

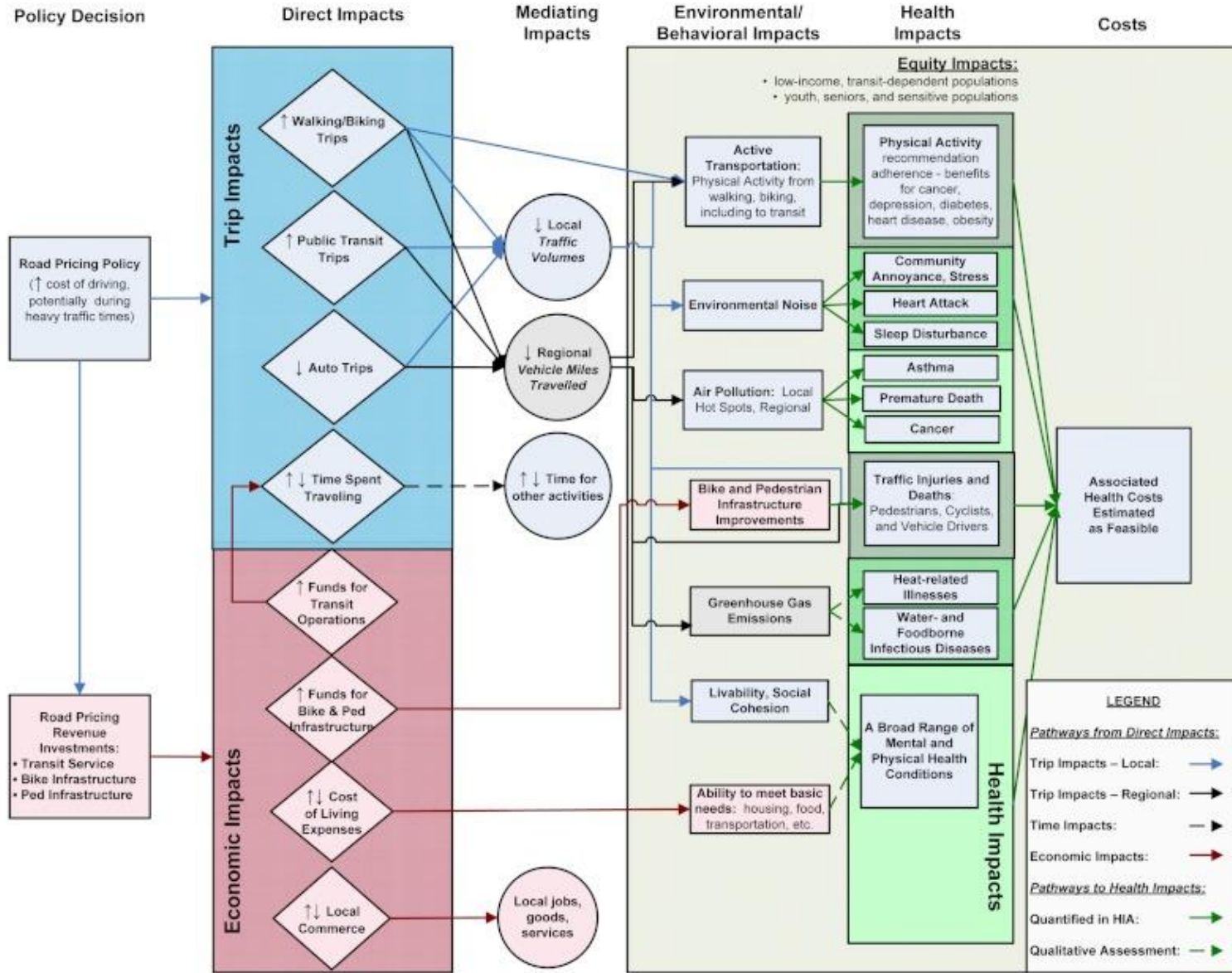
Refining The Modeling Assumptions To Understand The Population Health Impact After Introducing A Reduced-Risk Product Into A Market

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Director Global Scientific Engagement*

*Coresta Meeting – Hamburg , Germany
October 8, 2019*

Systematic process that uses an array of data sources & analytic methods. It considers input from stakeholders to determine the potential effects of a proposed policy, plan, program, or project on the health of a population and the distribution of the effects within the population.

Provides recommendations based on monitoring and managing those effects.



Health Impact Assessment



Characterization of health effects relies on qualitative and quantitative evidence.

- Local conditions and concerns
- Interviews with key informants
- Surveys
- Epidemiologic data (e.g., cross-sectional surveys, longitudinal studies, and intervention or experimental studies)
- Measurement of physical environmental/cultural conditions
- Expert opinion

Public Health Surveillance

- Identify patients and their contacts for treatment and intervention
- Detect epidemics, health problems, changes in health behaviors
- Estimate magnitude and scope of health problems
- Measure trends and characterize disease
- Monitor changes in infectious and environmental agents
- Assess effectiveness of programs and control measures
- Develop hypotheses and stimulate research

Source: CDC Course: "Introduction to Public Health Surveillance" (<https://www.cdc.gov/publichealth101/surveillance.html>)

Source: WHO HTPs Market Monitoring Information Sheet (<https://apps.who.int/iris/bitstream/handle/10665/273459/WHO-NMH-PND-18.7-eng.pdf>)

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Tobacco Harm Reduction -
The setting is different ... **BUT** ...
The principles are the same

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WHO – Surveillance to Monitor Heated Tobacco Products

- Collect Information on Users (demographics)
- Infrastructure should be established to collect and catalogue data & metrics
- Monitor growth trends in these products
- Development of metrics (e.g., product use, conversion rates, price, sales)
- Capture aspects of HTP positioning and sales strategy
- Track information on use through user surveys exploiting global surveys, etc.

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Original Japanese Modeling

Prior to Monitoring & Surveillance



Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

Estimating the population health impact of introducing a reduced-risk tobacco product into Japan. The effect of differing assumptions, and some comparisons with the U.S.

Peter N. Lee^a, Smilja Djurdjevic^{b,*}, Rolf Weitkunat^b, Gizelle Baker^b^a P.N. Lee Statistics and Computing Ltd., 17 Cedar Road, Sutton, Surrey, SM2 5DA, United Kingdom^b PMI R&D, Philip Morris Products S.A., Quai Jeanrenaud 5, CH-2000, Neuchâtel, Switzerland

ARTICLE INFO

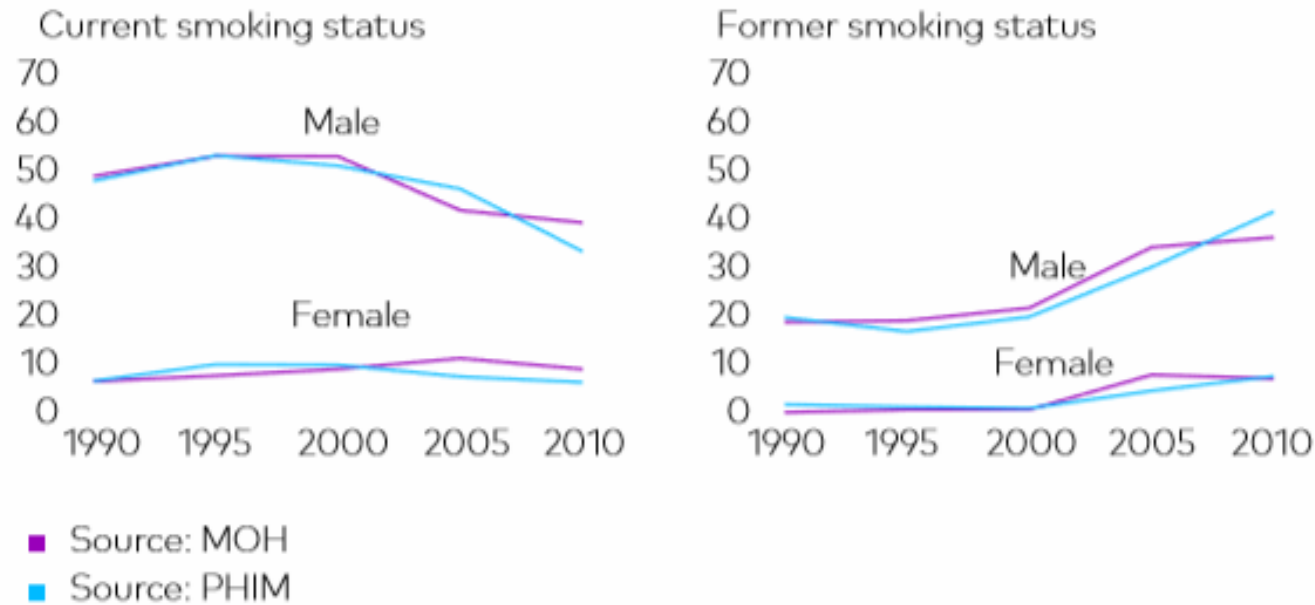
Keywords:

Smoking
Modelling
Attributable risk
Reduced-risk tobacco product
Harm reduction

ABSTRACT

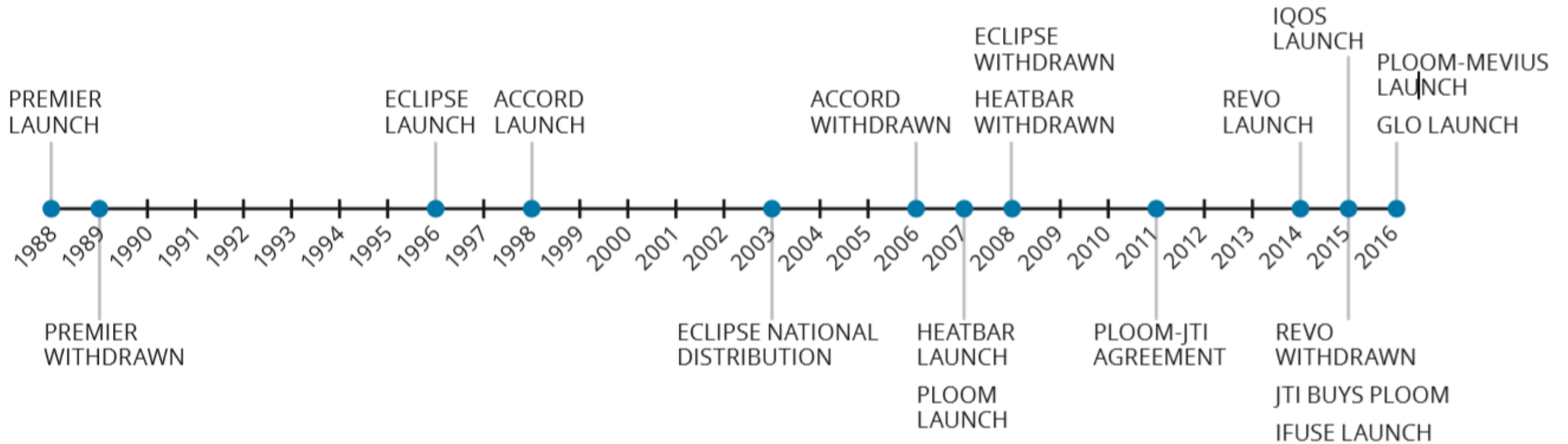
We estimated, using previously described methodology, the population health impact of introducing a reduced-risk tobacco product (RRP) into Japan. Various simulations were carried out to understand the impact on the population in different situations over a 20-year period from 1990. The overall reduction in tobacco-attributable deaths from lung cancer (LC), ischemic heart disease (IHD), stroke, and chronic obstructive pulmonary disease (COPD) for men and women combined was estimated to be 269,916 over the period if tobacco use disappeared completely at baseline. In contrast, reductions ranging from 167,041 to 232,519 deaths were estimated if the RRP totally replaced smoking at baseline (assuming that switching to it had an effect equivalent to 70%–90% of the effect of quitting). If, more plausibly, the RRP were introduced at baseline, with uptake rates consistent with the known uptake of the RRP IQOS[®], the reductions would still be substantial (from 65,126 to 86,885 deaths). Expressed as a percentage of attributable deaths, these proportions are larger than those for the U.S., based on likely uptake rates. We discuss various limitations of the approach, though none should affect the conclusion that the introduction of an RRP into Japan will substantially reduce tobacco-related deaths.

Smoking prevalence in 50-54 y/o age group. Comparison between Japan MOH data and PMI simulation



Cumulative Impact of THS Introduction on the Disease-Specific Mortalities 20 Years after the Introduction of RRP by Disease, Sex and f-value for all Ages Combined, all diseases (Lung cancer, COPD, Stroke, IHD) simulated for period 1990–2010

FIG. 1: HTP TIMELINE



Source: WHO HTPs Market Monitoring Information Sheet (<https://apps.who.int/iris/bitstream/handle/10665/273459/WHO-NMH-PND-18.7-eng.pdf>)

What can influence the Results and Interpretation?

Designing the Post-Market Surveillance

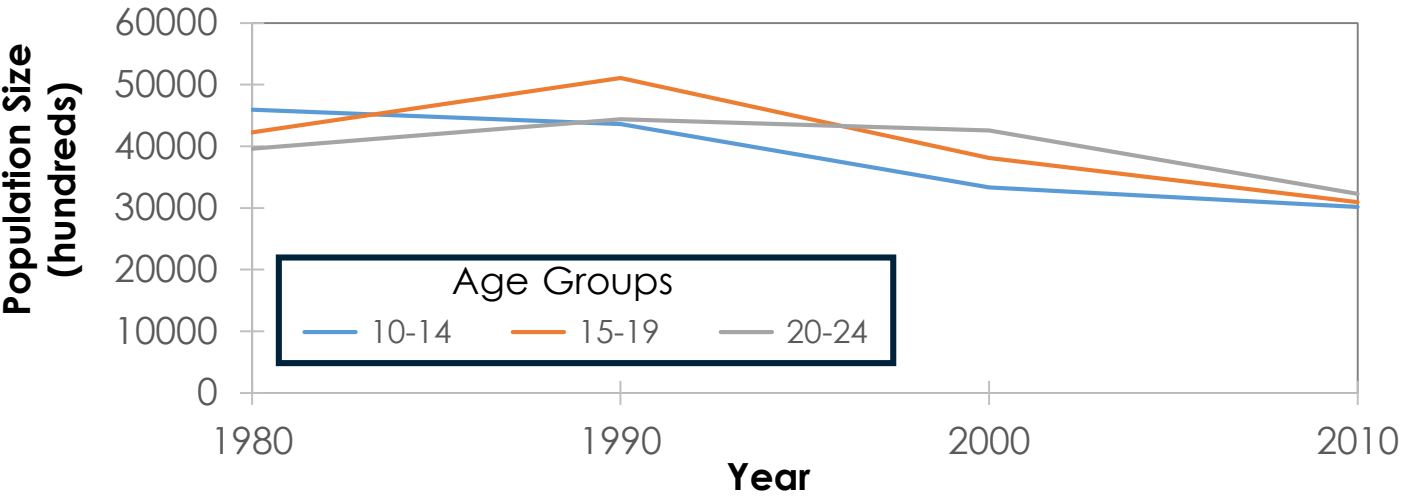
- Changes in a population
- Transition Probabilities
 - Who is switching to the RRP?
 - What is the rate of uptake?
 - What are the rates of use patterns?
 - Are there unintended consequences? (e.g., initiation)
- Population Relative Risk (the f-factor)
 - For exclusive use?
 - For dual use? (what is the pattern of dual use?)

Changes in the Japanese Population

Japanese Male Population - 2009

Country	Age	Population (hundreds)	% current smokers	% former smokers
Japan	10-14	43555	0.0	0.0
	15-19	51159	28.7	0.0
	20-24	44177	62.6	3.8
	25-29	40407	66.5	6.8
	30-34	38933	67.7	10.3
	35-39	45296	65.6	12.7
	40-44	52955	60.3	14.4
	45-49	44388	58.5	16.1
	50-54	39633	57.1	17.8
	55-59	37399	53.8	20.7
	60-64	31883	56.5	24.6
	65-69	21418	51.1	27.2
	70-74	15255	44.6	27.6
	75-79	11779	39.0	29.1

WHO Data: Japan Population 1980-2010

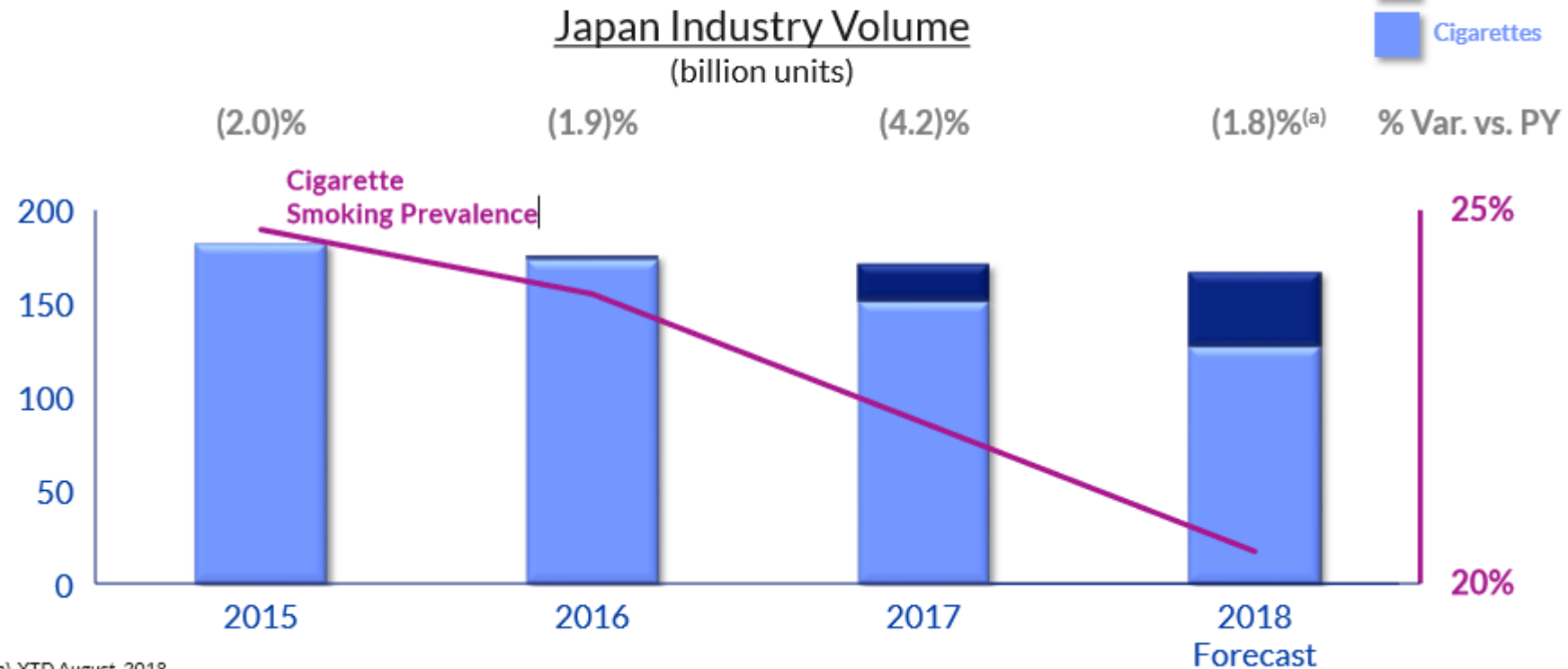


Source: <https://doi.org/10.1016/j.yrtph.2018.10.010> - Submitted August 2018.

Source: Population – United Nations Department of Economic and Social Affairs Population Division (2015)



RRPs: The Single Most Impactful Tool in Reducing Cigarette Consumption



(a) YTD August, 2018

Note: Industry volume reflects cigarettes and heated tobacco units

Source: PMI Financials or estimates, Tobacco Institute of Japan and PMI Market Research



Research paper

Effect of IQOS introduction on cigarette sales: evidence of decline and replacement

Michal Stoklosa,¹ Zachary Cahn,¹ Alex Liber,¹ Nigar Nargis,² Jeffrey Drope¹

► Additional material is published online only. To view please visit the journal online (<http://dx.doi.org/10.1136/tobaccocontrol-2019-054998>).

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Received 7 February 2019
 Revised 2 April 2019
 Accepted 29 April 2019

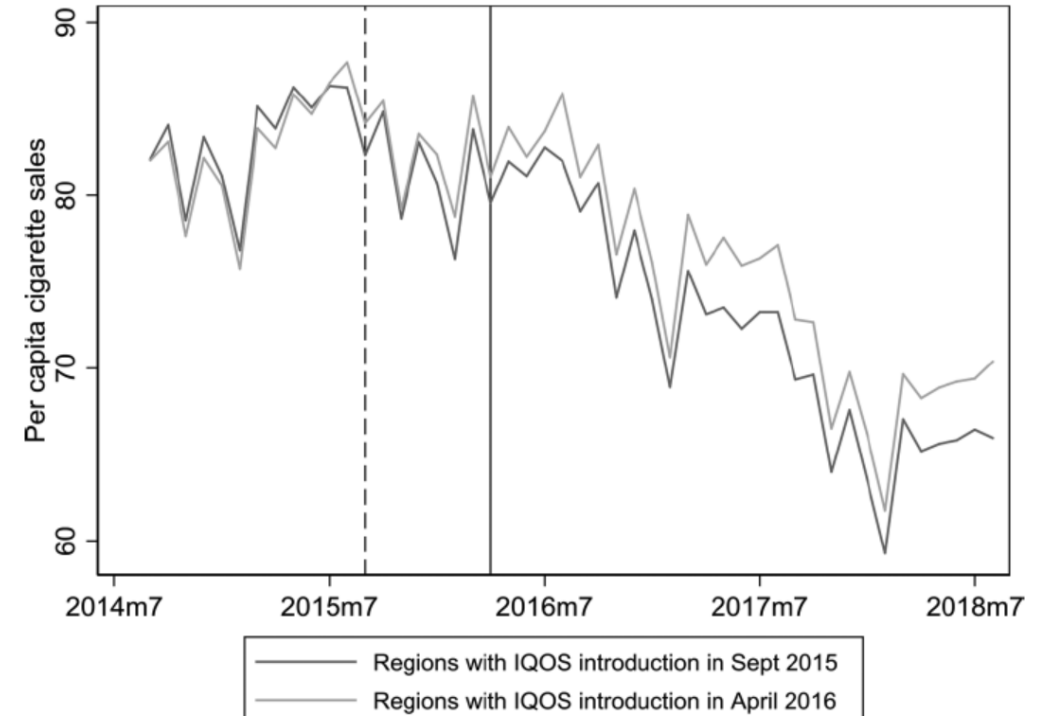
ABSTRACT

Background Philip Morris International, one of the largest transnational cigarette manufacturers, has heavily invested in its new heated tobacco product, IQOS, marketing it aggressively as a less harmful alternative to cigarette smoking. The company's assertions that the product replaces cigarettes in a market have never been independently tested. The objective of this study is to determine whether introduction of IQOS affected cigarette sales in a large economy.

Data and Methods Using 2014 to 2018 monthly retailer panel data from Japan, we analyse whether different dates of IQOS introduction across Japan's regions are reflected in the patterns of cigarette sales in those regions. A series of placebo models are estimated to test if events other than IQOS introduction could have better explained the observed trends in cigarette sales.

Results Cigarette sales begin to substantially decline at the time of the introduction of IQOS in each of 11 Japanese regions (Chow tests $p < 0.001$). IQOS

regular cigarettes. Unlike regular cigarettes, which combust tobacco leaves, HTPs heat a processed tobacco leaf substance at a high temperature slightly short of combustion. Unlike e-cigarettes, which aerosolise a liquid containing varying amounts of nicotine (or no nicotine at all), HTPs release the nicotine directly from tobacco leaf. The product has begun to show substantial sales growth in several countries where they have been introduced. Available in more than 44 countries as of the first quarter of 2019,¹ growth has been especially strong in Japan and Korea.^{2,3} The global HTP market leader is IQOS from Philip Morris International (PMI), which the company claims to generate a significantly lower quantity of "harmful or potentially harmful chemicals" compared with combustible cigarettes.⁴ PMI recently filed an application with the US Food and Drug Administration to commercialise the product in the USA.⁵ The application was recently approved.⁶ The company predicts



TIME

A Device That Heats Tobacco, But Doesn't Burn It, Can Now Be Sold in the U.S. Here's What to Know About IQOS

HREN

ays it has doubled supply of device in Japan

HEALTH • PUBLIC HEALTH

A Device Burn It, C V

JAPAN

Ja with new products

Taiga Uranaka

IQOS had a 71.8 percent share of Japan's H
Tobacco's (BATS.L) glo had 20.1 percent a
estimates.

HNB products accounted for 20.9 percent of Japan's tobacco
percent a year ago, according to an estimate by Satoshi Fujiw

Japan Tobacco has said it expects vaping products to account for 30 percent of the
domestic tobacco market by end-2020 and will spend heavily in the field as cigarette
sales drop.

Choose the option that is NOT a source of data used
for public health surveillance.

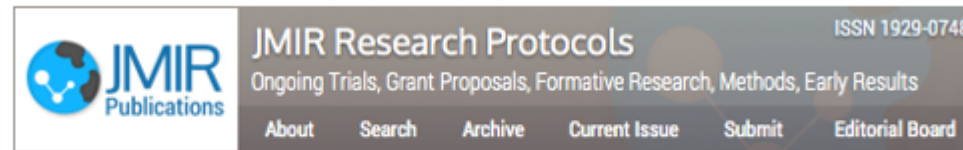
- A. Administrative data systems
- B. Vital records
- ✓ C. Newspaper articles
- D. Disease notifications
- E. Scientific Literature

Philip Morris International (NYSE:PM) may have cut its full-year earnings guidance simply because of unfavorable currency exchange rate fluctuations in Argentina and Turkey. While that wasn't completely unexpected, the [continued declining fortune](#) of its IQOS heat-not-burn electronic cigarette in Japan, its largest market for the device, is the real worrisome development.

GELESEN IN 3 MINUTEN



id on Thursday it has more than
rice in Japan, but demand continues
over smokeless products.



[JMIR Res Protoc](#). 2019 May; 8(5): e12061.

PMCID: PMC6532333

Published online 2019 May 9. doi: [10.2196/12061](https://doi.org/10.2196/12061)

PMID: [31094340](https://pubmed.ncbi.nlm.nih.gov/31094340/)

Household Surveys in the General Population and Web-Based Surveys in IQOS Users Registered at the Philip Morris International IQOS User Database: Protocols on the Use of Tobacco- and Nicotine-Containing Products in Germany, Italy, and the United Kingdom (Greater London), 2018-2020

Monitoring Editor: Gunther Eysenbach

Reviewed by Sabrina Kastaun and James Thrasher

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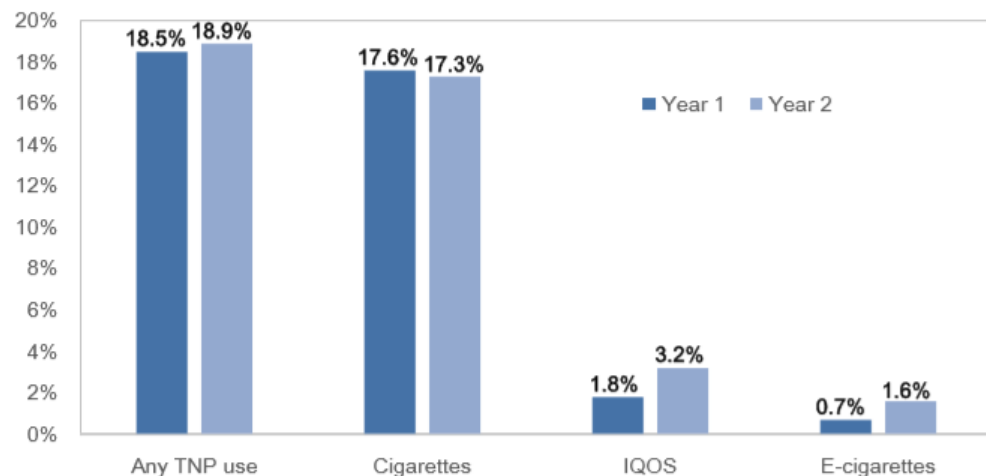
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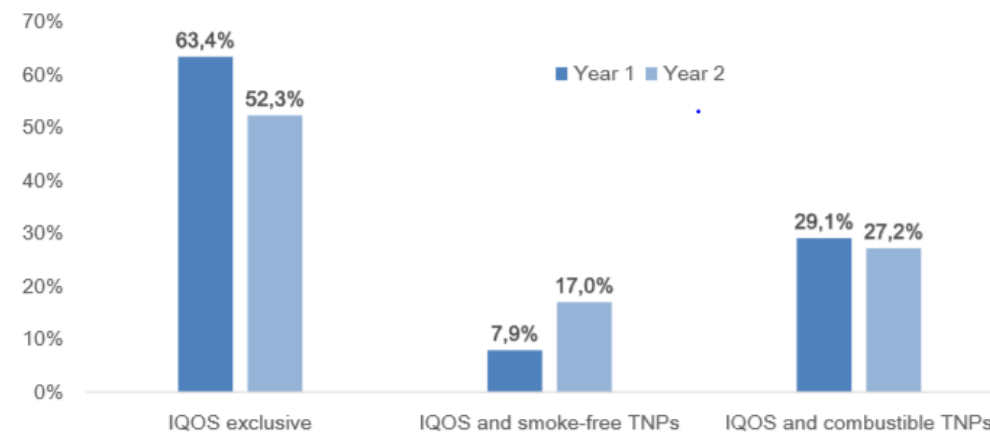
General Population Survey

Figure 1. Prevalence of use

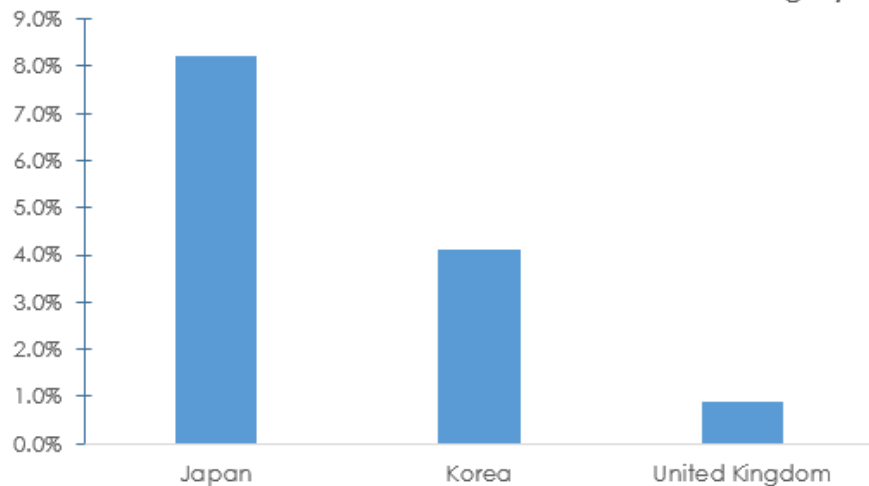


IQOS User Survey

Figure 2. Pattern of use



Euromonitor 2019 Data - Heat Not Burn Category



Source: <https://www.pmiscience.com/discover/news/GFN-2019-day-2>

Source: Euromonitor report

England prevalence rate

Smoking prevalence in England is at a **record low**



Surveillance System Attributes

Attribute	Question It Answers
Usefulness	How useful is the system in accomplishing its objectives?
Data quality	How reliable are the available data? How complete and accurate are data fields in the reports received by the system?
Timeliness	How quickly are reports received?
Flexibility	How quickly can the system adapt to changes?
Simplicity	How easy is the system's operation?

Surveillance System Attributes

Attribute	Question It Answers
Stability	Does the surveillance system work well? Does it break down often?
Sensitivity	How well does it capture the intended cases?
Predictive value positive	How many of the reported cases meet the case definition?
Representativeness	How good is the system at representing the population under surveillance?
Acceptability	How easy is the system's operation?