Research Article

Prevalence and Patterns of Tobacco and Nicotine Product Use in Italy: Findings from 2018–2024 Repeated Cross-Sectional Surveys

Steve Roulet[1], Karina Fischer[1], Tommaso Pellegatti[2], Umberto di Luzio Paparatti[3], Jessica Seifert[4], Pierpaolo Magnani[1]

1. PMI R&D, Philip Morris Products S.A., Switzerland; 2. Philip Morris Italia, Italy; 3. Sr Scientific & Medical Advisor, Philip Morris Italia, Italy; 4. Philip Morris International (United States), New York, United States

Background: Tobacco harm reduction aims to reduce the health burden of smoking by providing smoke-free alternatives, such as heated tobacco products (HTPs), for adults who would otherwise smoke. Philip Morris Products S.A. has been commercializing the Tobacco Heating System (*THS*) nationally in Italy since 2016. This study aims to measure the prevalence and patterns of use of tobacco and nicotine-containing products (TNPs) in Italy between 2018 and 2024.

Methods: This study was a repeated cross-sectional survey that comprised a representative General Adult Population Sample (GAPS) and a *THS* User Sample (TUS) of the adult population in Italy, from 2018 to 2024. The last GAPS survey (N ∼ 3000), conducted between 2023-2024, used a three-stage stratified random sampling method and was conducted face-to-face using computer-assisted personal interviews. The TUS survey (N ∼ 1000) was an online survey among randomly selected *THS* users registered in the PMI Italy's database of adult purchasers. Both survey questionnaires collected data on current, past, and never TNP use, including prevalence, frequency, intensity, history, patterns, and quitting of TNP use.

Results: The GAPS survey data showed that in 2024 current TNP use prevalence among Italian adults was 25.8%, unchanged from 25.7% in 2018, with cigarette smoking being the most used TNP over time. Between 2018 and 2024, cigarette smoking prevalence decreased from 24.3% in 2018 to 22.4% in 2024, while HTP use prevalence increased from 0.7% to 4.1% respectively, with *THS* (2.9%) accounting for approximately 70% of HTPs used in 2024. At the same time, *THS* initiation, relapse, and reinitiation among adult never and former TNP users in the GAPS remained low (0.1%) across the

 doi.org/10.32388/A7QW7V

survey periods. The TUS survey data showed that the proportion of *THS* users who did not smoke increased from 61.4% in 2018 to 75.9% in 2024. In line with previous years, the TUS survey data showed that 95.2% of *THS* users had a history of TNP use before switching to *THS*. Many *THS* users reported perceived improvement in terms of coughing (68.8%), breathing (68.3%), oral health (64.1%), overall physical health (61.7%), and overall health (61.6%) after switching to *THS*.
Conclusions: Between 2018 and 2024, the prevalence of TNP use among Italian adults remained stable. Over time, there was an increase in the adoption of HTPs, primarily *THS*, while the prevalence of cigarette smoking decreased. *THS* uptake among adult never and former TNP users has remained low over time. Data also show that the majority of *THS* users did not smoke and that a large proportion of *THS* users reported perceived improvements in health and functioning-related benefits after switching to *THS*. Continued surveillance of long-term HTP use in Italy remains essential.

Corresponding Author: Karina Fischer, karina.fischer@pmi.com

Introduction

Cigarette smoking remains one of the leading preventable causes of morbidity and mortality [1]. It is widely recognized among various health authorities and regulatory agencies that the primary risks linked to cigarette smoking stem from the inhalation of high levels and numbers of harmful and potentially harmful constituents (HPHC) produced during tobacco combustion [2][3][4]. While nicotine is known to be addictive, it is not the primary cause of smoking-related illnesses [5][6][7]. This understanding has given rise to the concept of tobacco harm reduction, a public health strategy that encourages adults who would otherwise smoke to transition to smoke-free products (SFPs) [5][8][9]. Examples of SFPs include e-cigarettes and heated tobacco products (HTPs), which deliver nicotine without the combustion of tobacco [8][9][10][11]. Various public health authorities have assessed the relative harms of SFPs compared to cigarettes, and tobacco harm reduction is now being implemented as a population-based strategy to tackle tobacco harm in several counties in the world [12][13][14][15][16][17]. Although SFPs are not without risk, if manufactured according to strict manufacturing requirements and scientifically substantiated, they emit substantially lower levels of HPHCs compared to cigarettes [18][19][20]. HTPs, for example, heat rather than burn tobacco, which significantly reduces the formation of combustion-related HPHCs [18][21][22][23]. In Italy, cigarette smoking continues to pose a considerable

public health challenge [24]. According to the Italian National Institute of Health, the prevalence of cigarette smoking among Italian adults has remained relatively stable in recent years. In 2024, approximately 23.8% (9.6 million) of the population aged 18 to 69 years old were identified as current smokers, with prevalence being higher among men (28%) compared to women (20%) [25].

Italy became one of the earliest adopters of HTPs in Europe [26], with Philip Morris Products S.A.'s Tobacco Heating System (*THS)* launching in the market nearly a decade ago, and the national roll-out in December 2016 [27][28]. Since the introduction of HTPs, the landscape of tobacco and nicotine-containing products (TNPs) in Italy has evolved. Therefore, it is important to continue assessing the prevalence and patterns of use of HTPs, particularly *THS*, among the adult population in Italy.

This study presents recent findings from a repeated cross-sectional survey of the adult population in Italy. The primary objective is to evaluate temporal trends in the prevalence and patterns of TNP use, with a particular focus on HTP and *THS*, and to assess the effect of HTPs and *THS* on TNP use. By examining trends in prevalence, initiation, relapse, reinitiation, intention to quit, and TNP use patterns, this study aims to provide ongoing evidence on the role of *THS* in the broader context of tobacco harm reduction. A secondary objective is to assess perceived health and functioning-related benefits among *THS* users since switching to *THS* use.

Methods

Study Design and Sampling Methods

This study is a repeated cross-sectional study conducted annually in Italy since 2018 (excluding 2020-2021 due to COVID-19 restrictions), with the fifth wave conducted in 2024.

Two distinct samples were used. One was a nationally representative general adult population sample (GAPS) (N=3,700 in 2024), recruited using a three-stage stratified random sampling method. This involved selecting municipalities, followed by electoral wards within those municipalities, and finally individuals from electoral lists, ensuring proportional representation of the general adult population in Italy. An annual sample size of 3,000 participants per year for the GAPS was deemed sufficient to estimate a 5.0% prevalence of *THS* use with a 95% confidence interval (CI) and a precision of ±0.78 percent units.

The second sample was a targeted *THS* user sample (TUS) (N=1,000 in 2024), which was randomly selected from Philip Morris Italy's *THS* owner database and comprised individuals who had consented to be contacted for research purposes. A yearly sample of 1,000 TUS participants was deemed sufficient to estimate a 50% rate of exclusive *THS* use with a 95% CI and a precision of ±3.10% units. In 2024, the GAPS survey was conducted over four monthly waves (September to December), while the TUS survey took place in a single wave during November and December 2024. Participants in the GAPS did not receive an incentive for completing the questionnaire, whereas those in the TUS survey received a gift voucher valued at 10 EUR, a standard incentive for online surveys using a consumer database. Additionally, the study adhered to the guidelines for Strengthening the Reporting of Observational studies in Epidemiology (STROBE; Supplementary Table S1) [29].

Inclusion criteria consisted of Italian adults who were of legal age to purchase TNPs in Italy (aged 18 years or older), currently residing in Italy, capable of reading, writing, and understanding Italian, and who provided consent to participate in the survey. For the TUS, additional inclusion criteria specified that participants must have used more than 100 tobacco sticks with the *THS* device in their lifetime, be current *THS* users, not be pregnant or breastfeeding, have internet access, and not be employed by Philip Morris International or any of its affiliates.

Mode of Administration and Data Collection

The GAPS survey was part of a multipurpose survey (Omnibus) that was administered face-to-face using computer-assisted personal interviewing (CAPI), while the TUS survey was conducted online via computer-assisted self-interviewing (CASI) or in later years computer-assisted web interviewing (CAWI).

Questionnaires

The GAPS survey questionnaire included standardized questions on current, past, and never use of TNPs; use patterns; frequency and intensity of use; initiation; relapse; reinitiation; and intention to quit. The TNPs measured as part of the survey included: cigarettes, other combustible tobacco products, HTPs, e-cigarettes, smokeless tobacco, and oral tobacco-derived nicotine (OTDN).

In line with the GAPS survey, the *THS* survey questionnaire also included standardized questions to assess current, past, and never use of TNPs, as well as use patterns, frequency, and intensity. Participants were also asked to rate their perceived change in health and functioning-related benefits since they switched from smoking cigarette to using *THS*, using the ABOUT™ Health & Functioning Instrument (7-

point rating scale from “very much improved” to “very much worse”). The question specifically asked “Overall, how much has each of the following changed (if at all) since you started using *THS*?”. The ABOUT Health & Functioning Instrument is part of the ABOUT Toolbox that was developed to provide a measure of the perceived health and functioning status associated with the use of different TNPs and with switching to SFPs. Each participant took less than 30 minutes to complete the surveys.

Definitions and Measurements

Current use was defined as using the TNP at the time of the survey and having exceeded the lifetime use threshold. The thresholds of lifetime use (minimum number of products or times a TNP was consumed in a lifetime) were defined as follows: for cigarettes, ≥100 cigarettes; for HTPs, ≥100 sticks; for e-cigarettes, ≥100 times; for other combustible TNPs, ≥50 times; for smokeless tobacco, ≥20 times; and for OTDN, ≥20 times [30][31][32].

Use patterns were defined as using one specific TNP (exclusive use), two specific TNPs (dual use), or more than two specific TNPs (poly use). Use patterns were also defined based on specific TNPs used, with exclusive *THS* use defined as using *THS* only; *THS* use together with SFPs defined as using *THS* together with other SFPs, such as other HTPs or e-cigarettes; and *THS* use together with combustible TNPs defined as using *THS* together with combustible TNPs, such as cigarettes. The exclusive *THS* use and *THS* together with other SFP categories were further grouped and defined as *THS* use without combustible TNPs.

Frequency was defined as the number of days a specific TNP was used in the last 30 days. Intensity was defined as the average number per day a specific TNP was used on the days the specific TNP was used.

Intention to quit cigarette smoking was defined using a single question “Are you currently considering quitting cigarette smoking?” with four response-items “Yes, plan to quit within next 30 days”, “Yes, plan to quit within next 6 months, but not within next 30 days”, “No, not thinking of quitting in next 6 months”, Don’t know / couldn’t say”.

Initiation was defined as starting to use a specific TNP in the last 12 months. Relapse was defined as using a specific TNP again after stopping/quitting the TNP for ≤12 months during the most recent attempt to quit TNPs. Reinitiation was defined as using a specific TNP again after stopping/quitting the TNP for >12 months during the most recent attempt to quit TNPs.

Statistical Analysis

Descriptive statistics were used to estimate the prevalence and patterns of TNP use (a) in total and (b) stratified by sex and age group. No hypothesis testing was performed. Categorical outcome measures were described by presenting the number of participants (n) and related proportion (%) within each category, and if applicable, also 95% CIs and the number of missing values. Continuous outcome measures were described by presenting the number of participants (n) and mean value within each participant group; and if applicable, also standard deviation, 95% CIs, median, minimum, and maximum, and number of missing values.

As of 2022, the data of the GAPS was weighted to the latest 2019 Italian Census population (N=50,243,518) [33]. Weighting was achieved using Random Iterative Method (RIM). RIM weighting is an iterative data fitting process that applies a weight factor to each participant's data to match the target reference population/sampling frame. The weighted results of the GAPS are presented as unweighted numbers (n) and weighted outcome measures.

All analyses were conducted using SPSS Statistics (version 28; IBM Corp., Armonk, NY, USA) and SAS (9.4).

Ethical Consideration

Participants in the GAPS provided verbal informed consent prior to participation. Participants in the TUS provided electronic informed consent by selecting an “I accept” option before beginning the online survey. All participants were informed of the voluntary nature of the study and their right to withdraw at any time.

Results

Results are presented by key endpoints, beginning with the GAPS results, then proceeding to TUS.

Disposition and Demographic Characteristics

In 2024, a total of 9,668 candidate participants within registered Italian households were invited to the GAPS survey; 5,950 (61.5%) were successfully contacted, with 3,700 (38.2%) completing the survey (Supplementary Figure S1). Of those, 52.2% were females (n=1,930), and 47.8% were males (n=1,770) with a mean age of 51.4 years (SD=17.2; range: 18-92) (Table 1). The sex and age distribution, as well as other demographic characteristics, including urban origin (city size), occupation/profession, and level of

education of the participants in the study, were overall similar to those of general adult population surveys in the previous study years (2018-2020, 2022, and 2023) [34].

For the TUS survey, 33,519 *THS* users were invited to the survey; 1,672 (5.1%) responded, and after eligibility screening and incomplete responses, 1,000 (3.1%) completed the survey. Of those, 53.2% (n=537) were male, and 46.8% (n=468) were female, with a mean age of 44.1 years (SD=11.7; range 20-79) (Table 1).

Sociodemographic Characteristics	GAPS (N=3,700)	TUS (N=1,000)
Sex, n (%)		
Male	1,770 (47.8%)	532 (53.2%) *
Female	1,930 (52.2%)	468 (46.8%)
Age group, years, n (%)		
18-29	448 (12.1%)	136 (13.6%)
30-39	588 (15.9%)	222 (22.2%)
40-49	531 (14.4%)	315 (31.5%)
50+	2133 (57.6%)	327 (32.7%)
Age statistics, years		
Min	18	20
Median	53	44.5
Mean [95% CI]	51.36 [50.8-51.9]	44.1 [43.37-44.83]
SD	17.2	11.7
Max	92	79
Monthly income groups, n (%)		
Low (€0-€1,265)	283 (7.6%)	121 (12.1%)
Mid (€1,266-€2,455)	995 (26.9%)	318 (31.8%)
High (€2,456+)	1062 (28.7%)	254 (25.4%)
Prefer not to answer	1360 (36.8%)	307 (30.7%)
Highest level of education, n (%)		
Degree	610 (16.5%)	338 (33.8%)
University without degree	88 (2.4%)	86 (8.6%)
Senior high school with diploma	1,630 (44.1%)	423 (42.3%)
Senior high school without diploma	138 (3.7%)	61 (6.1%)

Sociodemographic Characteristics	GAPS (N=3,700)	TUS (N=1,000)
Junior high school with diploma	964 (26.1%)	58 (5.8%)
Junior high school without diploma	73 (2.0%)	31 (3.1%)
Elementary school with leaving certificate	165 (4.5%)	1 (0.1%)
Elementary school without leaving certificate	27 (0.7%)	0 (0.0%)
No schooling	5 (0.1%)	2 (0.2%)
Areas, n (%)		
North-West	1094 (29.6%)	284 (28.4%)
North-East	611 (16.5%)	233 (23.3%)
Centre	657 (17.8%)	134 (13.4%)
South	844 (22.8%)	251 (25.1%)
Islands	494 (13.4%)	98 (9.8%)

Table 1. Sociodemographic Characteristics

** A total of n=1 (0.1%) did not define their gender as either male or female.*

CI, confidence interval; GAPS, General Adult Population Sample; SD, standard deviation;

TUS, THS User Sample

Current TNP Use Prevalence in GAPS

In 2024, the current prevalence of TNP use among Italian adults was 25.8% (95% CI: 24.4%–27.2%), stable since 2018-2019 when the prevalence was 25.7% (95% CI: 24.3%–27.1%) (Figure 1). Although cigarettes remained the most used TNP, among Italian adults in 2024, its prevalence declined from 24.3% (95% CI: 22.9%–25.6%) in 2018-2019 to 22.4% (95% CI: 21.1%–23.7%) in 2024. In contrast, HTP use prevalence rose from 0.7% (95% CI: 0.5%–1.0%) in 2018-2019 to 4.1% (95% CI: 3.5%–4.8%) in 2024 (Figure 2).

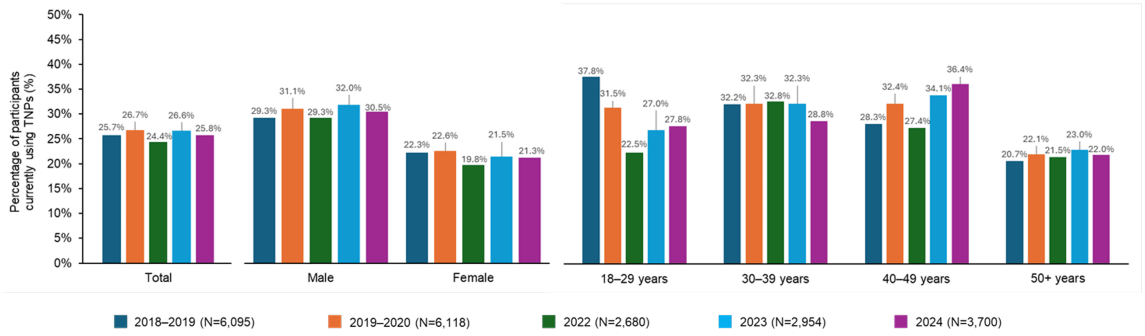

Figure 1. Prevalence of Current TNP Use by Sex and Age Group Over Time – General Adult Population Samples.

TNP, tobacco or nicotine-containing product

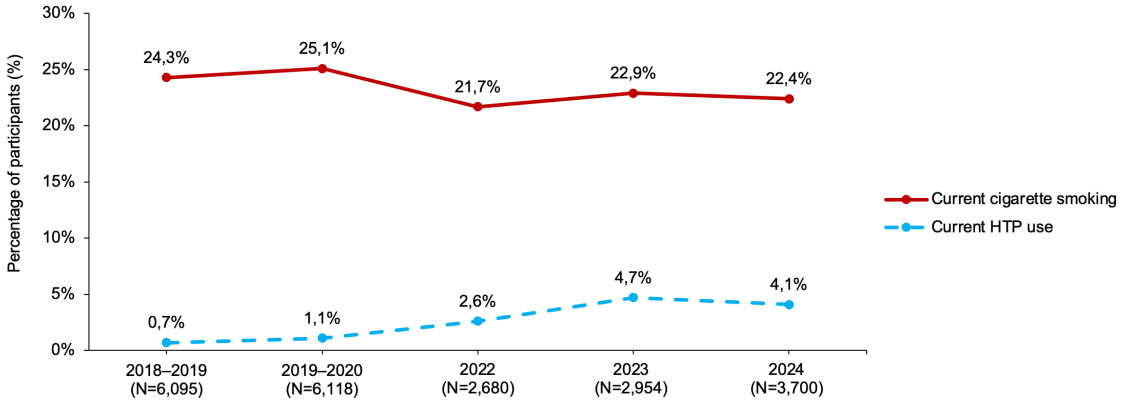

Figure 2. Prevalence of Cigarette Smoking and HTP Use Over Time – General Adult Population Samples.

HTP include THS, LIL, Glo, Ploom and Pulze which became commercially available in Italy at different times.

HTP, heated tobacco products; THS, Tobacco Heating System

In 2024, cigarette smoking prevalence was higher among males at 26.7% (95% CI: 24.7%–28.8%) compared to 18.4% (95% CI: 16.7%–20.2%) among females. Similarly, HTP use prevalence was slightly higher among males at 4.6% (95% CI: 3.8%–5.7%) than among females at 3.7% (95% CI: 2.9%–4.6%).

Among males, cigarette smoking prevalence remained stable over time at 27.5% (95% CI: 25.8% –29.2%) in 2018-2019 and 26.7% (95% CI: 24.7%–28.8%) in 2024, whereas among females, cigarette smoking prevalence declined from 21.3% (95% CI: 19.8%–22.8%) to 18.4% (95% CI: 16.7%–20.2%), respectively. During the same period, HTP use prevalence increased over time among males from 0.9% (95% CI:

0.6%–1.4%) in 2018-2019 to 4.6% (95% CI: 3.8%–5.7%) in 2024, and among females from 0.5% (95% CI: 0.2%–0.8%) to 3.7% (95% CI: 2.9%–4.6%), respectively.

In 2024, cigarette smoking prevalence was 21.6% (95% CI: 18.1%–25.5%) among individuals aged 18-29 years, 23.2% (95% CI: 19.8%–26.7%) among those aged 30-39 years, 29.3% (95% CI: 25.4%–33.4%) among those aged 40-49 years, and 20.8% (95% CI: 19.1%–22.5%) among those aged 50 years or older (Figure 3). Comparatively, 2024 data show that HTP use prevalence is decreasing with age from 9.4% (95% CI: 7.1%–12.4%) in the 18-29-year-old group to 1.7% (95% CI: 1.2%–2.3%) in the 50+ year-old group (Figure 4). Compared to 2018, cigarette smoking prevalence in 2024 declined among individuals aged 18-29 years (36.6% [95% CI: 33.1%–40.2%] in 2018) and those aged 30-39 years (29.9% [95% CI: 26.6%–33.4%]). In contrast, prevalence remained stable among adults aged 50 and older (19.5% [95% CI: 18.1%–20.9%] in 2018) and increased among the 40-49-year-old group (26.9% [95% CI: 24.3%–29.5%]). (Figure 4). In 2024, *THS* accounted for approximately 70% of HTPs used among both males and females, whereas it accounted for approximately 80% of HTPs among individuals aged 18-29 years, 70% among those aged 30-39 years, and 65% among those aged 40-49 years and 50+ years.

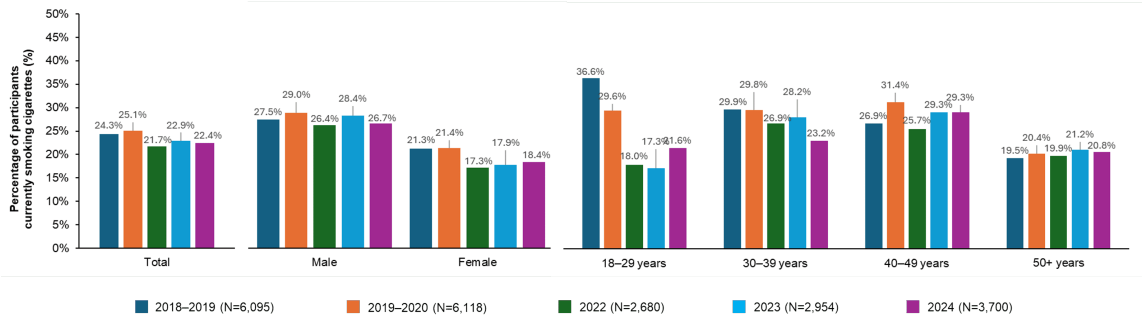

Figure 3. Prevalence of Current Cigarette Smoking by Sex and Age Group Over Time – General Adult Population Samples.

doi.org/10.32388/A7QW7V

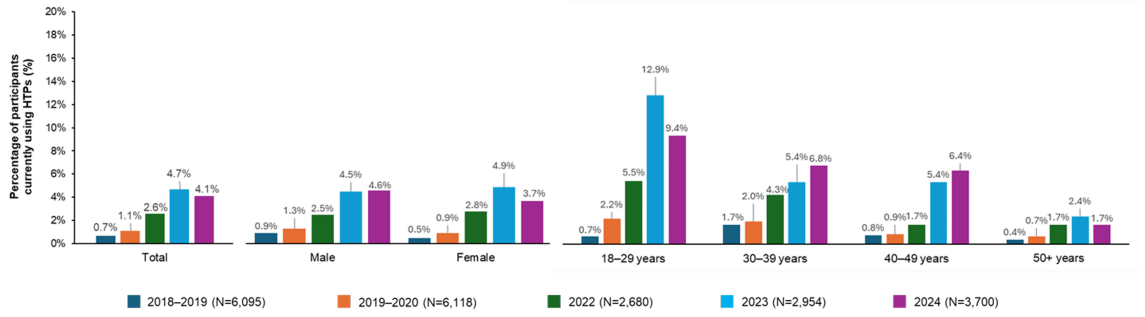

Figure 4. Prevalence of HTP Use by Sex and Age Group Over Time – General Adult Population Samples.

HTPs included THS, Glo, LIL, Ploom, and Pulze, which became commercially available in Italy at different times. In 2018-2019 and 2019-2020, the survey questionnaire only measured prevalence of THS.

HTP, heated tobacco products; THS, Tobacco Heating System

TNP Use Patterns in GAPS

The respective proportions of exclusive (one TNP only), dual (two different TNPs), and poly (>2 different TNPs) TNP use remained stable between 2018 and 2024. In 2018, 92.7% (95% CI: 91.2%–94.0%) of TNP users reported exclusive use, 6.1% (95% CI: 4.9%–7.5%) dual use, and 1.2% (95% CI: 0.7%–1.9%) poly use. In 2024, these figures were 91.4% (95% CI: 89.5%–93.1%) for exclusive use, 7.6% (95% CI: 6.1%–9.5%) for dual use, and 1.0% (95% CI: 0.5%–1.9%) for poly use in 2024.

Frequency and Intensity of TNP Use in GAPS

Regarding the frequency of TNP use, the 2024 study found that cigarette smokers smoked on average 28.0 days (95% CI: 27.6-28.4) in the 30 days prior to the survey. Similarly, HTP users used HTPs on average on 27.0 days (95% CI: 25.9-28.1), while *THS* users used *THS* on average on 27.5 days (95% CI: 26.2-28.7) in the 30 days prior to the survey.

In terms of intensity (number of TNP used on usage days), cigarette smoking remained stable over time, at 12.7 (95% CI: 12.4-13.1) cigarettes/day in 2018 and 13.4 (95% CI: 12.9-13.8) cigarettes/day in 2024. In contrast, the intensity of *THS* use increased from 7.9 (95% CI: 5.6-10.3) sticks/day in 2018 to 13.2 (95% CI: 12.0-14.5) sticks/day in 2024.

doi.org/10.32388/A7QW7V

History of TNP Use and Initiation in GAPS

In 2024, among all ever TNP users in the GAPS (n=1,306), 94.3% (95% CI: 92.9%–95.5%) reported that cigarettes were the first TNP they ever used regularly. Meanwhile, 1.8% (95% CI: 1.1%–2.6%) of ever TNP users reported HTPs as the first ever regular TNP used, with 1.3% (95% CI: 0.8%–2.0%) of ever TNP users selecting *THS* as the first TNP ever used regularly. Over time, cigarettes remained by far the first TNP ever used regularly (Table 2).

	2018-2019 (N=2,346)	**2019-2020 (N=2,286)**	**2022 (N=924)**	**2023 (N=1,066)**	**2024 (N=1,306)**
Cigarettes					
n (%)	2,209 (94.2%)	2,109 (92.3%)	882 (95.7%)	1,007 (94.5%)	1,228 (94.3%)
[95% CI]	[93.1%–95.1%]	[91.0%–93.4%]	[94.1%–96.9%]	[93.0%–95.8%]	[92.9%–95.5%]
HTP					
n (%)	–	–	24 (2.1%)	40 (3.4%)	32 (1.8%)
[95% CI]	–	–	[1.2%–3.1%]	[2.5%–4.7%]	[1.1%–2.6%]
THS					
n (%)	22 (0.9%)	42 (1.8%)	20 (1.6%)	27 (2.3%)	23 (1.3%)
[95% CI]	[0.5%–1.5%]	[1.3%–2.5%]	–	[1.5%–3.3%]	[0.8%–2.0%]
Other TNPs					
n (%)	40 (1.7%)	70 (3.1%)	11 (1.2%)	11 (1.0%)	20 (1.5%)
[95% CI]	NE	NE	NE	NE	NE

Table 2. First TNP Ever Used Regularly among Ever Users Over Time – General Adult Population Samples

n, unweighted n numbers.

HTPs included THS, Glo, LIL, Ploom, and Pulze, which became commercially available in Italy at different times.

'Other TNPs' includes other combustible tobacco products (cigars, cigarillos, beedis, kretek, tobacco pipes, water pipes [shisha/hookah]), oral tobacco-derived nicotine (i.e., nicotine pouches and lozenges), smokeless tobacco.

A proportion of participants used multiple TNPs at the same time and, as such, first ever TNP used was undefinable. Participants for whom first ever TNP used was undefinable are not included in this table.
95% CIs were estimated for prespecified products of interest. As 'Other TNPs' is an aggregated category, data are presented descriptively without 95% CIs due to heterogeneity across products.
CI, confidence interval; HTP, heated tobacco product; NE, not estimated; THS, Tobacco Heating System; TNP, tobacco or nicotine-containing product

In relation to initiation rate in the last 12 months among never TNP users 1 year prior to the survey (n=2,484), 1.6% (95% CI: 1.1%–2.1%) reported initiating TNP use with cigarettes in 2024, compared to 0.1% (95% CI: 0.0%–0.3%) who initiated TNP use with HTP, including *THS*, in 2024 (Table 3). Over time, initiation of TNP use with HTP remained much lower than initiation of TNP use with cigarettes.

	2018-2019 (N=3,811)	2019-2020 (N=3,900)	2022 (N=1,838)	2023 (N=1,982)	2024 (N=2,484)
Cigarettes					
%	0.5%	0.4%	2.1%	1.9%	1.6%
[95% CI]	[0.3%–0.8%]	[0.2%–0.7%]	[1.6%–2.9%]	[1.3%–2.5%]	[1.1%–2.1%]
HTP					
%	–	–	0.2%	0.6%	0.1%
[95% CI]	–	–	[0%–0.5%]	[0.3%–1.0%]	[0%–0.3%]
THS					
%	0.03%	0.05%	0.1%	0.5%	0.1%
[95% CI]	[0%–0.2%]	[0%–0.2%]	[0%–0.5%]	[0.3%–0.9%]	[0%–0.3%]
Other TNPs					
%	0.08%	0.03%	0.1%	0%	0%
[95% CI]	NE	NE	NE	NE	NE

Table 3. Initiation Rate of TNP Category and Brand Use in the Last 12 Months among Never Users Over Time – General Adult Population Samples

HTPs included THS, Glo, LIL, Ploom, and Pulze, which became commercially available in Italy at different times. 'Other TNPs' includes other combustible tobacco products (cigars, cigarillos, beedis, kretek, tobacco pipes, water pipes [shisha/hookah]), oral tobacco-derived nicotine (i.e., nicotine pouches and lozenges), smokeless tobacco. 95% CIs were estimated for prespecified products of interest. As 'Other TNPs' is an aggregated category, data are presented descriptively without 95% CIs due to heterogeneity across products.

CI, confidence interval; HTP, heated tobacco product; NE, not estimated; THS, Tobacco Heating System; TNP, tobacco or nicotine-containing product

Relapse and Reinitiation in GAPS

Among current TNP users (n=995) of the GAPS, 1.0% (95% CI: 0.5%–1.7%) relapsed to TNP use in the last 12 months after their most recent attempt to quit cigarettes, while 0.3% (95% CI: 0.1%–0.8%) reinitiated TNP use in the last 12 months after their most recent attempt to quit cigarettes. Relapse and reinitiation with *THS* after the most recent attempt to quit cigarettes remained consistently low (relapse: 0.0% [95% CI: 0.0%–0.0%]; reinitiation: 0.0% [95% CI: 0.0%–0.4%]).

THS Use Patterns in the TUS

In 2024, the majority of current *THS* users in the TUS (55.8% [95% CI: 52.7%–58.9%]) reported exclusive *THS* use. This figure remained relatively stable compared to 2018, when exclusive *THS* use was reported by 59.2% (95% CI: 56.5%–61.9%) of *THS* users in the TUS. Between 2018 and 2024, use of *THS* together with SFPs increased from 2.2% (95% CI: 1.4%–3.2%) in 2018-2019 to 20.1% (95% CI: 17.7%–22.7%) in 2024. As a result, the proportion of *THS* users who do not smoke reached 75.9% in 2024. During the same period, *THS* use together with combustible TNP decreased from 38.6% (95% CI: 51.9%–41.3%) in 2018-2019 to 24.1% (95% CI: 21.5%–26.8%) in 2024.

In line with the above, 56.6% (95% CI: 47.5%–66.1%) of current *THS* users in the GAPS reported using *THS* exclusively in 2024. An additional 7.4% (95% CI: 3.6%–13.6%) reported use of *THS* together with SFPs, resulting in a total of 64.0% of *THS* users who do not smoke in 2024. At the same time, 36.0% (95% CI: 27.8%–45.8%) reported *THS* use together with combustible TNP.

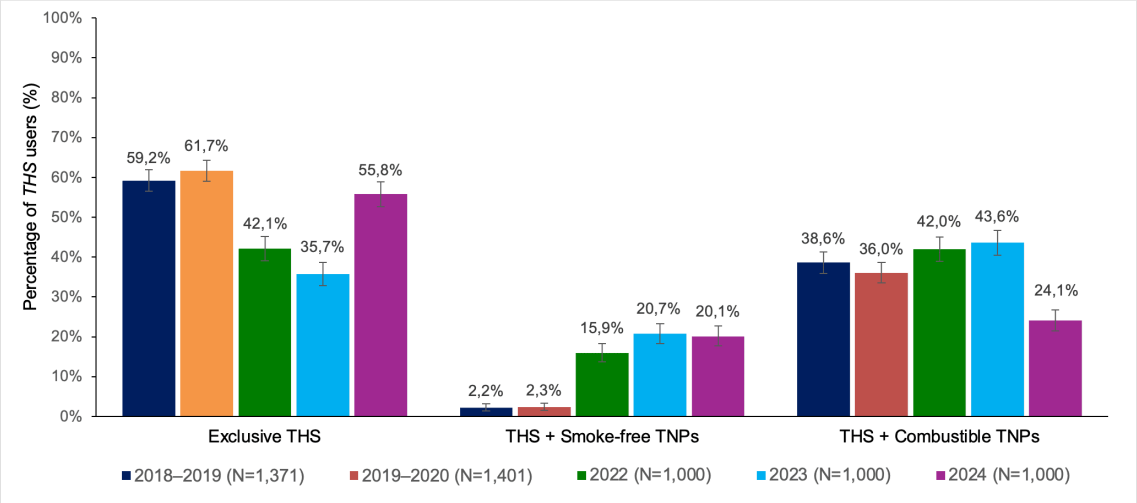

Figure 5. *THS* Use Patterns Among Current *THS* Users Over Time – *THS* User Samples.

Bars represent percentages, error bars indicate 95% CIs.CI, confidence interval; THS, Tobacco Heating System; TNP, tobacco or nicotine-containing product.

History of TNP use in TUS

In 2024, 95.2% (95% CI: 93.7%–96.4%) of *THS* users reported having a history of cigarette smoking or TNP use prior to switching to *THS* (Figure 6). Of those with a history of TNP use, 96.6% (95% CI = 95.4%–97.6%) were current cigarette smokers, while 0.3% (95% CI: 0.1%–0.7%) were former users who relapsed and 3.1% (95% CI: 2.1%–4.3%) were former users who reinitiated TNP use. The 2024 study results were overall similar to the previous study years.

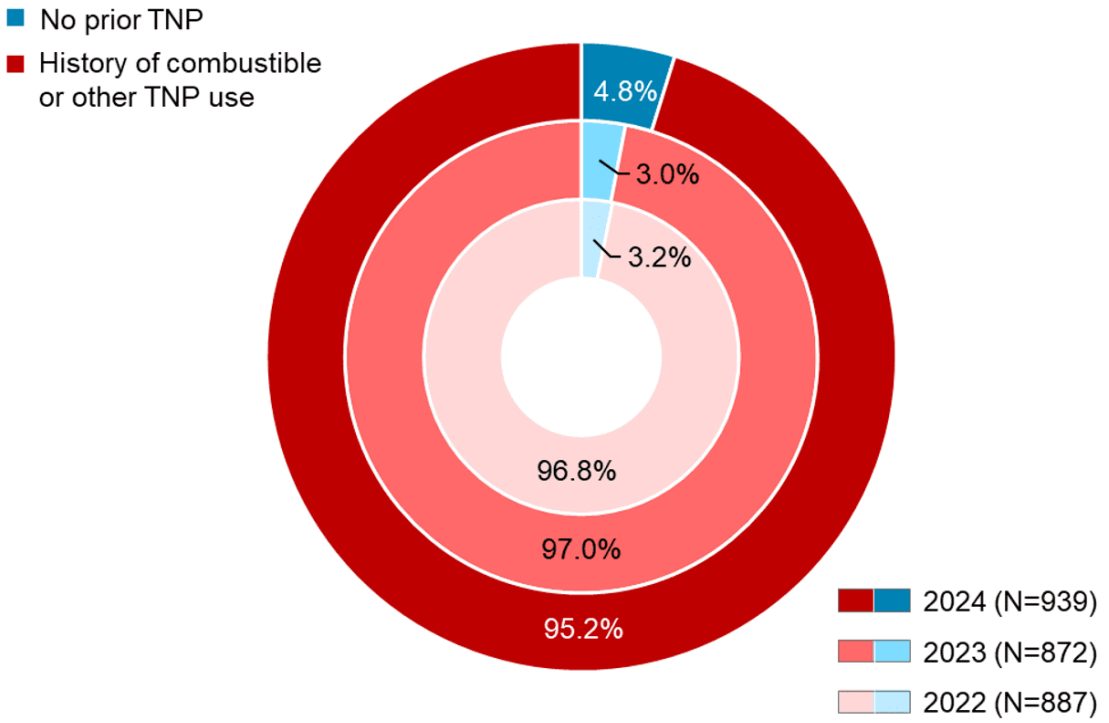

Figure 6. TNP Use History– *THS* User Samples

THS, Tobacco Heating System; TNP, tobacco or nicotine-containing product.

Chart shows percentage of THS users with no prior TNP history and those with a history of TNP use.

Data are based on current THS users with available information on history of cigarette or TNP use.

Data available from 2022 due to changes in measures.

Perceived Health and Functioning-Related Benefits of Switching to THS in TUS

Many *THS* users reported perceived improvements in health and functioning-related benefits after switching to *THS.* More specifically, *THS* users reported improvements in coughing (68.8%), breathing (68.3%), oral health (64.1%), overall physical health (61.7%), and overall health (61.6%). *THS* users who do not smoke reported greater benefits' improvements compared to dual users of *THS* with combustible TNPs (Figure 7).

doi.org/10.32388/A7QW7V

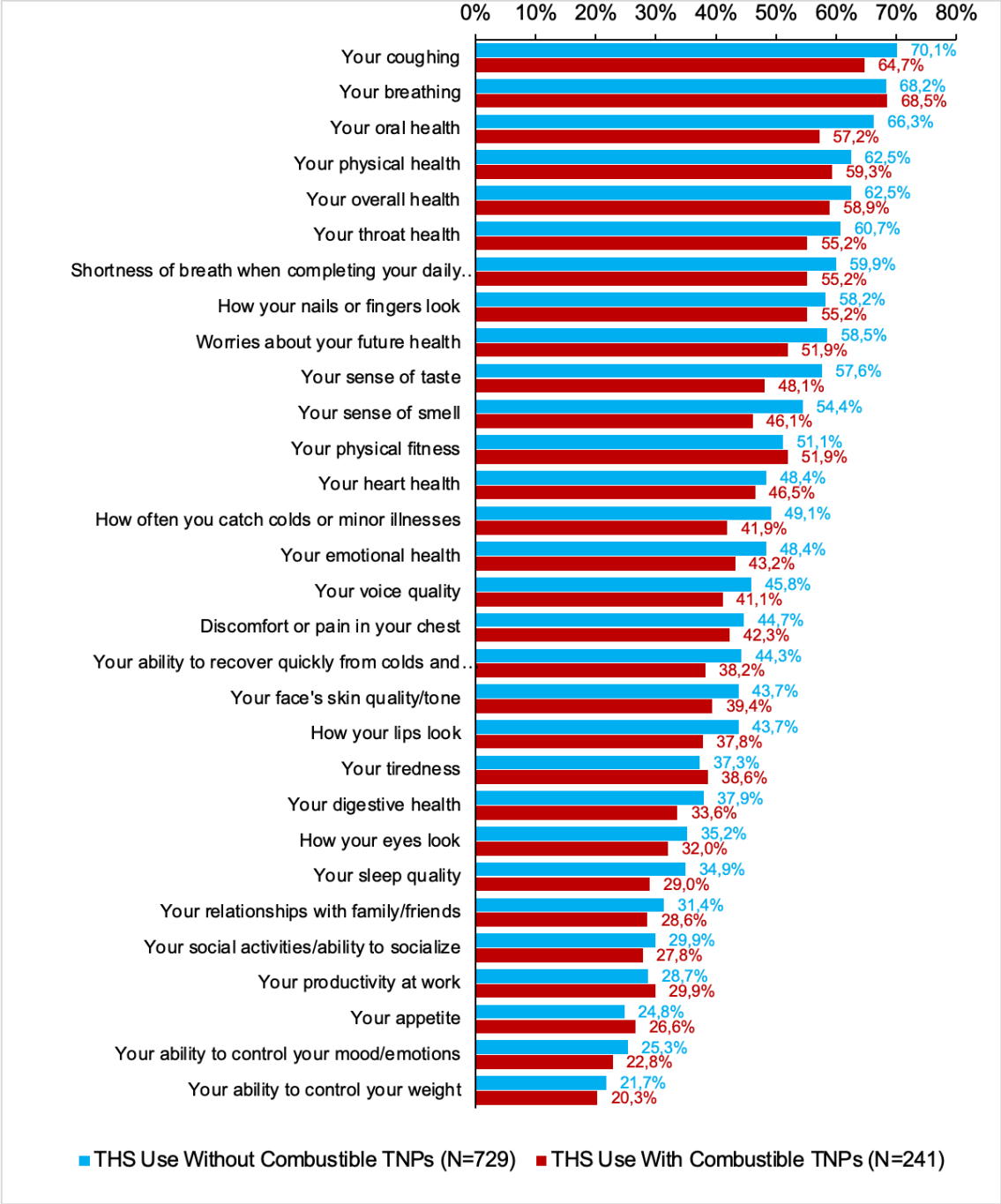

Figure 7. Percentage of *THS* users who Reported Perceived Improvement ("Very much improved", "Much improved", "A little improved") in Health & Functioning Benefits – *THS* User Sample in 2024

doi.org/10.32388/A7QW7V

Intention to Quit Cigarette Smoking in the GAPS and TUS

In 2024, among current *THS* users from the TUS who also smoked cigarettes (N=215), 30.2% planned to stop cigarette smoking within the next 30 days, 27.0% planned to stop cigarette smoking within the next 6 months but not within the next 30 days, and 20.0% did not plan to stop cigarette use in the next 6 months. In contrast, around 9.3% of adults who smoked cigarettes from GAPS planned to quit smoking cigarettes in the next 1 to 6 months.

Discussion

The 2024 cross-sectional study provides valuable data on the evolving trends in TNP use in Italy since 2018, with a particular focus on HTPs, such as Philip Morris's *THS*. The findings show that the overall prevalence of TNP use among Italian adults has remained stable at approximately 25%. During the same period, cigarette smoking prevalence has decreased from 24.3% in 2018 to 22.4% in 2024, while HTP use prevalence has increased from 0.7% in 2018 to 4.1% in 2024. The decrease in cigarette smoking prevalence coupled with an increase in the use prevalence of HTPs, such as *THS*, has also been observed in many other countries [35].

Our findings are consistent with recent Italian National Institute of Health data showing that cigarette smoking remains the most prevalent TNP use (23.8%) in 2024 in Italy [25]. Moreover, the *Progresses in assessing adult population health in Italy* (PASSI) survey reported an HTP use prevalence of 4.0% among the adult population (18-69 years) in 2024 [25]. Similarly, the Eurobarometer survey on Attitudes of Europeans towards tobacco and related products reported a 4% HTP use prevalence in May 2023 in Italy [36]. While prevalence estimates may vary across studies, the overall findings point towards a measurable decrease in cigarette smoking prevalence, accompanied by an increase in prevalence of SFPs such as HTPs.[27]

In relation to user demographic characteristics, our previous and current studies show a higher use prevalence of HTPs among adults aged 18-39 years old (9.4% among 18-29 year-olds and 6.8% among 30-39 year-olds in 2024) compared to adults aged 40 years and older (6.4% among 40-49 year-olds and 1.7% among 50+ year-olds in 2024) [34]. According to data from the Italian National Institute of Statistics (ISTAT), smoking prevalence is high among adults aged 20-24 years old and reaches its peak among adults aged 25-34 years old (26.9%) [37]. Globally, several studies report that HTP users are typically middle-aged adults [38][39][40], although some reviews report otherwise [35][41].

This cross-sectional study shows that in TUS, exclusive use of *THS* (55.8%) or *THS* use with other SFPs (20.1%) emerged as the predominant use pattern among *THS* users over time. Around a quarter of *THS* users (24.1%) reported dual use (*THS* with combustible TNPs) in 2024 compared to approximately 40% in 2018. The population-based analysis by Laverty *et al.* (2021), based on data from 28 European countries, similarly found that only 25.3% of daily HTP users were dual users of HTPs with combustible TNPs [42]. The most recent PASSI survey results released in May 2025 by the Italian National Institute of Health, show an even lower proportion of dual (cigarettes plus either E-cig or HTPs) use prevalence of 5% and an exclusive use of non-combustible products (either E-cig or HTPs) of 4% among Italians aged 18-69 years [25].

Our TUS survey adds further to the evidence by indicating that *THS* users report several perceived health and functional-related benefits after switching from cigarettes to *THS*. This includes reduced coughing, improved breathing, better oral health, and improved overall physical health. The reported perceived benefits may be more pronounced among exclusive users of *THS* than among those with dual use of combustible TNPs.

Regarding the impact of the introduction of HTPs on tobacco non-users, our study found that initiation rate with *THS* was low with 0.1% (95% CI: 0.0%–0.3%) in 2024 at population level (Table 3). Moreover, at population level, relapse and reinitiation rates with *THS* remained negligible with 0.0% (95% CI: 0.0%–0.0%) and 0.0% (95% CI: 0.0%–0.4%), respectively in 2024, supporting the notion of switching behavior and limited appeal among never or former TNP users. Finally, 2024 data from TUS survey shows that 95.2% of *THS* users had a history of cigarette or other TNP use prior to switching to *THS*.

These observations are reflected both in Italy and internationally. Accordingly, the Italian National Institute of Health data specify that, in Italy, around 3.1% of HTP users had never smoked before starting HTP use in 2023 [43]. Likewise, the latest Eurobarometer survey found that the rate of first use was 85% for cigarettes, 3% for HTPs, in Italy [36]. In addition, Li et al. (2021) observed that HTPs were predominantly used by current smokers, with findings consistent across several countries, including Australia, Canada, England, and the United States [44]. A further analysis of data from 28 European countries found that current smokers and former smokers were more likely to use HTPs than never smokers [42]. Current smokers had an adjusted odds ratio of 36.3 (22.9-57.5), meaning they were over 36 times more likely to use HTPs than never smokers, while former smokers had an adjusted odds ratio of 7.3 (4.3-12.3), meaning they were over 7 times more likely to use HTPs compared to never smokers [42].

These findings are further supported by a recent review of over 150 studies, which concluded that globally HTP use is mainly observed among adults with a history of cigarette smoking and that HTPs may accelerate the replacement of cigarette smoking without promoting initiation among never users [45].

Our surveys possess several strengths. Firstly, they use a standardized approach to monitoring TNP use, including repeated cross-sectional design, consistent sampling techniques, and standardized definitions throughout, allowing reliable year-over-year comparisons. The study uses large sample sizes, ensuring high precision in measuring TNP use patterns, including prevalence, initiation, and relapse. Moreover, it includes two samples: a representative general adult population and a sample of registered *THS* users, allowing for more granular exploration of *THS* use both on the population level and the *THS* user level. Multiple survey waves in the general population reduce seasonal bias, and annual updates to the questionnaire to reflect the dynamic evolution of TNPs on the market.

While valuable for monitoring TNP use across populations, our studies also have some methodological limitations. First, their cross-sectional design prevents causal inference, as the surveys do not track the same individuals over time. This limits the ability to assess longitudinal behavior change or product switching. Second, reliance on self-reported data may have introduced potential biases, including recall bias and social desirability bias. Third, sampling limitations exist: while GAPS surveys are probabilistic, TUS surveys are drawn from Philip Morris International's registered user base and may not represent the broader *THS* user population. In addition, generalizability may be limited, particularly among users who are not registered or are less engaged with the brand. Despite this, it is important to highlight that in Italy over 95% of *THS* users are registered in the consumer databases [46]. Lastly, updates to survey instruments to reflect evolving product categories may have impacted trend analysis and temporal comparisons. In the context of this study, the weighting applied to the GAPS survey beginning in its third year (2022) was considered when interpreting the study results.

Conclusion

In conclusion, the presented trend data, in line with data from public health authority-led studies, show that the prevalence of TNP use remains stable in the adult population in Italy. Our studies also show that HTP use prevalence has increased while cigarette smoking has decreased over time. This trend is further evidenced by a reduction in concurrent use of *THS* and combustible TNPs, with over 75% of *THS* users reporting no use of combustible TNPs. Initiation of TNP use with *THS* among never-TNP users and

reinitiation rates with *THS* among former TNP users continue to be low. In addition, our study highlights that *THS* users, particularly exclusive users, report a number of perceived health and functioning-related benefits since switching to THS, with top benefits being reduced coughing, improved breathing, better oral health, and improved overall physical health. Continued surveillance to monitor long-term use of HTPs, including but not limited to *THS*, in Italy remain essential.

Statements and Declarations

Potential competing interests

T.P. is an employee of Philip Morris Italia. U.d.L.P. is a consultant for Philip Morris Italia. All remaining authors are employees of Philip Morris International.

Funding

The work reported in this publication involved products and equipment developed by Philip Morris Products S.A, which is the sole source of funding and sponsor of this research. The funder was involved in study design; the collection, analysis and interpretation of data; the writing of the report; and in the decision to submit the article for publication.

Authors' contribution

K.F. managed and implemented fieldwork and supervised descriptive analysis. S.A. assisted in the interpretation of data, wrote the manuscript and supervised health benefits analysis. T.P and U.d.L.P. reviewed the manuscript and contributed to the literature search. J.S. oversaw report preparation. S.R. and P.M. contributed to the conceptualization of the study. All authors meet the criteria for authorship as outlined by the International Committee of Medical Journal Editors (ICMJE). Each author made substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data; participated in drafting the manuscript or revising it critically for important intellectual content; approved the final version to be published; and agreed to be accountable for all aspects of the presented work.

Acknowledgments

The authors express gratitude to all the study participants, investigators, and study management professionals who contributed to the design and execution of this study.

References

1. ^*World Health Organization. "Tobacco 2025." World Health Organization. https://www.who.int/news-room/fact-sheets/detail/tobacco.*
2. ^*Beaglehole R, Bates C, Youdan B, Bonita R (2019). "Nicotine Without Smoke: Fighting the Tobacco Epidemic With Harm Reduction." Lancet. **394**(10200):718–20.*
3. ^*O'Leary R, PR (2020). "Tobacco Harm Reduction in the 21st Century." Drugs Alcohol Today. **20**(3):219–34.*
4. ^*World Health Organization (2013). "WHO Framework Convention on Tobacco Control: Guidelines for Implementation of Article 5.3, Articles 8 to 14." World Health Organization.*
5. a, b*Abrams DB, Glasser AM, Pearson JL, et al. (2018). "Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives." Annu Rev Public Health. **39**:193–213.*
6. ^*Royal College of Physicians. "E-Cigarettes and Harm Reduction: An Evidence Review." RCP2024. https://www.rcp.ac.uk/media/t5akldci/e-cigarettes-and-harm-reduction_executive-summary_0_0.pdf.*
7. ^*U.S. Food and Drug Administration (2025). "Nicotine Is Why Tobacco Products Are Addictive." FDA. https://www.fda.gov/tobacco-products/health-effects-tobacco-use/nicotine-why-tobacco-products-are-addictive#3.*
8. a, b*McNeill A (2004). "Harm Reduction." BMJ. **328**(7444):885–7.*
9. a, b*Zeller M, Hatsukami D, Strategic Dialogue on Tobacco Harm Reduction G (2009). "The Strategic Dialogue on Tobacco Harm Reduction: A Vision and Blueprint for Action in the US." Tob Control. **18**(4):324–32.*
10. ^*Etter JF (2018). "E-Cigarettes and the Obsolescence of Combustion." Expert Rev Respir Med. **12**(5):345–7.*
11. ^*U.S. Food and Drug Administration (2020). "How Are Non-Combusted Cigarettes, Sometimes Called Heat-Not-Burn Products, Different From E-Cigarettes and Cigarettes?" U.S. Food and Drug Administration. https://www.fda.gov/tobacco-products/products-ingredients-components/how-are-non-combusted-cigarettes-sometimes-called-heat-not-burn-products-different-e-cigarettes-and.*
12. ^*Das Bundesinstitut für Risikobewertung (2022). "Health Risk Assessment of Nicotine Pouches. Updated BfR Opinion No 023/2022 of 7 October 2022." BfR-Stellungnahmen. p. 1-21. https://www.bfr.bund.de/cm/349/health-risk-assessment-of-nicotine-pouches.pdf.*

13. ^Slob W, Soeteman-Hernandez LG, Bil W, et al. (2020). "A Method for Comparing the Impact on Carcinogenicity of Tobacco Products: A Case Study on Heated Tobacco Versus Cigarettes." Risk Anal. **40**(7):1355–66.

14. ^Government of Canada, Office of Audit and Evaluation (2023). "Evaluation of the Health Portfolio Tobacco and Vaping Activities 2016-17 to 2020-21." Government of Canada. https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/evaluation/tobacco-vaping-activities-2016-2017-2020-2021.html#ex.

15. ^Hoek J, ER, Waa A, Wilson N, Thomson G (2020). "Proposed Vaping Regulations for NZ: Strengths and Limitations." Public Health Expert Briefing. https://www.researchgate.net/publication/339445006_Proposed_Vaping_Regulations_for_NZ_Strengths_and_Limitations.

16. ^Norwegian Institute of Public Health (2017). "Evaluation of Harm Reduction as a Strategic Element in Tobacco Work." Norwegian Institute of Public Health.

17. ^Global Institute for Novel Nicotine (GINN) (2025). "Greece Sets a European Precedent With Science-Based Regulation of Smoke-Free Products." Global Institute for Novel Nicotine (GINN). https://ginn.global/greece-sets-a-european-precedent-with-science-based-regulation-of-smoke-free-products/#:~:text=In%20a%20significant%20move%20towards%20tobacco%20harm%20reduction%2C,___regarding%20the%20reduced%20health%20risks%20of%20smoke-free%20alternatives.

18. a, bJaccard G, Tafin Djoko D, Moennikes O, et al. (2017). "Comparative Assessment of HPHC Yields in the Tobacco Heating System THS2.2 and Commercial Cigarettes." Regul Toxicol Pharmacol. **90**:1–8.

19. ^Haziza C, de La Bourdonnaye G, Merlet S, et al. (2016). "Assessment of the Reduction in Levels of Exposure to Harmful and Potentially Harmful Constituents in Japanese Subjects Using a Novel Tobacco Heating System Compared With Conventional Cigarettes and Smoking Abstinence: A Randomized Controlled Study in Confinement." Regul Toxicol Pharmacol. **81**:489–99.

20. ^Edwards SH, Hassink MD, Taylor KM, Vu AT (2022). "Quantitative Measurement of Harmful and Potentially Harmful Constituents, pH, and Moisture Content in 16 Commercial Smokeless Tobacco Products." Regul Toxicol Pharmacol. **133**:105199.

21. ^Mallock N, Boss L, Burk R, et al. (2018). "Levels of Selected Analytes in the Emissions of "Heat Not Burn" Tobacco Products That Are Relevant to Assess Human Health Risks." Arch Toxicol. **92**(6):2145–9.

22. ^Committees on Toxicity Carcinogenicity and Mutagenicity of Chemicals in Food Consumer Products and the Environment (2017). "Statement on the Toxicological Evaluation of Novel Heat-Not-Burn Tobacco Product." Committees on Toxicity Carcinogenicity and Mutagenicity of Chemicals in Food Consumer Products an

d the Environment. https://cot.food.gov.uk/sites/default/files/heat not burn tobacco statement.pdf#:~:text=Cigarette%20smoking%20has%20been%20associated%20with.

23. ^*Schaller JP, Keller D, Poget L, et al. (2016). "Evaluation of the Tobacco Heating System 2.2. Part 2: Chemical Composition, Genotoxicity, Cytotoxicity, and Physical Properties of the Aerosol." Regul Toxicol Pharmacol. **8 1** Suppl 2:S27–S47.*
24. ^*Carreras G, Minardi V, Lugo A, et al. (2022). "Italians Are Still Loyal to Conventional Cigarettes, Despite Novel Tobacco Products." Ann Ist Super Sanita. **58**(4):264–8.*
25. a, b, c, d*National Institute of Health (2025). "Streaming XXVII National Conference on Tobacco Addiction and the National Health Service." National Institute of Health. https://www.iss.it/-/streaming-xxvii-convegno-nazionale-tabagismo-e-servizio-sanitario- nazionale-30-maggio-2025.*
26. ^*Euromonitor International (2017). "Global Tobacco: Key Findings Part II: Vapour Products." Euromonitor International. https://app.researchpool.com/provider/euromonitor/global-tobacco-key-findings-part-ii-vapour-products#:~:text=Euromonitor%20International%27s%20Global%20Tobacco%3A%20Key%20Findings%20Part%20II%3A, as%20well%20as%20the%20factors%20affecting%20operating%20environment.*
27. a, b*Liu X, Lugo A, Spizzichino L, et al. (2018). "Heat-Not-Burn Tobacco Products Are Getting Hot in Italy." J Epidemiol. **28**(5):274–5.*
28. ^*Liu X, Lugo A, Spizzichino L, et al. (2019). "Heat-Not-Burn Tobacco Products: Concerns From the Italian Experience." Tobacco Control. **28**(1):113–4.*
29. ^*von Elm E, Altman DG, Egger M, et al. (2007). "The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for Reporting Observational Studies." Lancet. **370**(9596):1453–7.*
30. ^*Kasza KA, Edwards KC, Tang Z, et al. (2020). "Correlates of Tobacco Product Cessation Among Youth and Adults in the USA: Findings From the PATH Study Waves 1-3 (2013-2016)." Tob Control. **29**(Suppl 3):s203–s15.*
31. ^*Campbell C, Mandara S, Hart R, et al. (2025). "A Prospective 6-Week Actual Use Study of Glo Heated Tobacco Products in the United States." Am J Health Behav. **49**(3):302–22(21).*
32. ^*Wei L, SM, Hannel T, Largo E, Muhammad-Kah R (2023). "Examination of Lifetime Established Use Criteria for Adult Tobacco Product Users [Version 1; Peer Review: 1 Approved]." F1000Research. **12**(225).*
33. ^*Italian National Institute of Statistics (2019). "Permanent Census of Population and Housing." Italian National Institute of Statistics. https://esploradati.istat.it/databrowser/#/en/dw/dashboards.*

34. ^a, ^bRoulet S, Pellegatti T, Fischer K, Magnani P, di Luzio Paparatti U. "Tobacco- and Nicotine-Containing Product Use in Italy: Results From Two Cross-Sectional Studies." Qeios.

35. ^a, ^bScala M, Dallera G, Gorini G, et al. (2025). "Patterns of Use of Heated Tobacco Products: A Comprehensive Systematic Review." J Epidemiol. **35**(5):213–21.

36. ^a, ^bEuropean Commission (2023). "Special Eurobarometer SP539: Attitudes of Europeans Towards Tobacco and Related Products." European Commission. https://europa.eu/eurobarometer.

37. ^National Institute of Statistics (2023). "Smoking, Alcohol, Obesity and Sedentary Lifestyle." National Institute of Statistics. https://www.istat.it/wp-content/uploads/2024/12/Fumo Alcol eccosso-di-peso sedentarieta _Anno-2023.pdf.

38. ^Yi J, Lee CM, Hwang S-s, Cho S-i (2021). "Prevalence and Predictors of Heated Tobacco Products Use Among Male Ever Smokers: Results From a Korean Longitudinal Study." BMC Public Health. **21**(1):316.

39. ^Matsuyama Y, Tabuchi T (2022). "Heated Tobacco Product Use and Combustible Cigarette Smoking Relapse/Initiation Among Former/Never Smokers in Japan: The JASTIS 2019 Study With 1-Year Follow-Up." Tobacco Control. **31**(4):520–6.

40. ^Cheng HG, Noggle B, Vansickel AR, Largo EG, Magnani P (2025). "Tobacco Use, Risk Perceptions, and Characteristics of Adults Who Used a Heated Tobacco Product (IQOS) in the United States: Cross-Sectional Survey Study." JMIR Form Res. **9**:e57398.

41. ^Sun T, Anandan A, Lim CC, et al. (2023). "Global Prevalence of Heated Tobacco Product Use, 2015–22: A Systematic Review and Meta-Analysis." Addiction. **118**(8):1430–44.

42. ^a, ^b, ^cLaverty AA, Vardavas CI, Filippidis FT (2021). "Prevalence and Reasons for Use of Heated Tobacco Products (HTP) in Europe: An Analysis of Eurobarometer Data in 28 Countries." Lancet Reg Health Eur. **8**.

43. ^Mastrobattista L, Mortali C, Solimini R, Pichini S, Palmi I (2023). "The National Report on Tobacco Use 2023." Tabaccologia. **21**:22–6.

44. ^Li L, Borland R, Cummings KM, et al. (2021). "Patterns of Non-Cigarette Tobacco and Nicotine Use Among Current Cigarette Smokers and Recent Quitters: Findings From the 2020 ITC Four Country Smoking and Vaping Survey." Nicotine Tob Res. **23**(9):1611–6.

45. ^Fearon IM, Cordery SF, Fitzpatrick M, et al. (2024). "A Scoping Review of Behavioural Studies on Heated Tobacco Products." Cureus. **16**(7).

46. ^Pellegatti T, Paparatti UDL (2024). "Use of the Heated Tobacco Product IQOSTM in Italy: A Cross-Sectional Survey." Available at SSRN: https://ssrncom/abstract=4674189.

Supplementary data: available at https://doi.org/10.32388/A7QW7V

Declarations

Funding: The work reported in this publication involved products and equipment developed by Philip Morris Products S.A, which is the sole source of funding and sponsor of this research. The funder was involved in study design; the collection, analysis and interpretation of data; the writing of the report; and in the decision to submit the article for publication.

Potential competing interests: T.P. is an employee of Philip Morris Italia. U.d.L.P. is a consultant for Philip Morris Italia. All remaining authors are employees of Philip Morris International.