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Framing and scientific uncertainty in nicotine vaping product regulation: An examination of competing narratives among health and medical organisations in the UK, Australia and New Zealand

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Abstract

Aims: To compare the policy positions of health and medical organisations across Australia, New Zealand, and the UK as they relate to sale and supply of nicotine vaping products (NVPs) and evaluate factors that have informed the differences in policy recommendations among these countries.

Methods: We used mixed methods to analyse data from position or policy statements published by health and medical organisations regarding NVPs (n=30) and consultation documents submitted to government committees regarding policy options for the regulation of NVPs (n=26). Quality assessment of included documents was conducted using the six-item Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Text and Opinion Papers, and findings were presented narratively. Qualitative data were coded using NVivo 12 software and analysed using thematic analysis.

Results: An overwhelming majority of health bodies, charities and government agencies in the UK and New Zealand portrayed NVPs as a life-saving harm reduction tool. In contrast, concerns about addicting non-smoking youth to nicotine, a perceived lack of clear and convincing evidence of safety and efficacy and the potential to undermine tobacco control progress continues to define attitudes and recommendations towards NVPs among Australian health and medical organisations. Although the profoundly divided views among stakeholders seem to arise from empirical uncertainties and disagreements over the level and credibility of evidence, the source of most of these disagreements can be traced back to the fundamental and irreconcilable differences in the framing of the NVP debate, and varied tolerability of risk trade-offs associated with NVPs.

Conclusion: Progress in resolving the controversy surrounding NVP policy requires stakeholders to be frame-reflective and engage in a meaningful dialogue of risk trade-offs, as well as both intended and unintended consequences of proposed policies.

Key words: E-cigarettes, Nicotine, Regulation, Policy analysis

Background

The nicotine and tobacco product landscape has seen unparalleled changes in the last decade due to rapid technological innovation and evolving regulatory environments. The popularity and widespread adoption of new nicotine delivery technologies (such as nicotine vaping products [or NVPs, exemplified by e-cigarettes] and heated tobacco products) among tobacco smokers as a way to quit and/or reduce harm from their nicotine use has challenged conventional tobacco control approaches based on promoting abstinence and opposing industry involvement. It has sparked a debate regarding the role of nicotine in smoking cessation and harm reduction efforts (Abrams et al., 2018; Farsalinos & Le Houezec, 2015; Glantz & Bareham, 2018).

In general, the policy debate involves two main competing narratives (Green, Fielding, & Brownson, 2018). The first approach, exemplified by the UK and New Zealand, argues that because NVPs are likely to be much less harmful than combustible cigarettes, smokers who are unable or unwilling to quit should be encouraged to switch to these products to reduce their health risk. In the UK, the Medicines and Healthcare products Regulatory Authority (MHRA) initially announced it would regulate NVPs as a medicine. However, a dual regulatory pathway classifying NVPs as either a medicinal or a consumer product was finally adopted with the passing of the EU Tobacco Product Directive (TPD) in 2016 (The National Archives, 2016). Under the TPD, manufacturers may market NVPs that contain no more than 20mg/mL nicotine as either a consumer product or a medicine, while all products containing more than 20mg/mL must be licensed as medicines (European Commission, 2014). Only products licensed as medicines can make therapeutic claims, such as effectiveness for smoking cessation or health benefits. Similarly, in New Zealand, NVPs became legal to sell as a consumer product following the outcome of a court ruling in 2018 (The District Court of New Zealand, 2018). New Zealand is in the process of introducing new regulations for marketing NVPs as consumer products, while maintaining medicines regulation for NVPs with health claims.

The second approach, demonstrated by Australia, contends that the introduction of any new product that carries unknown but potentially harmful effects should be prohibited until the safety and efficacy of the product is established with adequate certainty. Australia bans the use of nicotine in NVPs unless the user holds a valid medical prescription written by a registered medical practitioner (Gartner C & Bromberg M, 2019). Because there are no NVPs listed on the Australian Register of Therapeutic Goods, Australians can only access nicotine for use in

NVPs for a therapeutic purpose (e.g. quitting smoking) via one of the legal pathways for accessing unapproved therapeutic goods. This includes personal importation, the Special Access Scheme, Authorised Prescriber Scheme and extemporaneous compounding (Therapeutic Goods Administration, 2014). Non-therapeutic use of NVPs containing nicotine is prohibited.

Although strong and unified advocacy by both government and non-government health agencies has played a significant role in advancing tobacco control policies, there are profoundly divergent standpoints when it comes to NVPs. This has resulted in a robust debate over the most appropriate regulatory framework (Green et al., 2018) and on what counts as evidence (Fairchild, Bayer, & Lee, 2019). The use of evidence in the health policymaking process is influenced by the interplay between a wide array of political and institutional factors including trade-offs between competing interests and priorities as well as ethical, financial and social justice considerations (Fallin-Bennett, Aleshire, Scott, & Lee, 2019). The process of evidence-based policymaking in NVP regulation is further complicated by the limited, and at times conflicting and contested bodies of evidence. A number of evidence-based reviews confirm that people who vape are exposed to fewer 'harmful and potentially harmful chemicals' than those who smoke (McNeill, Brose, Calder, Bauld, & Robson, 2018; National Academies of Sciences Engineering and Medicine, 2018; Royal College of Physicians, 2016). However, the evidence on the precise level of risk reduction possible from switching to NVPs is contested. A review of the evidence commissioned by Public Health England (PHE), which was updated in 2018, reaffirmed its previous estimate that NVPs are likely to be about 95% safer than conventional cigarettes (McNeill et al., 2018). While there is ongoing debate about the accuracy of this estimate due to reliance on a consensus study conducted with selected participants having potential conflicts of interests (Polosa, 2015), a consensus report from the National Academies of Sciences, Engineering, and Medicine (NASEM) concluded that "there is conclusive evidence that completely substituting NVPs for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes"(National Academies of Sciences Engineering and Medicine, 2018). There is also continued debate about whether NVPs are an effective smoking cessation tool or if, by contrast, they might discourage smokers from becoming abstinent. In addtion there is the concern NVPs might encourage non-smokers to begin vaping, and even progress to smoking cigarettes. Lastly, the long-term health outcomes from use of NVPs is unknown (Abrams et al., 2018; Glantz & Bareham, 2018; Green et al., 2018). Amidst these divided views and empirical uncertainties, a

number of health and medical organisations have published their own position statements or practice guidelines about NVPs. Yet, the extent to which these policy papers and statements are evidence-based, non-biased, and are the result of an analytical process is not clear. The aim of this study was to compare and evaluate the policy positions of health and medical organisations across Australia, New Zealand, and the UK as they relate to sale and supply of NVPs. Specifically, this study aimed to: (1) compare the positions taken by the health and medical organisations of Australia to those in the UK and New Zealand which have adopted a more permissive regulatory framework; (2) evaluate factors that have informed the differences in policy discourse among these countries; and (3) evaluate what rationale and evidence were used to justify the regulatory positions adopted.

Methods

Data sources

This study uses data from (1) position or policy statements published by health and medical organisations regarding NVPs and (2) submissions to government committees regarding policy options for the regulation of NVPs. Documents published by country-wide and/or federal level health bodies involved in health policymaking (including government agencies or legislators, non-profit health charities and professional health bodies) in the UK (England, Wales, Northern Ireland and Scotland), Australia and New Zealand were considered for inclusion. Technical and epidemiological reports, media releases and research articles were excluded. These countries were purposely selected to reflect the different policy frameworks in NVP regulations, with the UK having a supportive regulatory framework, Australia a highly restrictive regulatory approach and New Zealand a change from one that was similar to Australia to one more similar to the UK. The contrasting policy stances taken in these Commonwealth countries with very similar health systems, albeit based on the same body of literature, provides a unique opportunity to examine factors informing the differences in policy discourses and offers insights into the role of evidence in policymaking.

Search strategy

Three search strategies were employed in order to capture position statement published in the academic literature, as well as those only accessible in the grey literature. First, we searched five electronic databases (PubMed, EMBASE, PsycINFO, CINHAL, and Google scholar) for policy or position statements published in English from 2003 (to cover the literature from when

NVPs first entered the market) to June 12, 2019. This was followed by a Google search to further locate potential documents that were not captured by the scholarly database searches. The keywords used in the search strategy were organized to capture key concepts of the subject as ("E-cigarette" OR "E-cigarettes" OR "E-cig" OR "Electronic cigarette" OR "Electronic cigarettes" OR "Electronic Nicotine Delivery System" OR "Vaping" OR "Smoking") AND ("Policy" OR "Statement" OR "Position" OR "Guideline") AND "Association" OR "Department" OR "Council" OR "Foundation"). The detailed search strategy is presented in Figure 1.

We also conducted a hand search of websites of relevant medical organisations and government agencies to identify relevant policy papers. We considered written consultation documents submitted by health and medical organisations to the following parliamentary committee inquiries (these are the most recent, comprehensive and nation-wide inquiries):

1. The Australian House of Representatives Inquiry Into the Use and Marketing of E-cigarettes and Personal Vaporisers in Australia (2017) (Parliament of Australia, 2017)
2. The New Zealand Ministry of Health's consultation on Policy Options for the Regulation of Electronic Cigarettes (August 2016) (New Zealand Ministry of Health, 2016) and
3. The UK's Science and Technology Committee (Commons) inquiry into the health, regulatory and financial implications of e-cigarettes (2017) (Science and Technology Committee (Commons), 2017)

Four independent reviewers screened the records based on the eligibility criteria. Any discrepancies and/or disagreements between reviewers were resolved through discussion and consensus. Where the policy/position statement was not published in the last 12 months, contact was also made with the respective organisations requesting an up-to-date statement and if multiple versions of documents are available, the most recent one was included. The study protocol was registered on the International Prospective Register of Systematic Reviews (PROSPERO; CRD42019120203).

We used mixed methods to understand the range of policy positions taken by health and medical organisations in these countries toward NVPs and to evaluate whether the policy stances were the result of an analytical process. Using a published tool, we examined the logic

of the opinion expressed, credibility and robustness of the source of the opinion and the extent to which alternative opinions or arguments were described and logically defended.

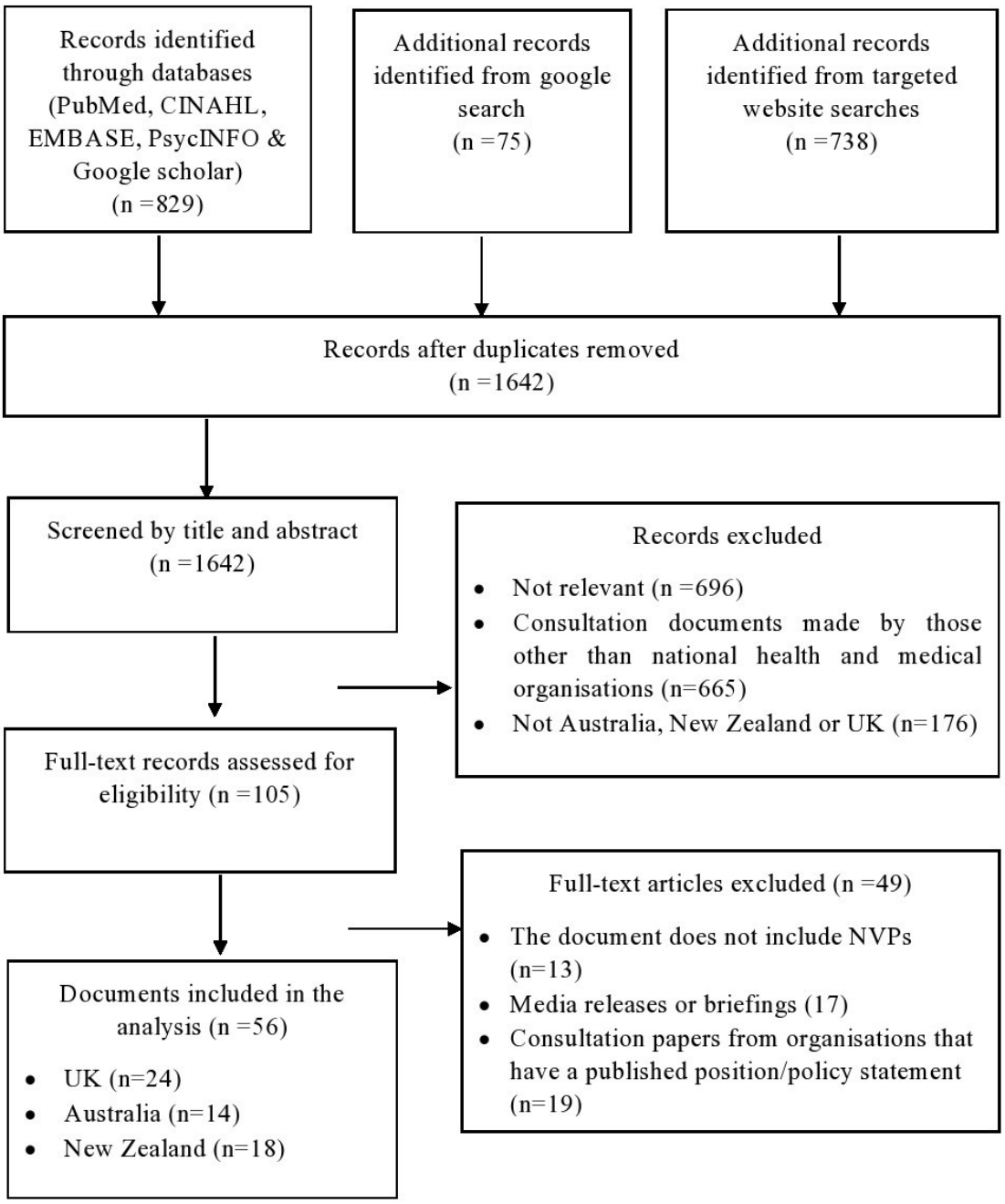

Figure 1. Preferred reporting items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram

Quality appraisal

We used the six-item Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Text and Opinion Papers (Supplementary file 1) (McArthur, Klugárová, Yan, & Florescu, 2015). The JBI is an international, membership based research and development organization within the Faculty of Health Sciences at the University of Adelaide. The instrument was developed by the JBI before being reviewed by an international methodological group (McArthur et al., 2015). Testing was undertaken by group members working in pairs. In the case of the current paper, two authors independently appraised all documents as per JBI criteria, and any disagreements raised were discussed and resolved through discussion and consensus with a third coder. Findings were then synthesised and presented narratively. Where there were sufficient data, we compared percentage agreement with each of the checklist items across countries.

Data extraction and analysis

Key policy recommendations and arguments made for and against adopting specific regulatory approaches were coded using NVivo version 12 software (QSR International Pty Ltd, Melbourne, Australia). The data were then qualitatively analysed using thematic analysis as per the procedures outlined by Braun and Clarke, which involves (1) familiarizing with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing the report (Braun & Clarke, 2006). Specifically, a line by line reading of included documents was first conducted to establish familiarity with the data. Guided by our research aims, a set of pre-specified (initial) codes were then generated which were merged into a higher level 'themes' based on similarity, representing a broader topic. In addition, an inductive approach was employed to identify new and emergent themes as we coded the data. A subset of the included documents were double coded independently by two authors. Any disagreements raised were discussed and resolved through consensus. The remaining documents were then coded by the first author, while both authors continued to meet throughout the coding process to make sure that coding criteria were being accurately and consistently applied. Other organisational attributes and document characteristics such as type of document (position statement, policy statement, and consultation document or practice guideline), year of publication as well as name and type of the organisation (professional health body, health charity, government health agency or others) were collected using a standardised data extraction format.

Results

Sample overview and stakeholder categories

Thirty position/policy statements and 26 consultation documents were included in the analysis. Table 1 depicts the characteristics of included documents categorized by country. The majority of documents come from either professional societies (n=23) or not-for profit health charities (n=27) while the rest were from government health agencies (n=6). A list of the organisations and links to included documents is provided in supplementary file 1.

Table 1. Characteristics of included documents, N=56

Attributes	**UK**	**Australia**	**New Zealand**	**Total, n (%)**
Type of document				
Position/policy statement	20	8	3	31 (55)
Consultation document	4	6	15	25 (45)
Sector*				
Peak health body	7	9	7	23 (41.1)
Government agency	3	2	1	6 (10.7)
Health charity	14	3	10	27 (48.3)
Year of publication				
2013	1	-	-	1 (1.8)
2014	3	-	-	3 (5.3)
2015	2	1		3 (5.3)
2016	3	1	15	19 (34)
2017	9	8	1	18 (32)
2018	4	4	2	10 (17.8)
2019	2	-	-	2 (3.6)

Position statements from professional health bodies, health charities and government agencies contained a range of arguments for and against different regulatory approaches for NVPs. Statements from health and medical organisations in Australia consistently supported the current highly restrictive regulation of NVPs, apart from two professional organisations (Royal Australia and New Zealand College of Psychiatrists [RANZCP] and Drug and Alcohol Nurses

Australasia [DANA]). Thus, most Australian stakeholders advocated for maintaining the *status quo* which regulates NVPs as a prescription medicine if they contain nicotine, or as tobacco products if they do not contain nicotine. On the other hand, the overwhelming majority of those in the UK and New Zealand supported a permissive regulatory framework (consumer product regulation or a dual regulatory pathway).

Although a number of rationales were put forward by opponents and proponents to justify the proposed regulatory recommendations, most differences centred on: (1) the policy objectives and framings that underpin the proposed regulatory frameworks, (2) what and how much evidence is needed for policymaking, and (3) consideration to and tolerability of various risk trade-offs. Although there were commonalities among stakeholders in the way these arguments were outlined, there were significant differences across countries which we discuss below.

Policy objectives and framings

Health and medical organisations in the UK and New Zealand presented NVPs as a life-saving harm reduction tool and stated that any regulatory framework governing nicotine containing products should aim to reduce the burden of smoking related death and diseases. They asserted that policies should consider the nicotine market as a whole and reflect the continuum of harm among all nicotine products. They recommended policies which incentivised smokers to switch to less harmful nicotine containing products (such as nicotine replacement therapies [NRTs] and NVPs) while being discouraged from using the most harmful nicotine containing product (combustible cigarettes). This regulatory framework, often referred to as tobacco harm reduction, was portrayed as a coherent policy that complements national tobacco control agendas such as New Zealand's *Smoke free 2025* goal, and as an appropriate policy response that feeds into and contributes to achieving a 'tobacco-free society' *[British Medical Association]*.

> *"The wide availability of e-cigarettes as an alternative to tobacco is likely, overall, to be playing a positive role in supporting tobacco-harm reduction, and consumer regulations will ensure a minimum standard of product quality."* British Medical Association, 2017

> *"The Ministry of Health believes vaping products have the potential to make a contribution to the Smoke free 2025 goal and could disrupt the significant inequities that are present."* Ministry of Health, New Zealand (position statement)

On the other hand, organisations in Australia have coalesced around a shared policy priority of protecting the health of specific 'vulnerable' populations (children, non-smokers and by-standers). They argued that if NVPs are allowed to be freely marketed, they may undermine existing tobacco control efforts by renormalizing smoking as a socially acceptable behaviour, and increase youth smoking with a potential to addict a whole generation of youth to nicotine. This approach, often described as 'precautionary', was portrayed as consistent with various national and international health policy frameworks. Organisations that took this view argued that it takes Australia's national circumstances into consideration, particularly the significant gains made in reducing smoking rates.

> *"Regulation should aim to protect the Australian community from the potential harms of e-cigarette use and ensure that e-cigarette use does not undermine Australia's significant tobacco control efforts."* Department of Health, Australia (Submission 297*)*

> *"The Australian Government Department of Health believes a precautionary approach to e-cigarettes and personal vaporisers is warranted, consistent with the harm minimisation principles which underpin the National Tobacco Strategy (NTS) 2012-2018 and Australia's policy framework for other drugs."* Department of Health, Australia (Submission 297*)*

The majority of joint health bodies representing members in both Australia and New Zealand (except RANZCP and DANA) have also supported a precautionary approach to NVP regulation.

The role of evidence in NVPs regulation: Why, what and how much?

What counts as evidence?

Despite their countries having similar tobacco control policies and population smoking prevalence, the public health communities in the UK and New Zealand have come to starkly different positions compared to Australia. Nearly all stakeholders, regardless of type of organisations or policy positions being put forward, claimed that their policy was evidence-based and cited relevant studies that supported their position. For instance, health and medical organisations in Australia generally cited evidence that strengthened their view that NVPs are a threat rather than an opportunity to public health. This scientific literature generally focused on the potential health risks associated with NVPs, for example: increased youth use of NVPs with a subsequent transition to cigarette smoking; dual use of NVPs and combustible cigarettes;

and concerns that NVPs could renormalise smoking and undermine tobacco control gains. Other potential health risks including concerns that NVPs are sustaining nicotine addiction and discouraging cessation attempts, adverse health effects of second-hand vapour exposure, and concerns of direct health harms including increased risk of respiratory and cardiovascular diseases were also widely cited.

On the other hand, much of the evidence cited by UK stakeholders to support or rebut some of the most frequent arguments (e.g. whether NVPs are a way into or out of smoking, the potential for NVPs to renormalise smoking, and the potential health risk from second-hand vapour exposure) came from UK data. These collections of evidence generally reinforced the notion that most of these concerns have not yet materialised in the UK despite widespread vaping, and that youth and young adult smoking prevalence has declined while vaping prevalence has increased. It was based on these arguments that the majority of health bodies in the UK advocated to apply 'a softer regulatory approach than exists for smoking in public.' *[British Medical Association]*

> *"There is no evidence that either NRT or e-cigarette use has resulted in renormalisation of smoking…None of these products has to date attracted significant use among adult never-smokers, or demonstrated evidence of significant gateway progression into smoking among young people."* Royal College of Physicians, 2016

Regulation in the face of uncertainty: Wait for the evidence or Weight of the evidence?

Whilst the need for long-term studies on the safety and efficacy of NVPs was universally acknowledged, stakeholders were divided when it came to how NVPs should be regulated in the context of growing but incomplete evidence. There were differing views on what was an adequate level of confirmatory evidence required before making any judgement or enacting a policy response. Stakeholders in the UK and New Zealand contended that while the long-term safety profile of NVPs remains uncertain, the currently available evidence base was sufficient to introduce a 'cautious, yet pragmatic' *[New Zealand Medical Association]* regulatory framework. The goal was to have NVPs available as a route out of smoking for current smokers without acting as a route into smoking for children and non-smokers. The Royal Australian and New Zealand College of Psychiatrists (RANZCP) reiterated the notion that the absence of long-term evidence does not justify banning a product known to have substantially low risk compared to smoking.

> *"Further research is required to ascertain the effectiveness of e-cigarettes and*

vaporisers as tools for smoking cessation and whether they may provide a novel route into smoking initiation. This does not justify withholding what is, on the current evidence, a lower-risk product from existing smokers while such data is collected" RANZCP

In contrast, all but two stakeholders in Australia [RANZCP and DANA] were in favour of maintaining the *status quo,* mainly on the basis that introduction of new products that carry unknown potentially harmful effects into the market before having confirmatory evidence of their safety and efficacy would be against the public's best interest. Provision of such evidence and burden of proof that new products are safe and effective was argued to fall to stakeholders who want to see a change in the current regulations.

"The longitudinal research that is required to establish safety will take time, but until more definitive evidence on safety becomes available the precautionary principle should be applied to these products" Australian Medical Association (Written submission 289)

"Health authorities and policy-makers should act to minimise harm to users and bystanders, and to protect vulnerable groups such as young people, until evidence of safety, quality and efficacy can be produced." National Health and Medical Research Council (CEO statement), 2017

Consideration to and tolerability of risk trade-offs

Risk trade-offs

Policy debates around NVP regulation have also highlighted various risk trade-offs associated with both allowing the sale of NVPs as a tobacco harm reduction tool and keeping NVPs off the market on the basis of a 'precautionary principle'. Although the inherent nature of risk trade-offs was universally recognised, the tolerability of these trade-offs appeared to vary between countries. Stakeholders in Australia emphasised the concern that NVPs have the potential to addict non-smoking youth to nicotine and framed them as one of the tobacco industry's tactics to influence and resist tobacco control policy and undermine progress in tobacco control.

"Concerns have been raised that the potential benefits of e-cigarettes in reducing harm to smokers may be outweighed by the risks that they may undermine tobacco control

efforts." National Health and Medical Research Council (CEO statement), 2017

As such, jeopardising the lives of young people for adult smokers to have access to these products was portrayed as an unacceptable risk trade-off. Potential adverse impacts and unintended consequences of the current approach were seldom addressed by those referencing the precautionary principle.

In contrast, those who placed tobacco harm reduction at the centre of their policy objectives (such as those in the UK) characterised NVPs as novel nicotine delivery technologies that might lead to a dramatic decline in the use of combustible cigarettes. They stated that promoting use of NVPs among smokers is 'in the interests of public health' *[Royal College of Physicians (RCP)]*. RCP argued that following an overly cautious regulation may cause more harm than benefit and that this was associated with the unacceptable trade-off of perpetuating smoking.

> *"A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking."* RCP (Royal College of Physicians, 2016)

Similarly, the public health community in New Zealand emphasised the potential benefits of NVPs and the unintended consequences of restrictive regulation in advocating a 'cautious, yet pragmatic' regulatory approach. This approach was portrayed as encouraging smokers to switch to vaping, but also giving due emphasis to the potential risk of uptake by children and non-smokers. Examples of specific controls advocated to deter access to NVPs by children and young adults included prohibiting sale to minors (aged 18 or below), prohibiting sale in vending machines and banning point of sale displays.

Quantifying relative risk

Although the notion that NVPs are less harmful compared to combustible tobacco products was universally acknowledged, there was debate over the precise level of risk reduction and the extent of health gains possible from switching to NVPs compared to abstinence. An overwhelming majority of organisations from the UK and New Zealand reiterated the Public Health England's (PHE) updated evidence review that reaffirmed its previous estimate that NVPs are about '95% safer than conventional cigarettes' (McNeill et al., 2018) or RCP's

independent review that concluded the long term health risk of NVPs is 'unlikely to exceed 5% of the harm from smoking tobacco'(Royal College of Physicians, 2016). This 'less harmful than combustible cigarettes' argument is based on the notion that the use of nicotine *per se* carries negligible health risk, and that it is the other constituents of tobacco smoke (tar, particulate matter and gases such as carbon monoxide) that cause most of the harm. This puts the potential health risks associated with NVPs in the context of the substantial harm associated with smoking.

In contrast, those who were in favour of a highly restrictive regulatory approach argued that NVPs 'MAY be less harmful than cigarettes, but they are NOT HARMLESS' *[The Thoracic Society of Australia and New Zealand and Lung Foundation Australia, Written submission 332],* and some stated that there is no safe level of exposure to nicotine (be it from combustible cigarettes or NVPs), particularly for young adults. Rather than making combustible cigarettes a point of reference against which the safety of other nicotine containing products are compared, advocates of restrictive regulation argued that the safety of NVPs must be considered in the context of abstinence (quitting or not taking up any nicotine use). They framed safety related discussions by the absolute term 'safe', rather than the relative term 'safer'.

> *"Evidence shows there are only two effective ways to minimise the long-term harms of smoking – to quit or to avoid take-up"* Cancer Council Australia and National Heart Foundation of Australia, Written submission 295

It was also argued that the current scientific evidence is insufficient to put a specific figure about how much safer NVPs are compared to combustible cigarettes. With this, PHE's '95% safer than smoking' estimate was criticised and labelled as 'unfounded and devoid of any scientific basis' *[Cancer Council Australia and National Lung Foundation of Australia Written submission 295].*

Specific regulatory options recommended

Specific regulatory measures that stakeholders mentioned included regulating packaging and labelling, quality standards, sale and supply, as well as banning vaping in smoke-free areas. The need to prevent minors and non-smokers from accessing NVPs was frequently discussed and universally agreed on by stakeholders, irrespective of the positions being taken on NVP regulation. Prohibiting the sale of NVPs to people aged 18 or below, and prohibiting vending machine sales were some of the policy measures recommended to prevent uptake by children

and young adults. There was also a general consensus that NVPs should not be advertised or marketed in a way that would appeal to children and non-smokers. The current UK restrictions (under EU TPD regulations) were considered sufficient by the majority of UK organisations.

> *"The current regulatory framework appears sufficient for addressing concerns about the use of e-cigarettes by children and young people, for whom regular use remains low and is largely confined to those that have already smoked."* BMA, 2017

However, the public health community in Australia consistently advocated applying the marketing and advertising restrictions of the *Tobacco Advertising Prohibition Act 1992* to vaping products. This Act prohibits all types of promotion, advertising, free distribution, sponsorship and point-of-sale display.

All but two stakeholders in Australia [RANZCP and DANA] advocated prohibiting use of NVPs, with or without nicotine, in smoke-free areas. Some health charities also recommended that vaping should be prohibited in legislated smoke free areas *'even if ultimately approved by the TGA for therapeutic use.' [Australian Council on Smoking and Health, written submission 285]*. An exception to this, however, was the policy statement published submission made by RANZCP, which recommended allowing the use of NVPs in smoke-free mental health facilities.

> *"The RANZCP also notes that many mental health facilities are now smoke-free and there may be benefits in allowing the use of e-cigarettes and vaporisers in these settings."* RANZCP written submission 294.

Some stakeholders in the UK and New Zealand pointed out the lack of evidence for harm from exposure to second-hand vapour, and suggested that businesses and local authorities should make reasoned decisions on whether to allow NVPs in their premises on a case-by-case basis.

> *"Unless we start to see rising youth smoking rates, rising regular e-cigarette use among 'never smokers,' or any convincing evidence for harm to bystanders, it is difficult to justify a blanket ban on e-cigarette use in indoor public places."* Cancer Research UK

Table 2 shows the results from the JBI tool. Irrespective of country, all the documents clearly identified their sources (Question 1), had demonstrated standing in the field of expertise (Question 2) and focussed on the interests of the relevant population (Question 3). However, where it was possible to assess, 8 out of 14 Australian documents (57%) did not explain the analytical process and logic in the opinion expressed, as opposed to 3 out of 12 New Zealand

publications (25%) and 5 out of 24 UK statements (21%) (Question 4). Similarly, 11 out of 14 Australian documents did not reference the extant literature (85%), compared to 5 out of 24 (45%) of those from the UK (Table 2). Finally, the practice of making strong assertions based on incomplete evidence was more common among stakeholders in Australia (11 out of 14) than the UK (10 out of 22) (85% vs 43% respectively) (Question 6) (Table 2). There were insufficient New Zealand data for a meaningful comparison.

Table 2: Results of critical appraisal of included documents using the JBI Critical Appraisal Checklist for Text and Opinion Papers

Document*	Q1: Source clearly identified?	Q2: Expertise	Q3: Interests of relevant population the central focus?	Q4: Analytical process & logic in the opinion expressed?	Q5: Reference to the extant literature?	Q6: Incongruence logically defended?
United Kingdom						
Action on Smoking and Health UK	1	1	1	1	1	1
Association for Respiratory Technology and Physiology	1	1	1	1	NA	NA
British Lung Foundation	1	1	1	1	1	1
British Medical Association	1	1	1	1	1	1
British Psychological Society	1	1	1	1	1	1
British Thoracic Society	1	1	1	1	0	0
Cancer Research UK	1	1	1	1	1	1
Institute of Health Promotion and Education	1	1	1	0	0	0
Pharmacists' Defence Association	1	1	1	0	0	0
Primary Care Respiratory Society UK	1	1	1	1	0	0
Public Health England	1	1	1	1	1	1
Royal College of General Practitioners	1	1	1	1	NA	1
Royal College of Physicians	1	1	1	1	1	1
Royal College of Psychiatrists	1	1	1	1	1	1

Royal Pharmaceutical Society	1	1	1	1	0	0
Royal Society for Public Health	1	1	1	1	1	1
Smoking in Pregnancy Challenge Group	1	1	1	1	1	1
UK Centre for Tobacco and Alcohol Studies	1	1	1	1	1	1
NHS Health Scotland	1	1	1	1	0	0
Scottish Directors of Public Health and Scottish Health	1	1	1	0	0	0
NI Chest Heart and Stroke	1	1	1	0	0	0
Pharmaceutical Society of Northern Ireland	1	1	1	0	0	0
ASH Wales	1	1	1	1	0	0
Public Health Wales	1	1	1	1	1	0
Australia						
Australian Council on Smoking and Health	1	1	1	0	0	0
Australian Dental Association	1	1	1	0	0	0
Australian Medical Association	1	1	1	1	NA	1
Cancer Council Australia and Heart Foundation Australia	1	1	1	1	1	1
Cancer Australia	1	1	1	0	0	0
Drug and Alcohol Nurses of Australasia	1	1	1	0	0	0

Department of Health	1	1	1	1	0	1
National Health and Medical Research Council	1	1	1	1	0	1
Public Health Association of Australia	1	1	1	0	0	1
Royal Australasian College of Physicians**	1	1	1	1	1	1
Royal Australasian College of Surgeons**	1	1	1	0	0	0
Royal Australian and New Zealand College of Psychiatrists**	1	1	1	1	0	1
Royal Australian College of General Practitioners**	1	1	1	0	0	0
Thoracic Society of Australia and New Zealand & Lung Foundation Australia**	1	1	1	0	0	1
New Zealand						
Action on Smoking and Health NZ	1	1	1	NA	NA	NA
Asthma and Respiratory Foundation NZ	1	1	1	0	0	0
Cancer Society of NZ	1	1	1	1	0	1
End Smoking NZ	1	1	1	1	1	1
Heart Foundation NZ	1	1	1	NA	NA	NA
Lung Foundation NZ	1	1	1	NA	NA	NA
Ministry of Health	1	1	1	1	1	1

New Zealand Drug Foundation	1	1	1	1	1	1
New Zealand Medical Association	1	1	1	0	NA	NA
New Zealand Nurses Organisation	1	1	1	1	NA	NA
Pharmaceutical Society of New Zealand	1	1	1	1	NA	NA
Pharmacy Guild of New Zealand	1	1	1	0	NA	NA
Public Health Association of New Zealand	1	1	1	1	NA	NA
Smoke-free Nurses Aotearoa New Zealand	1	1	1	1	NA	NA
Stroke Foundation of New Zealand	1	1	1	1	NA	NA

**1: Yes; 2: No; NA: Not Applicable*

***These are joint organisations representing both Australia and New Zealand*

Discussion

In this study, we examined the policy positions of professional health bodies, health charities and government agencies across Australia, New Zealand, and the UK as they relate to sale and supply of NVPs. It was evident from findings from this study that the public health communities in the UK and New Zealand have come to starkly different conclusions regarding the role of NVPs compared to Australia. Although the profoundly divided views among the public health community seem to arise from empirical uncertainties and disagreements over the level and credibility of evidence, the source of some of these disagreements can be traced back to the fundamental and irreconcilable differences in the framing of the NVP debate, which in turn influences their use of evidence. The type and credibility of evidence that was given greater weight in policymaking appeared to be contingent, at least partially, on the way the issue was framed and understood. Analysis of how the literature was cited (using the JBI checklist) indicated that this was often a non-critical description of corroborating evidence explicitly supportive of the assertion being put forward, while conflicting evidence was not addressed. In doing so, they tend to cite a fraction of the evidence or interpret the evidence differently. This was apparent from analysis of the cited literature (within each position or policy documents) in that most of the assertions made were based on strategic use of evidence, citing only evidence that corroborates the arguments being put forward.

Some of the prominent health bodies included in this study (such as Royal Australasian College of Surgeons, Royal Australian and New Zealand College of Psychiatrists, Thoracic Society of Australia and New Zealand and Royal Australasian College of Physicians) are joint organisations that represent members in both Australia and New Zealand. Although these health bodies are actively involved in the policy debates in both countries and submitted consultation papers having similar sentiments, these neighbouring countries have adopted different policy approaches to the regulation of nicotine and NVPs. The Ministry of Health and other health officials in New Zealand have not only endorsed a role for NVPs in reducing tobacco related harm, but are also proactively encouraging smokers to switch to vaping, and supporting stop smoking services to become ‘vaping friendly’ (New Zealand Ministry of Health, 2019). The Commonwealth Department of Health in Australia, on the other hand, supports a restrictive regulatory framework and insists that the approach is ‘evidence-based’ and ‘relevant to Australia’s national circumstances’ (Department of Health, 2018). These differences demonstrate how existing tobacco control policies and differences in policy styles between countries inform NVP related debates.

The concept of risk trade-offs is central to various decision-making theories (Amalberti, 2013) and is also inherent in NVP regulation. Yet, consideration and tolerability of these trade-offs appeared to vary between countries. For instance, while stakeholders in Australia agreed that NVPs are less harmful compared to combustible cigarettes, putting vulnerable populations (children and non-smokers) at any risk for adult smokers to have access to these products was portrayed as an unacceptable risk trade-off. The potential detrimental consequences (such as perpetuating smoking among both adults and youth), however, was seldom addressed by those referencing the 'precautionary principle'. This suggests much greater weight was given in Australia to potential risk to current non-smokers over potential benefit to smokers (Erku, Morphett, Steadman, & Gartner, 2019). Furthermore, it also suggests that maintaining the *status quo* is seen as the lower risk policy option, but without considering the potential risks of this policy. The net public health gain or loss from NVP use will ultimately be contingent on the regulatory framework adopted, with the highest benefit most likely to be realised if non-smoking youth are protected from taking up NVPs while persistent smokers are encouraged to switch.

Recent studies suggest that the use of research evidence in developing policy largely depends on wider socio-political priorities (Hawkins & Ettelt, 2019; Rein & Schön, 1996; Sohn, 2018). Understanding this process is, therefore, central to resolving disputes especially in areas that involve contested policy arenas, vehement debates and multiple stakeholders. A number of case studies on framing and use of evidence in health policy making has been published in different country contexts (Parkhurst, Ettelt, & Hawkins, 2018). While our study mainly examined reasons for differences in NVP-related policy between these countries, it also offers insights into the role of evidence and framing in policymaking. The notion that NVP-related policymaking should be informed by evidence was widely accepted, and often discussed amongst stakeholders in these countries, regardless of their stances on the issue of NVPs. However, what was portrayed as disagreements over the level and credibility of evidence were often actually differences in wider priorities and the acceptability of various risk trade-offs. This finding reinforces the notion that so-called evidence-based policymaking goes beyond a dispassionate evaluation of the evidence, but is instead influenced by a wide array of political and institutional factors. A frame-reflective policy conversation could therefore help resolve the debate concerning these products (Rein & Schön, 1996). This acknowledges that contentious policy issues may be understood in different ways by different stakeholders based on competing priorities. Such meaningful policy conversations would ensure the consideration of both intended and unintended consequences of current and proposed policies (Rein & Schön, 1996).

Study limitations

This study has a number of limitations that should be taken into account while interpreting the findings. Although we have employed rigorous and multiple approaches to identify and include all relevant documents, it is possible that we missed some position/policy statements that were not published or not made publicly available. As we have only included the most recent and updated statement from each organisation (if multiple versions of documents or updates were available), our study did not reflect or examine how their positions have changed over time. Although the written consultation documents included in our study were retrieved from the most recent nation-wide parliamentary inquiries (at the time of conducting this study), it was difficult to apply some of the items in the JBI appraisal tool to these documents. This was particularly the case for the New Zealand inquiry, where submissions most often consisted of structured responses to specific questions from the inquiry, which did not ask organisations to provide supporting evidence or references. The JBI instrument is in continual development and so resultant findings should be seen as preliminary. Hence, we have given greater prominence to the qualitative results. Finally, this study should be regarded as a snapshot, as the science surrounding NVPs is evolving. These include the possible effects of recent increases in nicotine concentration in some products in the United States. However, this does not yet apply to the UK where concentrations cannot exceed 2%. In addition, our review does not reflect emerging reports, again in the United States, concerning e-cigarette, or vaping, product use–associated lung injury (EVALI) (Navon et al., 2019). However, the overwhelming number of cases appear to have followed the use of black-market THC cartridges, possibly related to the addition of vitamin E acetate, rather than commercially produced NVPs (Navon et al., 2019; Taylor, 2019).

Conclusion

An overwhelming majority of health bodies, charities and government agencies in the UK and New Zealand presented NVPs as a life-saving harm reduction tool and supported a regulatory framework that would incentivise smokers to switch to them as a less harmful nicotine containing product. In contrast, concerns about addicting non-smoking youth to nicotine, a perceived lack of clear and convincing evidence of safety and efficacy and the potential to undermine tobacco control progress continues to define scepticism towards NVPs among Australian health and medical organisations. Although stakeholders from both sides of the argument claimed their position to be evidence-based and cited relevant literature that corroborated their arguments, fundamental differences in the policy objectives and framings that underpin the proposed regulatory frameworks and consideration to and tolerability of various risk trade-offs were at the

centre of the disagreements. Progress in resolving the debate surrounding NVPs require policy makers to be frame-reflective and engage in a meaningful dialogue which gives due consideration to various risk trade-offs and both intended and unintended consequences of proposed policies.

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Declaration of competing interest

All authors declare that there is no actual or potential conflict of interest.

References

Abrams, D. B., Glasser, A. M., Villanti, A. C., Pearson, J. L., Rose, S., & Niaura, R. S. (2018). Managing nicotine without smoke to save lives now: evidence for harm minimization. *Preventive Medicine, 117*, 88-97.

Amalberti, R. (2013). *Navigating safety: Necessary compromises and trade-offs-theory and practice*: Springer.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3*(2), 77-101.

Department of Health. (2018). Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia. Retrieved from https://www.health.gov.au/resources/publications/principles-that-underpin-the-current-policy-and-regulatory-approach-to-e-cigarettes-in-australia

Erku, D. A., Morphett, K., Steadman, K. J., & Gartner, C. E. (2019). Policy debates regarding nicotine vaping products in Australia: a qualitative analysis of submissions to a government inquiry from health and medical organisations. *International Journal of Environmental Research Public Health, 16*(22), 4555.

European Commission. (2014). Revision of the tobacco products directive. Retrieved from https://ec.europa.eu/health/tobacco/products/revision_en

Fairchild, A. L., Bayer, R., & Lee, J. S. (2019). The E-Cigarette Debate: What Counts as Evidence? *American Journal of Public Health, 109*(7), 1000-1006.

Fallin-Bennett, A., Aleshire, M., Scott, T., & Lee, Y. O. (2019). Marketing of e-cigarettes to vulnerable populations: An emerging social justice issue. *Perspectives in Psychiatric Care, 55*(4), 584-591.

Farsalinos, K. E., & Le Houezec, J. (2015). Regulation in the face of uncertainty: the evidence on electronic nicotine delivery systems (e-cigarettes). *Risk Management and Healthcare Policy, 8*, 157–167.

Gartner C, & Bromberg M. (2019). One does not simply sell e-cigarettes in Australia: An overview of Australian e-cigarette regulations'. *In L. Gruszczynski (Ed.), The Regulation of E-cigarettes: International, European and National Challenges* (L. Gruszczynski Ed.): Edward Elgar Publishing.

Glantz, S. A., & Bareham, D. W. (2018). E-cigarettes: use, effects on smoking, risks, and policy implications. *Annual Review of Public Health, 39*, 215-235.

Green, L. W., Fielding, J. E., & Brownson, R. C. (2018). The debate about electronic cigarettes: harm minimization or the precautionary principle. *Annual Review of Public Health, 39*, 189-191.

Hawkins, B., & Ettelt, S. (2019). The strategic uses of evidence in UK e-cigarettes policy debates. *Evidence & Policy: A Journal of Research, Debate Practice, 15*(4), 579-596(518).

McArthur, A., Klugárová, J., Yan, H., & Florescu, S. (2015). Innovations in the systematic review of text and opinion. *International Journal of Evidence-Based Healthcare, 13*(3), 188-195.

McNeill, A., Brose, L. S., Calder, R., Bauld, L., & Robson, D. (2018). Evidence review of e-cigarettes and heated tobacco products 2018. *A report commissioned by Public Health England. London: Public Health England, 6*.

National Academies of Sciences Engineering and Medicine. (2018). Public Health Consequences of E-Cigarettes. Retrieved from http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx

Navon, L., Jones, C. M., Ghinai, I., King, B. A., Briss, P. A., Hacker, K. A., & Layden, J. E. (2019). Risk factors for e-cigarette, or vaping, product use–associated lung injury (EVALI) among adults who use e-cigarette, or vaping, products—Illinois, July–October 2019. *Morbidity and Mortality Weekly Report, 68*(45), 1034.

New Zealand Ministry of Health. (2016). Policy Options for the Regulation of Electronic Cigarettes: A consultation document. Retrieved from https://www.health.govt.nz/publication/policy-options-regulation-electronic-cigarettes-consultation-document

New Zealand Ministry of Health. (2019). Vaping facts. Retrieved from https://vapingfacts.health.nz/

Parkhurst, J., Ettelt, S., & Hawkins, B. (2018). *Evidence Use in Health Policy Making: An International Public Policy Perspective*. Switzerland: Palgrave Macmillan.

Parliament of Australia. (2017). Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia. Retrieved from https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes

Polosa, R. (2015). E-cigarettes: Public Health England's evidence based confusion? *The Lancet, 386*(10000), 1237-1238.

Rein, M., & Schön, D. (1996). Frame-critical policy analysis and frame-reflective policy practice. *Knowledge and Policy, 9*(1), 85-104.

Royal College of Physicians. (2016). *Nicotine without smoke tobacco harm reduction*: Royal College of Physicians of London.

Science and Technology Committee (Commons). (2017). E-cigarettes inquiry. Retrieved from https://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2017/e-cigarettes-17-19/

Sohn, J. (2018). Navigating the politics of evidence-informed policymaking: strategies of influential policy actors in Ontario. *Palgrave Communications, 4*(1), 49.

Taylor, J. (2019). Characteristics of E-cigarette, or Vaping, Products Used by Patients with Associated Lung Injury and Products Seized by Law Enforcement—Minnesota, 2018 and 2019. *Morbidity and Mortality Weekly Report, 68*(47), 1096-1100.

The District Court of New Zealand. (2018). Ministry of Health v Philip Morris (New Zealand) Ltd [2018] NZDC 4478. Retrieved from http://www.districtcourts.govt.nz/all-judgments/2018-nzdc-4478-moh-v-morris/

The National Archives. (2016). Tobacco and Related Products Regulations 2016. Retrieved from http://www.legislation.gov.uk/uksi/2016/507/contents/made

Therapeutic Goods Administration. (2014). Liquid nicotine and personal importation for use in electronic cigarettes. Retrieved from https://www.tga.gov.au/behind-news/liquid-nicotine-and-personal-importation-use-electronic-cigarettes#.U7o-O8hiuDQ