

ORIGINAL ARTICLE

The Need for Policy on Labelling Requirement of E-liquid Products: A Case Study on Nicotine-containing E-liquid Refills Sold on E-commerce Platform in Malaysia

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ABSTRACT

Introduction: Discrepancies of nicotine content labelling of e-liquid products has been reported and it may have existed to circumvent legal requirements that imposes restrictions on the sale of nicotine-containing products in the market. Mandatory labelling requirement of e-liquid products is still pending in Malaysia. This case study aimed to examine labelling discrepancies of e-liquid refill products declared as nicotine-free sold in e-commerce platform in Malaysia. **Methods:** A total of 10 Malaysian-made e-liquid refill samples were purchased via a popular e-commerce platform available to Malaysian. The e-liquid refills were specifically chosen because it was declared to contain zero-nicotine. Nicotine concentrations were measured using a Gas-chromatography with flame-ionisation detector (GC-FID). **Results:** About 80% (n = 8) of the purchased e-liquid samples were contained nicotine despite being declared as nicotine-free. The average nicotine levels were 1.092 (0.989) mg/mL. **Conclusion:** This case study confirmed the presence of labelling discrepancies which non-comply with the existing Malaysian Poison Act. Such non-compliance will contribute to the sale of unrestricted nicotine products. As a result, it will increase addiction among novice smokers because e-liquid refills declared as “nicotine free” contained nicotine. Implementation of stringent legal requirement on the nicotine content of local e-liquid products is urgently needed as it will support the accomplishment of Malaysian Tobacco Endgame.

Keywords: Nicotine, Refill e-liquids, Labelling discrepancy, Tobacco end-game, Poison

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INTRODUCTION

Electronic cigarette (EC) is a new-technology device that imitates the conventional cigarette's function in delivering nicotine and other chemical contents to the users and it had become a worldwide phenomenon since being introduced in 2004 (1). Despite of uncertainties in terms of the safety and potential harmful effects to health, the device has gained wide acceptance among smokers as well as non-smoking population (2-7). The other main concern was that e-liquid comes in many varieties in terms of flavours to fit different preferences of smokers. A study has estimated that there were at least 7,700 unique flavours of e-liquids in the market (8).

EC device including its components and e-liquid products has been regulated across 28 European Union Member States through the amendment of a European Union Tobacco Products Directive (EUTPD) in 2016 (9). The directive is a legislative document which aimed to standardise the safety and quality of EC products (9). The EUTPD has outlined the design specifications of EC products including the permissible level of nicotine content of the e-liquid refill products, in which all the products should not exceed 20 mg/mL of nicotine (9, 10). Within the context of Malaysia, currently, there are no specific regulations or guidelines that particularly control the quality and safety of Malaysian-made e-liquid products especially on nicotine level of the products. Nicotine is listed under Group C poison of Poison Act 1952 where the sale and distribution of nicotine and any products containing nicotine were restricted only by licensed pharmacists (11). There is an abundance of e-liquid

products available in the local market and these products are easily accessible due to the non-stringent regulation that Malaysia currently has.

Nicotine plays a main role as an addictive agent in tobacco products (12) and can be toxic to human health when its dose is above 6.5 mg/kg (13, 14). The chemical will affect the neurochemistry of the human brain through a complex action to maintain tobacco addiction (15). Apart of that, the United States Department of Health and Human Services (USDHHS) has extensively discussed on a significant role of nicotine exposure in the development of atherogenesis and triggering acute coronary event (15). A long term exposure to nicotine has been linked with cardiovascular risk among smokers. It occurs when the sympathomimetic effects of nicotine caused the heart rate and myocardial contractility to increase (1).

Nicotine addiction among adolescents is one of the issues emphasised in a previous tobacco survey in Malaysia (16). The survey was Tobacco and E-cigarette Survey among Malaysian Adolescents (TECMA), which was a Malaysian national study of EC use among adolescents. It was found that 45% of ever EC users were not aware of the nicotine content in their tobacco products. Data from the Ministry of Health in Malaysia observed that the prevalence of adolescent smoking which was steadily controlled since 2010 (8.7%) (17) saw a sharp incline in percentage (about 5%) in 2017 (13.8%) (18). The increase was not well discussed in literature; however, we hypothesised that it may be linked with the introduction of EC in the Malaysian market in 2014. The Malaysian National Strategic Plan for Tobacco (2015-2020) aims for reduction of smoking prevalence to less than 5% in 2045. Such impact on the increment in adolescent smoking will create a roadblock in achieving the tobacco end game (19).

As regulation on nicotine labelling of e-liquid refill products is still lax, products sold in the physical or online retail markets are largely not adhering to any standard or guidelines. This poses significant risks to what have been discussed in the earlier paragraph. The notion that it is the responsibility of manufacturers to accurately label nicotine content of e-liquid refill products (20) still stand and support for this continues to accrue. In our previous report, we found that 41% ($n = 7$) of the e-liquid refills were not equipped with adequate labelling information particularly on nicotine content of the product while another 59% ($n = 10$) of the samples labelled with 0 and 6 mg/mL of nicotine were found to be inaccurate and we believe as misleading (21). In Malaysia, it has been largely accepted that electronic devices are grouped into EC and vape, with the former to contain nicotine and the latter with nicotine being absent. Therefore, this study aims to determine the nicotine levels in samples

of Malaysian-made e-liquid products declared as nicotine-free and sold in e-commerce platform by online retailers. From the results obtained, labelling discrepancies of nicotine between the declared and measured levels contained in the e-liquid will be determined. Results of this study are expected to assist public health policy makers in their effort to implement policies to prevent detrimental impacts arising from tobacco use to the Malaysian public.

MATERIALS AND METHODS

Sample collection

A total of 10 samples of e-liquid refills with varieties of flavours were purchased via online vendors. Our previously reported preliminary study has provided evidence on the discrepancies of nicotine labelling in 17 samples of Malaysian-manufactured e-liquids (20). However, the selection of samples was intended to represent commonly used e-liquids; labelling information was not the inherent selection criteria and only two samples were found to contain nicotine at variable levels despite being labelled as nicotine-free. On the other hand, the present study specifically sought out to measure e-liquids declared as containing zero-nicotine. Therefore, the analyses of only a handful of locally-manufactured e-liquids advertised as nicotine-free in the e-commerce platform in Malaysia is assumed to be able to give an indicative picture of the problems surrounding this issue. The samples were selected based on the 10 top rating e-liquids sold in one of the most popular e-commerce marketplace platforms in Malaysia. All the samples were advertised as nicotine-free and were Malaysian-made e-liquids. The samples were labelled with unique ID, stored in zip-locked bag and were placed in room temperature prior to the chemical analysis.

Nicotine analysis

Nicotine was analysed based on the use of gas chromatography method with flame-ionisation detector (GC-FID) Agilent HP-624 GC-FID (Agilent Technologies, CA, U.S.A). The method was adapted from Geiss and colleagues (2015) (22). Firstly, about 5 mL of each sample was transferred into 25 mL of volumetric flask. The sample was then diluted with isopropyl alcohol in five dilution factors. Two replicates were prepared for each of samples. Lastly, the sample was transferred into autosampler-vial prior analysis.

A J&W Scientific capillary column (DB-624, 30 m, 0.25 mm i.d., 1.4 μ m film thickness, Part-No. 122-1334) was utilised for chromatographic separation, in which a research grade (>99.99% purity) helium was used as carrier gas. The oven was programmed as follows, starting temperature 100°C, ramp 10°C min⁻¹ up to 260°C and isotherm at 26°C for 5 minutes,

detector and injector temperature 250°C. The splitless mode was used with carrier gas flow constant at 1.5 mL min⁻¹. The total run time was 22 minutes. A five points of calibration curve was generated and shown in Figure 1. The linearity was tested at a concentration of 0.2 mg/mL to 1.8 mg/mL. The coefficient determination (R²) of the calibration curve was 0.99994.

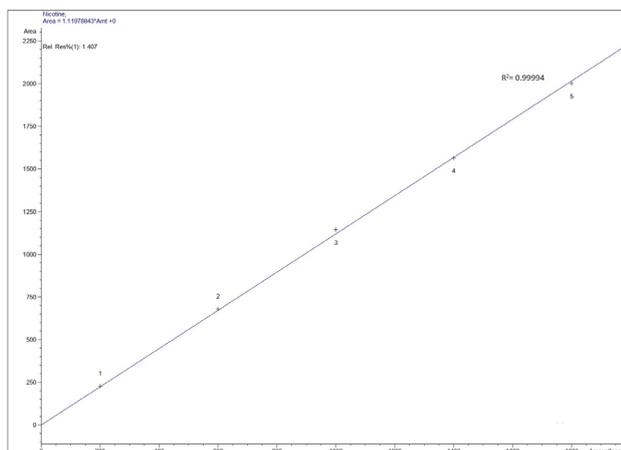


Figure 1 : Calibration curve of nicotine analysis using Gas chromatography with a flame ionization detector (GC-FID)

RESULTS

Labelling discrepancies of nicotine level were demonstrated in eight samples of locally manufactured e-liquids which were declared as “nicotine-free” on the label. Out of the 10 e-liquid samples, only two samples were accurately labelled, i.e. there were no nicotine detected as per declared on the label. The mean (standard deviation) of nicotine content measured in all samples was 1.092 (0.989) mg/mL. Figure 2 shows the level of nicotine content in all e-liquid samples. The detected concentrations of nicotine were varied and ranged from “undetected” to 2.505 mg/mL. Representative chromatogram of e-liquid samples was shown in Figure 3.

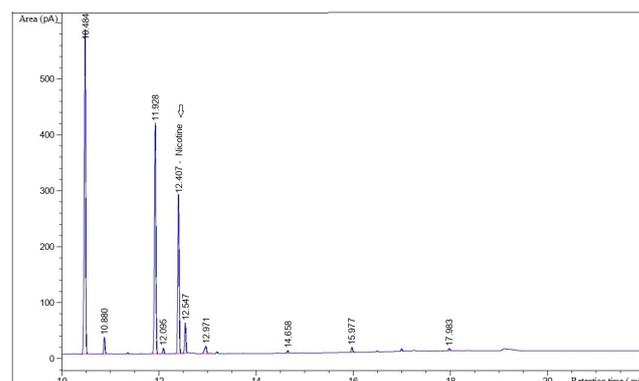


Figure 3 : Representative chromatogram of nicotine analysis in the e-liquid samples (sample's ID: EL07)

DISCUSSION

This study was primarily aimed to examine nicotine labelling discrepancies between the declared content indicated on the label and the actual measured level in samples of Malaysian-made e-liquid refills. The finding shows that 80% (n = 8) of the samples were found to contain nicotine in the average (standard deviation) of 1.092 (0.989) mg/mL. Only two samples were accurately labelled with “zero nicotine”. Thus, this study has proved the existence of labelling discrepancies issue of nicotine content in locally manufactured e-liquids being sold in e-commerce platform.

The issue of nicotine labelling discrepancy in e-liquids have been widely reported elsewhere particularly in e-liquids labelled with “no-nicotine” (23-25). In the United States (US), an average of 2.7 mg/mL (SD = 7.2 mg/mL) of nicotine were detected in 91.4% (n = 32) of e-liquid samples labelled with “zero-nicotine” (23). The average level of nicotine detected in local e-liquid products in the present study was lower compared to the finding reported elsewhere (23) (1.09 mg/mL vs 2.7 mg/mL). This might be due to the low nicotine content of e-liquid (6 mg/mL) that are mostly preferred by local EC users as reported in our previous study on vaping topography (26). In contrast, the EC users in the US, France, U.K, and Switzerland mostly favoured e-liquids with high nicotine levels and averaging at 16 mg/mL (27). The present study has confirmed the previous finding which has shown similar discrepancies in terms of nicotine content in Malaysian-made e-liquids (20). Due to the existing prohibition on the distribution of nicotine-containing products prescribed in the Malaysian legal system, the detection of nicotine in e-liquid refills declared as nicotine-free may have existed to circumvent the regulation that mainly aims to control the accessibility of nicotine-containing products in the market. The marketing tactics of manufacturers undermine the regulated tobacco control policy and such issues

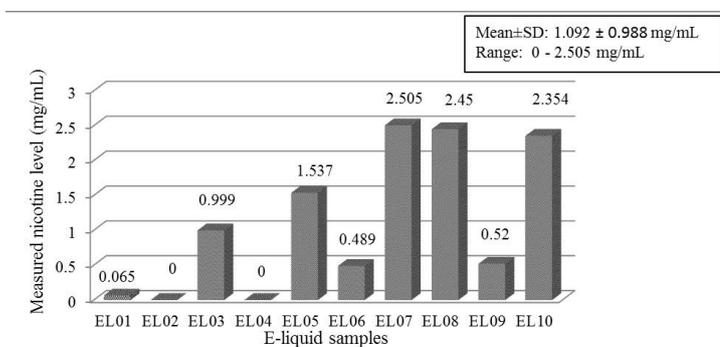


Figure 2 : Nicotine level of 10 Malaysian-made refill e-liquid samples labelled with “nicotine-free”

have been discussed in the United Kingdom and the US (28, 29).

In addition, the mislabelling of nicotine content in the e-liquid products may have been made worse due to the unavailability of mandatory e-liquid manufacturing standard guideline. With the high demands of products and the absence of standard guideline of e-liquid manufacturing, the accuracy of nicotine content can be overlooked by manufacturers. Guideline or standard has been made available in developed countries such as in the US and European Union (EU) (9, 30). In the US, the guideline has been established by the American E-Liquid Manufacturing Standards Association (AEMSA) while in EU, the legislation is provided in the European Union Tobacco Product Directive (EUTPD) (2001/37/EC) to improve e-liquid manufacturing standards (9,30,31). With evidence obtained in the present study, there is a clear need for the introduction of e-liquid manufacturing guideline to be made available in Malaysia if the government opt to make the sales of EC legal. Previous news has reported that the Malaysian government support the total ban of EC sales, even though it was still under review among the experts. At the earlier stage, the support for the ban was raised due to the mechanical safety of lithium batteries of EC after multiple incidence of explosion involved EC batteries reported worldwide (32-34). The support on the total ban have increased even more since the widespread news on death and respiratory distress problems linked with EC usage reported in the US in early 2019 (35).

Initially, the emergence of EC has been introduced as another kind of device that imitates the function of conventional cigarettes in delivering nicotine to user. However, one of the controversial public health concerns about the device is that EC may act as a gateway to conventional cigarette use especially among non-smoking young population (2,36,37). TECMA reported that 39% of adolescents have used EC without being aware the nicotine content in their e-liquid refills (16). Furthermore, the inaccuracy of nicotine content of e-liquid products may lead to young population being addicted to nicotine unintentionally, as low level of exposure to nicotine may be adequate to hook them to continuously use the device (38). It may also then lead the novice EC users to use other tobacco product and initiate the use of conventional cigarette (39-41). Thus, it indicates that the labelling discrepancies of nicotine content of e-liquids may not only threaten the health of current EC users, but the biggest impact of this issue goes to the non-smoking young populations who are attracted to the use this new-technology for recreational purposes. This study had several limitations. This study only

included chemical analysis of a small number of e-liquid refill samples across a few local brands due to budget limitations. Furthermore, this study has only included a single batch of e-liquid refill per sample. Given the huge number of Malaysian-made e-liquid refill brands and dynamic market of the products, this warrants a routine analytical testing to be conducted by the related authorities. Despite the small number of samples and in the absence of multiple batches being analysed, this is the first study that specifically emphasizes nicotine labelling accuracy in Malaysian-made e-liquid products labelled with nicotine-free.

CONCLUSION

This study demonstrated that nicotine content was detected in the eight out of 10 Malaysian-made e-liquid samples despite being advertised as nicotine-free e-liquids. This may serve as a proof that indicates the existence of labelling discrepancy issue on nicotine concentration in locally manufactured e-liquid products. Implementation of stringent legal requirement on the nicotine content of local e-liquid products is urgently needed as it will support the accomplishment of Malaysian Tobacco Endgame. It is anticipated that this finding will support the future development of the evidence-based EC-related regulation in Malaysia.

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