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Prevalence and patterns of tobacco use in Japan after the commercialization of a heat-not-burn alternative (IQOS) to cigarettes

Analysis and Evaluation of a Cross-Sectional Study

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Overview

- Background
- Tobacco Surveys in Japan
- What is IQOS
- PMI's Cross-Sectional Survey – Objectives
- Methods
- Results Waves 1-2, Year 1
- Conclusions

Background

“As new tobacco products become available to smokers, the need to accurately measure tobacco and nicotine use in the population becomes more important:

- Including other tobacco/nicotine products besides cigarettes
- Accurate assessing of product use behaviors
- Appropriate sampling methods”

(Hitchman et al, 2017)

Prominent Worldwide Tobacco Prevalence Surveys

- DEBRA in Germany (Kastaun et al., 2017)
- Smoking ToolKit Study in UK (Fidler et al., 2013)
- PATH (Hyland et al., 2017) and the National Health Interview Survey (NHIS) in the US (Centers for Disease Control., 2016).

Tobacco Surveys in Japan

- Japanese National Health and Nutrition Survey, collecting data on cigarette smoking, latest data from 2015 (www.mhlw.go.jp).
- JT's Smoking Prevalence Survey, latest data from 2016 (JT, 2017).

Unmet Informational Needs for Japanese Surveys

- Prevalence of use of other tobacco/nicotine products
- Usage of new products (e.g. IQOS)

What is IQOS?

- A novel tobacco product that heats tobacco instead of burning it (not exceeding 350 °C) (heat-not-burn product)
- No combustion takes place as has been reported (Cozzani et al, 2016)
- The absence of combustion is designed to significantly :
 - Reduce formation of harmful and potentially harmful smoke constituents (HPHCs), which has also been shown (Schaller et al 2016)
 - Reduce exposure to biomarkers of HPHCs (Haziza, 2017)
 - Levels of nicotine uptake are maintained (Picavet et al, 2016)



IQOS in Japan

- It was launched in Japan in November 2014 in Nagoya
- National Expansion was completed in first half of 2016.
- HeatSticks currently have a market share of 10% nationally (PMI Financials and Estimates June 2017)

Objectives

Aim: To assess tobacco use prevalence and patterns of tobacco product use in the Japanese population; to characterize the use of IQOS in real-world conditions

- Measure the point prevalence of use of tobacco/nicotine containing products
- Describe the patterns of tobacco product use: exclusive, dual and poly product use
- Describe relapse, re-initiation and quitting/stopping product use

PMI's Cross-Sectional Survey in Japan – Study Design

- Population-based annual survey to measure prevalence of use of tobacco products available in the Japanese market
- Enriched IQOS users sample to describe how IQOS is used in real-life
- Following the following Ethical Guidelines:
 - Good Epidemiological Practices (GEP)
 - Ethical Guidelines for Medical and Health Research Involving Human Subjects (Japan)
- The surveys are run in 4 waves (quarterly)

General Population Sample - Omnibus

- Omnibus is a syndicated method for data collection that contains more than one questionnaire
- Run in 4 yearly waves
- Sample size is 5,000 subjects/year
- Fieldwork for 1st and 2nd wave took place in December 2016 and March 2017 respectively

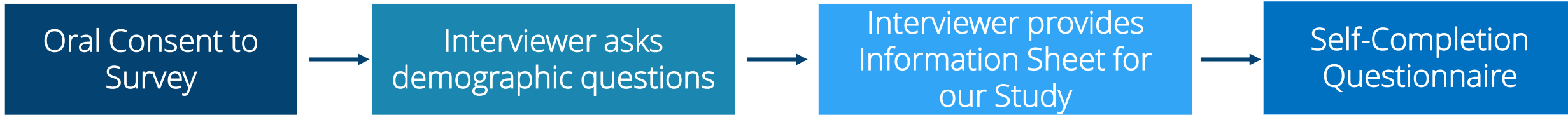
Omnibus 3 Stage Sample Design

Stage 1: Census Unit

Stage 2: Household
Selection

Stage 3: Respondent
within Household

Questionnaire Administration



IQOS Users Sample

- Population:
 - From PM-JP's IQOS user database
- Email invites are sent using quotas reflecting the sex/age distribution of the IQOS user database
- Sample size is 2,000 subjects/year
- Each wave of is composed of 500 participants, data collection takes place simultaneously to the general population sample.

Online Questionnaire Administration

Email invitation to
IQOS users in
PMJ's Database



Subject clicks on
link and is shown
informed consent



Consent signed
electronically



Screening
questions



Online Survey

Analysis

- All the data is summarized by means of descriptive statistics.
- The analysis is carried out unstandardized and standardized to the Japanese population (Weitkunat, 2001)
- For continuous data, summary statistics include the number and percent of subjects with non-missing data
- The arithmetic mean and 95% confidence interval, arithmetic standard deviation (SD) were calculated
- Categorical outcomes were summarized by frequency statistics providing the number and percent of subjects and 95% confidence interval.

Results from Waves 1 and 2: Subject Disposition

- General Population:
 - 8,000 households visited
 - Response rate= 30.3% (n=2,423)
- IQOS users sample:
 - 7,149 invites sent
 - Completion rate= 14% (n=1,000)

Demographic Characteristics

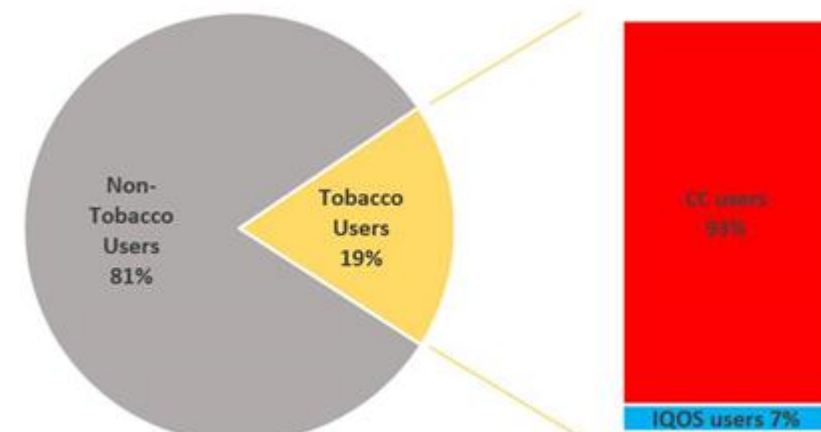
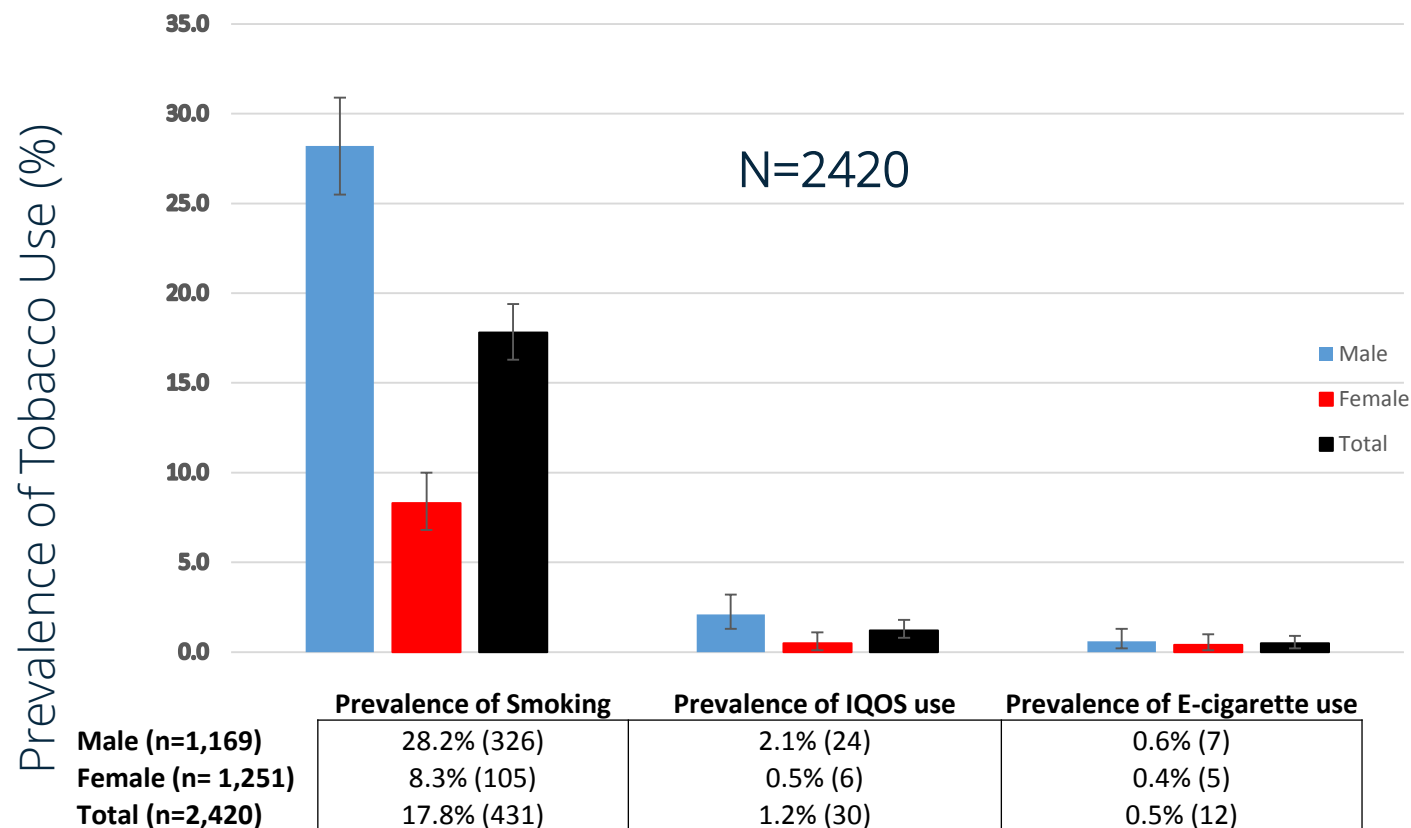
Variable	General Population Sample	IQOS Users Sample
Mean age (years)	53.6 ($\pm$ 17.9)	38.5 ($\pm$ 9.8)
Age group (%)		
20-29	11.0	21.0
30-39	14.9	36.8
40-49	18.3	28.4
50+	55.9	13.8
Sex:		
Male (%)	48	82
Female (%)	52	18

Age and Sex Distribution in the Japanese Population and Study Samples

		Sample populations		
		Japanese population	General sample (95%CI)	IQOS Users Sample (95%CI)
Male	20 - 29	11.3%	11.4% (9.5-13.4%)	20.3% (17.6-23.3%)
	30 - 39	14.2%	17.6% (15.4-20.0%)	36.8% (33.4-40.2%)
	40 - 49	16.9%	17.7% (15.5-20.1%)	28.9% (25.8-32.2%)
	50+	57.5%	53.3% (20.3-56.2%)	14.0% (11.6-16.6%)
Female	20 - 29	12.7%	10.6% (8.9-12.5%)	23.9% (17.9-30.8%)
	30 - 39	15.9%	12.4% (10.6-14.4%)	37.0% (29.9-44.4%)
	40 - 49	18.8%	18.8% (16.6-21.1%)	26.1% (19.9-33.1%)
	50+	52.6%	58.2% (55.4-61.0%)	13.0% (8.5-18.8%)
Total by sex				
	Male	48.3%	47.8% (45.8-49.9%)	81.6% (79.0-84.0%)
	Female	51.7%	52.2% (50.1-54.2%)	18.4% (16.0-21.0%)
Total by age group				
	20 - 29	12.0%	11.0% (9.7-12.3%)	21.0% (18.5-23.7%)
	30 - 39	15.1%	14.9% (13.5-16.4%)	36.8% (33.8-39.9%)
	40 - 49	17.8%	18.3% (16.7-19.9%)	28.4% (25.6-31.4%)
	50+	55.2%	55.9% (53.8-57.9%)	13.8% (11.7-16.1%)

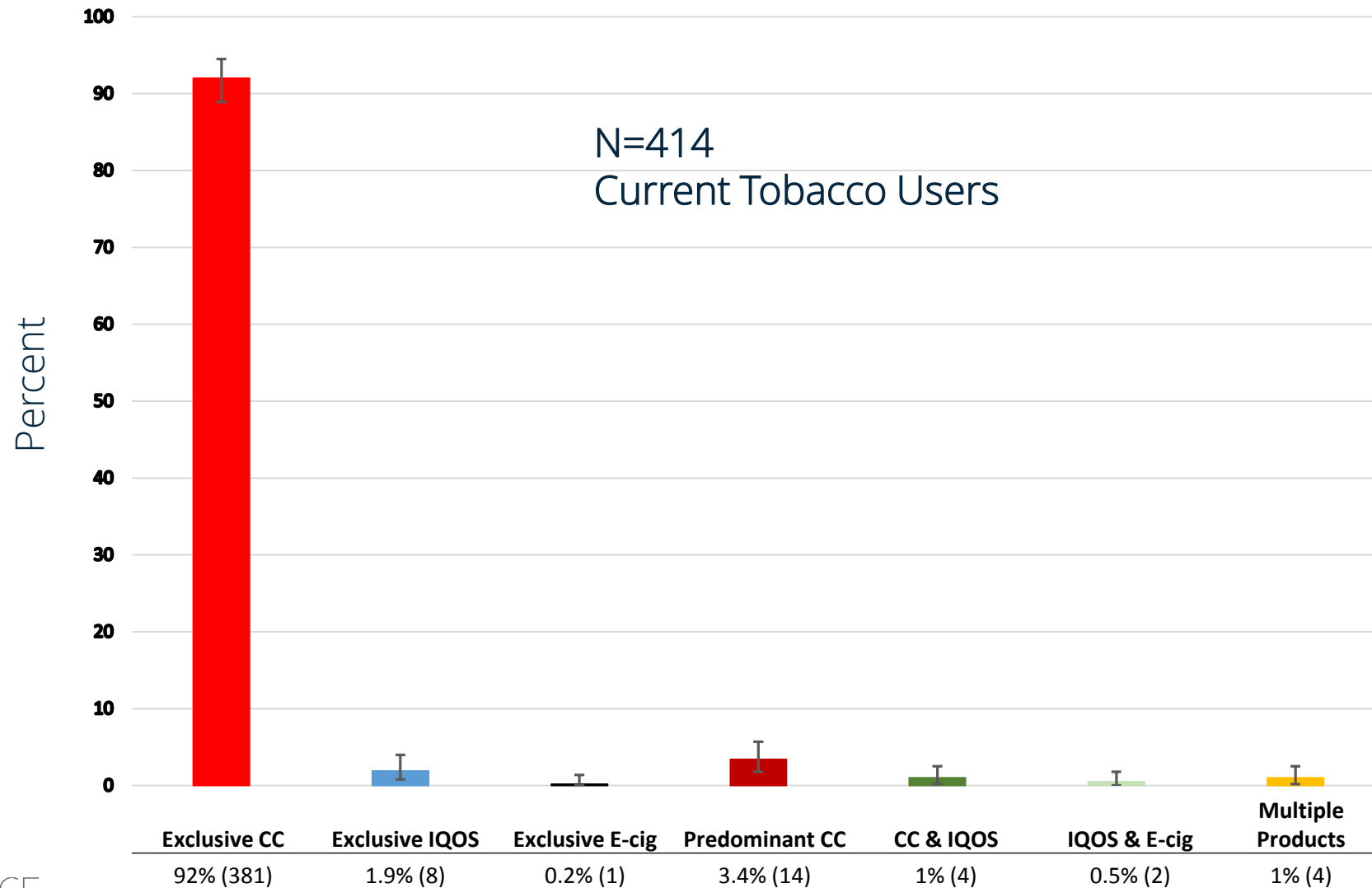
Chi-square tests: sex (p=0.8), age (p=0.9)
Source: Japanese Statistics Bureau (2015)

General Population Sample - Prevalence

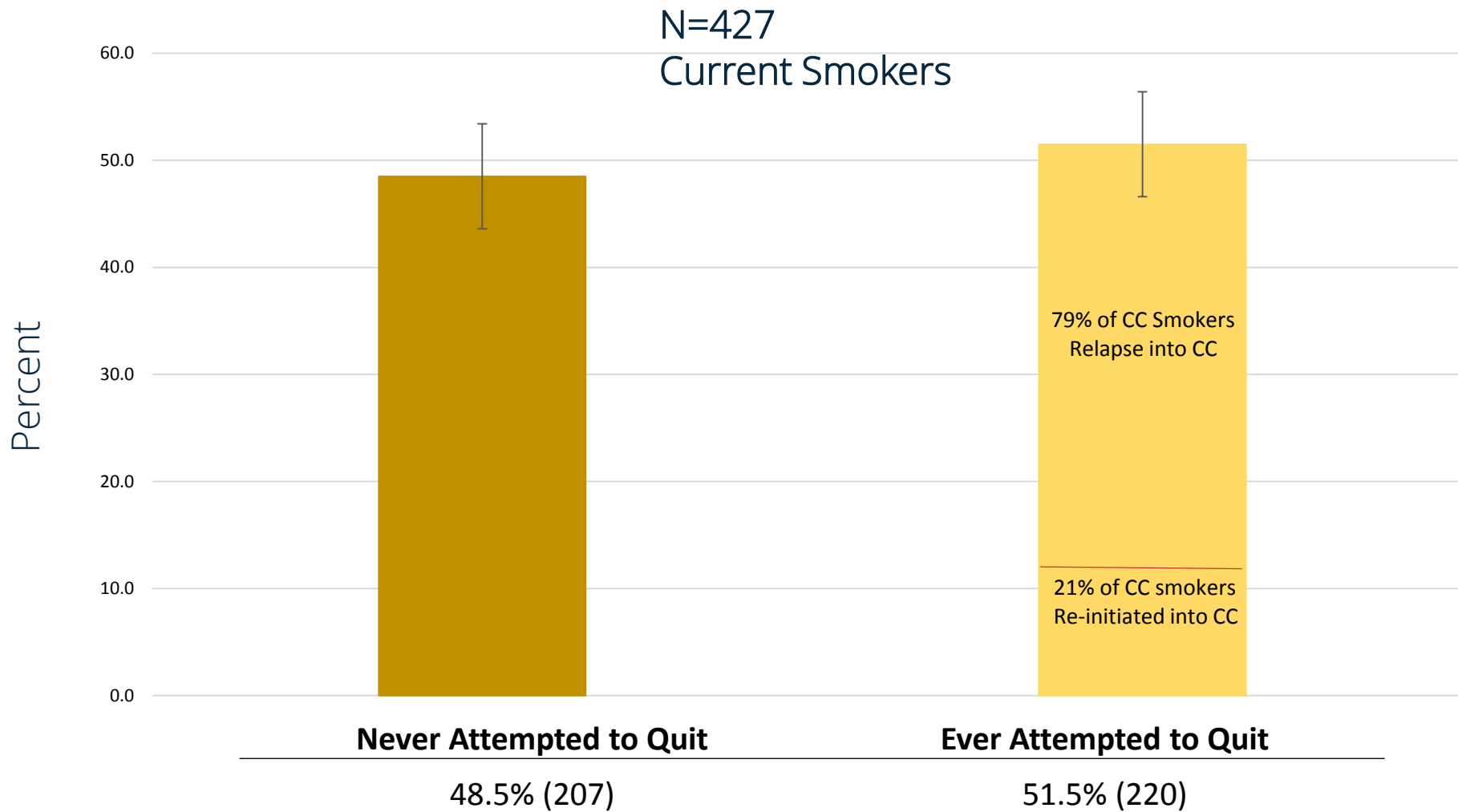


Out of all current tobacco users, 7% are IQOS users.

General Population Sample – Patterns of Use



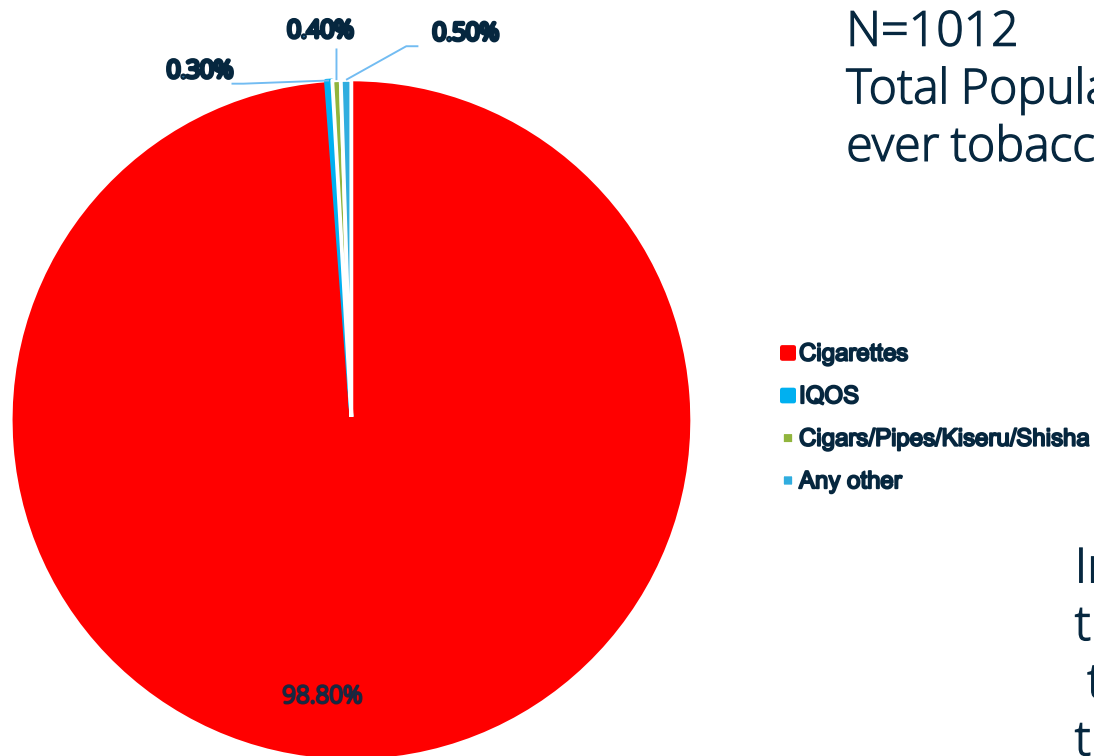
General Population - Relapse & Re-Initiation to CC



Out of the 51.5% CC smokers who quit smoking 79% relapsed into CC, while 21% reinitiated into CC.

Relapse = quitting < 12 months
Re-initiation = quitting ≥ 12 months

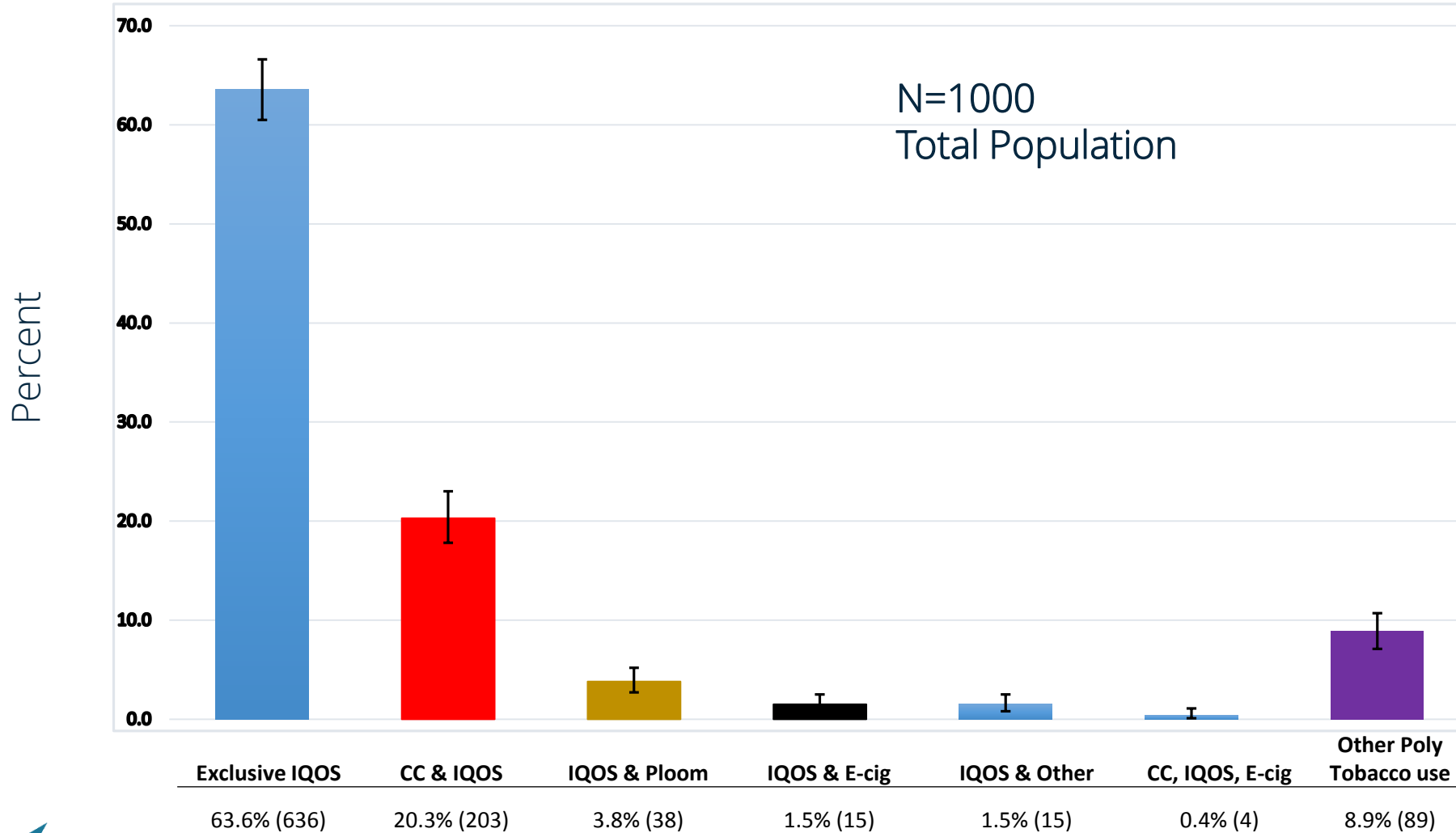
General Population - First Product Used



In the general population sample, to the question: "Please think back to the first tobacco or nicotine containing product that you ever used" 98.8% of all tobacco ever users responded they had initiated with CC, 0.4% with cigars, pipes, Kiseru or shisha and 0.3% with IQOS.

Cigarettes	IQOS	Cigar, Pipe, Kiseru	Any Other
98.8% (1000)	0.3% (3)	0.4 % (4)	0.5% (5)

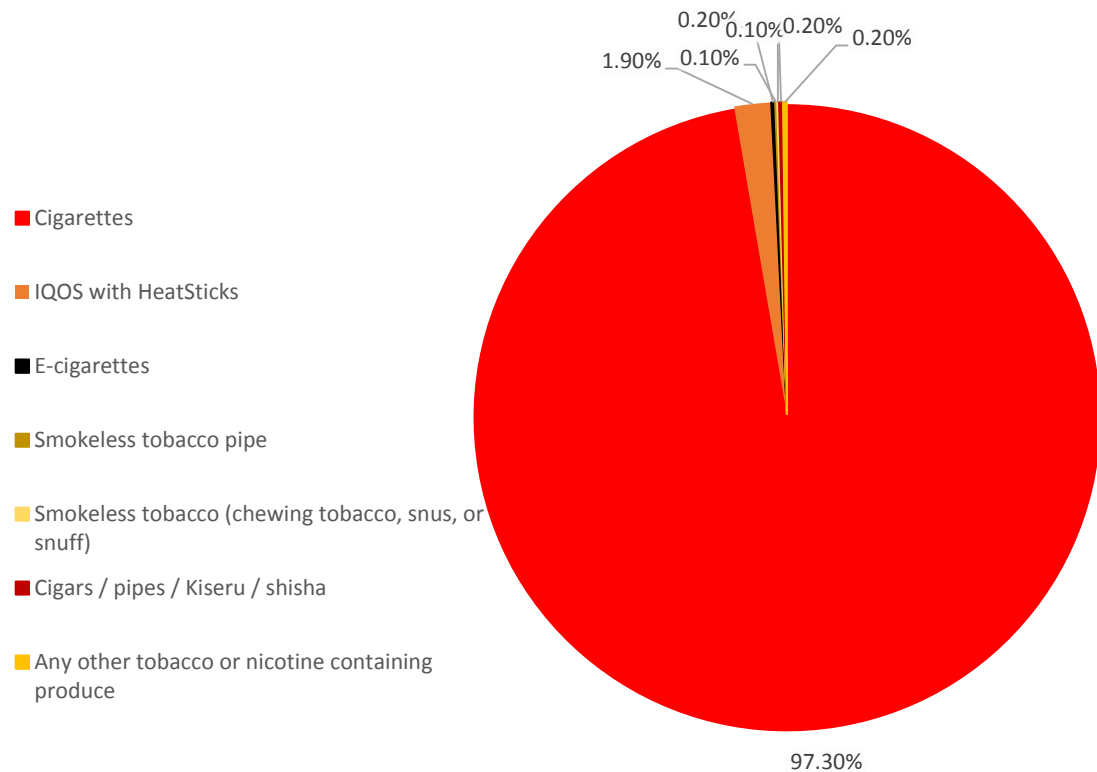
IQOS Users Sample – Patterns of Use



Out of all IQOS users
63.3% were exclusive
IQOS users.

IQOS User Sample- First Product Use

N=1000
Total Population



In the IQOS user sample, to the question: "Please think back to the first tobacco or nicotine containing product that you ever used" 97.3% of IQOS users responded they had initiated tobacco use with cigarettes and 1.9% with IQOS.

Cigarettes	IQOS	E-cig	Smokeless Tobacco Pipe	Smokeless Tobacco	Cigar, Pipe, Kiseru	Any Other
97.3% (973)	1.9% (19)	0.2% (2)	0.1% (1)	0.1% (1)	0.2% (2)	0.2% (2)

Conclusions (I)

- The prevalence of smoking in the general population was 17.8% (95%CI: 16.3-19.4%), the prevalence of IQOS use 1.2% (95%CI: 0.8-1.8%) and the use of e-cigarettes 0.5% (95%CI: 0.2-0.9%)
- The majority of tobacco users in both samples had initiated tobacco use with cigarettes, a very small percentage had initiated with IQOS (0.3% in the general population sample and 1.9% in the IQOS users sample)

Conclusions (II)

- Further waves will increase the precision of the prevalence estimates and will further contribute to the understanding of how IQOS is used under “real-world conditions” in Japan
- Generalizability of the General Sample:
 - Probability sampling method used for the general population sample
 - Joint age-sex distribution is comparable in the general sample and the Japanese population
 - Both unstandardized and standardized results were comparable
 - Results on the prevalence of smoking are consistent with the estimates provided by the WHO (19.3%) (2013 data) and the Japanese Health and Nutrition Survey (17.0%) (2015 data)

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