POSTERS ABSTRACTS

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Study to Quantitatively Assess THS Potential Messages (THS-PBA-03-US)

Authors: Beacher, Felix

Poster presentation

Organisations: PMI, Switzerland

Keywords: Marketing, Modified risk tobacco product

This study is part of a research program on perceptions and behavior related to the Tobacco Heating System (THS). The aim was to assess responses to five different “Messages”, to support the development of THS marketing material, for an application to the US FDA to authorize the marketing of THS as a modified risk tobacco product. Messages were evaluated in terms of:

• Intent to Use
• Change in Intention to Quit
• Comprehension
• Risk Perception

This was a five-arm parallel group experiment in 1,713 adults from the US population, with the five arms corresponding to the five Messages. Messages 1 to 4 contained claims that THS reduces exposure to harmful and potentially harmful constituents, but reductions in disease risk are not established. Message 5 contained a claim that THS reduces disease risk but is not risk free. Data analysis was descriptive. The main sample had four groups:

1. Smokers with no Intention to Quit Smoking Cigarettes (S-NITQ)
2. Smokers with the Intention to Quit Smoking Cigarettes (S-ITQ)
3. Former Smokers (FS)
4. Never Smokers (NS)

Also, an oversample of 358 Never Smokers from the legal age of smoking to 25 (LA-25 NS) was included. “Intent to Use” was comprised of items for “Intention to Try” and “Intention to Use”. Change in Intention to Quit was measured by comparing Intention to Quit pre- and post-exposure to the Messages. Comprehension was measured with multiple-choice questions. Risk Perception was assessed with PMI’s Perceived Health Risk and Addiction Risk scales.

Across all Messages, Intention to Try THS was 38% to 57% within S-NITQ, 36% to 54% within S-ITQ and <4% within FS, NS and LA-25 NS. Results on Intention to Use THS were broadly consistent with Intention to Try. Within S-ITQ 83% to 97% still intended to quit after exposure to the Message. In the main sample, Messages 3 and 5 had the highest comprehension level on disease risk (74% and 81%). For all Messages and groups, cigarettes were rated as highest risk, then THS, then e-cigarettes and lastly either Nicotine Replacement Therapies or cessation.

The reduced risk message (Message 5) and one reduced exposure message (Message 3) had satisfactory profiles for the main outcome measures and may be suitable for development into THS marketing material.
Reduced exposure to harmful and potentially harmful constituents after 90 days of use of tobacco heating system 2.2 menthol in the U.S.: a comparison with continued cigarette use or smoking abstinence

Authors: Boll, Yin (1); Haziza, Christelle (1); de La Bourdonnaye, Guillaume (1); Picavet, Patrick (1); Baker, Gizelle (1); Skiada, Dimitra (1); Merlet, Sarah (1); Franzon, Michael (1); Farmer, Frank (2); Lewis, William (3); Luedicke, Frank (1)

Poster presentation

Organisations: 1: Philip Morris International R&D, Philip Morris Products S.A., Neuchâtel, Switzerland (part of Philip Morris International group of companies); 2: Daytona Beach, Florida, United States; 3: Dallas, Texas, United States

Keywords: e-cigarette, tobacco constituents

This study is part of a clinical program to assess the Tobacco Heating System (THS) 2.2, a candidate modified risk tobacco product. The objective of this study was to assess the reduction in exposure to selected harmful and potentially harmful constituents (HPHCs) after 5 days of ad libitum use of THS 2.2 menthol (mTHS) in confinement and 86 days in an ambulatory setting compared to continued smoking of menthol cigarettes (mCC) and smoking abstinence (SA). Biomarkers of exposure (BoExp) to sixteen HPHCs were evaluated and selected Clinical Risk Endpoints (CRE) were monitored.

After 2 days of baseline (CC smoking), 160 healthy smokers of mCC, aged minimum 22 years, were randomized to continue to smoke mCC (n=41), to switch to mTHS (n=80), or to stop smoking (n=39) for 90 days in this open-label, randomized, controlled, 3-arm parallel group study. Twenty-four hour urine and blood samples were collected to evaluate the levels of BoExp and CRE using validated analytical methods. This study was conducted in the U.S. according to GCP and is registered in ClinicalTrials.gov (NCT01989156).

The average daily product use slightly increased from Baseline to the end of the entire exposure period in both, the mCC and mTHS study arms. Despite the increase in average product use, the total nicotine exposure measured as nicotine equivalents decreased from Baseline to Day 90 similarly in both arms. The levels of BoExp, except S-BMA, were significantly reduced at Day 5 in the mTHS arm as compared to mCC, approaching results obtained in the SA arm and were sustained throughout the entire exposure period. Monitored CREs started to show favorable changes indicating that the reduction in exposure may translate into changes in CREs.

Product evaluation at Day 90 showed slightly less satisfaction for mTHS compared to mCC. However mTHS achieved an equally efficient suppression of urge to smoke compared to mCC over the entire exposure period. mTHS was well tolerated.

mTHS showed significant, sustained reduction in exposure to HPHCs after 90 days of mTHS use, as compared to CC, approaching levels observed upon smoking abstinence. Monitored CREs started to show favorable changes.
Reduced exposure to harmful and potentially harmful constituents after 90 days of use of tobacco heating system 2.2 menthol in Japan: a comparison with continued cigarette use or smoking abstinence

Authors: Boll, Yin (1); Haziza, Christelle (1); Lama, Nicola (1); Donelli, Andrea (1); Picavet, Patrick (1); Baker, Gizelle (1); Ancerewicz, Jacek (1); Benzimra, Muriel (1); Franzon, Michael (1); Endo, Masahiro (2); Luedicke, Frank (1)

Poster presentation

Organisations: 1: Philip Morris International R&D, Philip Morris Products S.A., Neuchâtel, Switzerland (part of Philip Morris International group of companies); 2: Osaki Hospital Tokyo Heart Center, Tokyo, Japan

Keywords: e-cigarette, tobacco constituents

This study is part of a clinical program to assess the Tobacco Heating System (THS), a candidate modified risk tobacco product. The objective of the study was to assess the reduction in exposure to selected harmful and potentially harmful constituents (HPHC) after 5 days of ad libitum use of THS 2.2 menthol (mTHS) in confinement and 85 days in an ambulatory setting compared to continued smoking of menthol cigarettes (mCC) and smoking abstinence (SA). Biomarkers of exposure (BoExp) to sixteen HPHCs were evaluated and selected Clinical Risk Endpoints (CRE) were monitored.

After 2 days of baseline (CC smoking), 160 healthy smokers, aged 23 to 65 years, were randomized to continue to smoke mCC (n=40), to switch to mTHS (n=80), or to stop smoking (n=40) for 90 days in this open-label, randomized, controlled, 3-arm parallel group study. Twenty-four hour urine and blood samples were collected to evaluate the levels of BoExp and CRE using validated analytical methods. This study was conducted in Japan according to GCP and is registered in ClinicalTrials.gov (NCT01970995).

The average daily product use was stable in the mTHS arm (Baseline=13.1 mCC and Day 90=12.7 mTHS) and slightly increased in the CC arm (Baseline=12.5 mCC; Day 90=15.2 mCC) over the entire exposure period. The total nicotine exposure measured as nicotine equivalents were comparable in both arms (mTHS: mCC ratio of 104 % [95% CI: 66, 163]). The levels of BoExp, except S-BMA, were significantly reduced at Day 5 in the mTHS arm as compared to mCC, approaching results obtained in the SA arm and were sustained throughout the entire exposure period (−49% to −94% at Day 5; −41% to −94% at Day 90). Initial shifts of monitored CREs in the direction of SA were observed.

Product evaluation at Day 90 showed that the level of satisfaction for mTHS was comparable to mCC. Similarly mTHS achieved an equally efficient suppression of urge to smoke compared to mCC. mTHS was well tolerated.

mTHS showed significant, sustained reduction in exposure to HPHCs after 90 days of mTHS use, as compared to CC, approaching levels observed upon smoking abstinence. Initial favorable shifts of monitored CREs were observed.
Accuracy of self-reported smoking abstinence in a randomized clinical trial targeting low-socioeconomic status smokers.

Authors: Courtney, Ryan James (1); Clare, Philip (1); Martire, Kristy (1); Bonevski, Billie (2); Borland, Ron (3); Doran, Chris (4); Hall, Wayne (5); Farrell, Michael (1); Siahpush, Mohammad (6); West, Robert (7); Boland, Veronica (1); Iredale, Jaimi (1); Mattick, Richard (1)

Oral Presentation

Organisations: 1: University of New South Wales (UNSW) Australia; 2: University of Newcastle Australia; 3: Cancer Council Victoria Australia; 4: Central Queensland University Australia; 5: University of Queensland Australia; 6: University of Nebraska Medical Center US; 7: University College London UK

Keywords: smoking cessation, socioeconomic factors, method, biochemical verification, randomized controlled trial

Background: The need for biochemical verification in smoking cessation studies has been questioned. This study examined the acceptability and feasibility of biochemical verification of self-reported smoking abstinence in a clinical trial that sampled Australian low-socioeconomic status smokers.

Method: Participants were asked to provide a urine or saliva sample if they had met the following Russell Standard criteria at their final 8-month post-baseline interview: self-reported quit for six months, with no more than five cigarettes smoked in that period, and no cigarettes smoked in the past week. They were deemed abstinent if they returned a negative biochemical result (cotinine <115nmol/L). Participants claiming self-reported prolonged cessation were asked to attend either a collection centre or to have a trained nurse collect urine/saliva samples from their home. Participants were reimbursed $40 for test completion.

Results: Of the 880 participants who completed the final follow-up interview, 135 (15.3%) self-reported prolonged cessation. Of those, 125 agreed to complete a biochemical test, with 74 (59.2%) agreeing to attend a collection centre and 51 (40.8%) agreeing to a home visit. However, only 84 (62.2%) participants completed either a urine (n=80) or saliva (n=4) sample. The misclassification rate of self-reported abstinence was high with over half of those who provided the sample (n=47, 56.0%) returning a positive cotinine result. This means that of the 135 participants who self-reported prolonged abstinence, only 26.7% were confirmed to be abstinent. The remainder either failed to provide the sample, or returned a positive sample.

Conclusion: The attainment of reliable outcome data is difficult. Biochemical verification is a challenging undertaking but necessary to address high misclassification rates. It is paramount an acceptable protocol is set-up with adequate infrastructure provided for the monitoring and collection of samples. Biochemical verification is definitely still required to validate abstinence in clinical smoking cessation trials unless there is clear evidence that self-report is adequate for a given population and study design.
Predictors of retention in a randomised trial of smoking cessation in low-socioeconomic status Australian smokers

Authors: Courtney, Ryan James (1); Clare, Philip (1); Veronica, Boland (1); Martire, Kristy (1); Bonevski, Billie (2); Hall, Wayne (3); Siahpush, Mohammad (4); Borland, Ron (5); Doran, Chris (6); West, Robert (7); Farrell, Michael (1); Mattick, Richard (1)

Oral Presentation

Organisations: 1: University of New South Wales (UNSW) Australia; 2: University of Newcastle Australia; 3: University of Queensland Australia; 4: University of Nebraska Medical Center US; 5: Cancer Council Victoria Australia; 6: Central Queensland University Australia; 7: University College London UK

Keywords: smoking cessation, socioeconomic factors, method, retention, randomized controlled trial

Background Little is known about the factors associated with retention in smoking cessation trials, especially for low-socioeconomic status (low-SES) smokers.

Objectives To examine the factors associated with retention of low-SES smokers in the Australian Financial Interventions for Smoking Cessation Among Low-Income Smokers (FISCALS) trial.

Methods 1047 low-SES smokers were randomised. Participants completed computer assisted telephone interviews (CATIs) at baseline, 2-month and 8-month follow-up. Smoking-related, health-related, behavioural, sociodemographic and recruitment sources association with retention at 8-month follow-up were examined using binary logistic regression.

Results 946 participants (90%) completed the 2-month follow-up interview and 880 participants (84%) completed the 8-month follow-up interview. Retention at 8-months was associated with higher motivation to quit (OR: 1.15; 95% CI: 1.04, 1.27 p < .01), more recent quit attempts (OR: 1.20; 95% CI: 1.04, 1.40 p < .05), increasing age (OR: 1.05; 95% CI: 1.03, 1.07 p < .01), and higher level of education (OR: 2.24; 95% CI: 1.45, 3.46 p < .01). Lower retention at 8-months occurred for those recruited from posters placed in Department of Human Service Centrelink Offices (OR: 0.56; 95% CI: 0.35, 0.89, p < .05) than in participants recruited from Quitline or newspaper advertisements. No significant associations were found between health-related or behavioural factors and retention.

Conclusions In the context of high overall retention rates from disadvantaged smokers in a randomised trial, retention was greater in those smokers with higher motivation to quit, more recent quit attempts, increased age, higher level of education and for those recruited through Quitline or newspaper advertisements.
Acute human lung cell toxicity of some selected flavouring chemicals after simulation of vaping

Authors: Dartsch, Peter C. (3); Okle, Oliver (2); Mrva, Thomas Alexander (1)

Poster presentation


Keywords: flavouring, diacetyl, eliquid, aldehyde, happy liquid

Introduction. In contrast to cigarette smoking, the vapour of e-cigarettes is not the result of a combustion process and has been shown to have much lower health effects in vitro and in vivo. Flavouring chemicals in general can be easily inhaled because they are very volatile substances that readily evaporate from liquid forms into the air, a characteristic feature that is amplified by application of heat as usual for e-cigarettes. Here, we present data on the acute human lung cell toxicity of some selected flavouring chemicals after simulation of vaping.

Materials and methods. The investigations were done with the following 7 chemicals: Diacetyl (butane-2,3-dione), triacetin (1,2,3-triacetoxypropane), cinnamaldehyde, vanillin (4-Hydroxy-3-methoxybenzaldehyde), acetoin (3-hydroxybutanone), benzaldehyde, and 2,3-pentanedione (acetylproprionyl). The chemicals were used as 2 % solutions dissolved in a basic liquid of 50 % propylene glycol, 40 % vegetable glycerol and 10 % water without addition of nicotine. Liquids were transferred to a specially designed vaping apparatus and 20 puffs with a duration of 4-5 seconds and a pause of 10 seconds between two puffs were applied to the liquids. A common e-cigarette was used (eGrip OLED from Joyetech with a vaporiser of 1,7 Ohm and 3.3 Volt = 6.5 Watt). The vapour was piped into 20 ml of HEPES-buffered cell culture medium. After sterile filtration this primary extract was added at different test concentrations to cultures of human lung cells (A-549) with a seeding density of 10,000 cells/well in 96 well-plates. After 24 hours cell vitality was measured enzymatically by cleavage of XTT by the activity of mitochondrial dehydrogenases.

Results. The data of acute cytotoxicity clearly showed that both aldehydes (cinnamaldehyde and benzaldehyde) as very reactive compounds had the strongest acute toxic effect followed by both diketones (diacetyl and 2,3-pentanedione), vanillin and acetoin. Triacetin had no acute toxic effect at all which confirms its significant value as a food and pharmaceutical additive (E1518). The results will be discussed in detail under the light that even a moderate performance of the e-cigarette causes a significant acute toxicity of specific flavouring chemicals.
An update of the research studies that we have been supporting with our LC-MS/MS assays.

Authors: Doig, Mira Victoria; Feyerabend, Colin

Poster presentation

Organisations: ABS Laboratories Ltd, United Kingdom

Keywords: cotinine, nicotine, 3-HPMA, passive smoking, E-Cigs

Cotinine is a metabolite of nicotine and its presence in biological fluids indicates nicotine intake. Colin Feyerabend has been supporting smoking research since the 1970s. We still support passive smoking research by measuring cotinine in saliva and trends from the Health Survey of England since 1998 will be presented. Cotinine assays are also useful for hospitals as many surgeons recognise that wound healing after surgery is substantially quicker in non-smokers. In addition private medical insurance companies will charge lower premiums if the applicant can prove they are a non-smoker.

The validation of smoking cessation using cotinine alone is becoming increasing difficult with the massive expansion of the use of E-Cigs and over-the-counter NRT. In this situation measuring anabasine and cotinine in saliva has proved to be very useful as the presence of anabasine indicates that any cotinine levels present has come from tobacco rather than E-Cigs or NRT. The analysis of anabasine and cotinine in saliva samples now enables stop smoking advisors to help with the treatment of their patients as they know whether they are cheating or not!

Researchers have also been interested in investigating harm reduction when individuals change from smoking to E-cig use. We have supported such studies by looking at nitrosamine exposure by measuring for the metabolite 3-HPMA (3-hydroxypropylmercapturic acid) in urine. Researchers are also interested in the amount of nicotine absorbed by E-Cig users and whether they ‘self titrate’ like smokers do.

Summaries of some of the studies we have supported with these assays will be presented.
The in vitro assessment of an e-cigarette (Vype ePen) using a suite of pre-clinical tools

Authors: Gaca, M.; Breheny, D.; Crooks, I; Lowe, F; Minet, E; Thorne, D; Proctor, C

Poster presentation

Organisations: British American Tobacco, R&D Centre, Southampton SO15 8TL

Keywords:

The concept of the risk continuum has been considered for some years as a way to illustrate the reduced risk potential of a range of tobacco and nicotine products relative to cigarettes. In 2001, the US Institute of Medicine introduced a framework for studying the potential of novel products to contribute to tobacco harm reduction. Building on this and more recent US Food and Drug Administration (FDA) draft guidance, we recently published an integrated assessment framework which proposed the use of pre-clinical, clinical and population studies to assess the reduced risk potential of novel tobacco and nicotine products at the individual and population level.

There has been significant growth in the number of smokers currently using next generation products including e-cigarettes. E-cigarette products do not contain tobacco and the toxicant delivery of these aerosols are greatly reduced in comparison to conventional tobacco products, suggesting that they could hold promise as reduce risk products.

This paper will describe the in vitro assessment of a commercially available e-cigarette; Vype ePen, and compare the results relative to a reference 3R4F cigarette. Products were assessed across a range of in vitro toxicological assays specifically measuring mutagenicity and cytotoxicity, and showed greatly reduced responses relative to cigarettes. Following this, products were assessed using human cellular based in vitro assays that model some of the key events for smoking related diseases such as chronic obstructive pulmonary disease and cardiovascular disease. The data from these assays indicated that the biological response to Vype ePen aerosol was significantly lower relative to the reference cigarette.

Using MucilairTM, a reconstituted lung epithelial tissue culture, we further assessed functional key events and comparing global gene expression after short repeated exposure to cigarette smoke and e-cigarette aerosols matched for puff profile and mass deposition. Vype ePen aerosol induced minimal gene expression changes compared to the reference cigarette.

These in vitro assays were able to distinguish responses between Vype ePen e-cigarettes and a 3R4F reference cigarette. E-cigarettes have the potential to be reduced risk versus cigarettes, however a series of clinical and population studies measuring the longer terms effects of these new products on consumers is required to substantiate disease relevant risk reduction.

Funding: This work was fully funded by British American Tobacco
Differences in use of electronic and tobacco cigarettes between dual and exclusive smokers among adolescent in Poland

Authors: Gawron, Michal (1); Bebenek, Patryk (1); Madej, Daria (1); Sobczak, Andrzej (1,2); Goniewicz, Maciej (3)

Poster presentation

Organisations: 1: Medical University of Silesia, Poland; 2: Institute of Occupational Medicine and Environmental Health, Poland; 3: Roswell Park Cancer Institute, USA

Keywords: e-cigarette, adolescent, dual users, nicotine exposure

Significance: Electronic nicotine inhalers, commonly called electronic cigarettes or “e-cigarettes”, are battery-powered devices that provide inhaled doses of nicotine by delivering a vaporized liquid nicotine solution, usually including propylene glycol or glycerine. Despite the potential negative health effects of electronic cigarettes, these devices are increasing in popularity worldwide, especially among youth.

Aim: The aim of the study was to analyze differences in use of electronic and tobacco cigarettes between dual and exclusive smokers among Polish students aged 16-18.

Materials and Methods: We administered a cross-sectional survey to 2213 students in 21 secondary and technical schools in two regions; one in northern and one in southern Poland, between December 2013 and February 2014.

Results: 21.8% of all students were dual users. Dual users were more likely to smoke tobacco cigarettes everyday [(AOR 3.54 (95% CI 2.34-5.36)] and less likely to smoke a smaller number of cigarettes per day [AOR 0.27 (95% CI 0.12-0.57)] than exclusive tobacco cigarette users.

Conclusions: The frequency of dual use was higher than exclusive use of a single product among Polish adolescents. Young dual users smoke a higher number of tobacco cigarettes per day than exclusive tobacco cigarette users.

Conflicts of Interest: M.L.G. reports grants from Pfizer (2011 Global Research Award for Nicotine Dependence), a manufacturer of smoking cessation drugs, outside the submitted work. A.S. reports personal fees from eSmoking Institute, Poznan, Poland, and nonfinancial support from Chic Group LTD, a manufacturer of electronic cigarettes in Poland, outside the submitted work. The other authors have nothing to disclose.
Establishing a valid model to estimate the impact of introducing a reduced risk product on the population as a whole

Authors: Gilchrist, Moira (1); Baker, Gizelle (1); Sponsiello-Wang, Zheng (1); Lee, Peter N. (2); Fry, John (2); Lüdicke, Frank (1); Weitkunat, Rolf (1)

Poster presentation

Organisations: 1: Philip Morris International R&D, Philip Morris Products S.A., Quai Jeanrenaud 5, 2000 Neuchâtel, Switzerland (part of Philip Morris International group of companies); 2: P. N. Lee Statistics and Computing Ltd. 17 Cedar Road, Sutton, SM2 5DA, United Kingdom

Keywords: Population Health Impact Model, Risk assessment

PMI is developing products with the potential to reduce the risks of smoking-related diseases associated with smoking cigarettes (CC). To quantify the effect that marketing these products may have on the population health, PMI has developed a Population Health Impact Model (PHIM). The model uses publicly available data on smoking prevalence and disease risks together with assumptions on the product use and the relative exposure to a given potential reduced risk product (RRP) compared with CC and smoking cessation. The model estimates the change in smoking-attributable mortality by comparing smoking-attributable deaths in scenarios with and without the introduction of said RRP.

To assess the performance of the PHIM, a verification was performed to test that the assumptions were properly implemented. The model was validated, by testing that the assumptions produce reasonable estimates of a real population’s mortality rates. Specifically, the model was evaluated by comparing the simulation results to the published estimates and projections for the US population from 1990 to 2009, estimating the attributable deaths for ages 30-79 years.

PHIM projections were consistent with the US population data including the prevalence of current and former smoking by sex, age and year. The proportion of smoking-attributable deaths was consistent with the 2014 US Surgeon General Report, with the most significant difference being the lower proportion of lung cancer and COPD deaths projected from the PHIM, due to the high relative risk estimates from the CPS II study used in the Surgeon General Report.

1 Reduced Risk Products (“RRPs”) is the term we use to refer to products with the potential to reduce individual risk and population harm in comparison to smoking cigarettes. PMI’s RRP are in various stages of development, and we are conducting extensive and rigorous scientific studies to determine whether we can support claims for such products of reduced exposure to harmful and potentially harmful constituents in smoke, and ultimately claims of reduced disease risk, when compared to smoking cigarettes. Before making any such claims, we will rigorously evaluate the full set of data from the relevant scientific studies to determine whether they substantiate reduced exposure or risk. Any such claims may also be subject to government review and authorization, as is the case in the USA today.
Indoor air chemistry: an exploratory study on e-cigarettes shows no negative impact on indoor air quality

Authors: Gilchrist, Moira; Goujon, Catherine; Mitova, Maya; Mottier, Nicolas; Rouget, Emmanuel; Tharin, Manuel; Maeder, Serge

Poster presentation

Organisations: Philip Morris Products SA, Switzerland

Keywords: Environmental exposure, E-Cigarette, Indoor Air Quality

The impact on indoor air quality of using e-cigarettes is expected to be very different to cigarette use and has been the subject of numerous research papers. The available published work is often of limited value in judging the impact of e-cigarettes on indoor air quality since they were either conducted in uncontrolled environment (or environments with limited control) or were based on theoretical calculations. Philip Morris International has built an environmentally controlled, furnished room and developed analytical methods to measure air pollutants under diverse simulated indoor environments focusing on: (i) ISO measurement standards for Environmental Tobacco Smoke and, (ii) selected carbonyls and volatile organic compounds. The room is fully controlled and adjustable in terms of air renewal and the analytical methods have been developed, validated and accredited under ISO 17025.

An exploratory study on Indoor Air Quality for e-cigarettes was performed focused on relevant analytes in the context of e-cigarettes, i.e., particulate matter, nicotine and selected carbonyls. Three different e-cigarette products were tested, representing a range of e-liquid compositions and product designs. Multiple replicates with panelists, under one simulated condition (i.e., residential with air renewal set at 1.2 per hour, according to CEN-EN-15251:2007) were performed, including “background” sessions (no products used), against which vaping results are compared. During vaping sessions, panelists used the assigned product once every 40 minutes for 10 minutes duration over the course of 5 hours.

Results show that all the analytes measured when e-cigarettes are used were not different than background levels, with the exception of nicotine, which was detected at very low levels. The levels of nicotine measured varied between sessions, which can be explained by variability in e-liquid consumption. Nicotine levels ranging from 0.3 µg/m3 to 6.5 µg/m3 were observed and were directly correlated with the amount of liquid consumed during the different sessions. Based on these results, we conclude that using e-cigarettes indoor does not negatively impact air quality.
**Electronic cigarettes as a smoking cessation or harm reduction tool in patients with periodontitis: study protocol for a mixed methods feasibility study.**

**Authors:** Holliday, Richard (1,2); McColl, Elaine (3); Ryan, Vicky (3); Sniehotta, Falko (3); Bauld, Linda (4); Jakubovics, Nick (1); Preshaw, Philip (1,2)

**Poster presentation**

**Organisations:** 1: Centre for Oral Health Research, Newcastle University, United Kingdom; 2: Institute of Cellular Medicine, Newcastle University, United Kingdom; 3: Institute of Health & Society, Newcastle University, United Kingdom; 4: Stirling University, United Kingdom

**Keywords:** e-cigarettes, dental, periodontal, oral, smoking cessation

Periodontal diseases are highly prevalent and have a significant impact on the quality of life of large proportions of the population. The pathogenesis is multifactorial and several key risk factors have been identified. Among these, tobacco smoking is the most important known risk factor. Smokers have consistently demonstrated more severe disease, increased tooth loss and inferior responses to treatment.

The development and recent growth in popularity of electronic cigarettes (e-cigarettes) offers another option to patients wishing to quit or reduce tobacco smoking.

There is currently no clinical evidence addressing the potential effect of e-cigarette vapour on the periodontal tissues. Our hypothesis, to be tested in a future definitive trial, is that e-cigarette vapour is significantly less damaging than tobacco smoke. Additionally we hypothesise that e-cigarettes are attractive to smokers with periodontitis as a smoking cessation/reduction aid, leading to improved smoking cessation rates and periodontal treatment outcomes.

This study is a mixed methods feasibility study, incorporating a pilot randomised controlled trial and embedded qualitative process evaluation, with the aim of assessing the viability of delivering and studying the intervention prior to a definitive study. The focus of this study will be the deliverability, feasibility and acceptability of the e-cigarette intervention and of trial procedures, rather than clinical efficacy or effectiveness of the intervention.

**Methodology:**

Eighty patients who are smokers with severe chronic periodontitis will be recruited. They will all undergo non-surgical periodontal therapies. The control arm will be offered standard smoking cessation advice/referral and the intervention arm will be offered standard smoking cessation advice/referral and in addition will be provided with an e-cigarette starter kit and training. The follow up period will be 6-months following the initiation of periodontal therapy/ quit date. Measurements (periodontal, microbiological, immunological and smoking/ e-cigarette usage) will be collected at baseline, 4-weeks, 3-months and 6-months. Key feasibility outcome measures will be rates of participant eligibility, recruitment, receipt of allocated intervention and retention.

Analyses of the data collected will be descriptive, with 95% confidence intervals reported where appropriate. No formal statistical testing will be performed.

**Discussion:**

If shown to be feasible, a suitably designed and powered definitive study will be undertaken. Dental care professionals have an important role to play in providing smoking cessation advice and support. Patients with periodontitis are a particularly important patient group and an understanding of the impact of e-cigarettes on periodontal tissues is crucial for their management.
Comparison of Member State transpositions of TPDII Article 20

Authors: Ivanovic, Boris; Bliss, Dan; Jones, Ian William

Poster presentation

Organisations: JT International SA, Switzerland

Keywords: Electronic cigarette, TPDII, Article 20

On May 20th this year, provisions of the revised European Tobacco Products Directive (TPD) entered into force. Under this Directive, nicotine-containing e-cigarettes are specifically regulated in the Europe Union for the first time.

The inclusion of e-cigarettes in the revised TPD was intended not only to ensure a level of product quality and safety for these relatively new products, but also to harmonize the regulatory framework for e-cigarettes across all European Union Member States. While the provisions in the revised TPD do indeed set benchmarks for product quality and safety, differences in individual Member State transpositions have resulted in incomplete harmonization of these requirements across the European Union.

The purpose of this poster is to provide a visual overview of variations in Member States transpositions of the e-cigarette provisions in the revised TPD and to demonstrate the lack of full harmonization across the EU. This analysis should be of interest to business operators, regulators, and consumers, as it provides a flavor of the category's development direction in the EU.
Towards a bespoke regulatory framework for electronic cigarettes

Authors: Jones, Ian William

Oral Presentation

Organisations: JT International SA, Switzerland

Keywords: Electronic cigarette, regulation

Should electronic cigarettes be regulated? Most commentators would likely say ‘yes’, it is more the manner in which the products are regulated that is subject to ongoing debate. Electronic cigarettes are not tobacco products and neither are they medicinal products (unless manufacturers wish to make medicinal-related claims for their products). Thus existing regulatory regimes for tobacco and medicinal products are not necessarily best suited to electronic cigarettes. What is needed is a bespoke regulatory framework for electronic cigarettes that is comprehensive enough to give regulators and consumers the necessary assurances in respect to product quality and safety while at the same time allowing this relatively nascent product category to continue to grow and evolve.

This presentation set out a proposal for a balanced and workable regulatory framework for electronic cigarettes, covering both product and non-product provisions. The framework comprises of two-tiers, covering the minimum requirements to place products on the market (Tier 1) and additional requirements to substantiate product claims (Tier II). Specifically, the framework encompasses the following aspects; product specification, product performance, manufacturing, reporting, advertising, labeling and taxation.

The proposed regulatory framework is intended as a catalyst for further discussion. Further elaboration of this proposed framework could, hopefully, lead to the establishment of a bespoke regulatory regime for electronic cigarettes, benefiting not only consumers and regulators but also electronic cigarette companies, both big and small.
Liquid chromatographic analysis of carbonyl compounds in aerosols from high and low nicotine e-cigarette liquids mirroring realistic puffing topography

Authors: Kimber, Catherine Franciane (1); Kosmider, Leon (2); Kurek, Jolanta (2); Corcoran, Olivia (1); Dawkins, Lynne (3)

Poster presentation


Keywords: E-cigarette emissions, Low nicotine, Carbonyl

Background Previous studies using low nicotine tobacco cigarettes suggest a more intense puffing regime (more frequent and longer puffs), via compensatory behaviour, may augment exposure to potential toxins and carcinogens from tar. Although these are negligible in e-cigarettes by comparison, harsher vaping regimes combined with high voltage settings may result in increased inhalation of toxicants from the vehicle in nicotine solutions. The imminent European Tobacco Product Directive (EU-TPD) in May 2016 will restrict sales of nicotine concentrations > 20mg/mL, thus compelling e-cigarette users to reduce their nicotine intake. One possible result would be more intensive puffing to compensate (as documented by Dawkins et al., under review). This study aimed to establish whether more intense puffing regimes produce higher levels of potential toxicants from e-cigarette nicotine aerosols.

Methods Using HPLC/diode array analysis, four carbonyl compounds formaldehyde, acetaldehyde, acrolein and acetone were quantified in liquid (vehicle of propylene glycol and vegetable glycerine 50/50%) and aerosols produced from 24mg/mL and 6mg/mL nicotine solutions. Aerosols were generated by a smoking machine configured to replicate puffing topography data obtained from a sample of 12 experienced e-cigarette users using both these nicotine concentrations for one hour (Dawkins et al.).

Results Levels of aerosol carbonyls detected from 6mg/mL nicotine liquid were higher than those from 24mg/mL. Formaldehyde levels ranged from 3.058 to 4.966µg and from 0.950 to 1.770µg from the 6 and 24mg/mL liquids respectively. Acetaldehyde levels ranged from 2.119 to 2.736µg and from 0.831 to 1.143µg for 6 and 24mg/mL liquids respectively. Acetone levels ranged from 0.434 to 0.979 and 0.158 to 0.553µg in 6 and 24mg/mL liquids respectively. No acrolein was detected in nicotine solutions or in the aerosols. Levels of formaldehyde in nicotine solutions were not detected in the 6mg/mL and below the limit of quantification in the 24mg/mL. Levels of acetaldehyde ranged from 0.059 to 0.075µg/50µl in the 6mg/mL and 0.043 to 0.067µg/50µl. Levels of acetone was below the limit of quantification in the 6mg/mL and ranged from 0.080 to 0.094µg/50µl in the 24mg/mL nicotine concentration.

Conclusions The smoking machine, programmed with a more intensive puffing schedule to reflect compensation by experienced vapers on lower nicotine strength solution, resulted in higher aerosol levels of formaldehyde, acetaldehyde and acetone. Our findings suggest, vapers making a sudden switch to much lower nicotine strength e-liquids (either due the EU-TPD implementation or personal choice) may inadvertently increase their exposure to carbonyl compounds through compensatory puffing regimes.
What about the Older Smoker?

Authors: Kleykamp, Bethea (Annie)

Oral Presentation

Organisations: PinneyAssociates, United States of America

Keywords: Harm reduction, aging, development, electronic nicotine delivery devices

Globally, the number of older persons (60 years or over) is expected to more than double by the year 2050, from 841 million people to over 2 billion (WHO, 2013). An unprecedented outcome of such growth is that equal proportions of the population will be below age 20 and above age 60 (WHO, 2013). In addition, while some regions of the world are reporting reductions in smoking, these reductions are not always observed for older smokers. For example, survey data from the United States reveals that all age cohorts younger than age 65 had declines in smoking prevalence between 2005 to 2014 that ranged from 16.8% to 31.6%, whereas smoking prevalence slightly increased by 0.8% for smokers 65 or older (see Figure 2, Jamal et al., 2015). In combination the findings suggest an increase in the absolute number of older smokers in the general population and a concurrent decrease in the number of younger smokers. Despite an increasing number of older smokers, younger smokers are the focus of news headlines, peer-reviewed publications, and regulation. While a focus on tobacco/nicotine use among youth makes sense given that earlier initiation of smoking can predict subsequent regular smoking (e.g., Reidpath et al., 2014), the lack of attention on the growing number of older smokers is alarming. As noted in commentaries and systematic reviews over the last 5 years, there are unique concerns associated with being an older smoker (e.g., concomitant health issues, surgical complications, impaired quality of life) and there is limited research on how to best help aging smokers make decisions about their tobacco use (Kleykamp & Heishman, 2011; Cawkwell et al., 2015; Chen & Wu, 2015). Despite these challenges, this population of smokers may find the emerging technology of electronic nicotine delivery devices to be more effective and appealing for cutting down or stopping smoking compared to abstinence-only approaches or the use of smoking cessation medications. The goal of this presentation will be to provide an updated review of the literature as it relates to the older smoker and to provide a compelling argument for the use of electronic nicotine delivery devices as a harm reduction tool in this population. Most importantly, the goal of the review will be to increase dialogue around the topic of aging and tobacco in an effort to better understand and support the needs of older smokers.
Carbonyl compounds levels in mainstream smoke of cigarillos differ for ISO and human smoking

Authors: Kosmider, Leon (1,2); Madej, Daria (1); Knysak, Jakub (1); Koszowski, Bartosz (3); Pickworth, Wallace (3); Gawron, Michał (1); Kurek, Jolanta (1,2); Sobczak, Andrzej (1,2)

Poster presentation

Organisations: 1: School of Pharmacy with the Division of Laboratory Medicine in Sosnowiec, Medical University of Silesia, Poland; 2: Institute of Occupational Medicine and Environmental Health, Poland; 3: Health Center for Tobacco Research, Baltimore, MD, USA

Keywords: carbonyl, toxic, carcinogenicity, cigarillos, ISO

Background

Carbonyl compounds are among the compounds responsible for carcinogenicity and toxicity of cigarette smoke. Cigarillos resemble cigars and they have different design features than cigarettes which may influence smoking behavior and toxicant exposure from mainstream smoke. To date, there are very limited data on carbonyl compounds concentration in cigarillos smoke using ISO (cigarettes) and human puff topography from cigarillo smoking.

Aim

The aim of the study was to compare selected carbonyl compounds levels in mainstream smoke from cigarillos using ISO and human puff topography.

Methods

Five popular U.S cigarillos were investigated. Mainstream smoke was generated in the laboratory using the automatic smoking simulator Palaczbot® according to two smoking regimes: ISO method and human puff topography. Human smoking topography differed from ISO method: puff volume: 55 vs. 35mL; interpuff interval: 23 vs. 60sec.; puff velocity: 23 vs. 17.5mL/sec., respectively. Cigarillo products were smoked in triplicates until 9 mm from the product’s mouthpiece. Simultaneously, blank samples were collected to adjust for background concentration of investigated compounds. Mainstream smoke was collected in two impingers, each containing 35 mL of 2,4-dinitrophenylhydrazine solution. Carbonyl compounds were analyzed by HPLC with fluorescent detection (AT 1200, Agilent Technologies Inc.).

Results

Significant differences in carbonyl compounds levels were detected as a function of the smoke generation condition ISO vs. human puffing parameters: acetaldehyde (3207 vs. 5102), acrolein (118 vs. 261), propionaldehyde (340 vs. 569), crotonaldehyde (67 vs. 143) and butanal (449 vs. 639µg/1 product).

Conclusion

Carbonyl concentration in mainstream smoke of cigarillo was nearly twice as great when the cigarillos were smoked according to human topography standards compared to ISO standards. Measuring carbonyl compounds in cigarillos according to the ISO method underestimates exposure.

Funding: This work was supported by Medical University of Silesia, Katowice, Poland (grant No KNW-2-008/D/4/N)
**Evolution and study of the temperature in the resistance of electronic cigarettes**

**Authors:** Lalo, Helene; Soulet, Sébastien; Pairaud, Charly

**Poster presentation**

**Organisations:** LFEL, France

**Keywords:** Heat transfer, electronic cigarette, E-liquid degradation, resistance, temperature evolution

Electronic cigarette (EC) is a device designed to inhale nicotine in a safer way than classical cigarette. The rise of resistance temperature is a key factor in the nicotine delivery process, as it governs the e-liquid heating. Moreover the maximal temperature reached is also studied because of its importance on the e-liquid consumption.

This study describes the impact of: liquid composition, electrical power, material and geometry of resistance on the temperature rise in the EC resistance and of the maximal temperature reached.

Various resistances were built according to parameters that influence their mass. The temperature evolution was measured by a thermocouple with a K probe in contact with the surface of the resistance. The electrical energy is generated by a battery which delivered a power, fixed by varying the current according to resistance value. Several different e-liquids were used (from 100% PG to 100% VG) in order to study a wide choice of e-liquids (that we can find on the market).

Temperature rise and maximal temperature reached is dependent on almost all parameters studied in this article. Increasing resistance’s mass along with heat capacity aims to reduce temperature rise in hyperbolic manner. In an opposite way, the temperature linearly increases with power delivered. Maximal temperature reach is, for the most part, dependent on e-liquid composition.
Female snus use and health correlates

Authors: Lund, Ingeborg; Kvaavik, E.; Hansen, B.T.

Poster presentation

Organisations: FHI, Norway

Keywords:

Background: In recent years, snus (Swedish moist snuff) has become increasingly popular among females in Norway, with increased switching to snus from smoking among female adults, and a growing market shares for snus relative to cigarettes among female youth.

Aim: To investigate the associations between overweight and female snus use, and between self-reported general health and female snus use.

Methods: 25 233 women aged 18-45 years, randomly drawn from the National Registry, received a self-administered, structured questionnaire on lifestyle and health. The survey response rate was 54.5% (N=13 756). The associations between snus use and smoking on body mass index calculated from self-reported body weight and height, and self-rated general health was analysed by ordinal regressions.

Results: Daily snus users were less likely than never snus users to report overweight, and more likely to report poor general health. Occasional and former snus users did not differ significantly from never snus users with respect to BMI or global health.

Conclusion: As smoking, daily snus use is associated with a lower BMI and poorer general health, but the size of the effects are much smaller for snus. These findings might suggest that a shift from smoking to snus use among female smokers would mean less negative effect on self-evaluated general health, and a reduced difference in body weight compared to non-tobacco users.
Nicotine delivery from e-cigarettes: data and learnings from clinical pharmacokinetic studies

Authors: M. Fearon, Ian (1); Eldridge, Alison (1); Gale, Nathan (1); J. Shepperd, Christopher (1); McEwan, Mike (1); M. Camacho, Oscar (1); Mavropoulou, Eleni (1); Nides, Mitch (2); McAdam, Kevin (1); Proctor, Chris (1)

Poster presentation

Organisations: 1: British American Tobacco, Group R&D Regents Park Road Southampton, SO15 8TL, UK; 2: Los Angeles Clinical Trials, 4116 W. Magnolia Blvd. Suite 100, Burbank, CA 91505, USA.

Keywords:

Introduction.
Nicotine pharmacokinetic (PK) studies are an important tool in developing our understanding of actual nicotine delivery into the body from electronic cigarettes and other nicotine-delivery products. Furthermore, data from such studies may potentially be required as part of a regulatory package, particularly as part of an abuse liability assessment of a novel product.

Methods.
In two separate studies we examined blood nicotine levels during acute clinical use periods in subjects smoking cigarettes and using e-cigarettes. The first study (ISRCTN74070762; Belfast, U.K.) compared blood nicotine levels in 24 smokers using closed-system modular e-cigarettes according to a defined puffing schedule, with those seen when subjects smoked a cigarette typical of that sold in the study market. The second study (NCT02474849; Los Angeles, USA) examined blood nicotine in 18 vapers who were occasional smokers using the same modular e-cigarettes ad libitum and compared these levels to when subjects smoked a single, market-typical combustible cigarette. Both studies were approved by local, independent research ethics committees and were run in accordance with Good Clinical Practice. Subjects provided written informed consent prior to study participation and were deemed healthy following medical examination and clinical laboratory screening. Smoking status was verified by exhaled CO measurements. Before each study visit subjects abstained overnight from any tobacco or nicotine product use, also verified by exhaled CO. A 5 minute exposure period was used in both studies.

Results.
Compliance with abstention requirements and other inclusion/exclusion criteria was high. 22 subjects completed Study 1 while all subjects completed Study 2. In Study 1 blood nicotine Cmax was, on average, 5-fold greater for the combustible cigarette compared to the e-cigarette. In contrast, in Study 2 peak blood nicotine levels were similar for the cigarette and the e-cigarette.

Conclusions.
Our data show a high level of variability when subjects from different populations and with different smoking histories use similar products. Puffing schedule (standardised vs ad libitum) may also contribute to this variability. While this may support a need for standardisation of protocols for e-cigarette clinical research, to facilitate comparisons between products in different studies, study design needs to take into account study objectives and cohort, real-world usage patterns and which comparisons need to be made between one product and another.
A Journey of a Vaping Political Party from Conception to GFN

Authors: Mann, Rhydian Owen; Harding, Jessica; Gill, Peter; Bryan, Liam

Poster presentation

Organisations: Vapers in Power, United Kingdom

Keywords: advocacy, campaigning

A graphical timeline depicting the background to Vapers in Power, advocacy campaigns and outcomes from a political viewpoint
Toxicants in e-cigarette aerosols – a quantitative survey and comparison with cigarette smoke

Authors: Margham, J.; McAdam, K G.; Wright, C; Mariner, D; Forster, M; Murphy, J; Liu, C; Proctor, C

Poster presentation

Organisations: British American Tobacco, Group R&D Regents Park Road Southampton, SO15 8TL, UK

Keywords:

Background: Despite widespread use of e-cigarettes there have been few detailed chemical studies examining e-cigarette aerosol composition, with most studies to date focusing on specific compound groups. Here we report the most complete chemical comparison to date of emissions from an e-cigarette and a tobacco cigarette (~ 150 compounds), including FDA HPHC compounds, and species previously reported to be present in e-cigarette emissions.

Methods: Vype e-Pen Blended Tobacco flavour, and the Kentucky Reference Cigarette 3R4F were examined. Vype e-Pen was puffed in two separate 100-puff blocks using a 55/3/30 puffing regime (volume(cm3)/ duration(s)/ interval(s)), and 3R4F smoke was collected (in separate rooms) using the Health Canada 55/2/30 regime (ventilation blocked). With anticipated low levels of some e-cigarettes constituents, air/method blank analysis was made at the concurrently with, and in the same way as e-cigarette measurements. Independent contract labs used ISO17025 accredited methods to quantify the following emissions: carbon/nitrogen oxides, carbonyls/dicarbonyls, alcohols/dialcohols, phenols, o-heterocycles, chlorinated dioxins/furans; volatile, substituted and, polynuclear aromatic hydrocarbons; amides, azines, aromatic and aliphatic amines, nicotine & related compounds, nitrosamines, metals and radionuclides.

Results: 105 compounds were undetectable in Vype e-Pen emissions. 23 compounds were detected or quantified at comparable levels in Vype e-Pen emissions and air/method blank; hence it was concluded that e-Pen did not generate measurable levels of these 23. 15 compounds were quantified at higher levels in Vype E-pen emissions than the blank, but at substantially lower per-puff levels than 3R4F. Similar or higher per-puff emissions of four compounds (propylene glycol, glycerol, menthol and chromium) were measured from Vype E-pen in comparison to 3R4F. Nearly 100 of the compounds investigated were measurable in 3R4F emissions.

Conclusions: This study shows substantial chemical differences between emissions from e-cigarettes and tobacco cigarettes. Most cigarette toxicants examined could not be detected in the e-cigarette aerosol. Measuring air/method blanks is an essential step for identifying experimental artefacts amongst trace-level e-cigarette aerosol constituents.
Concepts and beliefs about smoking, nicotine and electronic cigarettes among healthcare professionals in Greece

Authors: Moisidou, Anastasia (1); Farsalinos, Konstantinos (2,3); Voudris, Vassilis (2); Barbouni, Anastasia (1)

Poster presentation

Organisations: 1: National School of Public Health, Greece; 2: Onassis Cardiac Surgery Center, Greece; 3: Department of Pharmacy, University of Patras, Greece

Keywords: smoking, nicotine, tobacco, electronic cigarettes, healthcare

Introduction. The study purpose was to evaluate the concept and beliefs of Greek healthcare professionals about smoking, nicotine and electronic cigarettes.

Methods. An online survey was performed, in which physicians and nurses working in private practice and in randomly selected public hospitals in Athens were invited to participate. The survey assessed demographics and knowledge and perceptions about nicotine and electronic cigarettes. A knowledge score was calculated by scoring the correct answers to specific questions with 1 point.

Results. A total of 262 healthcare professionals were included to the analysis (70.6% physicians). Most had daily contact with smokers in their working environment. About half considered that nicotine has an extremely or very important contribution to smoking-related disease. About a third considered nicotine replacement therapies as more addictive than smoking, while 76.7% overestimated their smoking cessation efficacy. Only 24.8% would recommend them as long-term smoking substitutes. A limited knowledge about electronic cigarettes was observed, with 45.0% considering them equally or more addictive than smoking, while 35.5% thought they involve combustion and most considered that nicotine in electronic cigarettes is synthetically produced. Only 14.5% knew about the pending European regulation, but 33.2% have recommended them to smokers. The knowledge score was 7.7 (SD: 2.4) out of a maximum of 16. Higher score was associated with specific physician specialties.

Conclusions. Greek healthcare professionals exhibit a knowledge deficit about nicotine, overestimating its adverse effects and avoiding its long-term use as a smoking substitute, and have misconceptions about the function and characteristics of electronic cigarettes.
Acute toxicity of a flavoured e-liquid according to TPD 2 is related to e-cigarette vaporiser resistance and electrical power

Authors: Mrva, Thomas (1); Poirier, Ophelie (2); Dartsch, Peter C. (3)

Poster presentation

Organisations: 1: Happy People GmbH, Germany; 2: Takasago Europe GmbH, Germany; 3: Dartsch Scientific GmbH, Germany

Keywords: TPD2, vaporiser, e-cigarette, cytotoxicity, cell culture

Introduction. In contrast to cigarette smoking, the vapour of e-cigarettes is not the result of a combustion process and has been shown to have much lower health effects in vitro and in vivo. Prompted by that background we used a specially created e-liquid in accordance to the German implementation of TPD 2 to investigate whether the vaporiser resistance in combination with electrical power of the e-cigarette might be responsible for the degree of acute toxicity on cultured human lung cells after vaping.

Materials and methods. The flavoured e-liquid according to TPD 2 consisted of a base liquid of 70 % vegetable glycerol, 30 % propylene glycol, 1.2 % nicotine and a flavour named “Blueberry/Cheesecake”. The liquid was transferred to a specially designed vaping apparatus and 10 puffs with a duration of 4-5 seconds and a pause of 10 seconds between two puffs were applied to the liquid. A common e-cigarette was used (eGrip OLED CL 30 from Joyetech with two different vaporisers of 1.0 and 0.4Ω and an electrical power ranging from 6.5 to 30 Watts). The vapour was piped into 10 ml of HEPES-buffered cell culture medium. After sterile filtration the primary extract was added at different test concentrations to cultures of human lung cells (A549) with a seeding density of 10,000 cells/well in 96 well-plates. After 24 hours cell vitality was measured enzymatically by cleavage of XTT by the activity of mitochondrial dehydrogenases.

Results. The results showed that even an e-liquid according to TPD 2 can produce a marked acute toxicity on cultivated human lung cells when vaping beyond the usual limits. By using a vaporiser with a resistance of 1.0Ω, cytotoxicity was measured above 15 Watts causing nearly complete cell death within 24 hours. By using the subohm vaporiser with a resistance of 0.4Ω, even the highest power of 30 Watts did not cause a cytotoxic effect.

Conclusions. The results indicate that vaping of an e-liquid in accordance to the German implementation of the TPD 2 also causes marked acute toxic effects when vaping at forced conditions. This effect might be related to an excess of free radicals. However, at common and moderate user conditions there are no toxic effects which might cause acute cell death within the lung or the respiratory tract. We, therefore, recommend a more detailed elucidation of e-cigarette users on the unwanted health effects when vaping at forced conditions.
Reduction in Harmful or Potentially Harmful Constituents Following Partial or Complete Substitution of Cigarettes with Electronic Cigarettes

Authors: O’Connell, Grant (1); Graff, Donald W. (2); Robinson, Edward (3); D’Ruiz, Carl D. (3)

Poster presentation

Organisations: 1: Fontem Ventures B.V., Netherlands, The; 2: Celerion, Lincoln, Nebraska, USA; 3: ITG Brands LLC, Greensboro, North Carolina, USA

Keywords: E-cigarettes, HPHCs, biomarkers

Electronic cigarettes are becoming an increasingly popular alternative to conventional tobacco cigarettes among smokers worldwide who wish to reduce their exposure to harmful or potentially harmful constituents (HPHCs). Although a number of studies have suggested that some HPHCs may be found at low levels in the aerosols of e-cigarettes, there is relatively little information available on the exposure to HPHCs resulting from the use of e-cigarettes compared to conventional tobacco cigarettes.

Clinically-confined smokers were randomized into groups that partially or completely substituted their usual cigarette brand with commercial e-cigarettes, or discontinued all tobacco or nicotine products, for five days. Thirteen urinary and blood biomarkers of smoke exposure, including those for carbonyls and tobacco-specific nitrosamines, were assessed at baseline and again after five days of e-cigarette product use or cessation.

Measurable nicotine metabolites were present in the samples from smokers who were using e-cigarettes, but levels of biomarkers for HPHCs were significantly lower, and many were indistinguishable from those of subjects who had quit smoking or using nicotine products entirely. Dual users who had substituted half of their self-reported daily cigarette consumption with e-cigarettes exhibited reduced biomarkers levels that were proportional to the reduced number of cigarettes smoked.

The study findings show that smokers who completely or partially replace their cigarettes with e-cigarettes, can expect to reduce their exposure to HPHCs. This data indicate the great potential that e-cigarettes may provide for smokers seeking an alternative to tobacco products and supports the case for regulating e-cigarettes differently from tobacco-containing products.
Factors governing the dispersion of exhaled particles during vaping of an e-cigarette

Authors: Prasauskas, Tadas (1); Martuzevicius, Dainius (1); Setyan, Ari (2,3); O’Connell, Grant (4); Cahours, Xavier (5); Colard, Stephane (5)

Poster presentation

Organisations: 1: Department of Environmental Technology, Kaunas University of Technology, Lithuania; 2: Laboratory for Advanced Analytical Technologies, Empa, Switzerland; 3: Institute of Environmental Engineering, ETH Zürich, Switzerland; 4: Fontem Ventures B.V., Amsterdam, The Netherlands; 5: SEITA-Imperial Tobacco, France

Keywords: Air quality, electronic cigarette, exhaled particles, dispersion, exposure chamber

Electronic cigarettes (e-cigarettes) are a relatively new alternative to conventional cigarettes and the prevalence of use is increasing amongst smokers worldwide. This raises new questions for example on the potential impact of e-cigarette use on indoor air quality and bystander exposures; evidence on this topic is still emerging. To that end, the aim of this study was to investigate the impact of different factors on the dispersion of exhaled e-cigarette particles at a bystander’s position, namely vaping topography, distance from bystander and room ventilation rate, following use of a commercial e-cigarette.

A room-simulating chamber with controllable ventilation rates with a temperature-regulated mannequin as a bystander was employed. Three experienced e-cigarette volunteers vaped an e-cigarette according to a set puffing regime, 0.5, 1.0, and 2.0 metres from the bystander. Inhaled puff, “hold” in body, and exhaled puff durations were recorded in order to represent volunteers’ different vaping topography. Four-way mixing ventilation was chosen as this is commonly used in residential buildings, with ventilation rates of 0, 1 and 2 air changes per hour. The supply air temperature and relative humidity was set to 20°C and 35%, respectively. Aerosol particles were analysed using a Fast Mobility Particle Sizer (FMPS) spectrometer, an Electric Low Pressure Impactor (ELPI) at the bystander’s position. The obtained data was fitted to regression model using partial least squares method to obtain the relationship between factors affecting exhaled particle concentrations in the room at the bystander’s position. Exhaled e-cigarette particles were also collected using a vacuum-assisted filter pad capture system and the chemical composition analysed.

The distance and the vaping topography exhibited the highest influence on dispersion of exhaled particles during vaping of an e-cigarette. As expected, a greater distance between e-cigarette user and a bystander resulted in lower maximum particle concentrations, although even at a close distance the decay of particle concentrations was very rapid. Although vaping topography was rather similar, significant differences between particle number concentrations were observed, which may be related to physiological differences and e-cigarette use behaviours amongst the volunteers. The ventilation rate did not significantly influence particle size distributions or maximum particle concentrations. This can be attributed to the fact that most of the exhaled particles evaporated immediately after exhalation thus affecting the removal of particles through evaporation, not displacement by ventilation air. This is not surprising as the chemical composition of the exhaled particles was shown to be largely composed of water.
Development of a Novel Survey Instrument to Assess Predictors of Intentions to Initiate E-cigarette Use

Authors: Russell, Christopher (1); Gale, Nathan (2); Ashley, Madeleine (2); McEwan, Michael (2); Prasad, Krishna (2)

Poster presentation

Organisations: 1: Centre for Substance Use Research Ltd, United Kingdom; 2: British American Tobacco (Investments) Ltd, United Kingdom

Keywords: E-cigarettes, initiation, intentions, predictors, survey

Background: The U.S. Food and Drug Administration’s MRTPA guidance states the need to provide estimates of individuals’ likelihood for initiating tobacco/nicotine use, and to identify psychosocial factors and product characteristics affecting this. To evaluate the net population health impact of e-cigarettes, it is important to assess the likelihood of their uptake by current, former and non-smokers.

Aim: To develop a novel, web-based survey measure of a range of variables hypothesised to explain variance in individuals’ intentions to initiate vaping.

Method: From a systematic review of social-science literature, a survey instrument was developed to assess smoking and e-cigarette related perceptions, attitudes and experiences, including those hypothesised in the literature to achieve good prediction of individuals’ likelihood of initiating vaping. This survey instrument was refined with feedback from focus groups comprising current smokers and local vape shop managers, and administered online to 306 smokers, 77 former-smokers and 148 non-smokers. Multivariable logistic regression models of hypothesised predictors of current smokers’ intentions to initiate vaping were used to assess the extent to which these intentions were associated with a range of perceptions of e-cigarettes and cigarettes.

Results: An intention to initiate vaping within 12 months was expressed by 41% (n=124) of current smokers. Numbers of former-smokers (n=27) and non-smokers (n=17) expressing this intent were insufficient to model ‘intention to vape’. Odds of intending to initiate vaping were significantly higher (p<0.05) among smokers who had already sought information about e-cigarettes in a shop (OR=4.06); increased positive expectancy of vaping (OR=3.61); increased expectation of enjoyment of vaping (OR=1.29); greater anticipated satisfaction from vaping compared to smoking (OR=2.08); greater perceived likelihood of experiencing long-term health harms from smoking compared to vaping (OR=2.00); and higher level of attraction to the flavours available through vaping (OR=1.29).

Conversely, odds of intending to initiate vaping were significantly lower (p<0.05) among smokers with stronger belief that vaping would harm their long-term health (OR=0.97); that e-cigarette vapour causes greater harm to bystanders than cigarette smoke (OR=0.72); and that vaping would be more expensive than smoking (OR=0.51).

Conclusions: A novel survey instrument, comprising items extracted and adapted from published smoking and e-cigarette-related survey and questionnaire measures, identified a number of perceptual variables that significantly affect current smokers’ odds of intending to initiate vaping within 12 months. Follow-up surveys of our sample will assess the extent to which these variables explain variance in their actual use of e-cigarettes up to 12 months later.
Electronic Cigarettes: An Effective Means for De-normalising Smoking?

Authors: Russell, Christopher; McKeeganey, Neil

Oral Presentation

Organisations: CSUR, United Kingdom

Keywords: Electronic Cigarettes De-normalisation of Smoking

The claim that use of electronic cigarettes is leading to a renormalisation of smoking has had a profound influence on electronic cigarette policy and regulation. Despite this there is a serious lack of evidence supporting the view that smoking is indeed becoming increasingly normalised as a result of electronic cigarette use. In this presentation we draw upon data from a recent online survey and interviews with smokers, non smokers, vapers and non vapers to look at the extent to which witnessing electronic cigarette use is having a significant impact in re-normalising smoking behaviour. We will look in detail at respondents awareness of smoking and vaping including their capacity to differentiate between these behaviours visually, their perceptions of smoking and vaping including the extent to which attitudes towards smoking are being influenced, positively or negatively, by witnessing electronic cigarette use. We will also present material from smokers as to whether they feel that their smoking behaviour has become more socially acceptable as a result of others use of electronic cigarettes. Finally, this presentation will consider the policy implications of a greater recognition that electronic cigarette use may actually be serving to de-normalise rather than re-normalise smoking.
Comparison of e-liquids on the Polish market and analysis of nicotine levels and tobacco alkaloids

Authors: Stachowiak, Aleksandra; Heinrich, Przemysław; Lipowicz, Justyna

Poster presentation

Organisations: LIPRO e-Liquid Production, Poland

Keywords: nicotine, headspace, e-liquid, vapour, vaping

Background

The use of e-cigarettes is becoming more popular in Poland. Still, a lot of e-liquids contain inaccurately labelled nicotine content and have incorrect packaging. Our aim was to compare nicotine levels and correctness of package labelling of e-liquids on the Polish market.

Method

For the purpose of our analysis we have taken 13 e-liquids available on the Polish market and applied Gas Chromatography with Nitrogen-Phosphorous Detector (GC-NPD). The samples were tested for nicotine concentration and presence of tobacco alkaloids.

Results

The samples were analyzed by GC-NPD to measure nicotine levels and tobacco alkaloids (myosmine, anabasine, cotinine and DL-nornicotine). We detected and determined a DL-nornicotine concentration at the levels of 0.72 mg/ml and 0.17 mg/ml in 2 samples only. Four samples had nicotine levels similar to the value declared on their packaging (+/- 10% of the declared value). One sample had a nicotine concentration of 20 mg/ml and the value on the packaging was 12 mg/ml.

Liquids from China have an old pictogram version. Four of the analyzed e-liquids (produced in the EU) have a correct packaging and labelling (a cardboard box containing an e-liquid bottle, a leaflet, a warning triangle, new pictograms, a country of origin). Three liquids produced in the EU were incomplete—no cardboard box for an e-liquid bottle, no leaflet, warning triangle or pictograms. Other e-liquids did not have a cardboard box for an e-liquid bottle, a leaflet, a warning triangle or pictograms.

Conclusion

Manufacturers should use high purity pharmaceutical nicotine. Some producers still use an old pictogram version. At present, packaging of many products is incomplete. However, TPD will force manufacturers to produce complete packaging and to label their e-liquids accordingly. Manufacturers should pay more attention to the amount of nicotine added to their e-liquids. Packaging should include information about the content of nicotine, which is a potentially carcinogenic alkaloid.
The European tobacco product directive and e-cigarette compliance: a test method for drop testing of e-liquid bottles

Authors: Tschierske, Nicole (1); O’Connell, Grant (2); Colard, Stéphane (3); Biel, Stefan S. (2)

Poster presentation

Organisations: 1: Reemtsma Cigarettenfabriken GmbH, Germany; 2: Fontem Ventures B.V., The Netherlands; 3: SEITA, Imperial Tobacco, France

Keywords: EUTPD, refill mechanism, e-liquid, standards, test method

The European Tobacco Directive requires a leakage free refill mechanism for electronic cigarettes [1]. Recently the EU proposed a standard for product performance detailing the requirements for e-liquid bottles [2]. Amongst others, this proposed technical standard specifies an e-liquid bottle performance “that emits no more than 20 drops of refill liquid per minute when placed vertically”. At this time, no method for testing this product characteristic has been proposed. Our study was performed in order to assess potential methods and their limitations for standardized product testing. We examined the influence of external (differences in conditioning and test temperature) and internal test factors (liquid viscosity from 100% glycerol to 100% propylene glycol, bottle filling height) on the product performance. Based on these insights, we hereby propose a test protocol to assess product compliance which aims to eliminate test variables that might bias results.


**Acetoin is a precursor to diacetyl in e-cigarette liquids**

**Authors:** Vas, C.; Waters, G.; Costigan, S.; McAdam, K.

Poster presentation

**Organisations:** British American Tobacco, Group R&D Regents Park Road Southampton, SO15 8TL, UK

**Keywords:**

Background: Diacetyl has been reported to be used for the creation of creamy, butter and vanilla flavour directions in e-cigarette liquids. However, inhalation of diacetyl in occupational settings has been shown to lead to the onset of a decline in respiratory function, and a condition known as bronchiolitis obliterans (a non-reversible obstructive lung disease). Acetoin has been used as an alternative to diacetyl in e-cigarette liquids, but while the toxicological data on it shows little of concern, its chemical similarity to diacetyl means that it could be converted to diacetyl is a possibility.

**Aim:** To understand the potential for conversion of acetoin to diacetyl in a number of different e-liquid matrices.

**Method:** Eight unflavoured e-liquids of different composition were prepared before being split into two samples. One sample was spiked with acetoin, and the second sample remained as a matching control. The sample pairs were analysed on the day of spiking, and five additional time points for a period of eight weeks. Three replicate measurements of acetoin and diacetyl were performed by GC-MS at Enthalpy Analytical, Inc.

In addition, one unflavoured e-liquid was prepared and spiked at six concentrations of acetoin ranging from 405 to 2509µg/mL with an un-spiked control. The samples were analysed on the day of spiking and three weeks later, for three replicate measurements of acetoin and diacetyl using GC-MS.

**Results:** For the eight week time course study neither acetoin nor diacetyl could be detected in the control samples. With the spiked acetoin samples, conversion from acetoin to diacetyl was not seen in nicotine-free e-liquids. However, e-liquids with alkaline pH brought about by inclusion of nicotine showed conversion of acetoin to diacetyl over this time period. The highest observed conversion of acetoin to diacetyl was 8% for a sample containing 2% w/w nicotine.

The effect of differing concentrations of spiked acetoin on diacetyl generation at one time point in an alkaline e-liquid showed a quasilinear relationship between the level of spiked acetoin and the amount of diacetyl formed. There was an apparent lower rate of conversion at the highest acetoin concentration, consistent with a combination of linear conversion of acetoin to diacetyl, combined with instability of generated diacetyl in the e-liquid.

**Conclusion:** Acetoin is a precursor to diacetyl in nicotine containing e-liquids. Action should be taken by e-liquid manufactures and flavouring suppliers to eliminate acetoin as a flavour ingredient.
E-cigarette: assessment of the so-called “gateway effect” based on product classification

Authors: Verron, Thomas (1); Cahours, Xavier (1); Cerson, Liz (2); O’Connell, Grant (3); Colard, Stephane (1)

Poster presentation

Organisations: 1: SEITA - Imperial Tobacco, France; 2: Imperial Tobacco Limited, UK; 3: Fontem Ventures B.V., Amsterdam

Keywords: E-cigarette, Gateway, Dynamic Population Modelling

Since electronic cigarettes (e-cigs) became popular as alternatives to conventional cigarettes, with subsequent market growth amongst smokers, there is currently a debate as to whether e-cigs may be a gateway to conventional cigarette smoking or not. Such fears are related to the possibility that prior use of e-cigs could conceivably result in conventional cigarette smoking initiation amongst never smokers. Although the common definition of a “gateway effect” is based on the concern that current use of a potential low-risk product could facilitate the use of higher-risk products in the future, there is actually no agreed method for assessing a gateway effect for e-cigs. Consequently, this creates a lack of clarity and confusion among researchers, politicians, media, vapers and smokers, which often leads to misleading study interpretations and conclusions being drawn.

To this end, we have described a framework based on product classification to assess any so-called “gateway effect”: ‘alternative product’, ‘transition product’, ‘substitution product’ or ‘gateway product’.

Each of these four categories corresponds to a different probability of a consumer switching from a potential low-risk product to a high-risk product, and vice versa, based on the motives for using them. Using an approach such as dynamic population modelling, it will be possible to classify e-cigs in one of these four product categories and thereby to assess whether e-cigs are a ‘gateway’ or a ‘roadblock’ to conventional cigarette smoking. Here we describe this innovative approach.
**Diacetyl and acetyl propionyl stability in e-liquids**

**Authors:** Waters, G.; Vas, C.; Costigan, S.; McAdam, K.

Poster presentation

**Organisations:** British American Tobacco, Group R&D Regents Park Road Southampton, SO15 8TL, UK

**Keywords:**

There is a current concern amongst e-cigarette users over the use of diacetyl (DA) and acetyl propionyl (AP) as flavourings in e-liquids. DA and AP are used to impart a butter and vanilla flavour in e-liquids. DA, whilst a food-grade flavouring, has known respiratory toxicity, and can cause a clinical condition called bronchiolitis obliterans. Research has shown that AP has similar respiratory toxicity to DA. Both DA and AP are potential contaminants of e-liquids. This study aimed to find the effect of DA and AP contamination on an e-liquid formulation.

An e-liquid style formulation with no flavouring was prepared. This formulation was spiked with known concentrations of DA and AP, ranging from 5µg/ml to 180µg/ml, and a non-spiked sample remained as a control. These samples were stored at 20°C ± 2°C in amber glass containers. Three replicates of each sample were analysed by GC-MS at Enthalpy Analytical 18 days after the samples were spiked with DA and AP.

Upon analysis, the amount of both DA and AP has significantly reduced from the amount that was originally injected. For the sample with the highest amount of spiked DA and AP, the amount reduced on average over the 3 replicates by 3x (DA) and 20x (AP). Both compounds have been shown not to be stable in an e-liquid formulation. Further work is planned in this area to determine the relevance of this.
The effect of organic acids on e-liquid: Nicotine stability and relief of irritative taste

Authors: Zhu, Yushu

Poster presentation

Organisations: Ruvian Technology Ltd., China, People's Republic of

Keywords:

Nicotine as an important ingredient in e-liquid can bring physiological satisfaction to vapers, high level of nicotine will cause throat irritation, some organic acids as flavoring additives could reduce such kind of unpleasant irritative taste. However, the addition of organic acids would alter the pH value of e-liquid that may affect nicotine stability. This study was to investigate a. The nicotine stability in e-liquid under the change of pH value resulted from additions of various amount of organic acids; b. Comparative analysis of levels of impact when different organic acids were added with similar doses; c. The taste modification capability of different organic acids in terms of easing the irritative taste caused by high dose of nicotine. Five most commonly used organic acids, citric acid, malic acid, tartaric acid, benzoic acid and methyl butyric acid were chosen and added into two e-liquids of mint flavor (3mg) and tobacco flavor (20mg). pH values of e-liquids with and without organic acid were measured by pH meter, nicotine concentration was analyzed by Gas Chromatography-Flame Ionization Detector (GC-FID), and taste evaluation was carried out by subjects divided into different groups depending on their actual vaping habits (e-cigarette use only group, conventional cigarette use only group and dual usage group). These investigations might provide information in regard to proper use of organic acid additives to ensure the stability of nicotine in e-liquids, as well as the potency of different organic acids in terms of easing the irritation caused by high dose of nicotine usage.
E-cigarette Aerosol Investigation: Release pattern of nicotine and other collected matters in E-cigarette generated aerosol based on different smoking regimes

Authors: Zhu, Yushu

Poster presentation

Organisations: Ruvian Technology Ltd., China, People's Republic of

Keywords: aerosol, research

Published studies in regard to E-cigarette generated aerosol mainly focused on identification and quantitation of the nicotine and other substitutes that released from E-cigarette vaping. However, investigations on the release pattern of these compounds and the correlation among these patterns under different smoking regimes (puff duration, puff volume, smoking interval) are still inadequate. The aim of this study is to comparatively analyze the release pattern of nicotine, major solvents (PG/VG) and other aerosol collected matters (ACMs) under either ISO smoking regime or Health Canada Intense Smoking Regime (HCI). Aerosol from Ruvian’s E-cigarettes was analyzed. Nicotine and other substitutes in aerosol were collected by Cambridge filter and extracted. Identification and quantitation of nicotine and major solvents were carried out by validated laboratory method. Other aerosol collected matters (ACMs) were measured by analytical balance. In this study, the following results will be presented:

1. Quantitative data of nicotine amount in aerosol for every 50 puffs were collected and the overall release trend for the whole smoking course would be presented;

2. Quantitative data of major solvent (PG/VG) in aerosol for every 50 puffs were collected and the overall release trend for the whole smoking course would be presented;

3. The amount change of other released ACMs would be presented and compared.

Furthermore, the correlation among releases of these analytes would be discussed by comparative analysis and the possible reasons for the observed either similar or discrepant release pattern would be discussed.