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

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“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

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)
• 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)
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 1\textsuperscript{st} and 2\textsuperscript{nd} 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
Oral Consent to Survey → Interviewer asks demographic questions → Interviewer provides Information Sheet for our Study → Self-Completion Questionnaire
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.
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
• 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

<table>
<thead>
<tr>
<th>Variable</th>
<th>General Population Sample</th>
<th>IQOS Users Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>53.6 (± 17.9)</td>
<td>38.5 (± 9.8)</td>
</tr>
<tr>
<td>Age group (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-29</td>
<td>11.0</td>
<td>21.0</td>
</tr>
<tr>
<td>30-39</td>
<td>14.9</td>
<td>36.8</td>
</tr>
<tr>
<td>40-49</td>
<td>18.3</td>
<td>28.4</td>
</tr>
<tr>
<td>50+</td>
<td>55.9</td>
<td>13.8</td>
</tr>
<tr>
<td>Sex:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (%)</td>
<td>48</td>
<td>82</td>
</tr>
<tr>
<td>Female (%)</td>
<td>52</td>
<td>18</td>
</tr>
</tbody>
</table>
### Sample populations

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Japanese population</th>
<th>General sample (95%CI)</th>
<th>IQOS Users Sample (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 - 29</td>
<td>11.3%</td>
<td>11.4% (9.5-13.4%)</td>
<td>20.3% (17.6-23.3%)</td>
</tr>
<tr>
<td>30 - 39</td>
<td>14.2%</td>
<td>17.6% (15.4-20.0%)</td>
<td>36.8% (33.4-40.2%)</td>
</tr>
<tr>
<td>40 - 49</td>
<td>16.9%</td>
<td>17.7% (15.5-20.1%)</td>
<td>28.9% (25.8-32.2%)</td>
</tr>
<tr>
<td>50+</td>
<td>57.5%</td>
<td>53.3% (20.3-56.2%)</td>
<td>14.0% (11.6-16.6%)</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 - 29</td>
<td>12.7%</td>
<td>10.6% (8.9-12.5%)</td>
<td>23.9% (17.9-30.8%)</td>
</tr>
<tr>
<td>30 - 39</td>
<td>15.9%</td>
<td>12.4% (10.6-14.4%)</td>
<td>37.0% (29.9-44.4%)</td>
</tr>
<tr>
<td>40 - 49</td>
<td>18.8%</td>
<td>18.8% (16.8-21.1%)</td>
<td>26.1% (19.9-33.1%)</td>
</tr>
<tr>
<td>50+</td>
<td>52.6%</td>
<td>58.2% (55.4-61.0%)</td>
<td>13.0% (8.5-18.6%)</td>
</tr>
<tr>
<td><strong>Total by sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>48.3%</td>
<td>47.8% (45.8-49.9%)</td>
<td>81.6% (79.0-84.0%)</td>
</tr>
<tr>
<td>Female</td>
<td>51.7%</td>
<td>52.2% (50.1-54.2%)</td>
<td>18.4% (16.0-21.0%)</td>
</tr>
<tr>
<td><strong>Total by age group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
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</tr>
<tr>
<td>50+</td>
<td>55.2%</td>
<td>55.9% (53.8-57.9%)</td>
<td>13.8% (11.7-16.1%)</td>
</tr>
</tbody>
</table>

Chi-square tests: sex (p=0.8), age (p=0.9)

Out of all current tobacco users, 7% are IQOS users.
General Population Sample – Patterns of Use

N=414
Current Tobacco Users

<table>
<thead>
<tr>
<th>Exclusive CC</th>
<th>Exclusive IQOS</th>
<th>Exclusive E-cig</th>
<th>Predominant CC</th>
<th>CC &amp; IQOS</th>
<th>IQOS &amp; E-cig</th>
<th>Multiple Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>92% (381)</td>
<td>1.9% (8)</td>
<td>0.2% (1)</td>
<td>3.4% (14)</td>
<td>1% (4)</td>
<td>0.5% (2)</td>
<td>1% (4)</td>
</tr>
</tbody>
</table>

CC= Cigarettes, E-cig = E-cigarettes
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
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.

<table>
<thead>
<tr>
<th>Product Type</th>
<th>N (%)</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarettes</td>
<td>98.8%</td>
<td>1000</td>
</tr>
<tr>
<td>IQOS</td>
<td>0.3%</td>
<td>3</td>
</tr>
<tr>
<td>Cigar, Pipe, Kiseru</td>
<td>0.4%</td>
<td>4</td>
</tr>
<tr>
<td>Any Other</td>
<td>0.5%</td>
<td>5</td>
</tr>
</tbody>
</table>
Out of all IQOS users 63.3% were exclusive IQOS users.
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.
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)
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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