

Weight of Evidence of Modern Oral Products



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Introduction: Tobacco Risk Continuum



*Not to scale – for illustration purposes only

- Premarket and modified risk tobacco product applications require information on how market availability of the new tobacco product(s) will affect tobacco and nicotine product selection and use behavior of current tobacco consumers.



Velo Actual Use Study Data (US)



Study Objective & Endpoints

To determine if cigarette smokers would adopt Velo pouch products and use them as an alternative to cigarette smoking.

Determine number and proportion of “established users”* of Velo

Determine number and proportion of “established users”* who reduce CPD consumption by $\geq 50\%$

Describe weekly average CPD consumption

Established use is defined as using ≥ 100 pouches over the 6-week actual use period.
CPD = cigarettes per day

Methods & Study Design

Key Inclusion Criteria:

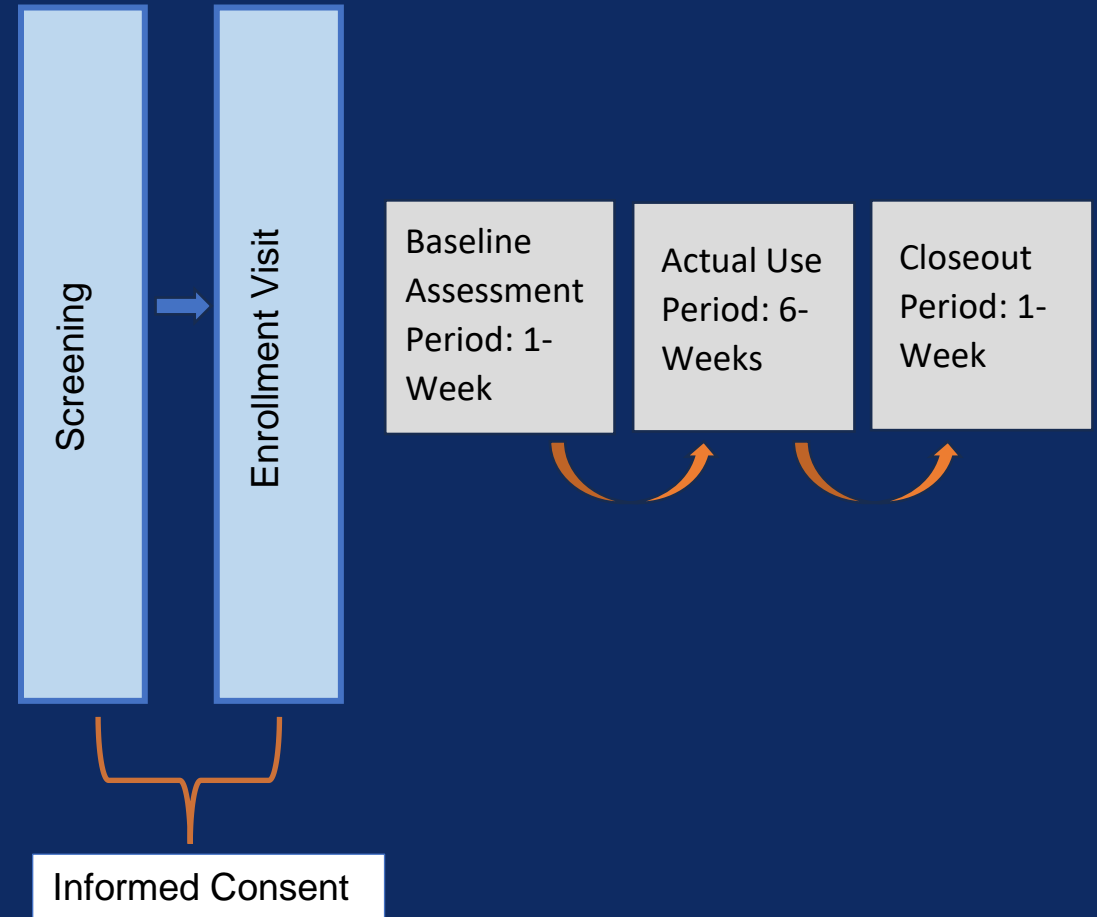
- Met lifetime criteria
- Adult current smokers, dual and/or poly tobacco product use allowed

Study Investigational Product (IP):

Participants were allowed to use any combination of 12 available IP
IP use not mandated

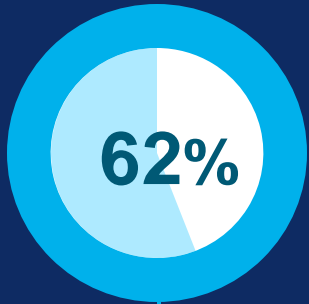
Data Collected:

Daily tobacco and/or nicotine containing product use



Results

Proportion of Established Users of Velo



575 subjects met the definition of established users of Velo by Week 6

50% CPD Reduction



117 established users of Velo reduced their CPD consumption by at least 50% by Week 6

Average CPD Reduction



Average CPD of all completed subjects (n=916) decreased from 11.9 at baseline to approximately 9.5 at Week 6

Established use is defined as using ≥ 100 pouches over the 6-week actual use period.
CPD = cigarettes per day



When made available, Velo leads to product adoption and smoking reduction.

Global Consumption & Use Data



Study Population



Study objective

Describe use patterns and behaviors of oral nicotine pouch consumers from multiple countries

Participants by Country (%)

- Denmark 20.2%
- Germany 29.9%
- Switzerland 19.8%
- Sweden 30%



Sex

- Male 61%
- Female 39%



Other Demographics

- Majority aged 35-44
- High level of educational attainment

Participant TNP Use

- Exclusive ONP Use 1.3% – 19.9%
- Dual use of ONP and CC 6%-11.1%
- Poly usage of ONP, CC & other non-combustibles 42%
- Poly-usage excluding ONP 30.3%-38.9%

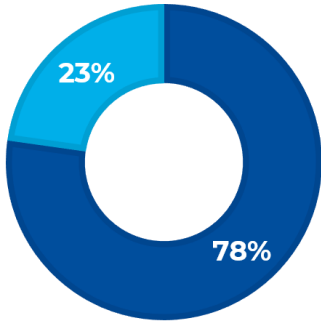


TNP: Tobacco or nicotine-containing product; ONP: Oral Nicotine Pouches; CC: Combustible Cigarettes

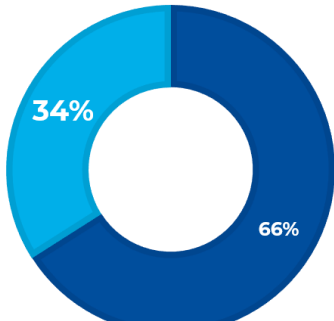
* "Dual-usage" and "Poly-usage" refer to concomitant use of two or more tobacco products, which may be a part of a transitional period to potentially reduced risk nicotine products.

Product Use Behaviors

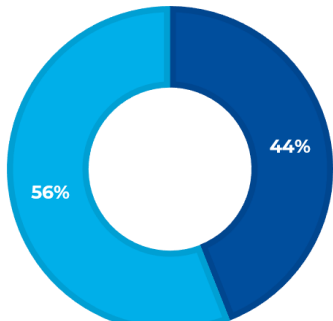
Frequency



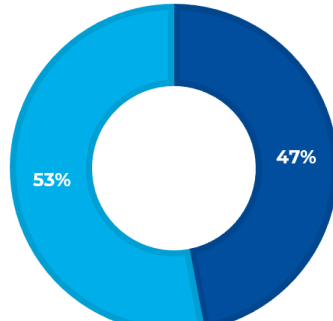
■ Daily ■ Weekly



■ Daily ■ Weekly



■ Daily ■ Weekly



■ Daily ■ Weekly

Sweden



Denmark



Germany



Switzerland



Mouth Hold Range

17-30 minutes

8-23 minutes

11-18 minutes

13-18 minutes

Higher Nicotine Strengths

14% used 16-20mg

25% used 16-20mg

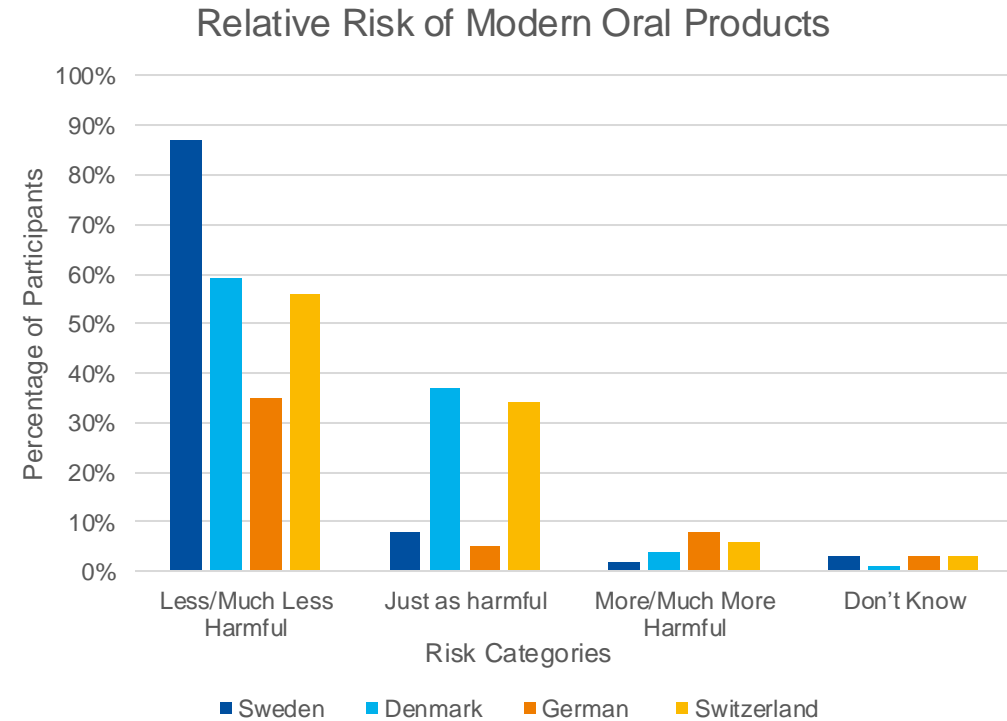
20% used 16-20mg

20% used 16-20mg

Flavor and Risk Perception



Menthol was the most often selected flavor across all countries, with highest proportion in Denmark (79.2%) followed by Switzerland (75.8%), Sweden (61.6%), and Germany (59.7%).



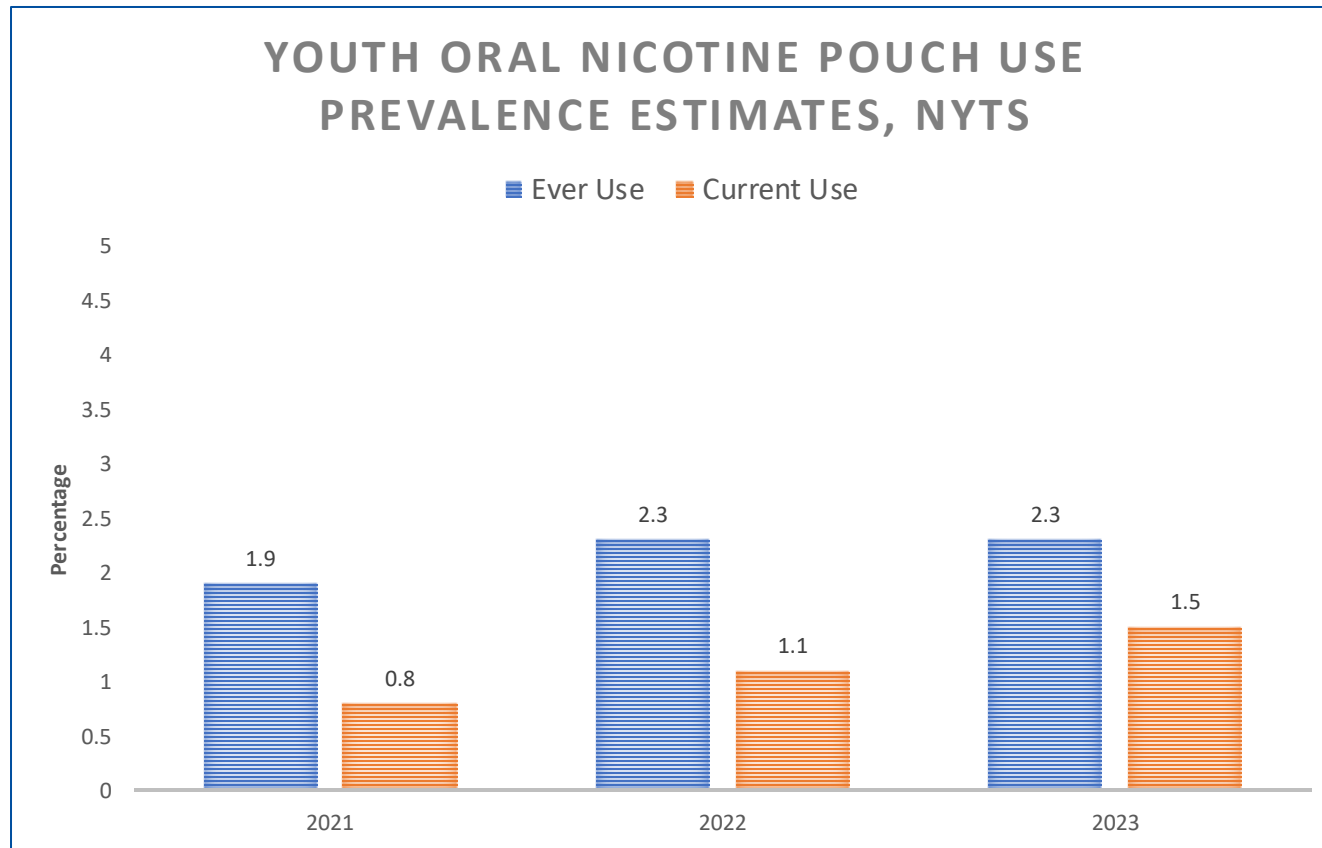
Perception of risk showed that most participants believed that modern oral products were less harmful than cigarettes.



Youth Prevalence Data (US)



Youth Prevalence 2021-2023, NYTS



Ever use – any use, even once or twice; Current use – use in the past 30 days; NYTS=National Youth Tobacco Survey; ENDS=Electronic Nicotine Delivery Systems

36% had heard of oral nicotine pouches, but few youth had ever used or were currently using oral nicotine pouches.



Prevalence of oral nicotine product use among youth is comparatively lower than ENDS, cigarettes, and cigars

Conclusions



- Among US smokers, Velo was adopted by a majority of participants and facilitated reductions.
- Among US youth, prevalence of oral nicotine pouch use has remained low over the
- In global markets where the oral nicotine pouch category is more advanced, we see terms of smoker migration

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