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NICOTINE POUCHES AS A NEW CATEGORY OF SMOKE-FREE PRODUCTS: BETWEEN HARM REDUCTION POTENTIAL AND NEW PUBLIC HEALTH CHALLENGES

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ABSTRACT

Nicotine pouches (NPs) represent a rapidly growing category of tobacco-free, oral nicotine products, whose popularity stems from the perceived discretion of their use, the absence of combustion, and the belief that they pose lower health risks compared to cigarettes. The aim of this review article is to provide a comprehensive synthesis of current knowledge regarding the health, pharmacological, toxicological, behavioral, and population-level effects associated with the use of nicotine pouches. The scope of the study includes the chemical characteristics of the products, the presence of toxic substances, cytotoxicity and biological effects, implications for oral health, pharmacokinetics and acute physiological effects, patterns of use, risk perception, co-use with other nicotine products, as well as regulatory implications and public health significance. The evidence indicates that nicotine pouches contain significantly fewer harmful and potentially harmful ingredients than cigarettes, snus, or chewing tobacco, which supports their harm-reduction potential among adult smokers who completely replace combustible products with them. At the same time, they are not biologically inert. Local changes in the oral mucosa have been demonstrated, along with varied cytotoxic effects primarily associated with non-nicotine components, acute cardiovascular effects dependent on nicotine dose, and the risk of acute poisoning, particularly in children following accidental ingestion. Epidemiological studies also document the rapidly growing use of NPs among adolescents and young adults, frequent co-use with cigarettes and e-cigarettes, and the significant role of marketing and favorable risk perception in the popularization of these products.

The available data suggests that the impact of nicotine pouches on public health is mixed: these products may serve as a harm-reduction tool for adult smokers, but at the same time, they may increase nicotine exposure among adolescents and people who have not previously used nicotine. The final balance of benefits and risks will depend on usage patterns, the level of market regulation, and the quality of future, independent, and long-term studies.

KEYWORDS

Nicotine Pouch, Oral Health, Nicotine, Tobacco-Free, Addiction, Public Health

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Introduction

Over the past decade, nicotine pouches have emerged as one of the fastest-growing categories of tobacco-free nicotine delivery products. These products are marketed as discreet, smoke-free, and potentially less harmful than traditional cigarettes, which aligns with broader shifts in global nicotine consumption patterns. These shifts include a decline in cigarette consumption, increased diversification of smoke-free products, and a growing tendency to experiment with oral forms of nicotine, particularly among adolescents and young adults. With the growing availability of NPs in Europe, North America, and Australia, assessing their actual impact on individual and public health has become a significant research priority.

The significance of this issue lies in the dual nature of the products under consideration. On the one hand, nicotine pouches do not generate smoke-related toxins, and biomarker studies and population modeling suggest that they may reduce exposure to many carcinogens and other harmful compounds in adult smokers who completely switch from cigarettes to these products [6, 28]. On the other hand, there is a growing body of evidence indicating their ability to cause local pathologies of the oral mucosa, acute physiological effects, nicotine poisoning, and to reinforce multi-product use among younger users. Attractive flavors, social media marketing, and ambiguous risk perception—which may encourage experimentation—play a particular role in the spread of NPs.

However, the state of knowledge regarding nicotine pouches remains inconsistent. Studies vary in terms of design, methodological quality, duration of observation, types of products evaluated, and independence from the industry. This includes chemical and toxicological analyses, in vitro studies, randomized

pharmacokinetic studies, clinical oral health studies, as well as epidemiological analyses and modeling of public health impacts. This heterogeneity makes it difficult to interpret the data simply and requires a systematic synthesis of the findings.

The aim of this review article is to provide a comprehensive and structured overview of the current state of knowledge regarding nicotine pouches, with a particular focus on their chemical and toxicological profiles, cytotoxicity, and biological effects, consequences for oral health, pharmacokinetics and acute systemic effects, patterns of use and risk perception, as well as potential public health implications and the regulatory framework. This study integrates data from clinical sciences, toxicology, pharmacology, epidemiology, and population modeling to elucidate both the harm-reduction potential and emerging risks associated with this product category.

1. Product characteristics and chemical variability

Nicotine pouches contain synthetic or tobacco-derived nicotine, as well as fillers, humectants, pH regulators and a wide range of flavouring agents. The significant heterogeneity of this product category is already evident at the level of chemical composition. Analyses have shown that the nicotine content can range from 1.79 to 47.5 mg per pouch, whilst the level of free-base nicotine varies significantly between brands [33, 34]. These differences are of fundamental importance for both the rate of nicotine release and its absorption through the oral mucosa.

Comprehensive chemical screening identified as many as 186 compounds in the 48 products analysed, including 8 classified as hazardous under the EU CLP Regulation and 13 flavourings not authorised by EFSA as food additives, such as myosmin and ledol [34]. In some cases, substances classified by the IARC as potentially carcinogenic were also found [34]. This means that although NPs are tobacco-free products, their formulations can be chemically complex and include ingredients raising significant toxicological concerns.

Compared to other nicotine products, nicotine pouches generally contain significantly fewer harmful and potentially harmful constituents (HPHCs) than snus, chewing tobacco or cigarettes. In one study, no nitrosamines or polycyclic aromatic hydrocarbons (PAHs) were detected in ZYN products [8]. At the same time, other analyses have shown the presence of low levels of tobacco-specific nitrosamines, such as NNN and NNK, with a maximum of 13 ng of NNN per pouch [33]. Although these values are low, the very presence of TSNAs indicates that nicotine pouches are not entirely free of toxic substances.

Product labelling also remains a significant issue. Incorrect, incomplete or unclear information regarding nicotine content is common; in one study, 29 out of 44 products did not provide clear information on nicotine levels [33]. Variations in nicotine content, free-base nicotine content, flavourings and additives directly translate into differences in the safety, pharmacokinetics and addictive potential of individual products.

2. Toxicological profiles and the significance of non-nicotine components

Comparisons between product categories indicate that NPs generally fall at the lowest end of the toxicity spectrum, alongside nicotine lozenges and gum used in nicotine replacement therapy, and well below moist snuff and snus in terms of HPHC content. This does not, however, imply that there is no risk. A key toxicological concern is the flavourings and other non-nicotine ingredients.

Several flavouring substances present in nicotine pouches have been identified as cytotoxic, and many of them may exceed the EFSA's acceptable daily intake levels under realistic usage scenarios [34]. These findings suggest that the toxicity of nicotine pouches may depend more on the composition of additives and the formulation than on the nicotine content itself. Consequently, the safety assessment of NPs cannot be limited to the amount of nicotine, but must take into account the entire chemical mixture.

It is worth noting that chemical analyses reveal extreme variability in product composition, encompassing both nicotine content and the presence of numerous flavouring compounds, humectants and pH regulators [33, 34]. Such variability makes it difficult to draw general conclusions regarding the safety of the entire category of NPs and highlights the need for standardisation of composition and labelling.

3. Cytotoxicity and biological effects in vitro

3.1. Review of in vitro study results

The results of in vitro toxicological studies remain inconclusive. Some studies indicate minimal or no cytotoxicity in NPs extracts, whilst others demonstrate measurable cytotoxic, oxidative and inflammatory effects. These differences often depend on the product brand, type of aroma, extraction methods, dosing protocol and cell model.

In several studies employing a range of tests, including the Ames test, the NRU test, the micronucleus test and 3D epithelial cell models, extracts from NPs showed no cytotoxicity, mutagenicity or genotoxicity. In comparisons with cigarette smoke (1R6F) and snus, significantly lower toxicity and limited induction of inflammatory mediators were observed. Real-time cell analysis also showed no increase in toxicity dependent on flavour or nicotine level during short-term exposure [15].

3.2. Evidence of oxidative stress and inflammatory activation

On the other hand, other studies have demonstrated clear biological effects. Increased expression of the oxidative stress marker HMOX1 and the inflammatory cytokine IL-6 was observed [34], as well as cytotoxicity in two out of five sachets tested, accompanied by an increase in reactive oxygen species and the expression of inflammatory genes [47], greater cytotoxicity of flavoured pouches than tobacco-flavoured snus in HGEP cells [34], as well as the activation of inflammatory and oxidative pathways in human gingival fibroblasts [1]. It is important to note that these effects did not correlate with nicotine concentration, suggesting a role for other components, such as flavourings, solvents or acids [47].

Further information was provided by ToxTracker tests and proteomic analyses. It has been demonstrated that snus, unlike NPs, activates pathways related to oxidative stress (Srxn1), protein damage (Ddit3) and DNA damage (Rtkn), indicating significant toxicological differences between tobacco-containing products and tobacco-free pouches. Gene expression studies further suggest that extracts from NPs cause only minor disruptions to signalling pathways under non-toxic exposure conditions, in contrast to the marked activation observed for snus [57].

3.3. The significance of ingredients other than nicotine

Studies conducted on various cellular models, including HGF-1, HGEP and airway models, consistently indicate that the toxicity observed is often independent of nicotine content. This reinforces the conclusion that additives and flavourings are the main toxic factors. Consequently, nicotine pouches can be placed below cigarettes and snus on the toxicological scale, but they cannot be considered biologically inert products.

4. Oral health and local biological effects

4.1. Changes in the oral mucosa

The most consistently documented category of health effects associated with NPs is localised lesions within the oral mucosa. Observational studies, case series and histopathological analyses have described white, hyperkeratotic, leathery or furrowed lesions located at the site where the sachet is habitually placed. The severity of the lesions ranged from mild to marked leukoplakic changes [2, 4, 23, 38, 39, 48].

Histopathological findings typically included parakeratosis, epithelial acanthosis, intracellular and connective tissue oedema, and chronic inflammatory infiltrates dominated by lymphocytes and macrophages [39]. Other clinical and observational reports also indicated epithelial thickening, oedema and local inflammatory infiltrates [2, 4, 23, 39]. These lesions are similar in appearance to those observed in snus users.

The mechanism behind these changes may be linked to both nicotine and chemical additives. Reviews suggest that flavouring substances may increase epithelial stress through mechanisms involving oxidative stress and the activation of the NF-κB and NLRP3 inflammatory pathways [58]. Furthermore, high pH values and a significant proportion of free-base nicotine, as described in chemical analyses, support the hypothesis of a possible local irritant or cytotoxic effect [33, 52].

4.2. Reversibility of changes and long-term uncertainty

Some data suggest that local changes in the mucous membrane may be partially reversible. In users switching from snus to tobacco-free nicotine pouches, a reduction in the severity of these changes and lower induction of pro-inflammatory cytokines was observed compared with exposure to snus [3]. This means that although NPs are not free from local adverse effects, they may cause less severe effects than smokeless tobacco products containing tobacco.

At the same time, the possibility of potentially precancerous lesions has been suggested, but this has not yet been confirmed. Most of the available studies are cross-sectional in nature, involve small sample sizes or are based on case reports, which makes it impossible to unequivocally assess the long-term risk of malignant transformation [2, 48]. The available evidence therefore consistently points to local mucosal pathology in NP users, but the clinical significance of these changes over the long term remains uncertain.

4.3. Oral health of smokers switching to NPs

Several clinical trials have assessed whether replacing cigarettes with nicotine pouches is associated with improved oral health. A pilot randomised trial of adult smokers using on!® pouches for 24 weeks demonstrated a significant improvement in the Modified Gingival Index (MGI), Gingival Bleeding Index (GBI) and Lobene Stain Index (LSI) in the group using NPs compared with those who continued smoking [31]. Users reduced their cigarette consumption by over 90%, suggesting that the primary mechanism of improvement was reduced exposure to tobacco smoke.

Additional findings come from a small pilot observational study, which showed that a new pouch design featuring an impermeable inner barrier reduced user-reported irritation and limited the severity of snus-like lesions in individuals switching from snus to the modified pouches [27]. Cross-sectional biomarker studies also indicate that exclusive NPs users show significantly lower exposure to tobacco toxins and more favourable inflammatory and respiratory biomarker profiles than smokers, which is consistent with potentially less damage to oral tissues [6].

Despite these promising results, systematic reviews highlight the lack of long-term clinical trials specifically focusing on NPs. This means that, although switching from cigarettes to nicotine pouches appears to lead to improvements in several oral health indicators in the short term, the durability and clinical significance of these benefits remain unclear [50].

5. Pharmacokinetics, nicotine delivery and addictive potential

5.1. Routes and determinants of absorption

Nicotine pouches deliver nicotine primarily via the buccal route, through the oral mucosa, bypassing first-pass metabolism. Nicotine that is not absorbed and is swallowed along with saliva undergoes intensive hepatic metabolism, which reduces its systemic bioavailability to approximately 20–30% [58]. This means that the main route of systemic nicotine delivery is local absorption through the buccal mucosa.

The effectiveness of this process depends on a number of factors: the product's pH, the proportion of free-base nicotine, the structure of the pouch matrix, moisture content, and duration of use. Products vary in pH from 6.86 to 10.1 and in free nicotine content from 7.7 to 99.2% [52], and these variables strongly influence the rate and extent of absorption through the buccal mucosa [1, 29]. Laboratory studies of dissolution and permeability have shown significant differences between brands; for example, Zyn exhibits a higher rate of nicotine release and greater permeability through the mucous membrane than Velo or Dryft, which highlights the importance of product formulation regardless of the nominal nicotine content [29, 43]. The nicotine flux alone is therefore not a sufficient predictor of systemic exposure, as its absorption through the mucous membrane is of key importance [25].

5.2. Pharmacokinetic profiles compared with cigarettes

Controlled clinical trials and meta-analyses indicate that low-nicotine formulations deliver less nicotine than cigarettes, whilst medium- and high-strength products may provide comparable or higher exposure. Pouches with a strength of 1.5–2 mg deliver significantly less nicotine than cigarettes, whilst 3.5–4 mg products provide similar total exposure, reaching approximately 92% of a cigarette's AUC, albeit with a lower Cmax of around 69%, and a significantly slower Tmax of 20–65 minutes compared to 5–8 minutes for a cigarette [20]. Overall, 4 mg pouches therefore provide a similar total exposure to nicotine as cigarettes, but with a slower rate of absorption and lower peak concentrations [30, 32, 35, 37, 46].

Higher-strength products, particularly those containing ≥8 mg, may exceed both the Cmax and AUC values observed when smoking cigarettes in some users. Randomised trials confirm this pattern. Lyft 10 mg pouches achieved higher Cmax and AUC values than cigarettes [37], whilst products containing 20–30 mg resulted in very rapid early absorption, sometimes similar to the initial kinetics of cigarettes [35]. In one comparison, the 9 mg Zyn pouch provided a higher Cmax than a cigarette, 27.9 versus 19.5 ng/ml respectively, despite a slower Tmax of 30 versus 6 minutes [44]. This means that high-strength pouches can deliver nicotine in quantities sufficient to satisfy smokers' nicotine cravings, and in some cases even surpass cigarettes in terms of systemic exposure [7].

5.3. Nicotine extraction and actual dosing patterns

The rate of nicotine extraction from nicotine pouches varies considerably, ranging from 24% to 62%, depending on the nicotine content, the product's structure and the duration for which the pouch is kept in the mouth. Shorter usage times in real-world conditions, ranging from 5 to 20 minutes, may significantly limit extraction compared with controlled laboratory protocols lasting 60 minutes [35]. More recent multicentre studies have demonstrated a dose-dependent increase in Cmax and AUC as the duration of pouch retention was extended to 10, 20 and 30 minutes, and have confirmed that swallowed nicotine contributes minimally to systemic exposure, as less than 2% of the detected nicotine was found in saliva [7].

User behaviour also plays a significant role. Frequent use, or so-called 'chain use', may increase the cumulative systemic dose beyond the level predicted on the basis of the pharmacokinetics of a single sachet [58]. For this reason, the results of single-use studies do not fully reflect exposure under conditions of daily, repeated use.

5.4. Comparison with NRT and other oral products

Low-dose pouches, particularly those containing 4 mg, deliver nicotine at a level comparable to nicotine replacement therapy lozenges and more effectively than nicotine gum [1]. Pharmacokinetic comparisons with moist chewing tobacco indicate that the proportion of nicotine in the form of free base is crucial for nicotine delivery, regardless of the total nicotine content [24]. Some pouch products, such as Zyn 6–8 mg, deliver nicotine just as quickly and in similar amounts to snus or moist snuff [32].

5.5. Addictive potential

Subjective user reports indicate that NPs reduce nicotine cravings and withdrawal symptoms, but are generally rated as less satisfying than cigarettes [30, 37, 46]. Satisfaction increases with nicotine content, suggesting that the addictive potential of many products may be lower than that of cigarettes, but comparable to other oral nicotine products [5, 11]. Slower absorption than with cigarettes usually limits immediate behavioural reinforcement; however, high-nicotine pouches can cause rapid increases in plasma nicotine concentrations, sometimes similar to the kinetics of cigarettes. This raises concerns regarding addictive potential, particularly among young people and those not previously exposed to nicotine.

6. Acute physiological effects and the toxicity of nicotine

6.1. Acute systemic effects

The acute physiological responses following the use of nicotine pouches are consistent with the known profile of nicotine's effects on the cardiovascular system. Controlled studies indicate an increase in heart rate, elevated blood pressure and increased arterial stiffness [19]. Oral nicotine products, including NPs and chewing pouches, cause measurable cardiovascular stimulation, although the effect on airway resistance is minor compared with cigarettes [19].

Pharmacokinetic and toxicological analyses show that even a single pouch can deliver a dose of nicotine exceeding the proposed acute reference doses by more than twenty times, which may lead to an increased heart rate and other symptoms of acute nicotine stimulation [45]. These effects depend on the nicotine dose, the proportion of free nicotine, and the product formulation.

6.2. Events related to nicotine toxicity

Although severe cases of poisoning are rare, they have been documented. Clinical case reports have mainly concerned children who, following accidental ingestion of sachets, exhibited nausea, dizziness, chills, agitation, vomiting and tachycardia [54, 55]. These cases required short-term clinical observation but did not result in any lasting effects.

This risk is significant due to the high nicotine content in some products and unclear labelling. Some pouches contain up to 47.5 mg of nicotine per pouch, often with insufficient labelling [33]. Analyses based on acute reference doses indicate very large exceedances of safe thresholds even with the use of a single pouch, which raises particular concerns regarding individuals with no prior exposure to nicotine and adolescents [45]. Although most cases of toxicity relate to accidental or paediatric exposure, the combination of high nicotine content, rapid absorption through the buccal mucosa and the discreet nature of use suggests that misuse or the simultaneous use of multiple pouches may lead to clinically significant toxicity.

7. Consumption patterns, risk perception and the influence of marketing

7.1. Frequency of use and demographic patterns

Population-based studies from many countries indicate that the use of e-cigarettes remains relatively low in absolute terms, but is growing rapidly, particularly among young adults, adolescents, men and those who already use other nicotine products. In the UK, current use of e-cigarettes among adults doubled between 2020 and 2024, reaching 1.0%, with higher prevalence observed among those aged 18–34 and men. In the same jurisdiction, the proportion of young people who had ever used NPs reached 3.3% in 2024, with current use standing at 1.2% [10].

In the United States, data from the Monitoring the Future study showed an increase in lifetime use of NPs among young people from 3.0% to 5.4% between 2023 and 2024 [17]. In Finland, following deregulation in 2023, a sharp increase in the use of NPs by adolescents was recorded; current use stood at 11.3% among boys and was strongly predicted by the use of other nicotine products [10]. In Poland, 24% of adults were aware of the existence of NPs, 9.2% had ever used them, and current use stood at 4.3%, with higher rates among younger adults, smokers and e-cigarette users [21]. In Australia, 19% of young adults reported recent use despite the illegality of retail sales, with the highest rates observed among those who concurrently used tobacco or e-cigarettes [22].

The pattern is consistent: nicotine pouches primarily attract groups that have already been exposed to nicotine, and the fastest growth in prevalence is observed among adolescents and young adults, just as was previously the case with e-cigarettes.

7.2. Perception of risk and vulnerability to use

Risk perception plays a central role in the uptake of nicotine pouches. In surveys, the majority of respondents perceive nicotine pouches as less harmful than cigarettes or smokeless tobacco products, or as equally harmful, but rarely as more harmful. At the same time, a significant proportion of respondents, ranging from 37% to 52%, express uncertainty regarding their harmfulness compared to cigarettes, e-cigarettes or smokeless tobacco products. Positive beliefs about NPs correlate with both susceptibility to use and actual use among adults and young people [40, 41].

This susceptibility is high even among young people who have not previously been exposed to nicotine. Among Australian adolescents and young adults aware of the existence of NP products, 66% reported curiosity, 55% a willingness to try them, and 46% an intention to use them within the next six months [9]. Among adolescents in the US, susceptibility specifically to pouches was 8.7%, and for other oral nicotine products it was even higher [56]. This susceptibility was predicted by positive attitudes towards the product, low perceived addictiveness, use by peers or family, and current use of e-cigarettes [9]

7.3. Marketing and social media

The impact of marketing on users' perceptions and behaviour is clear. Social media analyses show that platforms such as TikTok often portray nicotine pouches in a positive light, emphasising flavours, lifestyle appeal and the discreet nature of their use, whilst offering minimal discussion of the risks [36]. This type of messaging normalises the use of nicotine pouches and may reinforce the perception of their safety, replicating mechanisms previously observed with e-cigarettes. Exposure to marketing strongly predicts experimentation among adults who already use tobacco [42].

8. Combined use with other nicotine products

One of the most consistent findings of the research is the high level of dual and poly-product use. In practice, this means that nicotine pouches rarely completely replace other nicotine products, particularly among adolescents and young adults.

In the 2021 NYTS US survey, 64.2% of current NRT users also used e-cigarettes, and 52.6% used at least two tobacco products [26]. In the US national monitoring study for 2021–2024, dual use of e-cigarettes and NPs increased by 14.75% per quarter, alongside a rise in multi-product use [13]. Young people using smokeless tobacco products, e-cigarettes or cigarettes had the highest odds ratios for using NPs [16].

A similar pattern is observed among adults. In the UK, 69% of NPs users also used other nicotine products; 56% smoked cigarettes and 39% used e-cigarettes [53]. Co-use is similarly common in US adult samples, particularly among those who both smoke cigarettes and use e-cigarettes. Survey results generally indicate that the majority of NP users are dual or multi-product users [17, 22].

The available evidence suggests several mechanisms of co-use. Firstly, adults may use NPs as a functional substitute in places where smoking or vaping is prohibited [53]. Secondly, a catalytic effect is observed among adolescents, whereby starting to use one product increases susceptibility to using other nicotine products [1]. Thirdly, flavour-driven experimentation correlates strongly with the use of multiple nicotine products among young people [12]. Taken together, these findings indicate that NPs more often function as complementary products rather than as full substitutes.

9. The public health context and regulatory implications

9.1. Harm reduction potential

Biomarker studies indicate that exclusive users of nicotine pouches are exposed to significantly lower levels of tobacco-derived carcinogens and combustion markers than smokers, which supports the harm-reduction potential for adults who switch entirely from cigarettes to these products [6]. Among other findings, levels of NNAL were shown to be 91% lower and levels of COHb 46% lower in exclusive users of nicotine pouches compared with smokers [6]. Population-level modelling suggests that widespread substitution of cigarettes with nicotine pouches could prevent hundreds of thousands of premature deaths over the course of several decades [28].

These findings justify treating NPs as potential harm-reduction tools for established smokers, placing them at the lower end of the toxicological risk continuum, alongside nicotine replacement therapy products. At the same time, it is emphasised that population-level benefits are conditional: they depend on whether these products are used primarily by adult smokers as full substitutes for cigarettes.

9.2. Population risks

The potential benefits may be limited or offset by increased use among young people, high-nicotine formulations, the appeal of flavours, and inconsistent regulatory oversight. Rapidly rising use among adolescents and young adults, misconceptions about safety, exposure to marketing, and high rates of multi-product use raise concerns that NPs may increase exposure to nicotine rather than reduce harm at the population level.

9.3. Regulatory variation

Regulatory approaches to nicotine pouches vary considerably. Some countries regulate them as tobacco products, others treat them as medical devices or consumer goods, and in many jurisdictions there is no specific regulatory framework, which allows for the widespread distribution of flavoured formulations with high nicotine content [14]. An additional problem is the inconsistency in the monitoring and classification of NPs relative to other smokeless tobacco products, which hinders international comparisons and accurate estimates of prevalence.

The available data point to the need for a coherent public health strategy which, on the one hand, would support adult smokers in switching to lower-risk products by clearly communicating the relative risks, and, on the other hand, would prevent young people from taking up smoking by regulating flavours, marketing and product display at points of sale. This also requires standardisation of labelling and restrictions on nicotine concentrations to reduce the risk of overdose and addiction.

10. Limitations of current knowledge

Despite the rapidly growing number of studies on nicotine pouches, the current evidence base remains underdeveloped, fragmented and subject to numerous methodological limitations.

The most common problem is the lack of long-term and epidemiological data. No prospective cohort studies have been conducted to analyse the chronic use of NPs, the incidence of disease, or long-term effects on the oral cavity or the cardiovascular system. Many reviews emphasise that studies rely mainly on short-term biological or behavioural endpoints rather than clinical measures of disease. In the field of oral health, systematic reviews identify only three small studies, all of which are burdened by a high risk of bias, heterogeneous designs and limited reporting of usage patterns [48]. Similarly, assessments of the impact on public health are based primarily on modelling rather than on observed outcomes from real-world populations [28].

Furthermore, most population-based studies are cross-sectional in nature, which means they do not allow for causal inferences regarding the links between the use of NPs, exposure to marketing, susceptibility to use, or behaviours related to quitting. Numerous studies rely on self-reports without biochemical verification, which increases the risk of recall bias and misclassification. This is particularly important because text-only survey items may underestimate awareness levels and misidentify users of smokeless tobacco products as NPS users, thereby reducing the accuracy of prevalence estimates. Many studies have also used online convenience samples of uncertain representativeness, particularly with regard to adolescents and young adults.

Additionally, a major problem is the high degree of heterogeneity in products, formulations and usage patterns. NP products vary significantly in terms of nicotine content, pH, free base content, flavourings and additives, leading to inconsistent exposure and varied health effects. Chemical analyses document extreme variability: from 1.79 to 47.5 mg of nicotine per pouch, 186 detected chemical compounds, and the presence of unauthorised or potentially carcinogenic flavourings [33, 34]. Furthermore, individual user behaviours, such as the duration of a single use or the number of pouches per day, are rarely reported, even though they strongly influence nicotine release and actual exposure [48].

On top of that, the results of in vitro toxicological studies are inconsistent, and methodological differences make it difficult to compare them. Different extraction methods, dosing protocols, exposure times and cell models limit comparability between studies. The extracts commonly used exceed realistic human exposures or are not prepared according to standardised procedures, which limits their translational relevance. Furthermore, studies rarely account for chemical interactions within complex mixtures of flavouring substances, despite evidence of potential synergistic toxicity [47].

The pharmacokinetic evidence base is dominated by short-term, randomised crossover trials, often industry-sponsored, conducted on small sample sizes and under controlled laboratory dosing conditions. Meta-analyses highlight the small number of available studies, significant heterogeneity and the risk of systematic error. High-potency products, exceeding 10 mg, are poorly studied, and the predominant single-use protocols do not allow for the assessment of cumulative exposure or the trajectory of dependence under real-world conditions [51].

A significant proportion of research into NPs, particularly regarding pharmacokinetics, toxicology and harm reduction, is funded or conducted by entities linked to the tobacco industry. This raises concerns regarding selective reporting, an overly optimistic interpretation of the potential for harm reduction, and the need for independent replication of the results.

Data on adolescent trajectories, addiction and transitions between products remain insufficient. Although use among adolescents is increasing, the available studies are mainly cross-sectional in nature and do not allow for a reliable assessment of developmental risks, long-term addiction or gateway patterns. Studies on marketing exposure do not allow for the establishment of temporal causality, and measures of susceptibility lack confirmed longitudinal validation. Furthermore, youth samples are often not representative at the national level, which limits their usefulness for public policy [18].

There are significant regulatory inconsistencies and monitoring issues. The international classification of NTPs is highly inconsistent, and monitoring systems do not always distinguish between nicotine pouches and smokeless tobacco products, leading to inaccurate estimates of prevalence and hindering international comparisons. Labelling inconsistencies, including the absence of nicotine content information on packaging, further complicate exposure assessment [33].

Finally, there are also limitations regarding the modelling of public health impacts. Agent-based and counterfactual models rely on assumptions concerning initiation, cessation of use, transition rates between products, levels of toxic substances, and relative risk. These assumptions have not yet been validated empirically over the long term, and sensitivity analyses are unable to fully capture the complexity of behaviour

under real-world conditions. For this reason, projections of large reductions in mortality should be interpreted with caution.

Taken together, these limitations indicate that research into NPs is at an early stage of development. The research is characterised by short follow-up periods, small sample sizes, cross-sectional designs, high product variability and a limited number of independent studies. This situation highlights the need for rigorous, longitudinal and independent studies to more accurately determine the actual health risks and population-level impact of nicotine pouches.

Conclusions

Nicotine pouches currently occupy a dual position in the modern landscape of nicotine use. On the one hand, they are smoke-free nicotine delivery systems with significantly reduced levels of harmful and potentially harmful constituents compared to cigarettes, snus and other traditional tobacco products. The results of chemical analyses, biomarker studies and population modelling support the view that they can serve as harm-reduction tools for adult smokers who completely replace cigarettes with them. These benefits include reduced exposure to tobacco-derived carcinogens and combustion markers, and, in the short term, an improvement in certain indicators of oral health among those who are quitting smoking.

On the other hand, nicotine pouches are not risk-free products. Their use is associated with local changes in the oral mucosa, including keratinisation, epithelial thickening, oedema and inflammatory infiltrates. In vitro studies indicate the potential for cytotoxicity, oxidative stress and the activation of inflammatory pathways, with non-nicotine components, particularly flavourings, likely playing a significant role. Pharmacokinetically, these products effectively deliver nicotine via the buccal route, and higher-strength formulations can achieve exposure equal to or higher than that of cigarettes, which is relevant to their addictive potential. Acute systemic effects include increased heart rate, blood pressure and arterial stiffness, and cases of nicotine poisoning, particularly in children, highlight the need for effective preventive measures.

At the population level, the rapidly rising use of Nics among adolescents and young adults, their frequent co-use with e-cigarettes and cigarettes, the perception that they pose a lower risk, and the strong influence of marketing—particularly on social media—are of particular concern. In these groups, NPs tend to function as complementary products rather than substitutes, which limits their harm-reduction potential and increases the risk of extended exposure to nicotine.

From a public health perspective, the available data point to the need for policies that balance two objectives: supporting adult smokers in switching to products with relatively lower risks, whilst simultaneously preventing nicotine initiation among young people. This includes the need to regulate nicotine concentrations, flavours and marketing targeted at young people, standardise product labelling, improve monitoring of NP use, and develop independent long-term research.

Ultimately, the impact of nicotine pouches on public health will depend not so much on the product technology itself, but rather on patterns of use, user characteristics, and the quality and effectiveness of the regulatory framework. Only long-term, independent and methodologically rigorous research will determine to what extent NPs will become a harm-reduction tool for adult smokers, and to what extent a new source of risks for younger cohorts and those who have not previously used nicotine.

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