Bogotá D.C., septiembre 29 de 2020

Señora
Carolina Piñeros Ospina
Representante legal – directora ejecutiva
Red PaPaz
Ciudad.

Asunto. Respuesta a petición de información en relación con el Proyecto de Ley número 339 de 2020 Senado "Por la cual se actualiza y modifica el impuesto al consumo de cigarrillos, tabaco elaborado y productos afines y se dictan otras disposiciones".

Cordial Saludo.

Extendiendo nuestro más sincero saludo en estos tiempos de pandemia y esperando se encuentre usted bien de salud, a continuación damos respuesta a la petición remitida por usted el día 25 de septiembre de 2020, solicitando la siguiente información:

1. Copia del documento titulado "Sensibilidad de las ventas de cigarrillo legal al contrabando en Colombia" del Profesor Jorge Tovar de la Universidad de los Andes, realizado en 2016 con la financiación de la Compañía Colombiana de Tabaco, y que se cita en la Exposición de Motivos del Proyecto de Ley.
2. Copia de los documentos en los que se apoya la siguiente afirmación contenida en la Exposición de Motivos del Proyecto de Ley:

> Igualmente, con el propósito de profundizar las acciones de promoción de hábitos de consumo más sanos, procura la introducción de medidas tributarias para que, conforme a las leyes de oferta y demanda, se promueva la migración del consumo de cigarrillos tradicionales hacia los nuevos dispositivos, que según la literatura científica recogida hasta el momento, implican un menor riesgo sobre la salud de los consumidores, al evitar la combustión. (Subrayas no originales).

En referencia a lo anterior, se anexan algunos documentos de la siguiente manera:

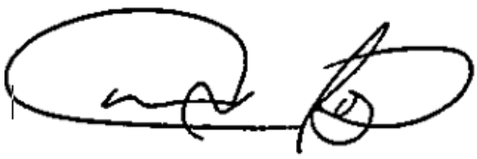
1. Anexo 1, con el documento del profesor Jorge Tovar de la Universidad de Los Andes, titulado "Sensibilidad de las ventas de cigarrillo legal al contrabando en Colombia" del año 2016.
2. Anexo 2, 3 y 4, con los siguientes documentos que soportan la afirmación relacionada en el texto subrayado en el numeral dos de la petición allegada, que a su vez están relacionados en la exposición de motivos del proyecto de ley en cuestión.
    - Etter, Jean-Francois & Queloz Sebastien (2019). "An online survey of users of tobacco vaporizers, reasons and modes of utilization, perceived advantages and perceived risks". Public Health. N° 19.

- Bates, Clive. "Tobacco harm reduction in England – England's Tobacco Control Plan". Internationale Erfahrungen. Páginas 168-185.
- Bekki, K., Inaba Y., Uchiyama S., Kunugita N. (2017). "Comparison of Chemicals in Mainstream Smoke in Heat-not-burn Tobacco and Combustion Cigarettes". Department of Environmental Health, National Institute of Public Health. Chemical Evaluation of Heat-not-burn Tobacco. Páginas 201-207.

De esta manera queda resuelta la petición, en los términos que exige el artículo 23 de la Constitución y la jurisprudencia vigente a propósito del derecho de petición.

Agradecemos su atención y quedamos atentos a cualquier requerimiento e información.

Cordialmente.



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Sensibilidad de las ventas de cigarrillo legal al contrabando en Colombia

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Bogotá 12 de Octubre 2016

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Introducción

El contrabando es una de las actividades ilegales que más daño hace a la economía de un país. Por un lado, anotan por ejemplo Buehn y Farzanegan (2012) estudiando el caso de 54 países (entre los que no está Colombia), el contrabando se asocia a altos niveles de corrupción, a la baja capacidad para cumplir la normativa vigente, además de a impuestos y aranceles altos. Por otro lado, como anota Lovenheim (2008) para el caso específico de cigarrillos, el contrabando impacta negativamente las ventas del producto legal. En esta línea, y analizando el caso de la frontera entre los Estados Unidos y México, Buehn y Eichler (2009) estudian la problemática del contrabando diferenciando explícitamente entre aquel relacionado con bienes ilegales y el relacionado con bienes legales. En el caso de estos últimos concluyen que la evasión tanto de aranceles como impuestos son grandes motivadores del contrabando. En general, por tanto, hay evidencia que sugiere que el contrabando tiene efectos dañinos sobre la economía.

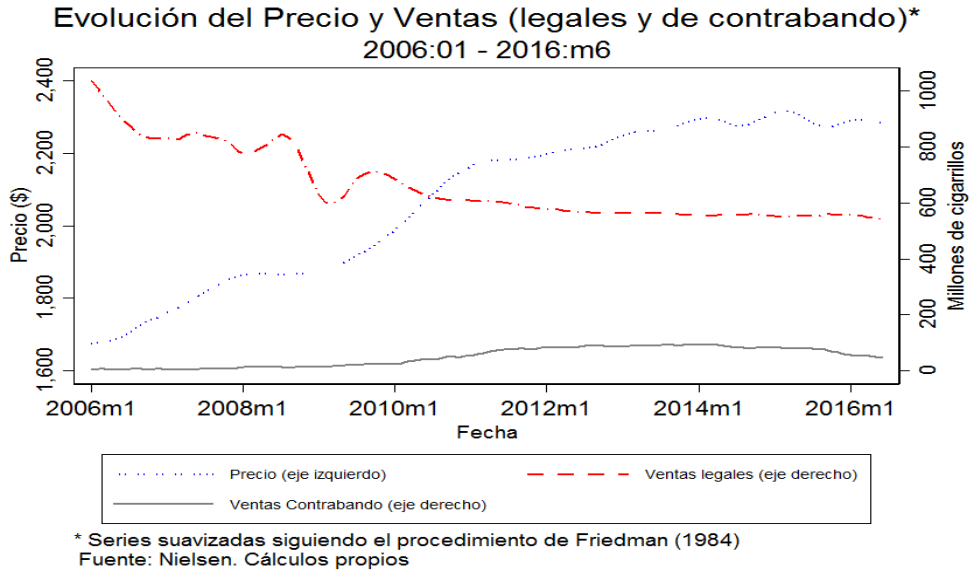
Este trabajo, enfocándose en los cigarrillos, cuantifica el impacto del contrabando sobre el mercado formal en Colombia. Para ello se utilizan dos aproximaciones. Por un lado, se estima el impacto de las ventas de contrabando sobre las ventas legales. Por otro, se estima la elasticidad cruzada entre el contrabando y ventas legales.

Datos

El ejercicio se basa en datos mensuales facilitados por la Compañía Colombiana de Tabacos S.A. (Coltabaco), para el período que va desde enero del 2006 a junio de 2016. Hay datos disponibles de ventas (millones) de cigarrillos, así como del precio por segmento. El precio de los cigarrillos se agrega mensualmente estimando el promedio ponderado por las cantidades vendidas. Hay dos variables adicionales: el valor del impuesto (que se agrega mensualmente siguiendo los mismos principios que en el caso del precio) y las cantidades de contrabando. Esta última información no viene desagregada por segmentos.

Originalmente hay 2159 observaciones que se reducen a 1393 una vez se eliminan las observaciones que no cuentan simultáneamente con datos de precios, cantidades y/o impuestos. Una vez agregada la información mensualmente hay 126 observaciones disponibles.

Figura 1



* Series suavizadas siguiendo el procedimiento de Friedman (1984)
Fuente: Nielsen. Cálculos propios

La Figura 1 presenta la evolución suavizada de los precios, las ventas legales y (sin suavizar) de contrabando. Se observa un incremento de los precios explicado en buena parte por un incremento real del impuesto de 28,5% a comienzos del 2010 (Tovar 2015).

Contrabando Ventas Legales

El impacto del contrabando en las ventas legales se modela siguiendo a Gruber et al. (2003). El modelo a estimar se basa en la siguiente ecuación:

$$Q_t = \alpha + \beta P_t + \gamma C_t + \theta X_t + \varepsilon_t \qquad (1)$$

En la ecuación (1), Q_t hace referencia a las ventas legales observadas en el período t. P_t es el precio en t y X_t incluye los controles relevantes que en este caso son efectos fijos de año para controlar por diferencias macroeconómicas o sectoriales que puedan afectar Q, variables indicadores de trimestre que controlan por estacionalidad y una tendencia para capturar la evolución de las ventas[2].

[2] En otras especificaciones se controló por desempleo mensual como indicador del ciclo económico, pero no resultó estadísticamente significativo y, además, no impactó de manera relevante los coeficientes de interés.

En el modelo de Gruber et al. (2003), a diferencia de lo que se tiene en este caso, no hay datos directos de contrabando, por lo cual deben seguir un camino indirecto para estimar las elasticidades deseadas. En particular, anotan en su trabajo, en la medida que exista un monto relevante de contrabando, ignorar esta variable puede resultar en estimativos sesgados. La primera sugerencia para corregir el problema es incluir directamente en el modelo una medida de contrabando. Si bien ellos no lo pueden hacer, en el caso que nos atañe sí es posible incluir esta variable directamente: C_t.

En la ecuación (1), el precio puede ser endógeno. En este caso, como en Gruber et al. (2003) o Galbraith y Kaiserman (1997) se explota la información de impuestos disponibles[3]. Galbraith y Kaiserman (1997) anotan que en el caso de los cigarrillos, la endogeneidad del precio puede verse atenuada porque la variación del precio está en gran parte inducida por el impuesto existente. En el caso colombiano esto también es una posibilidad. De hecho, los resultados de la estimación por mínimos cuadrados ordinarios (sin instrumentar) y la versión instrumentada son muy similares. A continuación se presentan los resultados instrumentados mediante el método de *información limitada de máxima verosimilitud* ideal para ejercicios con un número relativamente bajo de observaciones en su versión log-log.[4]

La Tabla 1 muestra los resultados obtenidos de estimar por variables instrumentales la ecuación (1). Los coeficientes estimados muestran los signos esperados incluido el de interés, γ. Al ser los estimativos en logaritmos, los coeficientes se pueden interpretar directamente como elasticidades: un incremento de un 1% en el contrabando va a reducir en 0,27% las ventas de cigarrillo legal. Considerando que en promedio se venden 49 millones de unidades de contrabando al mes, un incremento de 490,000 unidades, reducirá la ventas legales (que venden en promedio 658 millones al mes) en 1,776.000 unidades al mes.

[3] Otros estudios, como Tovar (2012) han utilizado este tipo de instrumentos para corregir la endogeneidad potencial de los precios.

[4] La versión en niveles presenta resultados cualitativamente iguales. Se controló por autocorrelación serial de los errores.

Tabla 1

Impacto de Contrabando en las Ventas Legales	
	(a)
Variable dependiente Cantidad Ventas Legales	
Precio cigarrillo legal	-5.59
	[1.76]***
Ventas de Contrabando	-0.27
	[0.15]*
Dummy Primer Trimestre	-0.18
	[0.05]***
Dummy Segundo Trimestre	-0.119
	[0.05]***
Dummy Tercer Trimestre	-0.093
	[0.04]**
Trend	0.005
	[0.00]**
Constante	47.97
	[12.86]***
Efectos fijos de año	Si
R2	0.59
Observaciones	126
Errores estándar en corchetes	
* Significativo al 10%, ** al 5%, ***al 1%	
Fuente: Nielsen. Cállculos propios	

La Tabla 1 presenta una elasticidad precio de la demanda alta para lo que suele ser común en trabajos desarrollados para el sector de cigarrillos. Si bien, en este caso no es la variable de interés, si vale la pena discutir el resultado, en particular establecer la validez estadística del instrumento. Para ello, en primer lugar se revisa el R^2 y el estadístico *F* de la primera etapa. El primero es 0.97. El segundo rechaza la hipótesis de que todos los controles sean simultáneamente cero con un nivel de significancia del 1%. Además, la prueba F de los instrumentos excluidos también rechaza la hipótesis nula de que sean cero. Se revisó también la prueba LM de *Kleibergen-Paap* para comprobar si el modelo se encuentra subidentificado. Con un $Chi^2(1)$ igual a 7.30 se rechaza al 1% de significancia la hipótesis nula de que el modelo está subidentificado[5]. En conclusión, el instrumento es válido y, estadísticamente hablando, el resultado es válido.

Una vez establecida la validez estadística del ejercicio, procedemos a investigar económicamente el valor obtenido de la elasticidad precio de la demanda. Para ello se corrieron algunas

[5] También se realizan pruebas de que los instrumentos sean débiles. En todos los casos se rechazó está hipótesis. En este caso es un resultado natural porque el instrumento utilizado es relativamente estándar y de frecuente uso en la literatura de estimación de demanda.

regresiones restringidas (es decir, ignorando algunas variables consideradas en nuestro modelo). Inicialmente se corrió la regresión planteada en la ecuación (1), excluyendo inicialmente las variables menos tradicionales: tendencia y las cantidades de contrabando. En este caso, siempre utilizando el mismo instrumento descrito con anterioridad, la elasticidad precio de la demanda se reduce (en valor absoluto) a -1,7, un valor más parecido a estimaciones previas. Al agregar la tendencia, aún sin incorporar la variable de contrabando, la elasticidad sube (en valor absoluto) a -3,6. En este punto se decidió evaluar en detalle la definición de tendencia. El indicador de tendencia utilizado es mensual. Por tanto, se procedió a definir tendencia anual y ver el impacto de está tanto en este ejercicio restringido como en el modelo completo de la ecuación (1). En la versión restringida (sin variable de contrabando) la tendencia anual no es significativa. En el modelo completo (incluyendo la variable de contrabando), la tendencia anual es marginalmente significativa al 10%.

La tendencia captura la evolución de las ventas del sector independiente de factores como el precio, estacionales o choques normativos anuales. El signo positivo sugiere que, *ceteris paribus*, hay un efecto incremental sobre las ventas de cigarrillos durante el período considerado. El coeficiente, en términos económicos, es lo suficientemente bajo para argumentar que si bien tiende a subir su impacto es bajo sobre las ventas. Parece, por tanto, relevante mantenerla.

Al introducir la variable de contrabando y correr la ecuación (1), la elasticidad aumenta (en valor absoluto) al nivel reportado en la Tabla 1. Cabe anotar que si se excluye la tendencia de la ecuación (1), la elasticidad precio de la demanda es -4,9. Si bien es más baja que lo reportado en la Tabla 1, aún es relativamente alta.

Revisada la validez estadística y económica del modelo, se concluye que al incorporar el contrabando a la ecuación (1), la sensibilidad del precio a las ventas legales aumenta. Es decir, el impacto del contrabando se da a través de dos efectos, uno directo, otro indirecto. El directo, que captura la Tabla 1, es que un incremento del contrabando reduce las ventas legales. Otros, indirecto, es que un incremento del contrabando vuelve más sensible las ventas legales a cambios en los precios. Esta hipótesis se evalúa en la siguiente sección.

Modelo de Demanda

Estimar un modelo completo de demanda exige información de precios y de cantidades, tanto de cigarrillos legales como de cigarrillos de contrabando. La información de precios de contrabando, sin embargo, es tremendamente limitada. Se construyó, de manera indirecta (asumiendo que por definición el contrabando no paga impuestos), una serie deduciendo del precio de cigarrillos legales el impuesto al consumo pagado[6]. El resultado se comparó con el precio del contrabando disponible para junio de 2016, el cual resultó ser algo más alto del estimado. Por tanto, la serie de contrabando a utilizar se ajustó con base en la diferencia entre el precio legal de cigarrillos de segmento bajo y medio-bajo de 2016 y el precio de contrabando disponible para junio de 2016. El resultado se utilizó en los modelos de demanda.

Con la información descrita se procedió a estimar un modelo tipo *Almost Ideal Demand System* (AIDS) desarrollado por Deaton y Mullbauer (1980) y expandido por Banks et al. (1997). El modelo, depende de la validez de la información para poder estimar además las participaciones en el gasto necesarias para estimar el modelo de ecuaciones simultáneamente. La estimación del modelo AIDS, sin embargo, no resultó satisfactoria. Utilizar simultáneamente información de cantidades y precios de contrabando, ambos por definición (particularmente los precios) con errores de medición en un sistema de ecuaciones generó problemas insalvables. Además, hay que tener en cuenta que por construcción de la serie de precios de contrabando, la variación relativa respecto a los cigarrillos de segmentos bajos es, esencialmente nula. El modelo estimado resultó altamente inestable, sin robustez para poder garantizar que los coeficientes estimados fuesen válidos. Esto derivó en elasticidades propias de la demanda que no eran estadísticamente significativas y elasticidades cruzadas no muy confiables.

Dado lo anterior se procedió a estimar un modelo de demanda log-log que, como anota Alston et al. (2002), sigue siendo utilizado en modelos enfocados en bienes individuales. La principal diferencia con el modelo AIDS es que no se estima por medio de ecuaciones simultáneas, sino que se estima la demanda de cada bien de manera independiente. El modelo a estimar se define por la siguiente ecuación:

$$\ln Q_{it} = \alpha + \eta_{i1} \ln P_{1t} + \eta_{i2} \ln P_{2t} + \eta_{i3} \ln P_{3t} + \eta_{i4} \ln P_{4\tau} + \eta_{im} \ln M_t + \varepsilon_t \qquad (2)$$

[6] En este caso se agregaron los segmentos como bajo que incluye cigarrillos de segmento bajo y medio-bajo, medio, que incluye medio-alto y algo y segmento premium.

donde *Q* hace referencia a cantidad de cigarrillos vendidos del segmento *i*, P_i, *i=1….4* son los cuatro segmentos de cigarrillos en que se dividió la muestra (contrabando, bajo y medio-bajo, medio-alto y alto, y premium) y *M* es el ingreso[7]. Se impuso además la condición de homogeneidad exigida por la teoría:

$$\eta_{i1} + \eta_{i2} + \eta_{i3} + \eta_{i4} + \eta_{im} = 1 \qquad (3)$$

La ecuación (3) establece que la suma de las elasticidades de demanda del bien *i* (incluido el ingreso) deben ser igual a cero. Se procede a estimar, por tanto, la ecuación (2) sujeta a la restricción (3). La estimación debe corregir dos problemas adicionales: la endogeneidad del precio del bien *i* y del gasto total[8].

Se estima la ecuación (3) para *i* igual al segmento de contrabando y segmento bajo y bajo-medio utilizando como instrumento para el segmento bajo y bajo-medio el impuesto correspondiente. Cuando *i* es igual a contrabando además del tradicional problema de endogeneidad en el precio puede haber un problema de medición. Dado que por definición no hay impuestos para los cigarrillos de contrabando no se puede utilizar éste como instrumento. Como instrumento del precio de contrabando se utiliza el impuesto a los cigarrillos del segmento bajo y bajo-medio que sin dudas son exógenos y además están correlacionados. El modelo se estima por mínimos cuadrados en tres etapas. Nótese que se estiman dos modelos de la ecuación (2). Uno para el segmento de contrabando, y otro para el segmento bajo y medio-bajo.

[7] El ingreso en este caso se construye con base en la información de precio y cantidades disponibles. Es decir, en la práctica es el gasto total en cigarrillos por parte de los consumidores.

[8] Una función teórica de demanda incluye como control el ingreso. Cuando no está disponible es válido incluir el gasto total, estimado por el precio por la cantidad, pero ello puede estar correlaciona con el error (Alston et al., 2002).

Tabla 2

Elasticidad cruzada entre cigarillos de contrabando y del segmento bajo y Medio Bajo

	Contrabando	Segmento Bajo . Medio-Bajo
Contrabando	-1.468 [0.44]***	1.408 [0.50]***
Segmento Bajo . Medio- Bajo	2.238 [1.03]**	-3.652 [1.18]***

La casilla *(i,j)* se interpreta como el cambio en la demanda de *j* ante una variación en el precio de *i*

Errores estándar en corchetes

* Significativo al 10%, ** al 5%, ***al 1%

Fuente: Nielsen. Cálculos propios

La ecuación (2) se estima incluyendo como en Alston et al. (2002) controles de estacionalidad trimestral, tendencia, tendencia al cuadrado y, además, efectos fijos de año. La Tabla 2 reporta las elasticidades obtenidas a partir dos estimaciones: una con la cantidad de contrabando como variable dependiente, otra con la cantidad de cigarrillos de segmento bajo y bajo-medio. En ninguna de las dos ecuaciones hay evidencia estadística de sustituibilidad entre el contrabando (o el segmento bajo y medio - bajo) y cigarrillos de segmento medio-alto y alto o Premium. La elasticidad propia de la demanda es algo más baja que la reportada en la Tabla 1, pero las dos ecuaciones no son directamente comparables[9].

Los resultados de la Tabla 2 (primera columna) indican que un incremento del 10% en el precio de los cigarrillos de segmento bajo y medio-bajo lleva a incrementos de 22% en la cantidad contrabandeada. En otras palabras, un incremento de esa magnitud en el precio, utilizando la cantidad de contrabando promedio para el período considerado, llevaría a la entrada ilegal al país de casi 11 millones de unidades adicionales.

[9] Por un lado está estimación es por segmento y, como se anotó antes, incluir la cantidad de contrabando tiene un efecto notorio sobre la elasticidad propia.

La segunda columna muestra que incrementos de 10% en el precio del cigarrillo de contrabando conlleva aumentos en la demanda de cigarrillos legales de 14%. Es decir, a medida que la lucha contra el contrabando se haga más eficaz, el impacto sobre los operadores legales será positivo.

Conclusión

Este documento ha realizado dos ejercicios para entender el impacto del contrabando sobre las ventas legales de cigarrillos en Colombia. El primer ejercicio evaluó el impacto directo del contrabando sobre las ventas de cigarrillos legales en Colombia. El segundo ejercicio cuantificó el impacto que un incremento en el precio de los cigarrillos legales tendría sobre las ventas de cigarrillos legales, específicamente sobre las ventas del segmento bajo y medio-bajo.

Con respecto al primer ejercicio se encontró que un incremento de un 10% en la cantidad de contrabando que entre al país conlleva una reducción de 2,7% en las ventas de cigarrillo legal. El segundo ejercicio mostró que un aumento del 10% en el precio de los cigarrillos de segmento bajo y medio-bajo lleva a incrementos de contrabando del 22%.

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BMC Public Health

RESEARCH ARTICLE Open Access

An online survey of users of tobacco vaporizers, reasons and modes of utilization, perceived advantages and perceived risks

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Abstract

Background: Tobacco vaporizers heat tobacco without burning it, to produce an inhalable aerosol. Various models have recently appeared on the market, mostly manufactured by the tobacco industry, but few of the studies published on tobacco vaporizers are independent from the manufacturers. The goals of this study were to explore who uses tobacco vaporizers, how these products are used, reasons for utilization, perceived advantages and risks.

Methods: Online questionnaire collected from October 2016 to January 2018 in self-selected visitors aged > 18 to an anti-addiction website.

Results: We obtained 170 valid responses, of whom 104 were using tobacco vaporizers. For homogeneity, we included only the 102 users of the Brand 1 tobacco vaporizer in our analysis, as there were only two users of other vaporizers.
Among these 102 vaporizer users, about half were current cigarette smokers (57%), the rest were former cigarette smokers. The median age was 41, and the median duration of utilization was 9 months.
Most (88%) used the vaporizer daily, 8% were occasional users and 4% were past users. Among current smokers, 80% were currently trying to reduce their cigarette consumption and 29% were trying to quit. The vaporizer was used mainly to replace cigarettes (94%), because it was perceived to be less toxic than cigarettes (89%), to help stop smoking or to avoid starting smoking again (72%), or to reduce cigarette consumption (71%).
Current smokers who were daily or occasional vaporizer users reported smoking a median of 8.0 cigarettes per day, compared with 20.0 per day before they started to use the vaporizer ($p < .0001$, Wilcoxon signed-rank test).

Conclusions: In this online sample of early adopters, Brand 1 was by far the most frequently used tobacco vaporizer. It was used by current or former smokers only, mainly to replace cigarettes, and satisfaction ratings were good. Users considered the tobacco vaporizer to be less toxic than cigarette smoke and perceived it to be helpful for reducing or stopping smoking.

Keywords: Tobacco vaporizer, E-cigarette, Nicotine, Tobacco withdrawal symptoms, Cigarette consumption, Internet

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Background

Tobacco vaporizers heat tobacco rather than burning it, to produce an inhalable aerosol [1]. They contain a battery-powered heating element and an insertion site for the tobacco refill sticks [1]. The vaporizers produce an inhalable aerosol that might be > 90% less toxic than the smoke produced by a combustible cigarette because of the temperature at which the tobacco is heated (around 300 °C instead of > 900 °C for a combustible cigarette) [2–4]. At this lower temperature pyrolysis occurs, but not combustion [5].

For more than 25 years, studies have tended to show that the aerosol produced by tobacco that is heated but not burned is less toxic than cigarette smoke [6–8]. Biomarker analysis in humans [9–11], animals [12, 13] and on human cultured cells [14, 15] also showed reduced toxicity from the aerosol produced by heated tobacco products compared to cigarette smoke. Nonetheless, the aerosol from tobacco vaporizers is not free of toxicologically active substances [5, 16–21], and some consider that such aerosols should be described as smoke because pyrolysis occurs in some devices [5].

Unlike e-cigarettes that heat liquids that can contain nicotine, tobacco vaporizers heat tobacco. The nicotine supplied by some vaporizers reaches the bloodstream at a speed approaching the delivery speed achieved by inhaling cigarette smoke [22], but at lower concentration [22, 23].

In recent years, different models of tobacco vaporizers have appeared on the market, mostly manufactured by the tobacco industry which is investing substantial sums of money in the research and development of these products. For instance, since November 2014 Philip Morris International (PMI) has sold a tobacco vaporizer named IQOS in various countries where it is commercially quite successful [1, 24], particularly in Japan where sales of IQOS refills represented 15.5% of the tobacco market in September 2018 [24]. In December 2016 PMI submitted an application to the United States Food and Drug Administration to register IQOS as a modified-risk tobacco product [1]. Similarly, British American Tobacco have launched a tobacco vaporizer named "glo" and invested one billion GBP in the development of new tobacco vaporizing devices [25].

Very few of the studies published on tobacco vaporizers are independent of the manufacturers [3, 5, 16, 19–21, 23, 26–28] and many questions remain unanswered. For example: who uses tobacco vaporizers, why and how are these products used, what are the perceived advantages and risks, what are the effects on cigarette consumption, are the vaporizers used by non-smokers, do they encourage cigarette consumption, are they addictive?

Independent research is needed to allow policy makers, legislators, clinicians, manufacturers, retailers and consumers to make informed decisions. Thus, the goals of this study were to explore who the tobacco vaporizers users are, how vaporizers are used, reasons for utilization, and perceived advantages and risks.

Methods

Qualitative phase

Participants were enrolled via the anti-addiction website www.stop-dependance.ch which is run by the second author. We conducted brief interviews by e-mail with eight self-selected visitors to this website who were aged 18 or older and were currently using, or had used, a tobacco vaporizer. We also conducted telephone interviews with five of these users to identify reasons for use, perceived advantages and drawbacks, opinions and satisfaction with the product. These qualitative data were used to design the closed-format questionnaire used in the quantitative phase.

Quantitative phase

We posted a questionnaire in French and English on www.stop-dependance.ch and asked discussion forums, websites and anti-tobacco leagues to post a link to the questionnaire. We also posted this link on Facebook. Most respondents came from stop-dependance.ch.

Data were collected between October 2016 and January 2018.

Participants were aged 18 or older and they were using, or had used, a tobacco vaporizer (any brand). We recorded Internet Protocol (IP) addresses to identify and delete duplicate records.

Before answering the questionnaire, participants were informed that:

> "Cigarette" referred to "real" combustible cigarette.
>
> "E-cigarette" referred to a product that heats a liquid producing an aerosol that can be inhaled.
>
> "Tobacco vaporizer" or "vaporizer" referred to a product that heats tobacco producing an aerosol that can be inhaled.

Only current or former users of tobacco vaporizers, using any brand or model, were included in the study.

The questionnaire covered:

- Current or past utilization of a tobacco vaporizer and intention to use it, brand and model (open-ended questions).
- Reasons for using one, duration and frequency of utilization, number of refills and puffs per day, number of puffs per refill (note: Brand 1 is designed to produce a maximum of 14 puffs per stick, and at

the time of data collection only tobacco and menthol flavors were available for Brand 1 refill sticks [2]), monthly expenditure on vaporizers and refills.
- Assessment of the taste, perceived feelings, satisfaction and perceived advantages and disadvantages.
- Perceived risk and comparison of risk with combustible cigarettes.
- Current or past utilization of tobacco, age at smoking initiation, number of cigarettes per day, duration of smoking, time to first cigarette after waking [29] (combined to compute the Heaviness of Smoking Index, HSI [30],)
- Current or past utilization of nicotine replacement medications, other medication for stopping smoking or e-cigarettes. Intention to stop smoking or to reduce smoking, previous quit attempts, tobacco dependence (on a scale from 0 to 100) [31], confidence in ability to stop smoking
- Age, gender, country of residence
- Presence of a tobacco related disease, cannabis use and hazardous alcohol consumption (AUDIT-C) [32].

Statistical analysis

Before starting this exploratory study, the intended sample size was 200, which would have allowed us to obtain a 95% confidence interval of +/− 7% for variables whose frequency is 50%, and of +/− 6% for a frequency of 25%. It would also have allowed us to detect a 20% difference between groups for dichotomic variables with a frequency of 50%, with a power of 80% and a p value of 0.05. We estimated that this level of precision was sufficient for this exploratory study.

We reported medians rather than means, because medians are less sensitive to extreme values. We compared current and former smokers using Mann–Whitney U-tests for medians, χ^2 tests for proportions. Bonferroni correction was used for multiple comparisons and Wilcoxon signed-rank test was used to compare median cigarette consumption among current smokers before and after they started using a vaporizer. As we made 132 comparisons between current and former smokers, the corrected significance threshold was $p = 0.05/132 = 0.0004$. We indicated 95% confidence intervals for proportions in Tables 4 to 6. Prices in other currencies were converted to Euros.

Ethics and informed consent

The study protocol was submitted to the ethics committee of the canton of Geneva which did not examine it because the committee considered that this type of study (an online survey) did not require approval, according to the Swiss laws that regulate medical research.

We informed participants that their answers would be anonymously stored on a computer file for statistical analyses and that they would not be transmitted to third parties. We did not request a formal consent for participation, consent was implicit.

Results

Participation

Qualitative phase

Eight participants responded by e-mail, of whom five were also interviewed by telephone; two were former Brand 1 tobacco vaporizer users, and six were current Brand 1 vaporizer users. Of these eight participants, five were males, seven were current smokers, one was a former smoker, and all used non-menthol tobacco sticks. During the telephone interviews, it appeared that for all users the taste or flavor of the aerosol produced by the vaporizer was the main determinant of the intention to use or to stop using the tobacco vaporizer. The taste or flavor was described as a bad tobacco taste ($n = 3$, including the two former vaporizer users), a burnt taste ($n = 1$), a straw taste ($n = 1$), a tea taste ($n = 1$), a popcorn taste ($n = 1$) and a good tobacco taste ($n = 1$).

A few days after the interviews, these five participants were invited to answer and comment on a preliminary version of the closed format questionnaire, derived from the interviews and from our previous surveys [33]. This phase enabled us to modify and rewrite many questions.

Quantitative phase

We enrolled 170 participants, including: 104 users of tobacco vaporizers (Brand 1, $n = 102$; Brand 2, $n = 1$; Brand 3, $n = 1$); 46 incomplete results (respondents who did not mention which product they used); 18 e-cigarette users; one user of nicotine inhaler and one duplicate record.

For homogeneity, and as there were only two users of other types of tobacco vaporizers, we only included the 102 users of the Brand 1 vaporizer in our analysis.

The median age of the 102 participants was 41 years (25th and 75th percentiles: 30 and 51 years; range: 20 to 70 years). About half were women (53%) and current smokers (57% of all respondents; 56% of current users of Brand 1). The distribution of respondents by country was: Switzerland (83%), France (11%), Greece (1%), Italy (1%), Russia (1%), Norway (1%) and Canada (1%).

The majority (76%) of participants scored positively for hazardous alcohol consumption according to the screening test AUDIT-C.

A minority (14%) had used cannabis during the previous 12 months, and 4% had used cannabis at least four times a week during the previous year.

Before they started to use the tobacco vaporizer, all participants were smokers (daily 92%; occasionally 4%) or former smokers (4%). Most current smokers (80%) reported currently trying to reduce their cigarette consumption. Around one third (29%) were trying to quit smoking, but few (9%) had decided to stop smoking, either immediately or within the next 30 days, and a minority (15%) were "very confident" that they could successfully stop smoking if they tried.

Most respondents (96%) were current tobacco vaporizer users; only four (4%) were former vaporizer users. Around one third (35%) were currently also using an e-cigarette, either occasionally (9%) or every day (26%). A minority (7%) were currently also using a nicotine medication either occasionally (2%) or every day (5%). Around one quarter of respondents (27%) were using only the tobacco vaporizer, without concomitant consumption of cigarettes, e-cigarettes or nicotine medications.

The characteristics of these 102 tobacco vaporizer users are summarized in Tables 1 and 2.

Tobacco vaporizer utilization

Among the 98 current users of the Brand 1 tobacco vaporizer, the median duration of utilization was 8.8 months (269 days, 25th and 75th percentiles: 59 and 469 days). The majority (94%) used it during both week days and at the weekend; 92% used the vaporizer every day and 8% occasionally (Table 3). Among daily vaporizer users 29% were also smoking every day, whereas among occasional vaporizer users 75% were smoking every day.

The first puff of the day on the vaporizer took place 30 min (median) after waking (25th and 75th percentiles, 15 and 60 min), and the first cigarette of the day was also smoked 30 min (median) after waking among current smokers (25th and 75th percentiles: 10 and 50 min). Among dual users (current users of both vaporizers and cigarettes), 14.8% took their first puff of the day on their vaporizer within five minutes after waking, and 15.7% smoked their first cigarette of the day within five minutes after waking.

Among the 98 current vaporizer users, the median number of refill sticks per day was ten (25th and 75th percentiles: 5.75 and 10); the median number of puffs per day was 150 (25th and 75th percentiles: 50 and 210) and the median number of puffs per stick was 12 (25th and 75th percentiles: 10 and 14). The median monthly expenditure on tobacco vaporizers and refill sticks was 110 Euros (25th and 75th percentiles: 59 and 161). About half the participants (48%) said they had ever used the tobacco vaporizer instead of a smoking cessation medication to reduce or to quit smoking.

Most users (59%) had ever used the vaporizer and combustible cigarettes concomitantly (i.e. on the same day), and 15% had done so for more than one month.

Table 1 Characteristics of users of the Brand 1 tobacco vaporizer: Internet survey, 2016–2018

	All users
Number of respondents	102
Gender (males %)	47.0
Age (years)[a]	41 (30, 51)
Hazardous alcohol consumption:	
AUDIT-C Score ≥ 4 among males (%)	75.6
AUDIT-C Score ≥ 3 among females (%)	76.1
Ever used cannabis in past 12 months:	
- Ever (%)	14.0
Does your spouse/fiancé smoke	
- Yes (%)	43.0
In general, would you say your health is:	
- Very good to excellent (%)	49.5
Do you currently use a nicotine medication? (patch, chewing-gum, tablet, inhaler, nasal spray)?	
- Yes, every day (%)	5.1
- Yes, occasionally (%)	2.0
Do you currently use an e-cigarette?	
- Yes, every day (%)	26.0
- Yes, occasionally (%)	9.0
Use only vaporizer (no consumption of cigarettes, e-cigarettes or nicotine medication) (%)	26.5

[a] Median (25th and 75th centiles)

Table 2 Characteristics of users of the Brand 1 tobacco vaporizer, Tobacco use: Internet survey, 2016–2018

	All users
Number of respondents	102
Tobacco use: (in current users of the tobacco vaporizer, $n = 98$)	
- Daily smoker (%)	34.8
- Occasional smoker (%)	21.3
- Former smoker (%)	43.8
- Never smoker (%)	0.0
Currently, do you use oral or snuff tobacco:	
- Yes, (occasionally or every day) (%)	8.2
Before using a tobacco vaporizer, were you a smoker (or user of snuff/oral tobacco):	
- Daily smoker (%)	92.0
- Occasional smoker (%)	4.0
- Former smoker (%)	4.0
- Never smoked (%)	0.0
Number of cigarettes per day before using the tobacco vaporizer[a]	20.0 (10.5, 21.5)
The first time you used nicotine, which product did you use:	
- A cigarette, cigar or pipe (%)	98.0
- An electronic cigarette (%)	2.0
Age when began to smoke everyday (years)[a]	16.5 (15.75, 18.0)
Tobacco vaporizer utilization:	
- Every day (%)	88.2
- Occasionally (%)	7.9
- Former user (%)	3.9
Do you intend to use a tobacco vaporizer in the future?	
(Intend to use/certain to use one) (%)	90.3
Among former users: duration of utilization (days)[a]	5.0 (3.0, 5.0)
Current smokers ($n = 58$):	
- Number of cigarettes per day[a]	10.0 (3.75, 16.25)
- How long after waking do you smoke the first cigarette of the day (minutes)[a]	30.0 (10.0, 50.0)
- Heaviness of smoking index (HSI) (%):	
0–1:	31.6
2–4:	68.4
5–6:	0.0
- Cigarette dependency (self-rating scale of 0 to 100)[a]	80.0 (43.75, 96.0)
- Decided to stop smoking (now or in the next 30 days) (%)	9.0
- Intend to stop in the next six months (%)	7.1
- Sure to succeed stopping smoking if you try (very sure) (%)	14.5
- Currently trying to stop smoking (%)	28.6
- Currently trying to reduce cigarette consumption (%)	80.0
- Duration of most recent quit attempt (days)[a]	14 (3.0, 90.0)
- Duration of longest quit attempt (days)[a]	135.0 (21.0, 365.0)
Former smokers ($n = 40$):	
- When did you stop smoking (days ago)[a]	67 (36.0, 438.0)
- Before stopping, number of cigarettes per day on average[a]	20.0 (10.5, 23.0)

[a] Median (25th and 75th centiles)

Table 3 Modes of utilization in current users of the Brand 1 tobacco vaporizer: Internet survey, 2016–2018

	Current users
Number of current users	98
Duration of utilization (days)[a]	269.0 (59.0, 469.0)
Utilization:	
Every day (%)	91.8
Occasionally (%)	8.2
Before using your vaporizer, how many cigarettes did you smoke per day, on average (current daily or occasional vaporizer users who were smokers when they started to use the vaporizer, $n = 94$)[a]	20.0 (10.0, 20.0)
Number of cigarettes per day now (among all current vaporizer users and current smokers)[a]	8.0 (3.0, 15.0)
Number of cigarettes per day now (among every daily vaporizer users and current smokers)[a]	7.5 (3.25, 13.75)
Number of refill sticks per day[a]	10.0 (5.75, 10.0)
Total number of cigarettes plus vaporizer refills per day (in current smokers)[a]	16.5 (12.0, 21.0)
First utilization of the day of vaporizer, how many minutes after waking (minutes)[a]	30.0 (15.0, 60.0)
Number of puffs per day on the vaporizer[a]	150.0 (50.0, 210.0)
Number of puffs per stick[a]	12.0 (10.0, 14.0)
Duration of one recharge of the battery (hours)[a]	24.0 (12.0, 48.0)
Number of sticks per one recharge of the battery[a]	20.0 (20.0, 20.0)
Monthly expenditure for vaporizer and sticks (Euros)[a]	110.0 (59.0, 161.0)
Intention to use vaporizer for more than one year (%)	58.9
Utilization of vaporizer and cigarettes on the same day:	
- Ever (%)	59.2
- For more than one month (%)	15.4
Reason for using both vaporizer and cigarettes on the same day:	
- To reduce cigarette consumption (%)	57.6
- In places where smoking is prohibited (%)	19.7
- Because I like to use both (%)	28.8
Utilization of the vaporizer instead of a smoking cessation medication:	
- Ever (%)	48.1
- For more than one month (%)	28.4

[a] Median (25th and 75th centiles)

The most frequent reason for concomitant use of both the vaporizer and combustible cigarettes on the same day was to reduce cigarette consumption (58%; other reasons are listed in Table 3).

The majority (84%) of participants intended to continue using the tobacco vaporizer in the future and, among active users, 59% intended to use it for more than one year.

Reasons for use

The tobacco vaporizer was used mainly (in decreasing order of frequency) to replace cigarettes; because it was perceived to be less toxic than smoking tobacco; to stop smoking or to avoid starting smoking again; to reduce tobacco consumption with no intention of stopping smoking; and because respondents did not want to smell of tobacco smoke. Other reasons are listed in Table 4.

Perceived effects

The majority (59%) of respondents rated the taste of the vaporizer as either good or very good, whereas 6% rated it bad or very bad. About half (45%) described the vaporizer taste as a good tobacco taste, 19% as a straw taste, 19% as a tea taste, 10% as a popcorn taste, 4% as a bad tobacco taste and 3% as a burnt taste. Two thirds (68%) of participants reported that the taste of the vaporizer was either different or very different from the taste of a cigarette. Most (61%) reported that the vaporizer taste to be advantageous for stopping smoking (Table 5).

Table 4 Reasons for using the tobacco vaporizer: Internet survey, 2016–2018

Quite true to totally true (%)	All users
Number of respondents	102
To replace cigarettes	94.1 (89.5–98.7)
Less toxic than smoking tobacco	89.2 (83.2–95.2)
To stop smoking or to avoid starting smoking again	72.3 (63.6–81.0)
To reduce my tobacco consumption but without the intention of stopping smoking	71.3 (62.5–80.1)
Because I don't want to smell of tobacco smoke	70.7 (61.8–79.6)
To cope with tobacco withdrawal symptoms	69.6 (60.7–78.5)
Because I like using it	65.0 (55.7–74.3)
To not disturb others with tobacco smoke	57.4 (47.8–67.0)
To reduce my tobacco consumption in preparation for stopping smoking	56.4 (46.7–66.1)
Because I'm dependent on my vaporizer	53.5 (43.7–63.3)
To manage urges to smoke	49.0 (39.3–58.7)
Because all the other smoking cessation methods I tried have failed	41.6 (32.0–51.2)
Because, despite my efforts, I'm not able to stop using my vaporizer	37.4 (27.9–46.9)
To manage stress	35.3 (26.1–44.5)
To avoid the need to go outside to smoke	26.0 (17.4–34.6)
In situations or places where smoking is prohibited	23.0 (14.8–31.2)
Cheaper than tobacco	14.0 (7.2–20.8)
The vaporizer helps me control my weight	4.0 (0.2–7.8)
I cannot smoke because of a disease	2.0 (0.0–4.7)

95% confidence intervals are indicated in brackets

Among former smokers, 68% answered that the tobacco vaporizer had helped them to stop smoking and, among current smokers, 85% said that the vaporizer helped them to reduce their cigarette consumption.

Current smokers who were daily or occasional vaporizer users reported smoking a median of 8.0 cigarettes per day, compared with 20.0 per day before they started to use the vaporizer ($p < .0001$, Wilcoxon signed-rank test).

Most (92%) participants estimated the vaporizer use to be less dangerous for their health than cigarette smoking: 100 times less dangerous (21%), 10 times less dangerous (49%), two times less dangerous (22%).

A minority (9%) reported strong throat irritation with the vaporizer, and 55% rated the throat hit provoked by the vaporizer as weak or very weak. One third (31%) reported the vaporizer taste could make them want to smoke a cigarette versus 69% who said the vaporizer taste did not make them want to smoke.

Satisfaction

On a scale from zero to ten, the median satisfaction score was eight (25th and 75th percentiles: 7 and 9). More than half the users (56%) had ever recommended several other people to use the tobacco vaporizer and 22% thought that several people had begun to use the vaporizer because of their recommendation or because of their example. The nicotine intake from the vaporizer was considered to be sufficient by 90% of users. The majority of ex-smokers (67%) expressed fear that they would start smoking again if they stopped using the vaporizer.

The perceived advantages of the vaporizer were, in decreasing order of frequency: it was easy to not smoke when using the vaporizer; the vaporizer did not produce a bad smell; since starting to use the vaporizer respondents were coughing less; users had better breath; they were less short of breath after a physical effort, and their senses of taste and smell improved (Table 6).

The perceived disadvantages were, in decreasing order of frequency: users were afraid they would become dependent on the vaporizer; the vapor from the vaporizer should be more concentrated; the vaporizer should act more quickly; it should be easier to inhale on the vaporizer; the vaporizer should provide more nicotine. Side effects of the vaporizer, reported by some users, were: sore throat ($n = 5$), stomach pain ($n = 4$), headache ($n = 3$), dry mouth (n = 3), cough (n = 3), and bad breath ($n = 2$).

In an open-ended question (free text, 26 answers collected) on how the vaporizer could be improved, participants answered that it should be less fragile because it breaks easily ($n = 4$), it should be possible to reduce the nicotine level in the refills (n = 4), there should be a wider choice of tastes ($n = 3$), and various other responses ($n = 15$).

Table 5 Perceived effects of using the Brand 1 tobacco vaporizer: Internet survey, 2016–2018

	All users
Number of respondents	102
How would you describe the 'hit' or 'throat hit' provoked by your vaporizer:	
- Strong to very strong (%)	14.7 (7.9–21.5)
- Medium (%)	30.4 (21.5–39.3)
- Weak to very weak (%)	54.9 (45.2–64.6)
Would you describe the vaporizer taste as:	
- Good to very good (%)	59.4 (49.8–69.0)
- Neutral (%)	34.7 (25.4–44.0)
- Bad to very bad (%)	5.9 (1.3–10.5)
Is the taste of your vaporizer similar of the taste of a cigarette?	
- Similar (%)	1.0 (0.0–2.9)
- Near to very near (%)	31.0 (22.0–40.0)
- Different to very different (%)	68.0 (58.9–77.1)
Would you say the taste of your vaporizer is an advantage or a disadvantage for stopping smoking?	
- Advantage to big advantage (%)	60.8 (51.3–70.3)
- Disadvantage to big disadvantage (%)	10.8 (4.8–16.8)
Could the taste of your vaporizer make you want to smoke a cigarette?	
- A lot (%)	2.9 (0.0–6.2)
- Low to moderate (%)	28.4 (19.6–37.2)
- Not at all (%)	68.6 (59.6–77.6)
Does your vaporizer irritate your throat?	
- Strongly (%)	9.0 (3.4–14.6)
- Not at all (%)	65.0 (55.7–74.3)
How would you estimate the general risk to health from the vaporizer, compared to cigarettes?	
- 100 times less dangerous (%)	20.8 (12.9–28.7)
- 10 times less dangerous (%)	49.5 (39.7–59.3)
- 2 times less dangerous (%)	21.8 (13.9–29.8)
- Probably the same risk as cigarettes (%)	6.9 (2.0–11.8)
- Probably more dangerous than cigarettes (%)	1.0 (0.0–2.9)
Former smokers (n = 40):	
Did your vaporizer help you to stop smoking?	
- Yes (a little to absolutely) (% of former smokers)	67.5 (53.0–82.0)
Current smokers (n = 58):	
Does (did) your vaporizer help you to reduce your cigarettes consumption?	
- Yes (a little to absolutely) (% of current smokers)	84.5 (75.2–93.8)

95% confidence intervals are indicated in brackets

Comparison between current and former smokers

We compared current and former smokers for each variable and report here results with a p value less than 0.05, although they are not statistically significant when using Bonferroni correction (corrected $p = 0.0004$): former smokers said more frequently than current smokers that their reason for using the vaporizer was that, despite their efforts, they were not able to stop using it (55% versus 26%, $p = 0.006$); that they used it because they were dependent on the vaporizer (72% versus 37%, $p = 0.004$); that they liked using it (74% versus 59%, $p = 0.025$); that they used it to avoid disturbing others with tobacco smoke (70% versus 49%, $p = 0.04$) and because it was less toxic than smoking tobacco (100% versus 81%, $p = 0.014$).

In addition, more former smokers than current smokers responded that the vaporizer taste did not make them want to smoke a cigarette at all (82% versus 59%, $p = 0.031$).

Discussion

The main findings of this online survey in mostly Swiss and French visitors to an anti-addiction website were that Brand 1 was by far the most frequently used tobacco vaporizer, that the tobacco vaporizer was used mainly to replace cigarettes and that it scored highly in terms of satisfaction. Also, users considered the vaporizer to be less toxic than cigarette smoke, although we used ad hoc (i.e. not formally validated) question to assess this. The vaporizer was perceived to be helpful for reducing cigarette consumption or for stopping smoking, and also to diminish respiratory symptoms such as coughing and shortness of breath after physical effort. All these results should of course be confirmed by experimental studies.

In this online sample, the tobacco vaporizer was used exclusively by current and former smokers. Most current smokers (dual users) reported currently trying to reduce their cigarette consumption and around one third were trying to quit smoking. But only around 10% had decided to stop smoking immediately or in the next 30 days, and their confidence in their ability to successfully quit smoking was low.

Most vaporizer users were also current smokers, but concomitant cigarette smoking reduces the potential of vaporizers to lower the risk of tobacco-related harm.

Among dual users (current users of vaporizers and cigarettes), the proportion of users who smoked their first cigarette within five minutes after waking and the proportion of users who used the vaporizer within five minutes after waking were the same. Time to the first puff is a useful indicator of dependence [29], and this result suggests that the addictiveness of both products is similar.

The side effects reported with the vaporizer (sore throat, stomach pain, headache, dry mouth, cough and bad breath) were rare, but many users feared becoming dependent on the vaporizer.

Table 6 Satisfaction with, and perceived advantages and disadvantages of, the tobacco vaporizer: Internet survey, 2016–2018

	All users
Number of respondents	102
Are you satisfied with your vaporizer (scale of 0 to 10)[a]	8.0 (7.0, 9.0)
I like the feeling I get when I inhale the vapor from my vaporizer	
- Somewhat agree to totally agree (%)	66.7 (57.4–76.0)
Have you ever recommended other people to use a vaporizer:	
- Yes, one person (%)	24.5 (16.2–32.8)
- Yes, several people (%)	55.9 (46.3–65.5)
Do you think that other people began to use a vaporizer because of your recommendation or your example?	
- Yes, one person (%)	25.7 (17.2–34.2)
- Yes, several people (%)	21.8 (13.8–29.8)
I'm afraid I may start smoking again when I stop using my vaporizer	
- Somewhat agree to totally agree (% of former smokers)	64.7 (56.3–74.1)
Perceived advantages - Somewhat agree to totally agree (%):	
It's easy not to smoke when I use my vaporizer	82.0 (74.5–89.5)
It does not produce a bad smell	73.0 (64.3–81.7)
I cough less	68.0 (58.9–77.1)
I have better breath	66.0 (56.7–75.3)
I get less short of breath after a physical effort	60.7 (51.1–70.3)
Improved senses of taste and smell	43.0 (33.3–52.7)
Perceived disadvantages: - Somewhat agree to totally agree (%)	
I'm afraid of becoming dependent on my vaporizer	57.6 (47.9–67.3)
The vapor should be more concentrated	24.0 (15.6–32.4)
My vaporizer should act more quickly (faster relief of urge to smoke)	20.2 (12.3–28.1)
It should be easier to draw/inhale on the vaporizer	19.0 (11.3–26.7)
Vaporizer should deliver more nicotine	10.0 (4.1–15.9)

[a] Median (25th and 75th centiles); other results are proportions with 95% confidence intervals

With respect to product design, the majority of users perceived that the aerosol produced by the tobacco vaporizer was concentrated enough and quickly relieved the urge to smoke [2, 11]. Most participants in our study said it was easy to draw on the vaporizer and that it provided enough nicotine. One crucial point that may explain the success of the Brand 1 vaporizer - that could also explain the failure of first generation heat-not-burn tobacco products, because they scored poorly in this respect [34] - is that the satisfaction produced with Brand 1 tobacco vaporizer seems to be due to its taste, which was well liked, while the "throat hit" was described as only medium to weak. The majority of vaporizer users described the taste as good, different from the taste of a cigarette and helpful for stopping smoking, and the majority said the taste would not make them want to smoke a cigarette.

According to users, the vaporizer could be improved by providing refills with lower nicotine content to allow users to reduce their nicotine intake, by making the device less fragile and by expanding the choice of tastes.

Participants in our survey had relatively high rates of hazardous alcohol consumption (positive AUDIT-C test), which is in accordance with the high rates of hazardous alcohol consumption in smokers [35, 36] and is probably not specific to Brand 1 tobacco vaporizer users. Participants also had a high rate of cannabis consumption, which is in accordance with the high rate of cannabis consumption usually observed in smokers [36] and is probably not specific to Brand 1 vaporizer users. Nevertheless, these high levels of alcohol and cannabis use must be kept in mind when considering tobacco vaporizer users.

Study strengths and limitations

Although a new systematic review that compared industry-funded with independent studies of heated tobacco products [20] found that independent and industry-funded studies produced largely similar findings, our study is innovative and the aspects covered have not been previously reported by independent researchers who are not linked to the manufacturers of tobacco vaporizers.

We used a practical and feasible way of enrolling tobacco vaporizer users, and had to rely on an online survey in self-selected volunteers. We therefore had no way of ensuring that the respondents to our online questionnaire were actually using the brand of tobacco vaporizer that they mentioned. Participants were among the first users of this product, soon after it was launched, and are innovators and early adopters that may differ from the late majority [37]. In the qualitative phase, the sample size ($n = 8$) may have been too small to reach data saturation, and a larger sample may have provided more information. In the quantitative phase, the number of participants was lower than intended, probably owing to the novelty of tobacco vaporizers and, given the very low prevalence of heated tobacco product use at the time of data collection, obtaining a representative sample of 200 users would have required a prohibitively large survey, which was not feasible given our resources. For these reasons, our study only included a small sample of innovators and early adopters mainly from Switzerland and France and may not be representative of all Brand 1 vaporizer users in all countries. Moreover, participants were recruited via an anti-addiction website and may have been more motivated to reduce or stop smoking than other Brand 1 vaporizer users. Users who take part in online survey research may also differ from other vaporizer users, in that they may be more educated. Thus, participants in our study may differ from average Brand 1 vaporizer users, and our results may have limited generalizability. Finally, we used an ad hoc questionnaire that had not been submitted to formal validation, although it was pre-tested online and iteratively improved in eight participants. The questionnaire for the quantitative phase was designed for users of all types of tobacco vaporizers, but because all participants in the qualitative phase were using Brand 1, we may have missed some elements specific to other types of vaporizers when designing the questionnaire. It should be noted that some of the other currently available vaporizers were not yet on the market when the questionnaire was designed.

Nonetheless, despite its limitations, this exploratory study contributes valuable information about who uses tobacco vaporizers and how and why such products are used. Further research should be conducted in more representative samples of tobacco vaporizer users, include other brands of tobacco vaporizers, and use experimental methods.

Conclusions

In this online, self-selected sample of early adopters, the Brand 1 tobacco vaporizer was by far the most frequently used tobacco vaporizer. It was used by current or former smokers only, mainly to replace cigarettes, and satisfaction ratings were good. Users considered the tobacco vaporizer to be less toxic than cigarette smoke and perceived it to be helpful for reducing or stopping smoking.

Abbreviations

AUDIT-C: Alcohol Use Disorders Identification Test-Consumption; GBP: Great Britain Pound; HSI: Heaviness of Smoking Index; IQOS: I Quit Ordinary Smoking; PMI: Philip Morris International

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

SQ and JFE conceived the study. SQ undertook the statistical analyses and wrote the first draft of the paper. JFE oversaw all aspects of the study. Both authors have contributed to and have approved the final manuscript.

Ethics approval and consent to participate

The study protocol was submitted to the ethics committee of the canton of Geneva, Switzerland, which did not examine it because the committee considered that this type of study (an online survey) did not require approval, according to the Swiss laws that regulate medical research.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Tobacco harm reduction in England – England's Tobacco Control Plan

Clive Bates

England has adopted a broad-based comprehensive approach to tobacco control, adopting the main tools of established tobacco control: tobacco taxation; smokefree environments; advertising bans; standardised packaging; warnings and risk communications; support for smokers wishing to quit and some product regulation. However, what is different and interesting in England is the very positive approach taken to vaping and its role as a harm reduction approach in tobacco control. Harm reduction is recognised as integral to tobacco control in the WHO Framework Convention on Tobacco Control:[1]

> „1(d) ‚tobacco control' means a range of supply, demand and **harm reduction strategies** that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke;" (emphasis added)

England is rightly seen as one of the world's most progressive backers of tobacco harm reduction. The approach covers law and regulation, taxation, communications, research and service provision. There is a broad consensus in favour of tobacco harm reduction among the main agencies and non-governmental organisations, including key players like Public Health England, Cancer Research UK, the Royal College of Physicians, Action on Smoking and Health and a group of credible academics.

In 2017, the Department of Health (UK/England) released its tobacco control plan for England: *Towards a smoke-free generation: tobacco control plan for England*[2] and followed up with a delivery plan.[3] The embrace of vaping and other low-risk alternatives to smoking runs through the text. This is probably the first significant government policy paper anywhere that recognises and pursues the opportunities of tobacco harm reduction, rather than defining these technologies as a threat to be suppressed. For that, the Department of Health and its allies deserve considerable credit.

How did England's positive approach to vaping emerge?

The history is instructive, because it shows that decisions and leadership positions taken by consumers and by key individuals at decisive moments

changed the course of policy. There was not a single point at which the government in England decided to be pro-vaping.

In 2010, e-cigarettes became a visible political issue for the first time. The Medicines and Healthcare Products Regulatory Agency (MHRA) noticed the presence of nicotine products on the UK market that were growing in popularity but were not licensed as medicines. The MHRA recommended that the products should be regulated as medicines and those products without marketing authorisation (all e-cigarettes at the time) should be taken off market in 21 days. The MHRA went out to consult on the proposal,[4] receiving submissions from the usual medical and health organisation supporting the *de facto* ban. But something else happened: over 1,000 consumers wrote in explaining their personal experience with e-cigarettes and imploring the regulator not to remove them from the market. These personal and visceral accounts cut through and the proposal was shelved.

But it was shelved only until December 2012, when the European Commission brought out its proposal for a revision to the Tobacco Products Directive (TPD). At that time, the TPD in force had been agreed in 2001, and predated the emergence of vaping products.[5] The Commission proposed a single approach: regulate these products as medicines. For regulators, this was simple and elegant. Just adopt a regulatory framework and related institution that already exists – all achieved by neat cross reference between the new Tobacco Products Directive (nicknamed TPD-2) and the Medicines Directive.[6] A perfect solution, but only if you are a bureaucrat. For consumers and producers, it was a nightmare. The basic problem is that vaping products are not medicines, their users are not patients and the manufacturers do not make therapeutic claims. With one important exception, the manufacturers would be unable to bear the weighty burdens of a medicine regulation approval process. Nevertheless, the UK government decided in June 2013 that it would back the Commission's proposal and lined up with health organisations to back the medicalisation proposal.

As with the abortive attempt to impose medicine regulation in 2010, the proposed directive galvanised consumers and pro-harm reduction public health experts into a massive and ultimately successful advocacy effort to defeat this measure in the European Parliament. This time, consumers from all over Europe wrote to their MEPs and explained their personal experience and what these products had meant to them as they struggled with smoking. The personal experiences cut through all the false and misleading claims about the risks of vaping that had been put to the Parliament. On 8 October 2013, the European Parliament rejected medicine regulation and the legislature started an intense and secretive process of defining the measures that eventually became the framework for regulating vaping products at EU level, Article 20 of the revised Tobacco Products Directive.[7]

This began to change minds in England – the testimonies from consumers were so compelling and authentic that open-minded public health experts started to listen more carefully. A decisive turning point was the first 'E-cigarette Summit', which was held on 12th November 2013 at the prestigious Royal Society in London. This brought vapers and public health experts together to discuss the issues and look at the science, both what was known and what was then unknown, in a meeting ably chaired by the widely respected academic, Professor Ann McNeill. However, the E-cigarette Summit produced something more subtle and valuable as well: it generated empathy, humility and the ability on the part of experts to 'walk in their shoes' and to see the world as smokers and vapers see it. That moved the expert community into a place where they saw the opportunity as greater than the threat and started to think positively about the potential for thousands and maybe millions of smokers to switch from smoking to vaping.

Through its experience in fighting battles over the future of vaping between 2010 and 2014, the consumer movement strengthened and built its own consumer organisation, the New Nicotine Alliance.[8]

While consumers were fighting a very public and inspiring battle for the control over what was for them a life-or-death technology, there were also interesting developments at the highest levels in the UK government. In 2009, Number 10 Downing Street had set up a 'Behavioural Insights Team', which quickly became known as the 'Nudge Unit' after the famous book by Richard Thaler and Cass Sunstein. The concept was to promote 'good' behaviours (stopping smoking, making sensible pension provision, conserving energy) by using 'nudges', or subtle changes to the 'choice architecture' – the way choices are presented to citizens. As early as 2010, the Nudge Unit started to raise the prospects of e-cigarettes as a clever and cost-effective way of reducing the burden of smoking-related disease on the National Health Service and securing policy goals by encouraging people to take responsibility for their own health on their own initiative and at their own expense. For modern policy makers, this is an ideal goal, involving the state as an enabler, rather using its coercive powers to force behaviour change. The idea received the backing of the UK's most senior civil servant, Sir Jeremy Heywood, the Cabinet Secretary[9] and eventually the then Prime Minister David Cameron.[10] There was therefore backing for policy innovation in the UK government at the very highest level.

Further developments included the successful introduction of vaping as an option at one of the Stop Smoking Services. Louise Ross, the manager of the smoking cessations service in Leicester, understood smokers and could really see this working. She became (and remains) a vocal champion of harm reduction but backed by her direct personal front-line public health work.

This convinced many that there was an opportunity to revitalise these services with something that many smokers actually wanted to try. The UK's National Centre for Smoking Cessation and Training went on to produce guidance on the role of e-cigarettes for professional smoking cessation services.[11] The guide was produced with support and involvement of vapers and is an excellent resource for anyone professionally engaged in smoking cessation.

As the consensus started to build in 2014, the lead advocacy organisation, Action on Smoking and Health (ASH), came around to the consumer perspective on public health grounds, and its chief executive, Deborah Arnott, became a champion using her formidable diplomatic skills to build a coalition behind the idea. Cancer Research UK, the main cancer charity in the UK, was also in the process of re-evaluating its position, and again a courageous individual, Professor Linda Bauld, took the intellectual lead and brought Britain's large health charity into recognising the role for e-cigarettes in cancer prevention. Data supports Cancer Research UK in taking this stance: one study showed the cancer potency of 15 key carcinogens was 250 times lower (0.4%) in e-cigarette aerosol compared to cigarette smoke.[12] Cancer Research UK recognised the opportunity for a novel strategy for addressing the single most important cause of cancer in the UK and embraced the tobacco harm reduction concept. Other major organisations joined to form a consensus position to align with a statement of high-level principles.[13] The organisations included: Public Health England; Action on Smoking and Health; Association of Directors of Public Health; British Lung Foundation; Cancer Research UK; Faculty of Public Health; Fresh North East; Healthier Fu-tures; Public Health Action (PHA); Royal College of Physicians; Royal Society for Public Health; UK Centre for Tobacco and Alcohol Studies; UK Health Forum.

In another decisive development, one of the key players in ASH, Martin Dockrell, was seconded to Public Health England to lead its tobacco control programme. Dockrell set about commissioning in-depth evidence reviews, which give the basis for policy in England in the years to come. This included an initial assessment in 2014, and then the ground-breaking report in 2015 in which PHE said that vaping was likely to be at least 95% lower risk than smoking.[14] PHE continues to publish high quality evidence reviews commissioned from the UK expert community.[15]

The Royal College of Physicians is justly famous for its 1961 report *Tobacco and Health*, in which it set out in detail the known risks of smoking as they were understood at the time. That report and its equivalent from the US Surgeon General a year later altered the course of public health and started the concept of tobacco control. In 2016, it released a significant new report, *Nicotine without smoke: tobacco harm reduction*.[16] This report confirmed the scientific basis to be positive about vaping, despite the residual unknowns. In particular, the RCP

endorsed the low risk estimates of PHE, with the following carefully constructed formulation:

> „Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure." (Section 5.5 page 87)

This statement recognises uncertainty in both directions ("unlikely to exceed", "may be substantially lower") so it is providing an anchor for relative risk perceptions but without being a single point estimate. The idea was to help physicians, consumers and the public more generally to to get a feel for the consensus expert view of the relative risk of smoking and vaping. Although both PHE and RCP have been criticised for these estimates, it is normal practice to use numbers to communicate risk or to simplify complex science in order for people to have a sense of risk. We do this for example with Body Mass Index or alcohol consumption guidelines. There were even claims the tobacco industry might be involved in these numbers somehow, but this was completely untrue – it was the judgement of the RCP's Tobacco Working Group and PHE's expert consultants, none of whom had links to the industry or any sort.

The Royal College of Physicians also gave an important piece of policy advice which is taken more seriously in England than anywhere else. It concerns the risks of bad policy choices making the situations worse:

> „A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, e.g. exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.
> However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult." (Section 12.10 page 187)

Government officials in England were the first to really recognise the issues raised by the Royal College of Physicians. In its regulatory impact assessment for the TPD-2[17], the government noted the potential for harmful unintended consequences:

„207. There is a risk that due to the potential price increase and reduction of choice of e-cigarettes, people will choose to switch back to smoking, thus harming their health. This possibility is considered in the sensitivity analysis.
208. There is a risk that a black market will develop with potentially harmful e-cigarette products, due to consumers no longer having the same degree of choice in the legal market."

Academic groups also played a significant, and probably decisive, role in consolidating support for vaping as a tobacco harm reduction for England. Researchers at Kings College London, University College London, Queen Mary College London, South Bank University and University of Nottingham produced high quality research and data. In particular the group, at UCL adapted the monthly smoking toolkit survey to measure the uptake and use of e-cigarettes giving a high-resolution picture of the use of e-cigarettes in England. The academic leaders in England also share an intellectual heritage that originates from Professor Michael Russell, who died in 2009. Professor Russell memorably coined one of the great catch phrases of tobacco harm reduction as early as 1976: *People smoke for the nicotine but die from the tar*.[18]

England's targets are focussed on smoking

The single most important aspect of England's approach to tobacco control is the overriding focus on *smoking*. This is because the purpose of tobacco control is to reduce premature death and serious disease, and smoking – the inhalation of the products of combustion of dried and cured tobacco leaf – is by far the dominant cause of disease and premature death. It is important therefore to recognise what is *not* the priority. The policy does not give primacy to reducing nicotine use or reducing all tobacco use. This is important because there are potential trade-offs to be made between objectives – for example, if it was possible to reduce smoking by using safer forms of nicotine the goal of reducing smoking would prevail over the goal of reducing nicotine use.

This is reflected in the goals of the tobacco control plan, which are to:

„– reduce the number of 15-year olds who regularly smoke from 8% to 3% or less
– reduce smoking among adults in England from 15.5% to 12% or less
– reduce the inequality gap in smoking prevalence, between those in routine and manual occupations and the general population
– reduce the prevalence of smoking in pregnancy from 10.5% to 6% or less
The aim is to achieve these objectives by the end of 2022."

The focus on *smoking*, rather than on nicotine, tobacco use or other goals is appropriate from a public health perspective, because it is the smoke that causes the harm and this gives clarity to the policy framework. The way the targets are specified does not, therefore, preclude the use of reduced-risk tobacco and nicotine products to achieve the smoking-related targets. This idea is explicitly endorsed in support of tobacco harm reduction.

Data and monitoring

England has excellent data resources monitoring levels of smoking, vaping and other forms of nicotine use. There is also good data on behaviours – for example intention and attempts to quit smoking – and on beliefs and attitudes. Three main sources stand out:

- The Office of National Statistics and Public Health England collaborate and include smoking and vaping questions in the major household surveys and provides headline prevalence figures and local-level data.[19]
- The Smoking Toolkit Survey, Smoking in England, measures a range of smoking, vaping and quitting behaviours and is conducted monthly by academics at University College London.[20]
- Action on Smoking and Health with YouGov provides annual surveys of use, behaviours, risk perceptions and attitudes.[21]

Current data from the authoritative ONS surveys show very positive progress in the direction of smoking and vaping trends:

- UK adult (≥ age 18) smoking prevalence fell from 20% in 2011 to 14.7% in 2018
- Number of smokers 2018 = 7.2 million

Vaping prevalence is measured in a different survey (Opinion and Lifestyle Survey) which covers 16,000 households in Great Britain (GB = England, Scotland, Wales but not Northern Ireland) and adults ≥ age 16.

- Vaping prevalence reached 6.3% in 2018 a rise from 3.7% in 2014 and very low levels in 2011
- Number of vapers in 2018 = 3.2 million

Vaping has become a large-scale phenomenon relative to smoking and appears to be having significant downward pressure on smoking rates. In England, we are witnessing tobacco harm reduction in action and starting to benefit from a public health win.

Evidence-based support for tobacco harm reduction

In the tobacco control plan, the government explicitly commits to an evidence-based approach and argues that this leads directly to endorsement of tobacco harm reduction.

> **„4. Backing evidence-based innovations to support quitting**
> We are committed to evidence-based policy making, so we aim to:
> – Help people to quit smoking by permitting innovative technologies that minimise the risk of harm.
> – Maximise the availability of safer alternatives to smoking.
> The best thing a smoker can do for their health is to quit smoking. However, the evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco. The government will seek to support consumers in stopping smoking and adopting the use of less harmful nicotine products."

This embraces the opportunity of new technologies instead of defining them as threat. However, the position is not unconditional: it is contingent on foundations in supporting evidence and monitoring the marketplace for adverse effects.

> „The Department of Health] will, based on the evidence reviews undertaken by [Public Health England], review policy and regulation of nicotine delivery systems to provide an environment that facilitates smokers taking action to improve their health and the health of those around them, whilst minimising any risk of new nicotine addiction in children.
> [The Department of Health] will monitor the impact of regulation and policy on e-cigarettes and novel tobacco products in England, including evidence on safety, uptake, health impact and effectiveness of these products as smoking cessation aids to inform our actions on regulating their use."

As well as looking for problems or benefits arising from the products, this will also include assessment of the policies. This means the government will also monitor for *harmful unintended consequences of regulation* and respond accordingly.

To this end, Public Health England will update its evidence reports on e-cigarettes and other novel nicotine delivery systems annually until the end of the Parliament in 2022 and will include within quit smoking campaigns messages about the relative safety of e-cigarettes.

Evidence updates (see 2015 version) that cut through the detached academic activism and media clickbait about vaping are playing an important role in responsible government policy.

Indoor vaping – let property owners decide policy

There is no robust evidence of material harm from secondhand vapour. The vapour is much less toxic than cigarette smoke and there is no 'sidestream' vapour released from the device while not in use by the users. Cigarettes burn continuously at the tip releasing smoke even when not in use.

It is not just an absence of evidence of harm: the evidence that is available suggests the possibility of material harm from second-hand vapour would be minimal – whereas second hand cigarette smoke, especially the smoke generated when a user is holding a lit cigarette, has been associated with cancer and heart disease in bystanders. For example, one study estimated lifetime cancer risk from passive vaping compared to passive smoking.[22] The difference was of the order of 10,000 times i.e. negligible:

> „ECLR [Excess Lifetime Cancer Risk] for passive smokers is 5 orders of magnitude higher than the passive vaper."

Even if there are traces of hazardous agents in e-cigarette vapour, they are present at such low concentrations in exhaled vapour that they pose no meaningful risk to bystanders when compared to occupational exposure limit values (a benchmark of acceptable risk).[23]

The primary issue with vaping is one of *nuisance* rather than a material health threat. Excessive restrictions on where people can vape is a potential source of unintended consequences: if smokers are trying to switch from smoking to vaping, it would raise the chance of distraction or relapse.

In the absence of material risk to the health of bystanders, there is a very weak justification for a mandated regulatory approach in which a general prohibition would override the preferred approaches of property owners and managers. Consider the following approaches to vaping:

1. A bar wants to have a vape night every Thursday
2. A bar wants to dedicate one room where vaping is permitted
3. A corrections facility that is smoke-free wants to support inmates to manage nicotine withdrawal and related tensions by allowing them to vape
4. In a town with three bars, one decides it will cater for vapers, two decide they will not allow vaping
5. A bar manager decides on balance that his/her vaping customers prefer it and his/her other clientele are not that bothered – he'd do better by allowing it
6. A hotel wants to allow vaping in a few rooms and in its bar, but not in its restaurant
7. An office workplace decides to allow vaping breaks near the coffee machine to save on wasted smoking break time and encourage smokers to quit by switching
8. A care home wants to allow an indoor vaping area to encourage its smoking elderly residents to switch during the coming winter
9. A vape shop is trying to help people switch from smoking and wants to demo products in the shop
10. Vaping might be permitted in railway stations or airport terminals, but not on trains and aircraft
11. Many shops, public buildings and places catering for children decide not to allow vaping at all

Figure 1: hypothetical examples of 'bottom up' vaping policies

The argument is that there is no good rationale to override these reasonable decisions with a blanket prohibition when there is no plausible material risk to bystanders. The absence of a legislated ban does not create a 'right to vape' but it makes the vaping policy in any space a matter for the owner or manager rather than for government or legislature.

Public Health England has produced guidance for employers and organisations looking to introduce policies around e-cigarettes and vaping in public and recommend such policies to be evidence-based.[24] PHE recommends that e-cigarette use is not covered by smokefree legislation and should not routinely be included in the requirements of an organisation's smokefree policy. Action on Smoking and Health (UK) produced a set of structured questions to guide employers through vaping policy options.[25]

PHE will support local areas looking to implement local smokefree policies differentiating the levels of harm caused by existing tobacco products including e-cigarettes and other novel products.

This recognises that decisions on vaping policy should rest with owners and managers of properties and steers them not to include vaping in organisational smoke-free policies by default. This implicitly acknowledges that there is no justification (for example, material harm to bystanders or workers) to override the preferences of property owners with blanket vape-free laws. This is an ethically robust position to take.

Marketing restrictions on vaping products

The United Kingdom is bound by the European Union Tobacco Products Directive and its restrictions on the advertising, promotion and sponsorship of vaping devices and e-liquids (these are detailed Article 20(5) of Directive 40/14/EU).[26] These provisions essentially ban advertising in any medium capable of crossing a border – TV, radio, internet, publications etc. The Directive does not have jurisdiction over advertising that is fixed within a member state – billboards, point-of-sale, etc. The UK abides by the directive, but England has taken a more permissive approach to the advertising that is not covered by the Directive. Heated tobacco products are classified as tobacco products and all advertising of these products is banned by default because it is covered by the legislation designed to eliminate advertising of cigarettes.

The starting point for policy makers is to be clear on what the policy is supposed to achieve – what is the risk it is supposed to address. Advertising of cigarettes is largely banned in the EU because smoking kills 700,000 EU citizens annually, and advertising is thought to increase the appeal of this product and therefore potentially mean more people smoke, smoke more, smoke for longer or don't quit as soon as they might. Many activists have simply argued for applying the same measures to vaping products as to tobacco products. However, the basic justification – death and disease caused by smoking is just not valid for e-cigarettes.

These justifications for bans or restrictions on cigarette advertising cannot simply be applied to e-cigarette advertising or to any reduced risk product. As alternatives to smoking, e-cigarettes function as a form of stop-smoking technology. Advertising for e-cigarettes is a form of anti-smoking advertising. A ban on e-cigarette advertising might therefore be damaging to public health by erecting barriers to entry to a new and disruptive technology (vaping products) in a market dominated a harmful and entrenched incumbent (cigarettes). Again, it

is essential for policymakers to adopt an open-minded approach to unintended consequence of what superficially seem like positive policies.

The UK's approach to e-cigarette advertising was that adopted by the UK Committee on Advertising Practice (CAP) in 2014. The starting point is that conventional "legal, honest, decent, truthful" standards should apply, as they do to all advertising. That is in itself a significant protection. The CAP also produced useful guidelines on e-cigarette advertising that provide a reasonable balance of interest between protection of minors and promotion of new low-risk products to smokers. The framework is somewhat similar to the controls on alcohol advertising[27] controlling aspects of content and placement, but not imposing outright bans.

The CAP has recently consulted on allowing certain health claims to be permitted – a highly positive development. This draws a distinction between therapeutic claims (e.g. helps to stop smoking) and health claims (e.g. vaping greatly reduces exposure to carbon monoxide) and allows truthful and evidence based statements to be made in advertising.[28]

If the regulation of e-cigarette advertising had purely been a UK matter, then it is likely England would have a workable and proportionate system. Unfortunately, through the Tobacco Products Directive the EU all forms of advertising capable of crossing a border are banned outright.

Risk-proportionate taxation of nicotine products

The UK has one of the highest tobacco tax regimes in Europe and the wider world. In September 2019, a pack of 20 Marlboro cigarettes sells for around £11.50 (€13.00). Of this, £3.12 is the pre-tax price and £8.38 is the tax, the excise duty plus value added tax. Approximately, 73% of the price is tax. Budget cigarettes are cheaper but carry a higher burden of tax.

There are strong reasons not to tax reduced-risk alternative smoke-free nicotine products at all. This would reflect their value in supporting smoking cessation and addressing ethnic and socio-economic health inequalities. In the UK, over-the-counter nicotine replacement therapy (NRT) even attracts a tax subsidy, a reduced rate of value added tax (VAT), for its perceived value in reducing smoking.[29]

High and regressive tobacco taxation that falls disproportionately on poor or marginalised ethnic groups presents formidable ethical challenges. For users,

the obvious mitigating response has been to seek out illicit untaxed supply or down-trading to tobacco products that attract lower duties (typically, hand-rolling tobacco or "budget" brands). However, it is important to have as many *lawful* options as possible to mitigate the unfairness implicit in tobacco taxation – that includes facilitating low-cost pathways to switch from smoking to low risk alternatives. For that reason, we recommend a system of risk-proportionate taxation is implemented, as advocated by Chaloupka, Sweanor and Warner.[30]

So far, the UK has stuck loosely to the principles of risk proportionate taxation, though there is still room for improvement. The current rates of tobacco duty

- Nicotine replacement therapy sold over the counter attracts a tax subsidy – NRT attracts a reduced rate of VAT – 5% compared to the standard 20%. The evidence to support a tax discount for NRT sold over the counter is very weak.
- Non-pharmaceutical, non-tobacco oral nicotine products (for example, Zyn) attract no excise duty, but the full 20% rate of VAT is applied. These products are rising in popularity in many markets, but are not yet significant in the UK.
- E-cigarettes attract no excise duty, but the full 20% rate of VAT is applied. Depending on the approach taken, vaping can be as much as 90% cheaper than smoking. Economic factors are understood to be a major driver of switching and can provide a significant economic benefit to poor households – they may be important in addressing health and welfare inequalities.
- Heated tobacco products attract both excise duty and VAT. However, a separate category has been defined for heated tobacco products, so this allows for risk-based differentiation in future. The excise duty is currently at set the same level as hand-rolling tobacco on a weight basis: £234.65 per kg (September 2019). But because relatively small amounts of tobacco is used in the heated tobacco consumables, the price of heated products like iQOS is about half that of the equivalent cigarettes.
- Chewing tobacco attracts a lower excise duty than cigarettes or heated tobacco, £125.20 per kg. However, the main issue with smokeless tobacco is that oral tobacco (snus) is banned throughout the European Union, with the exception of Sweden. This is despite the low levels of smoking and smoking-related disease in Sweden that is attributable to snus.

The UK New Nicotine Alliance of consumers has advanced a powerful case to adopt risk-proportional taxation.[31] The NNA sets out key principles it want to see adopted by the government.

1. **The tax regime has implications for human life**. Given cigarettes and smoke-free alternatives are substitute products there will be positive price cross-elasticities between smoking and smoke-free products. A significant

tax on smoke-free products will cause a relative increase in the demand for combustibles – and will, therefore, cause more smoking. The default excise rate should be zero, proceeding with caution if higher rates are proposed.

2. **Setting the level: the highest level applied to any smoke-free product should be substantially lower that the lowest rate applied to any combustible product**. Maintain a significant differential between the cost of being a smoke-free product user and a smoker to maintain an incentive to switch and to avoid developing a black market or encouraging home-made production.
3. **Recognise cost burdens of tax administration**. Vaping is likely to have at least a 95% lower risk than smoking. If excise duties were set proportionate to risk relative to smoking to create a proportionate deterrent, then the tax yield for e-cigarettes would be so low it would not be worth the cost of collecting. The only way to make a non-zero tax viable is to tax smoke-free *disproportionately* to risk, thereby imposing a disproportionate deterrent to users switching.
4. **Comparison with NRT – therapeutic value**. Smoke-free products in fact produce a *net health benefit* by reducing smoking. From an economic and tax perspective, such products should be viewed more like over-the-counter medicines. Some jurisdictions apply a reduced sales tax to nicotine replacement therapy – a tax *subsidy* – to reflect its positive public health value.

It is argued that because tax-take is falling from cigarettes as people switch or quit, then excise duty should be applied to alternative products to compensate. This does not have an economic rationale, even if superficially appealing politically. Tax should be raised from the least distorting and most efficient tax base available: there is no reason why cigarette excise losses should not be recovered from taxes on, for example, carbon dioxide, fuel charges, removal of tax subsidies or by cutting spending that is less cost-effective than reducing smoking.

Innovation and heated tobacco products

The Tobacco Control Plan recognises the potential value of innovation. This is an important feature of tobacco policy, because many jurisdictions have erected substantial barriers or even outright prohibitions of products like e-cigarettes or heated tobacco products.

> „In addition there has been the development and very recent introduction of novel tobacco products that claim to reduce the harm of smoking. We welcome innovation that will reduce the harms caused by smoking and will evaluate whether products such as novel tobacco products have a role to play in reducing the risk of harm to smokers."

The UK has an open mind to innovation that could reach more people with a product they find acceptable and pleasurable. However, the UK has not shown that it has a fully open mind about tobacco harm reduction: it supported the ban on oral tobacco (Swedish snus) despite extensive evidence that snus is responsible for Sweden's anomalously low rate of smoking (5% daily smoking in Sweden compared to an average of 24% in the European Union).[32]

Medicalisation and treatment using e-cigarettes

Though there was a battle over medicalisation of e-cigarettes in 2010 and 2013, the UK government still sees this as an important route to market that is allowed under the Tobacco Products Directive.

> „The Medicines and Healthcare products Regulatory Agency (MHRA) will ensure that the route to medicinal regulation for e-cigarette products is fit for purpose so that a range of safe and effective products can potentially be made available for NHS prescription.
> [Public Health England] will provide evidence-based guidance for health professionals to support them in advising smokers who want to use e-cigarettes or other nicotine delivery systems to quit."

The tension over medicalisation is no longer there as long as it is available as a parallel track and not a mandatory pathway. Products with a medical marketing authorisation may be more readily used in healthcare settings or even prescribed as treatment options. It is possible that they could also have product specifications and marketing approaches that would not be permitted under the Tobacco Products Directive, for example higher nicotine strength than the 2% limit imposed by the Directive.

The key issue here is the need for a positive approach by health and medical professionals – what they say needs to be realistic and patient-focussed. England already has good officially-blessed guidance on e-cigarettes for health professionals and it will be very helpful to have this routinely updated. Simplifying the medical licensing option is of lesser importance, but could provide some benefits within healthcare settings, but only as long as it remains *an option*.

Advice to healthcare professionals and to users

There is now recognition among tobacco control professionals and public sector practitioners that e-cigarettes can be used constructively to reduce harm. For example, in Britain the National Centre for Smoking Cessation and Training and Public Health England, the government's public health agency, have developed evidence-based guidance and training for health and smoking cessation professionals.[33] [34] It provides a clear and measured assessment of the state of science and best practice. This is a summary of the advice given to UK health professionals by the National Centre For Smoking Cessation and Training and Public Health England:

"**Recommendations for practice**

1. Be open to e-cigarette use in people keen to try them; especially in those who have tried and failed to stop smoking using licensed stop smoking medicines.
2. Provide advice on e-cigarettes that includes:
   - E-cigarettes provide nicotine in a form that is much safer than smoking.
   - Some people find e-cigarettes helpful for quitting, cutting down their nicotine intake and/or managing temporary abstinence.
   - There is a wide range of e-cigarettes and people may need to try various types, flavours and nicotine dosages before they find a product that they like.
   - E-cigarette use is not like smoking and people may need to experiment and learn to use them effectively (e.g. longer 'drags' may be required and a number of short puffs may be needed initially to activate the vaporiser and improve nicotine delivery). They may also need to recognise when atomisers need replacing.
   - People previously using e-cigarettes while smoking (e.g. to reduce the number of cigarettes that they smoke) may need to consider changing devices and/or nicotine concentrations when making a quit attempt.
   - Although some health risks from e-cigarette use may yet emerge, these are likely, at worst, to be a small fraction of the risks of smoking. This is because e-cigarette vapour does not contain the products of combustion (burning) that cause lung and heart disease, and cancer."

The National Health Service, which is widely respected in the UK, has also taken up the cause and provides pragmatic advice and factual information to smokers looking to quit. The NHS has incorporated vaping as a harm reduction strategy in its "Live Well" advice and "One You" campaign.

Public Health England has also built vaping into 'Stoptober', the annual government-backed stop-smoking campaign. Stoptober embraced e-cigarettes in

October 2017 and became the first government backed smoking cessation campaign to advertise the idea of vaping to quit smoking on television.

This is a balanced and open-minded approach and reflects an emerging consensus on how to exploit the opportunities of e-cigarettes, while containing any risks. More examples of innovative public sector initiative are available via a page devoted to England on the Counterfactual website.[35]

Brexit and UK tobacco policy

The government believes that some aspects of its policy could be improved and that the constraints imposed by the EU Tobacco Products Directive were removed.

> „Over the course of this Tobacco Control Plan, the government will review where the UK's exit from the EU offers us opportunities to re-appraise current regulation to ensure this continues to protect the nation's health. We will look to identify where we can sensibly deregulate without harming public health or where EU regulations limit our ability to deal with tobacco.
> In particular, the government will assess recent legislation such as the Tobacco Products Directive, including as it applies to e-cigarettes, and consider where the UK's exit provides opportunity to alter the legislative provisions to provide for improved health outcomes within the UK context."

This might give the opportunity, for example, to lift some EU-imposed restrictions that have no support in evidence. For example, bans on advertising, limits on nicotine strengths, excessive warnings, and limits on tank and container size.[36 37]

A more pessimistic view of Brexit and vaping is possible, depending on the precise form of Brexit that the UK takes. For example, it is possible that the UK will remain in a lengthy transitional period or measures necessary to secure an open border between Ireland and the UK in Northern Ireland (the 'backstop') will mean that the UK stays in close regulatory alignment with single market regulation. That would likely include the Tobacco Products Directive. However, in doing so the UK would also become a 'policy-taker' and be excluded from negotiations and voting on new measures. The UK could therefore find itself complying with a new version of the Tobacco Products Directive in the mid-2020s having had little say in its development. It is likely that losing the UK voice at the table will be disadvantageous to vapers and smokers across the European Union. The EU will lose a champion of the rational and pragmatic harm reduction approach, increasing the relative weight of abstinence-only ideological perspectives in the decision-making.

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[Report]

Comparison of Chemicals in Mainstream Smoke in Heat-not-burn Tobacco and Combustion Cigarettes

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Abstract **:** Because of the health effects of secondhand smoke, the Japanese government is trying to establish an effective law for total avoidance of secondhand smoke in indoor environments for tobacco-free Tokyo Olympic and Paralympic games 2020, as requested by the International Olympic Committee (IOC) and the World Health Organization (WHO). Meanwhile, Philip Morris International has begun selling a new heat-not-burn tobacco, iQOS, which it claims is designed not to produce secondhand smoke. There is little scientific data, however, of the hazards and toxicity of iQOS. In this study, we evaluated several harmful compounds (nicotine, tar, carbon monoxide (CO) and tobacco-specific nitrosamines (TSNAs)) in the mainstream smoke and fillers of iQOS, and compared their concentrations with those from conventional combustion cigarettes. The concentrations of nicotine in tobacco fillers and the mainstream smoke of iQOS were almost the same as those of conventional combustion cigarettes, while the concentration of TSNAs was one fifth and CO was one hundredth of those of conventional combustion cigarettes. These toxic compounds are not completely removed from the mainstream smoke of iQOS, making it necessary to consider the health effects and regulation of iQOS.

Keywords **:** heat-not-burn tobacco, tar, nicotine, carbon monoxide, tobacco specific nitrosamines.

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Introduction

The health effects of secondhand smoke have been widely recognized as a common issue worldwide by the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) [1], and secondhand smoke was categorized as a carcinogen to humans (Group 1) by the International Agency for Research on Cancer (IARC) [2]. On the other hand, tobacco companies are developing new products, such as electronic cigarette and heat-not-burn tobacco. iQOS, a representative product of heat-not-burn tobacco sold by Philip Morris International *Inc*. (NY, USA), is spreading rapidly in Japan. Philip Morris claims that the revolutionary features of iQOS are no emission of secondhand smoke, tobacco specific smell or cigarette ash. Considering these features, it can be assumed that the number of iQOS users will increase in the future.

The Japanese government is considering measures to prevent secondhand smoke, based on FCTC article 8, because the International Olympic Committee (IOC) and the WHO agreed to promote tobacco-free Tokyo Olympic and Paralympic Games 2020. The government is trying to establish an amendment to prevent secondhand smoke and to totally prohibit smoking in indoor environments, especially in restaurants, bars, *etc*, because at present there are no legal restraints in indoor or outdoor environments in Japan. In spite of

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increasing numbers of heat-not-burn tobacco users, however, there has been no explicit risk assessment of iQOS, because there is only limited scientific evidence of its safety.

In this first study of the evaluation of heat-not-burn tobacco, we analyzed the concentration levels of basic harmful components (nicotine, tar, carbon monoxide (CO) and tobacco-specific nitrosamines (TSNAs)) in the mainstream smoke and tobacco fillers of first-generation iQOS, which became available in Japan in 2014.

Materials and Methods

Apparatus and reagents

Gas chromatography (GC) coupled with a flame ionization detector (FID) was used to quantify the nicotine in the mainstream smoke and tobacco filler. The analytical column was HP-INNOWAX (30 m × 0.25 mm i.d, 0.25 μm) (Agilent technologies, CA, USA). Liquid chromatography-tandem mass spectrometry (LC-MS/MS), Micromass Quattro LC (Waters, MA, USA) was used to quantify TSNAs. The analytical column used for LC-MS/MS was Zorbax Eclipse XDB C-18 (2.1 × 150 mm, 3.5 μm) (Agilent technologies). A non-dispersive infrared analyzer (NDIR, IR200) (Yokogawa Electronic Co., Tokyo, Japan) was used for the measurement of CO. Nicotine 97%, sodium hydrate > 97%, L-ascorbic acid > 99.6%, dibasic potassium phosphate > 99.0%, citric acid > 98%, *n*-hexane > 96%, dichloromethane > 99%, dimethylsulfoxide > 99.0%, 2-propanol > 99.7%, methanol (High performance liquid chromatography (HPLC) grade) > 99.9%, acetic acid > 99.7% and hydrogen peroxide 30% were purchased from Wako Pure Chemical Industries, *Ltd*. (Osaka, Japan). Acetonitrile and ammonium acetate ≥ 99.99% were purchased from Sigma-Aldrich *Inc*. (St. Louis, MO, USA), and *n*-heptadecane was purchased from Tokyo kasei Co., *Ltd*. (Tokyo, Japan). *N'*-nitrosonornicotine (NNN), 4-(Methylnitrosamino)-l-(3-pyridyl)-l-butanone (NNK), *N'*-nitrosoanatabine (NAT), *N'*-nitrosoanabasine (NAB), NNN-d_4, NNK-d_3, NAT-d_4 and NAB-d_4 were obtained from Tronto research chemicals. Concentrated nitric acid 60% was purchased from Kanto Chemical Co., *Inc*. (Tokyo, Japan). The water used for the sample preparation and analysis was deionized, and further purified using a Milli-Q water system (Millipore Co., Bedford, MA, USA). In this study, we used conventional combustion cigarettes (3R4F and 1R5F) from the University of Kentucky (Lexington, KY, USA), and iQOS (regular and menthol) from Philip Morris International *Inc*. (NY, USA). According to a previous report of conventional combustion cigarettes, 1R5F is a low yield cigarette, and 3R4F is a relatively high yield cigarette [3]. According to International Organization for Standardization (ISO) 3402, these cigarettes were used for measurement after being placed at 22ºC temperature and 60% humidity for 2 days [4].

Preparation of mainstream smoke and filler samples

Mainstream smoke was collected according to the intense regime described in Standard operating procedure (SOP) 01 [5] and health Canada, official method T-115 [6]. Briefly, mainstream smoke was collected under the conditions of 55 m*l* puff volume, 2 s puff duration, 30 s puff interval, and 100% blocking of the filter ventilation holes with Mylar adhesive tape, although there are no filter ventilation holes in iQOS. The puff number of one conventional combustion cigarette was 9 times, and that of Heat-not-burn tobacco was 11 times. Each sampling was performed by 3 conventional combustion cigarettes or Heat-not-burn tobacco. The tobacco fillers were taken out from each cigarette for analysis of each component, and we prepared samples fractured by a blender (KC-4508) (Twinbird Co., Niigata, Japan). These samples were extracted by 2-propanol and ammonium acetate, and analyzed by an appropriate method of SOP for nicotine and TSNAs, as described below.

Measurement of concentrations of nicotine, tar, CO and TSNAs

As a member of WHO collaborating centers for tobacco control, we developed the WHO tobacco laboratory network (TobLabNet) Official Method SOP for the measurement of each component of tobacco filler and combustion cigarette. In this study, we applied these methods for evaluating iQOS. We measured the nicotine, CO and TSNAs in the mainstream smoke of iQOS according to the WHO TobLabNet Official Method SOP03 [7] and SOP10 [8]. Nicotine and CO were measured using GC-FID and NDIR after the collection and pretreatment of mainstream smoke. TS-

NAs were measured using LC-MS/MS. The nicotine in the tobacco fillers was measured according to the method of SOP04 [9], and the TSNAs in the tobacco fillers were measured according to the method of SOP03. We used the same analytical instruments for the tobacco fillers and the mainstream smoke. The amount of tar exhausted in the mainstream smoke was calculated by subtracting the amount of nicotine and water from the total particulate matter (TPM).

Results and Discussion

The concentrations of tar, nicotine, TSNAs and CO detected in the tobacco filler and mainstream smoke of iQOS are shown in Tables 1 and 2, respectively. The transfer rates of each compound from tobacco filler to mainstream cigarette smoke are shown in Table 2. These concentrations were compared with conventional combustion cigarettes 1R5F and 3R4F, which are widely used for tobacco research.

Concentrations of tar, nicotine and CO in mainstream smoke and filler of iQOS

Tar and nicotine are the major components in the particulate phase, and CO is a chemical compound in the gas phase of mainstream smoke. The amounts of tar and nicotine are printed on the tobacco packages, but the contents of nicotine and tar in iQOS remain to be defined, in contrast to other combustion cigarettes in Japan. Therefore, we measured the concentrations of these compounds in the samples of iQOS. The concentrations of nicotine in the fillers of iQOS were 15.7 mg/g (regular) and 17.1 mg/g (menthol) (Table 1), almost the same as in conventional combustion cigarettes (3R4F: 19.7 mg/g, 1R5F: 15.9 mg/g) (Table 1). Nicotine in the mainstream smoke of iQOS (regular: 1.1 mg/cig, menthol: 1.2 mg/cig) (Table 2) was also detected at a level comparable with 1R5F (1.0 mg/cig) and relatively lower than 3R4F (1.7 mg/cig) (Table 2). By using these values, we estimated the transfer rates of nicotine at 23.4% (regular) and 23.5% (menthol) (Table 2), indicating that iQOS has more effective transfer rates than the conventional combustion cigarettes (3R4F: 11.3%, 1R5F: 11.5%) (Table 2). On the other hand, the concentration of tar in the mainstream smoke of iQOS was half or less than that of the conventional combustion cigarettes. From a comparison with other data reported by Schaller *et al*., these concentrations were at almost the same level [10].

Next we measured the concentration of CO in the mainstream smoke of iQOS. It is well known that CO causes adverse effects on the lungs, hearts and blood vessels [11], and there are many reports on the mechanism of CO generation processes in cigarette smoke [12, 13]. In these reports, CO is produced by an oxidative reaction with the carbon constituent, especially at a higher range of combustion temperature >350ºC. Because combustion cigarettes operate by heating at 900ºC during a puff, while iQOS can operate at a maximum of 350ºC, we anticipated a lower level of CO exhaust from iQOS than from combustion cigarettes. We found that the actual concentration of CO emitted by iQOS (regular: 0.44 mg/cig, menthol: 0.43 mg/cig) (Table 2) was approximately one-hundredth of that emitted by the conventional combustion cigarettes (3R4F: 33.0 mg/cig, 1R5F: 29.7 mg/cig) (Table 2). The lower concentrations of CO in the mainstream smoke of iQOS was considered to be due to its heating mechanism.

Concentrations of TSNAs in mainstream smoke and filler of iQOS

TSNAs are well known carcinogenic compounds in cigarettes, and are mainly generated from nicotine in the manufacturing process of tobacco leaf. In this experiment, we analyzed the concentration levels of four major TSNAs (NNN, NAT, NAB, NNK) in tobacco filler and in the mainstream smoke of iQOS and conventional combustion cigarettes. Previous *in vivo* studies have shown that NNK and NNN, especially, are highly carcinogenic [14], and are evaluated as carcinogenic to humans (Group 1) by the IARC, while NAB and NAT are not so highly carcinogenic.

When we measured the four kinds of TSNAs in the fillers of iQOS and conventional combustion cigarettes, they were detected at almost the same ratio in every kind of cigarette. The concentration levels of TSNAs detected in tobacco fillers and mainstream smoke of iQOS, however, were significantly lower than those of conventional combustion cigarettes, although the transfer rates of NNN, NAT and NNK in iQOS were slightly higher than those in conventional combustion cigarettes. According to a previous report about the

levels of TSNAs in commercial cigarettes [15], it was suggested that the downward trend of TSNA levels in mainstream smoke reflects the improvements in quality achieved by industry and the agricultural community for the reduction of TSNA levels. We speculated that the lower TSNA levels in iQOS found in this study was achieved by a specific technique in the production of tobacco leaf.

Conclusion

In this study, we could provide important information showing that the concentration levels of hazardous compounds in the mainstream smoke of iQOS are much lower than those in conventional combustion cigarettes. Although it is low concentration, toxic compounds are definitely included in the mainstream

Table 1. Concentrations of tar, nicotine, CO and TSNAs in tobacco fillers of iQOS (regular and menthol) and conventional combustion cigarettes (3R4F and 1R5F)

Element	Tobacco filler (concentration per gram)				Tobacco filler (concentration per cigarette)			
	iQOS regular	iQOS menthol	3R4F	1R5F	iQOS regular	iQOS menthol	3R4F	1R5F
Tar	–	–	–	–	–	–	–	–
					(mg/cig)			
Nicotine (mg/g)	15.7 ± 0.2	17.1 ± 0.6	19.7 ± 0.2	15.9 ± 0.3	4.7 ± 0.1	5.1 ± 0.2	15.0 ± 0.1	8.7 ± 0.1
TSNAs (ng/g)					(ng/cig)			
NNN	314.7 ± 4.8	336.7 ± 9.3	2477.0 ± 86.0	3067.0 ± 122.0	94.4 ± 1.4	101.0 ± 2.8	1889.0 ± 66.0	1691.0 ± 67.0
NAT	332.5 ± 5.2	315.0 ± 6.8	1758.0 ± 56.0	1656.0 ± 55.0	99.8 ± 1.6	94.5 ± 2.0	1341.0 ± 43.0	913.0 ± 30.0
NAB	18.5 ± 2.5	17.2 ± 1.2	85.0 ± 1.0	84.0 ± 2.0	5.6 ± 0.8	2.6 ± 0.4	65.0 ± 1.0	46.0 ± 1.0
NNK	170.4 ± 1.0	194.1 ± 2.0	697.0 ± 31.0	747.0 ± 19.0	51.1 ± 0.3	58.2 ± 0.6	532.0 ± 24.0	412.0 ± 10.0
Total of TSNA	836.1 ± 9.1	863.0 ± 13.4	5018.0 ± 83.0	5554.0 ± 167.0	250.8 ± 2.7	258.9 ± 4.0	3826.0 ± 63.1	3061.0 ± 92.0
CO	–	–	–	–	–	–	–	–

Values are mean ± SD, TSNAs: tobacco specific nitrosamines, NNN: *N*-nitrosonornicotine, NAT: *N'*-nitrosoanatabine, NAB: *N*-nitrosoanabasine, NNK: Nicotine-derived nitrosamine ketone, CO: carbon monoxide

Table 2. Concentrations of tar, nicotine, CO and TSNAs in mainstream cigarette smoke and transfer rates of each component in iQOS (regular and menthol) and conventional combustion cigarettes (3R4F and 1R5F)

Element	Mainstream cigarette smoke				Transfer rate (%)			
	iQOS regular	iQOS menthol	3R4F	1R5F	iQOS regular	iQOS menthol	3R4F	1R5F
TPM (mg/cig)	44.0 ± 11.4	49.9 ± 8.6	36.9 ± 1.9	28.9 ± 2.3	–	–	–	–
Water (mg/cig)	33.1 ± 10.2	35.3 ± 8.3	10.1 ± 0.9	8.8 ± 1.1	–	–	–	–
Tar (mg/cig)	9.8 ± 3.0	13.4 ± 2.2	25.2 ± 1.5	19.2 ± 1.3	–	–	–	–
Nicotine (mg/cig)	1.1 ± 0.1	1.2 ± 0.1	1.7 ± 0.1	1.0 ± 0.1	23.4	23.5	11.3	11.5
CO (mg/cig)	0.44 ± 0.04	0.43 ± 0.04	33.0 ± 1.8	29.7 ± 1.7	–	–	–	–
TSNAs (ng/cig)								
NNN	19.2 ± 2.1	24.9 ± 3.5	311.1 ± 24.3	240.7 ± 6.6	20.3	24.7	16.4	14.2
NAT	34.0 ± 3.1	37.2 ± 3.9	246.4 ± 16.9	183.1 ± 6.0	34.1	39.4	18.3	20.1
NAB	4.5 ± 0.5	5.5 ± 0.6	30.4 ± 2.0	26.2 ± 0.5	80.3	211.5	46.8	57.0
NNK	12.3 ± 1.5	13.8 ± 2.6	250.4 ± 13.7	107.0 ± 5.0	24.1	23.7	47.1	26.0
Total of TSNA	70.0 ± 7.2	81.4 ± 10.4	838.2 ± 53.7	557.1 ± 15.7	27.9	31.4	21.9	18.2

Values are mean ± SD, TPM: total particulate matter, TSNAs: tobacco specific nitrosamines, NNN: *N*-nitrosonornicotine, NAT: *N'*-nitrosoanatabine, NAB: *N*-nitrosoanabasine, NNK: nicotine-derived nitrosamine ketone, CO: carbon monoxide

smoke of iQOS. Mitova *et al*. showed that exhalation from smokers increased the background levels of some compounds, such as acetaldehyde and nicotine, in the office [16], so adverse effects of these compounds may easily spread to an unspecified population in the public and in crowded indoor places, such as restaurants via secondhand smoking. Various other hazardous compounds, such as volatile organic compounds (VOCs), are also included in both the particle and gas phases of mainstream smoke of iQOS [10, 17]. In consideration of this, we need further chemical evaluation and studies of their health effects in order to support regulation of iQOS in the future.

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Conflicts of Interest

The authors declare no conflicts of interest.

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加熱式タバコと燃焼式タバコの主流煙中に含まれる有害成分の比較

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要　　旨：受動喫煙による健康影響が懸念される中, たばこ規制枠組条約（FCTC）締約国として我が国でもその対策が推進され, 現在, 2020年東京オリンピック・パラリンピックの開催に向けて, 受動喫煙防止のための効果的な法の整備が国際オリンピック委員会（IOC）と世界保健機関（WHO）の要請のもと進められている．一方, Philip Morrisは新型タバコとして, 加熱式タバコiQOSの販売を開始した．iQOSは, 副流煙が低減化された新型タバコとして販売されているものの, 受動喫煙や毒性に関しては限られた情報しかない．本研究では, 科学的な観点からiQOSを評価するため, タバコ葉およびタバコ主流煙中の主成分であるタール, ニコチン, 一酸化炭素およびタバコ特異的ニトロソアミン（TSNAs）の濃度レベルを従来の燃焼式タバコ（標準タバコ）と比較した．iQOS専用のタバコ葉および主流煙からは, 標準タバコと同程度のニコチンが検出されたのに対して, TSNAsは, タバコ葉および主流煙のいずれも標準タバコの5分の1程度にまで濃度が低減され, 燃焼マーカーとしても知られる一酸化炭素（CO）は, 標準タバコの100分の1程度の濃度であった．しかしながら, この様な有害成分は完全に除去されているわけではなく, 少なからず主流煙に含まれていた．今後, iQOSの使用規制には, 有害成分の情報に加え, 受動喫煙や毒性などの情報から, 総合的に判断していく必要がある．

キーワード：加熱式タバコ, タール, ニコチン, 一酸化炭素, タバコ特異的ニトロソアミン．

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