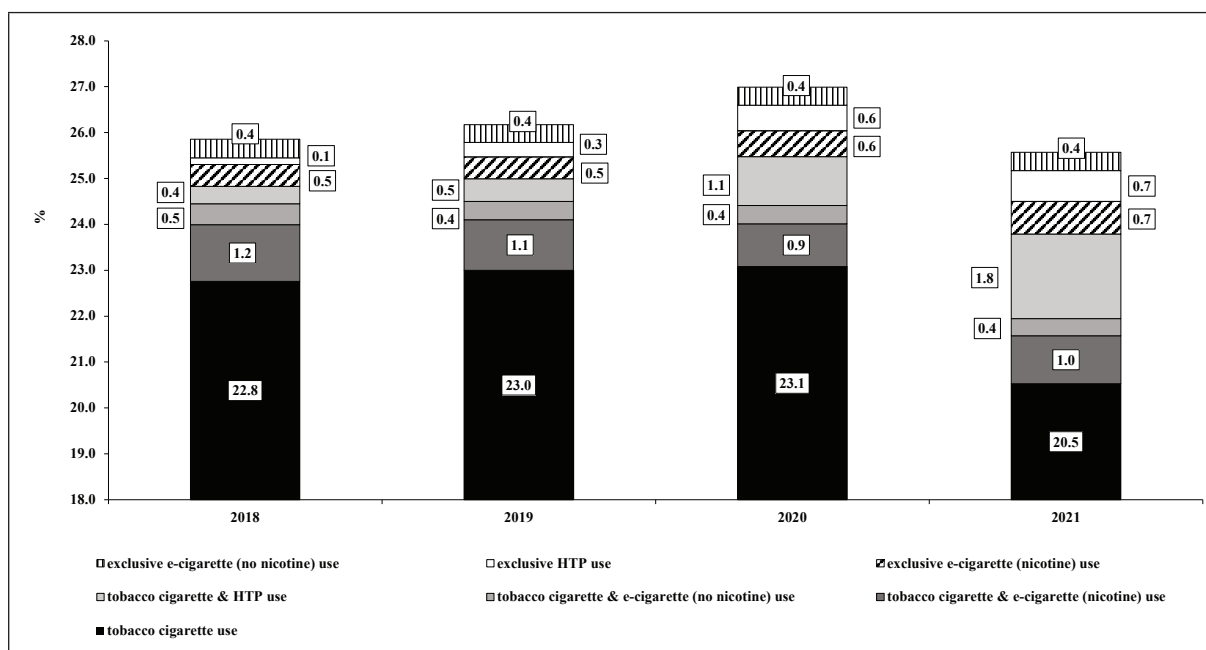
Models stratified by age class for e-cigarette or HTP use were estimated due to a significant interaction between age and smoking status in both models (model for e-cigarette use:  $p < 0.001$ ; HTP use:  $p = 0.0193$ ). E-cigarette users aged 18-34 and 35-49 years were more likely to be males than females. Both e-cigarette and HTP users older than 35 years were more likely to report high education level. Moreover, both e-cigarette users aged 50-69 years and HTP users among respondents of all ages were less likely to be former smokers compared to current smokers. Users among never smokers were very few (*Table 1*). By analyzing separately e-cigarette use with or without nicotine (data not shown) former smokers aged 18-34 years were more frequently users without nicotine compared to current smokers, whereas among respondents aged 35-69 years users with nicotine were less likely to be former smokers.

## DISCUSSION

Our findings on a slight decrease in prevalence of conventional cigarettes, a stall in prevalence of e-cigarette users, and an increase in HTP users were in broad agreement with data observed in a series of repeated representative surveys of Italian adults [10]. Moreover, the substantial increase in HTP use is consistent with sales data: the proportion of HTP sales on total tobac-

**Figure 1**

Prevalence of current electronic cigarette (e-cigarette) or heated tobacco products (HTP) use in the total population and by smoking status, 2018-2021.

**Figure 2**

Prevalence of tobacco cigarette, electronic cigarette and heated tobacco products (HTP) use by years, PASSI 2018-2021.

co products grew from 2.0% in 2018 to 11.7% in 2021 [13]. Finally, in a representative survey conducted in Italy during the COVID-19 lockdown in 2020, a stall in smoking prevalence, albeit with an increase in smoking intensity, and an increase in both e-cigarette and HTP use were recorded [14].

The use of novel products was mainly characterized by a dual use, with 56% of e-cigarettes and 73% of HTP users continuing smoking conventional cigarettes. Moreover, 86% of smokers did not use novel tobacco products at all, suggesting that the vast majority of smokers were not attracted by novel products. A cross-sectional survey on e-cigarette use conducted in 2021 among English people found that 30.5% of e-cigarette users were dual users, the proportion of adult smokers who currently used e-cigarettes increased rapidly from 6.7% in 2012 to

17.6% in 2014, and then, up to 2021, it stalled at around 17%, as if no more than 1 out of 6 smokers were satisfied with vaping. As a consequence, among nicotine addicted subjects the proportion of exclusive tobacco smokers remained high also in the UK (83.1%) [15].

A possible benefit of the use of novel products is their use among former smokers, hypothesizing that these subjects made a complete shift from conventional cigarettes to novel products. In this paper, few users of e-cigarettes or HTP were able to make a complete shift. Only non-nicotine e-cigarette users aged 18-34 years were more likely to completely shift to e-cigarettes, i.e., were more likely to be former than current smokers, whereas users of both novel products aged 50-69 years were more likely to continue smoking, showing more difficulties in making a complete shift to novel products.

**Table 1**

Association between current electronic cigarette (e-cigarette) and heated tobacco product (HTP) use<sup>a</sup> and demographic, socio-economic characteristic, and smoking status, Italy 2018-2021. Total numbers of survey participants in each strata of the population and prevalence ratios with corresponding 95% confidence intervals

	Total		Current e-cigarette users			Current HTP users			
	N (%) 101,458 (100)	N (%) 2,427 (2.5)	PR (95% CI)			N (%) 1198 (1.4)	PR (95% CI)		
			18-34 years	35-49 years	50-69 years		18-34 years	35-49 years	50-69 years
<b>Sex</b>									
Women	52,109 (50.5)	975 (2.0)	1*	1*	1*	594 (1.3)	1*	1*	1*
Men	49,349 (49.5)	1452 (3.1)	1.45 (1.20-1.75)	1.3 (1.09-1.57)	0.9 (0.74-1.09)	604 (1.4)	0.82 (0.66-1.02)	0.88 (0.67-1.15)	0.78 (0.55-1.12)
<b>Year</b>									
2018	31,234 (27.2)	776 (2.6)	1*	1*	1*	149 (0.5)	1*	1*	1*
2019	31,934 (27.6)	760 (2.4)	1.03 (0.83-1.28)	0.88 (0.73-1.07)	0.83 (0.67-1.04)	266 (0.8)	1.66 (1.13-2.44)	1.48 (1.00-2.19)	1.34 (0.86-2.08)
2020	16,361 (20.7)	344 (2.3)	1.06 (0.80-1.41)	0.87 (0.65-1.17)	0.77 (0.56-1.04)	241 (1.7)	4.14 (2.77-6.17)	2.32 (1.51-3.55)	2.29 (1.36-3.84)
2021	21,929 (24.5)	547 (2.6)	1.39 (1.10-1.75)	1.07 (0.84-1.37)	0.77 (0.60-1.00)	542 (2.6)	5.86 (4.05-8.48)	4.67 (3.19-6.82)	3.49 (2.23-5.46)
<b>Level of education**</b>									
Low	31,638 (31.3)	650 (2.0)	1*	1*	1*	254 (0.9)	1*	1*	1*
High	69,686 (68.7)	1,775 (2.7)	1.12 (0.90-1.40)	1.74 (1.43-2.11)	1.48 (1.21-1.82)	944 (1.5)	1.03 (0.77-1.38)	1.57 (1.13-2.19)	1.66 (1.12-2.48)
<b>Economic status***</b>									
None economic difficulties	57,051 (54.4)	1,286 (2.4)	1*	1*	1*	724 (1.5)	1*	1*	1*
Some difficulties	35,035 (36.0)	880 (2.5)	1.02 (0.85-1.24)	1.11 (0.90-1.38)	1.01 (0.82-1.26)	373 (1.2)	0.8 (0.64-1.02)	0.79 (0.57-1.08)	1.14 (0.80-1.63)
Many difficulties	8,925 (9.6)	257 (2.9)	0.96 (0.69-1.34)	1.3 (0.98-1.72)	1.02 (0.73-1.42)	92 (1.1)	0.73 (0.44-1.20)	1 (0.65-1.52)	0.75 (0.38-1.48)
<b>Geographic area</b>									
Northern Italy	38,495 (34.8)	891 (2.5)	1.12 (0.90-1.40)	1.04 (0.83-1.31)	0.79 (0.63-1.00)	463 (1.5)	1.16 (0.89-1.50)	1.28 (0.90-1.82)	1.19 (0.75-1.90)
Central Italy	24,806 (22.0)	712 (3.1)	1.38 (1.12-1.70)	1.41 (1.13-1.76)	0.98 (0.78-1.24)	317 (1.5)	1.28 (1.00-1.65)	1.05 (0.72-1.53)	1.38 (0.87-2.20)
South Italy and Islands	38,157 (43.2)	824 (2.2)	1*	1*	1*	418 (1.1)	1*	1*	1*
<b>Smoking status</b>									
Current	24,508 (24.7)	1,489 (6.3)	1*	1*	1*	820 (3.9)	1*	1*	1*
Former	17,779 (17.2)	691 (4.1)	1.07 (0.85-1.36)	0.85 (0.70-1.04)	0.49 (0.4-0.61)	266 (1.8)	0.75 (0.57-0.99)	0.53 (0.38-0.74)	0.43 (0.29-0.63)
Never	59,092 (58.1)	246 (0.4)	0.11 (0.08-0.14)	0.07 (0.05-0.10)	0.03 (0.02-0.04)	112 (0.2)	0.06 (0.05-0.09)	0.03 (0.02-0.05)	0.03 (0.01-0.05)

<sup>a</sup>Respondents who declared to use both e-cigarette and HTP were defined as HTP users since many harmful substances are at higher concentration in HTP compared to e-cigarette (N=38).

Abbreviations: PR: prevalent ratio of current users vs non-current users. 95% CI: 95% confidence interval. PR and 95%CI were estimated using a Poisson regression model with robust variance after adjustment for sex, survey year, level of education, economic status, geographic area and smoking status.

\*Reference category. \*\*Level of education was assessed by asking: "What is your level of education?" "none or elementary school or junior high school" = Low; "high school or university" = High. \*\*\*Economic status was assessed by asking: "With the available financial resources how do you get to the end of the month?" "very easily or easily" = None economic difficulties; "with some difficulties" = Some economic difficulties; "with many difficulties" = Many economic difficulties.

In addition to the lack of a complete shift to novel products among current smokers, we observed that their use doubled among never smokers, suggesting that they are used for initiating nicotine dependence.

Public health implications of these results are that novel products cannot be considered a technology to

help smokers to quit, especially HTP and nicotine e-cigarettes, and that their use is increasing among never smokers and youths.

Limitations of this study were those inherent to the cross-sectional design, including the impossibility to infer causality in the observed associations. Our results

should be confirmed by prospective cohort studies. Furthermore, sales data on e-cigarettes are not yet available for Italy, so we were not able to verify whether the plateau of e-cigarette use we recorded was consistent with official sales data.

In conclusion, after 10 years from the introduction of e-cigarettes and 5 years from that of HTP in Italy, although novel products enjoyed huge fiscal and regulatory benefits compared with conventional cigarettes, the vast majority of nicotine addicted people were still loyal to conventional cigarettes, and almost two out of three novel tobacco product users kept on smoking conventional cigarettes.

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tion strategies” (ACAB) project funded by the 2018 Health Research Grant by the Tuscany Region. The work of SG is partially supported by AIRC within the AIRC Investigator Grant (IG) 2021 n. 25987.

### Ethics approval and consent to participate

The study was conducted according to the guidelines of the Declaration of Helsinki, and is part of the Italian surveillance system PASSI (Progressi delle Aziende Sanitarie per la Salute in Italia). The Ethics Committee of the Italian National Institute of Health (ISS - Istituto Superiore di Sanità) has issued a favourable ethical opinion on the Italian behavioural surveillance system PASSI. The protocol number of the final opinion is CE-ISS 06/158 - 8th of March 2007. PASSI complies with General Data Protection Regulation and informed consent was obtained from all subjects involved in the study.

### Conflict of interest statement

All Authors must declare any conflicts of interest.

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