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Assessing use of inhalable nicotine products within complex markets: the dilemma of heated tobacco products

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ABSTRACT

The introduction of electronic inhalable products, such as nicotine vaping products (NVPs) and heated tobacco products (HTPs), has further diversified the nicotine market landscape. This poses unique challenges in measuring self-reported nicotine use behaviours, which have been the hallmark of tobacco surveillance systems. This paper raises concerns of potential measurement error for electronic inhalable product use in surveys due to similarities in product design between NVPs and HTPs, as well as changing trends in cannabis administration. We identify several strategies for addressing this issue (eg, including descriptive preambles in surveys that differentiate product classes from one another; incorporating survey questions that probe beyond an initial question regarding product use). In the absence of comprehensive validation studies, caution is warranted when interpreting survey results that rely on self-reported HTP use.

INTRODUCTION

The combustible cigarette has been the dominant form of nicotine use throughout modern history.¹ However, cigarette consumption has been in steady decline across many countries of late, due in large part to widespread knowledge of the dire health consequences of combusted tobacco and the implementation of comprehensive tobacco control policies.² This has prompted unprecedented diversification of regional nicotine market-places, as long-established alternative products (eg, cigars, waterpipe/hookah/shisha/narghile, smokeless tobacco) have gained popularity³ and new products have been unveiled. Two newer products are nicotine vaping products (NVPs; often termed ‘e-cigarettes’) and heated tobacco products (HTPs). Both product types involve electronic devices that produce inhalable nicotine-containing aerosols but do not rely on combustion to do so. Whereas NVPs aerosolise a liquid containing nicotine but *no actual tobacco leaf*, HTPs heat *actual tobacco leaf* often in the form of manufactured sticks or capsules. Due to this nuance, we use the acronym NVP in place of the term electronic nicotine delivery system,⁴ so as to differentiate the two electronic product categories that we primarily discuss. Likewise, we use the acronym HTP for devices that heat actual tobacco leaf, as opposed to terms used interchangeably by manufacturers (see [table 1](#)) that suggest a complete lack of combustion (‘heat-not-burn’) despite evidence that charring does occur during HTP use.⁵

What this paper adds

- ⇒ Inhalable nicotine products, including nicotine vaping products and heated tobacco products, continue to populate the global nicotine market-place.
- ⇒ Similarities between electronic inhalable nicotine product classes, as well as the use of analogous devices to administer cannabis, present measurement challenges that have received little attention in the tobacco control literature.
- ⇒ Survey estimates of nicotine use will be impacted by growing availability of these products, as accurately capturing use of distinct electronic inhalable products via self-report is difficult.
- ⇒ We outline several recommendations that population-based surveys could apply to establish better practices in measuring use of electronic inhalable nicotine products, as well as future directions for investigating this issue.

Accurate measurement of nicotine use behaviours is crucial for tracking prevalence and trends in use, including transitions between different nicotine products. The monitoring of real-world use patterns is predominantly achieved via national and international health surveillance systems (eg, Behavioral Risk Factor Surveillance System, Global Adult Tobacco Survey, Youth Risk Behavior Surveillance System), along with other large observational studies (eg, US Population Assessment of Tobacco and Health Study, International Tobacco Control Policy Evaluation Project, National Youth Tobacco Survey) that focus on tobacco and/or nicotine use. The WHO’s Framework Convention on Tobacco Control specifically calls for establishing ‘...programmes for national, regional and global surveillance of the magnitude, patterns, determinants and consequences of tobacco consumption...’⁶ underscoring the need for valid and reliable measures to inform nicotine science and regulation.

The influx of electronic inhalable products poses unique challenges in measuring nicotine use behaviours, particularly in jurisdictions with complex market-places. This Special Communication details our underlying concerns with potential measurement error and misclassification of electronic inhalable nicotine product use in surveys.



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Table 1 Product class labels used by multinational tobacco corporations

Terminology used in this manuscript	Korea Tobacco & Ginseng	Japan Tobacco International	Philip Morris International	British American Tobacco
New inhalable products	Next-generation products	Reduced risk products	Smoke-free products	Reduced risk products
Heated tobacco products	Heat-not-burn products	Tobacco vapour products (<i>directly heated*</i> and <i>indirectly heated vapour†</i> subtypes)	Heated tobacco systems	Tobacco heating products
Nicotine vaping products	Liquid vape-type electronic cigarettes	Electronic cigarettes	E-vapours	Vapour products

Data obtained from https://en.ktng.com/down?fnm=Product_Innovation.pdf&orgFnm=Product_Innovation.pdf; <https://www.jti.com/about-us/what-we-do/our-reduced-risk-products>; <https://www.pmi.com/smoke-free-products>; <https://www.bat.com/provingreducedrisk>

*Refers to heated tobacco products that exclusively use tobacco sticks.

†Refers to 'hybrid' heated tobacco products that use tobacco sticks and an e-liquid cartridge simultaneously.

We subsequently identify strategies for better understanding and addressing the subject as it pertains to HTPs.

Historical context around electronic inhalable nicotine products

NVPs were first patented in 2003 and over the ensuing decade became major players in many nicotine markets.⁷ Technological innovations in the mid-to-late 2010s sparked considerable increases in NVP popularity, among not only current and former adult cigarette smokers⁸ but also youth and young adults in a handful of Western countries.^{9–10} This fast-paced evolution has transformed NVPs into an expansive product category encompassing devices of all shapes, sizes and user modifiability,¹¹ in addition to thousands of unique flavours added to nicotine solutions.¹² NVP devices and nicotine solutions are manufactured by multinational corporations and independent companies. Common NVP retail environments include brick-and-mortar 'vape shops', gas stations, convenience stores, pharmacies, supermarkets and various internet-based vendors, depending on the country/region.¹³

Tobacco companies first commercialised HTP technology in the 1980s. These earlier HTPs failed to garner meaningful consumer interest.¹⁴ In 2014, a new generation of HTPs were debuted with Philip Morris International's (PMI) launch of IQOS in Japan, followed shortly thereafter by the British American Tobacco's (BAT) *glo* and Japan Tobacco International's (JTI) *Ploom TECH*. As of February 2021, IQOS is available through mainstream channels in 62 national nicotine markets.¹⁵ The global HTP market is significantly less developed than for NVPs and is dominated by multinational corporations, with IQOS retaining the highest market shares internationally. Devices are primarily sold in brand-specific 'boutique' stores reminiscent of popular technology company storefronts (eg, Apple, Microsoft). In 2019, more than half of HTP sales worldwide occurred in Japan,¹⁶ which has remained the leading HTP market since IQOS's introduction. The Republic of Korea is the second largest HTP market, where the Korea Tobacco & Ginseng's (KT&G) *lil* product line competes with other major HTP brands. Although IQOS has gained popularity in certain Central and Eastern European metropolitan centres,¹⁷ HTP use remains uncommon in Western countries, where IQOS has been marketed for multiple years (eg, Canada, England, Germany, Spain, Poland).^{18–19} The sale of HTPs remains banned in China—the largest cigarette market in the world—however, China National Tobacco Corporation has piloted a number of HTP brands in neighbouring markets, including the Republic of Korea, the Philippines and Laos.²⁰

CHALLENGES OF MEASURING ELECTRONIC INHALABLE NICOTINE PRODUCT USE

Similarities in nicotine product design

Measurement challenges posed by electronic inhalable products stem from an array of overlapping characteristics and lack of distinctive features between individual product classes. This is most evident between HTPs and NVPs due to marked similarities in device design characteristics, including a reliance on battery-powered electronics, 'high-tech' components (eg, inhalation-activated LED [light emitting diode] lights), sleek colour schemes, and metal or hard plastic device bodies (figure 1). Exhaled emissions can be visually similar between certain NVP and HTP device brands, and popular subtypes of both products require users to purchase premanufactured single-use materials for consumption during use. The numerous NVP device subtypes already available (eg, tanks, pods, pod mods, etc) may lead consumers to think of HTPs as an additional NVP device category, rather than an entirely separate class of products. Another added complication comes from a handful of 'hybrid' HTP devices available regionally, most notably Ploom TECH, *glo Sens* and *lil Hybrid*. These products are commonly regulated as HTPs and treated as such in research settings, yet they differ from IQOS and the original *glo* series by simultaneously using a tobacco stick/capsule and a liquid-containing pod. JTI's Ploom TECH device looks almost identical to their popular NVP devices (*Logic*) (figure 1). In the USA, Ploom TECH is rebranded as *Logic Vapeleaf*, which may further confuse users in differentiating the two product classes.²¹

There may also be confusion stemming from the cigarette-like tobacco sticks that many HTP devices heat. In certain countries (eg, Japan, Republic of Korea, USA), tobacco sticks share brand identity and packaging design with popular conventional cigarette brands, including *Marlboro*, *Mevius*, *Kent* and *Dunhill*.



Figure 1 Various heated tobacco product and nicotine vaping product devices.

Tobacco sticks for HTPs are often placed side-by-side with cigarettes in retail locations. New tobacco-free herbal sticks (eg, *Nicoless*, *Healrier*) are also being manufactured, some of which are free of nicotine altogether. While use of herbal sticks is relatively uncommon, they show it is possible to be an IQOS-style device user without heating actual tobacco leaf.

Regulatory frameworks for new tobacco products

Regulatory agencies rely on rigid frameworks for evaluating new products against predetermined standards and subsequently implement guidelines which can be enforced consistently. Appropriate and comprehensive taxonomies are key to successful regulation, yet the spectrum of electronic inhalable products makes such classification difficult. Both Ploom TECH and IQOS consistently fall under the 'HTP' designation, even as Ploom TECH's toxicological profile appears more similar to that of NVPs than other HTPs.²² In practice, regulatory classifications can sometimes exacerbate measurement challenges: the Korean legal term for NVP translates as 'electronic tobacco', while HTPs are called 'cigarette-type electronic tobacco' (table 2), making it easy for consumers to infer that HTPs are a subcategory of NVPs.²³

Consumer perceptions about new tobacco products

Whereas regulators have a vested interest in rigid classifications and nomenclature, product users in the real world do not. Regardless of attempts by public health organisations, regulatory agencies and manufacturers²⁴ to communicate product class distinctions, users may not adhere to them. As discussed above, one issue arises from similarities in the design of different tobacco product classes. Historically this has been the case with other product types as well, such as users referring to little cigars as cigarettes due to their similar physical features.²⁵ An adjacent issue stems from terminology preferences used by tobacco users when describing the act of using a certain product (eg, some users of the NVP brand Juul have preferred brand-specific verbs to describe use of that brand ('juuling') rather than general terms such as vaping).²⁶ Additionally, certain marketing strategies used by tobacco companies, such as the use of Marlboro branding for both conventional cigarettes and tobacco inserts for IQOS, may create additional challenges in monitoring use of new tobacco products. For inhalable nicotine products, this may be exacerbated by verbs for use becoming less intuitive (eg, do you 'vape', 'smoke', 'puff' or 'use' HTPs?). Terminology tendencies may also differ according to HTP users' device subtype preferences. Given the shared characteristics between NVP devices and 'hybrid' HTP devices such as Ploom TECH, it could be that 'hybrid' users more often conflate their device with NVPs and describe its use as 'vape/vaping'. Alternatively, IQOS users might differentiate the two product classes more often but describe its use as 'smoke/smoking' because of the similarities between tobacco sticks and cigarettes.

Industry strategies for marketing new tobacco products

Those who are arguably least incentivised by rigid classification systems are the companies that manufacture nicotine products. From a marketing perspective, there is value in maintaining brand consistency across an entire suite of modified exposure/risk nicotine products, regardless of whether products are characterised as NVPs, HTPs or something else entirely. Indeed, throughout this piece we have referred to IQOS as a distinct HTP device brand; however, PMI is currently test-marketing an entirely separate device branded as IQOS VEEV, which fits the general parameters of an NVP device.²⁷

This 'branded house' marketing approach²⁸ has been embraced by other multinational tobacco companies. KT&G has introduced a range of different devices under the lil brand, two of which exclusively use tobacco sticks (lil Plus, lil Mini), one that uses both tobacco sticks and a liquid-containing cartridge simultaneously (lil Hybrid), and another that exclusively uses cartridges prefilled with nicotine solution (lil Vapor). BAT has also test-marketed two 'hybrid' devices under the glo brand (glo iFuse, glo Sens) alongside its tobacco stick-based devices (glo Pro, glo Mini, glo Nano, glo Hyper). JTI has added a tobacco stick-based device (Ploom S) beside its popular Ploom TECH 'hybrid' devices. Additionally, different companies are using different terms when referring to electronic inhalable product classes (table 1), prompting further confusion. Nicotine market-places will grow only more complex as other multinational tobacco companies pursue similar marketing strategies for their modified risk product lines.

Changing trends in cannabis use

Increasing liberalisation of cannabis unveils additional complexity, as alternative modalities for cannabis consumption continue to gain regional popularity. This is especially the case in North America, where vaping products for nicotine are already popular.^{29 30} Tobacco companies have had interest in pursuing cannabis products since the 1970s,³¹ are currently patenting new devices for the administration of cannabis³² and have begun acquiring cannabis companies in an effort to diversify product offerings. For instance, Altria (parent company of Philip Morris USA) recently acquired a majority stake in Cronos Group, a Canadian cannabis company.³³ Similarly, BAT recently purchased a 20% stake in Organigram holding and has begun to manufacture cannabinoid oil pods compatible with its *Vuse Alto* NVP device.³⁴

Measurement of HTP use faces an analogous issue with loose-leaf vapourisers, which can be used to aerosolise dried plant material, including both tobacco and cannabis. While the PAX vapouriser was originally marketed in the early 2010s as a device to heat loose-leaf tobacco,³⁵ the manufacturer has since embraced PAX's popularity among cannabis users and now advertises their devices exclusively as dry-herb cannabis vapourisers.³⁶ Because PAX devices can be used for heating tobacco, they were listed as an example brand in the WHO's 2020 HTP information sheet³⁷ and have been included as an HTP device brand choice in some tobacco use surveys.¹⁸ Further, cannabis products that mirror contemporary HTP technologies are beginning to emerge. Omura currently markets its *Series X* device for use with cannabis 'flowersticks', together resembling glo devices and tobacco sticks for glo and lil.³⁸ Other companies have manufactured sticks filled with hemp that are compatible with IQOS.³⁹

CHALLENGES AND FUTURE DIRECTIONS FOR MEASURING HEATED TOBACCO PRODUCT USE

Measurement validity is an important consideration when designing studies and interpreting findings that rely on self-reported nicotine use measures. As market-places grow in complexity, so does the assessment of nicotine use. This Special Communication considers ramifications of a diversifying market-place on survey research. Two areas of concern are most evident from our observations:

1. Measuring HTP use is challenging where HTPs are new to the market but vaping products are already well established,

Table 2 Region-specific factors surrounding electronic inhalable nicotine products

	Japan	Republic of Korea	England	Canada	USA
Year that contemporary HTPs were first introduced	2014	2017	2016	2017	2019
Availability and sales of HTP	The HTP market is diverse and includes many brands and device subtypes, including tobacco stick-based devices and several 'hybrid' devices. In 2020, comprised 99.5% of 'Smokeless Tobacco, E-Vapour Products and Heated Tobacco' sales*.	Tobacco stick-based devices and 'hybrid' devices are available for purchase. In 2020, comprised 86.7% of 'Smokeless Tobacco, E-Vapour Products and Heated Tobacco' sales*.	Opening of a London-based IQOS boutique storefront and has expanded to other regions. In 2020, comprised 3.4% of 'Smokeless Tobacco, E-Vapour Products and Heated Tobacco' sales*.	IQOS and glo have been marketed in major cities. In 2020, comprised 4.5% of 'Smokeless Tobacco, E-Vapour Products and Heated Tobacco' sales*.	IQOS has been marketed in a limited capacity and authorised to the market through FDA's premarket tobacco product application process. Loose-leaf vapourisers (eg, PAX) are accessible for purchase as well, and Ploom TECH (rebranded as Logic Vapeleaf) is sold online in six states. In 2020, comprised 0.1% of 'Smokeless Tobacco, E-Vapour Products and Heated Tobacco' sales*.
Sales of NVP	In 2020, comprised 0.4% of 'Smokeless Tobacco, E-Vapour Products and Heated Tobacco' sales*.	In 2020, comprised 3.1% of 'Smokeless Tobacco, E-Vapour Products and Heated Tobacco' sales*.	In 2020, comprised 96.4% of 'Smokeless Tobacco, E-Vapour Products and Heated Tobacco' sales*.	In 2020, comprised 81.6% of 'Smokeless Tobacco, E-Vapour Products and Heated Tobacco' sales*.	In 2020, comprised 44.8% of 'Smokeless Tobacco, E-Vapour Products and Heated Tobacco' sales*.
Use of cannabis	In 2021, the past-year prevalence of cannabis use among individuals aged 15–64 years old was estimated at 0.1%†.	Recent measures of prevalence of use are lacking; however, just 8072 illicit cannabis plants were eradicated in 2019, equivalent to 0.2% of that in the USA‡.	In 2018, the past-year prevalence of cannabis use among individuals aged 15–64 years old was estimated at 7.6%†.	In 2017, the past-year prevalence of cannabis use among individuals aged 15–64 years old was estimated at 14.8%†.	In 2018, the past-year prevalence of cannabis use among individuals aged 15–64 years old was estimated at 19.4%†.
Nomenclature	Verb: preferred Japanese verb for smoking tobacco approximately translates to 'inhaling a tobacco product', which further complicates differentiating HTP and conventional cigarette use.	Verb: preferred Korean verb for smoking tobacco approximately translates to 'inhaling a tobacco product'. Use of similar terms: Korean legal term for HTPs translates to 'cigarette type electronic tobacco', and NVPs often are referred just as 'electronic tobacco'.	–	–	–

* According to Euromonitor International sales data (<https://www.euromonitor.com>).

† According to the United Nations Office on Drugs and Crime's World Drug Report 2021 (<https://data.unodc.org/data/drugs/Prevalence-general>).

‡ United Nations Office on Drugs and Crime, 2021. Drug Market Trends: Cannabis & Opioids. World Drug Report 2021.

FDA, Food and Drug Administration; HTPs, heated tobacco products; NVPs, nicotine vaping products.

and also in jurisdictions where verbs are used interchangeably when referring to HTPs and cigarettes.

- Modalities for administering cannabis are converging with those for nicotine, making it important to capture information not only about 'product classes' but also the substances being administered.

As the latter concern is already being discussed within the scientific community,^{40–43} we will largely focus on the first issue below. This is not to say the latter concern has been addressed to the fullest extent. Many national or international surveillance systems have yet to modify questionnaires to collect information about which substances are being administered during use of various products/devices; few validation studies have quantified the extent of misclassification introduced by this issue; and the relative prevalence of cannabis and NVP use versus that of HTPs in many regions makes this a pressing concern. Moreover, the two issues are interconnected, and increasingly so as cannabis products that emulate HTPs continue rolling out (eg, Omura's Series X). Some survey strategies noted below are relevant to the broader challenge of disentangling substances from devices or products. Avoiding measurement error when assessing electronic inhalable nicotine product use will require awareness of trends and products in the cannabis market.

That aside, we contend that the challenges of measuring HTP use have yet to be appropriately recognised. This notion is supported by a handful of studies scrutinising self-reported HTP measures. Brose *et al*⁴⁴ performed split sample tests to compare two survey strategies for collecting self-reported awareness of HTPs. Half of a 2017 general adult population sample in England reported their HTP awareness and ever use status after being shown the preamble 'Heat-not-burn tobacco products use a technology whereby tobacco is being heated as opposed to being burnt', while the other half's survey further included 'Some of the popular brands of heat-not-burn tobacco products include *Ploom* and *IQOS*'. The prevalence of self-reported HTP awareness and ever use was 7.8% and 1.3%, respectively, among the respondents who were shown written HTP device brand examples, compared with 10.8% and 2.2% for the other group. Lee *et al*⁴⁵ examined the test–retest reliability of nicotine use measures among 121 self-reported nicotine users from a 2019 web survey of Korean adults. While use patterns involving cigarettes and/or NVPs demonstrated moderate to high agreement, HTP use patterns (eg, exclusive use, HTP–cigarette concurrent use and HTP–NVP–cigarette concurrent use) were highly discordant. In a 2018 sample of nicotine users from England, Canada, Australia and the USA, Miller *et al*¹⁸ evaluated responses from self-reported ever users of HTPs about the device brands they had used. Approximately 6% of self-reported HTP ever users reported a brand that was an NVP or cannabis vapouriser and 24% selected 'don't know'.

Even slight differences in survey structure can impact a survey's ability to obtain accurate information on HTP use. For instance, using a 'check all that apply' item to simultaneously assess multiple nicotine products (eg, 'Which of the following products have you ever used...') is likely more susceptible to underestimating product use than stand-alone forced-choice survey questions (eg, 'Have you ever used an HTP?'...Yes/No...; 'Have you ever used an NVP?'... Yes/No...; etc).⁴⁶ Surveys may benefit from incorporating descriptive preambles that aid respondents in disentangling product classes from one another.^{47 48} This could take the form of written product class definitions, examples of specific product brands, device images embedded throughout the survey and so forth. Depending on the jurisdiction in which a survey is being

administered, it might be preferable to enquire about individual HTP brands rather than the overarching product class (eg, IQOS is currently the only Food and Drug Administration-authorized HTP device in the USA). Other considerations include the nomenclature used to differentiate product classes (eg, referring to HTPs as heat-not-burn; distinguishing HTPs from NVPs with 'HTPs contain actual tobacco leaf...NVPs do not contain actual tobacco leaf'); the order in which product classes are asked about (eg, does the survey first ask questions about cigarettes, NVPs, HTPs, etc); the formatting of questionnaire items (eg, for ascertaining device brand information, should surveys use a dropdown list (eg, similar to the Miller *et al* survey¹⁸) or open-ended format?); and the overarching survey structure (eg, is the survey largely sequenced around individual product classes or more so around intention/perception/opinion/etc constructs?).

There is an urgent need to evaluate measurement validity of self-reported HTP use, both to understand the extent of misclassification in surveys and to discern which of the above methods most effectively mitigate misclassification. While the criteria frequently relied on for validating self-reported tobacco use (biomarkers of exposure to nicotine (eg, cotinine) and tobacco (eg, tobacco-specific nitrosamines)) are not always specific to individual product classes, other strategies can provide insight, as demonstrated by Brose *et al*,⁴⁴ Lee *et al*⁴⁵ and Miller *et al*.¹⁸ Survey developers must consider incorporating items that probe beyond a singular initial question about product use. This should involve ascertaining information about the device brand(s) that a respondent has used, and potentially other factors, such as device ownership. Another tactic for web-based surveys is to request that self-reported users of a specified product submit an image of their device. Additionally, cohort studies are uniquely situated to retrospectively examine response consistency over time (ie, do baseline self-reported ever users of HTPs still report HTP ever use at follow-up?).

Crucially, the quality of information ascertained from a survey will depend on the development steps taken prior to implementing the survey on the field. How potential respondents interpret questions and instructions is a major determinant of survey data validity. Insight on terminology tendencies and perceived differences between different products (eg, a product containing tobacco (HTP) vs a product containing liquid nicotine (NVP)) can be gained through qualitative research approaches such as focus groups and cognitive testing studies. For HTPs specifically, there is a particular need for focus groups and cognitive testing among current users of HTPs, as well as among users of other nicotine products (eg, current cigarette smokers).

Until more qualitative and quantitative evaluations of measurement validity are conducted, there is not solid grounding to explicitly recommend specific protocols for assessing self-reported use of electronic inhalable nicotine products. As such, caution is warranted when interpreting survey results that rely on self-reported HTP use until more is known about measurement validity. Comparisons of HTP prevalence rates and correlates of use across multiple data sources should consider methodological differences as a potential explanation of results. With longitudinal data, researchers must consider whether HTP measurement validity was consistent over time. It is possible that a baseline wave of HTP data collected in a jurisdiction where HTPs had recently entered the market is more prone to misclassification than a follow-up wave, either due to modified survey methods or a change in awareness of HTPs within the sampled population.

CONCLUSIONS

The evolution of nicotine market-places has implications on research methods used in tobacco regulatory science, including reliance on self-reported survey data. Shared characteristics between distinct inhalable product classes, as well as the use of similar devices to administer cannabis and other substances, pose a challenge to measurement validity in population surveys. We contend that measuring HTP use is particularly challenging in jurisdictions where HTPs are new and NVPs are well established, and we call for more research evaluating this concern. Studies that rely on self-reported HTP use should be interpreted with this limitation in mind. Moving forward, a multifaceted comprehensive method development approach will be crucial to develop consensus methods for measuring electronic inhalable product use in population surveys.

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