

A first pass, using pre-history and contemporary history, at understanding why Australia and England have such different policies towards electronic nicotine delivery systems, 1970s–c. 2018

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ABSTRACT

Aims The United Kingdom and Australia have developed highly divergent policy responses to electronic nicotine delivery systems (ENDS). To understand the historical origins of these differences, we describe the history of tobacco control in each country and the key roles played in setting ENDS policy in its early stages by public health regulations and policy networks, anti-smoking organizations, ‘vaper’ activist networks and advocates of harm reduction policies towards injecting drug use. **Methods** We analysed key government reports, policy statements from public health bodies and non-government organizations (e.g. cancer councils and medical organizations) on ENDS; submissions to an Australian parliamentary inquiry; media coverage of policy debates in medical journals; and the history of tobacco control policy in Australia and England. Key discourses about ENDS were identified for each country. These were compared across countries during a multi-day face-to-face meeting, where consensus was reached on the key commonalities and divergences in historical approaches to nicotine policy. This paper focuses on England, as different policy responses were apparent in constituent countries of the United Kingdom, and Scotland in particular. **Results** Policymakers in Australia and England differ markedly in the priority that they have given to using ENDS to promote smoking cessation or restricting smokers’ access to prevent uptake among young people. In understanding the origins of these divergent responses, we identified the following key differences between the two countries’ approaches to nicotine regulation: an influential scientific network that favoured nicotine harm reduction in the United Kingdom and the absence of such a network in Australia; the success of different types of health activism both in England and in Europe in opposing more restrictive policies; and the greater influence on policy in England of the field of illicit drug harm reduction. **Conclusions** An understanding of the different policy responses to electronic nicotine delivery systems (ENDS) in England and Australia requires an appreciation of how actors within the different policy structures, scientific networks and activist organizations in each country and region have interpreted the evidence and the priority that policymakers have given to the competing goals of preventing adolescent uptake and encouraging smokers to use ENDS to quit smoking.

Keywords Australia, e-cigarettes, ENDS, England, harm reduction, history, illicit drugs, policy, vaping.

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Submitted 8 October 2019; initial review completed 30 October 2019; final version accepted 22 December 2020

INTRODUCTION

Electronic nicotine delivery systems (ENDS) [1] are a controversial new technology which has provoked strongly polarized responses within the field of tobacco control [1,2]. Policymakers in Australia have banned the sale of

ENDS in order to prevent their uptake among youth, while those in the United Kingdom have encouraged smokers to use ENDS for smoking cessation or harm reduction [3]. These divergent policies are rooted in disagreements about whether ENDS are likely to produce greater reductions in tobacco related harm in the population by diverting

smokers to a safer route or whether they will increase aggregate harm by recruiting new smokers and stopping smokers from quitting [4].

In England, policymakers have embraced the potential for ENDS to reduce tobacco-related harm by encouraging smokers to use ENDS to quit smoking or as a long-term substitute for cigarettes [5]. They have accordingly regulated ENDS in ways that facilitate smokers' access. In Australia, by contrast, public health authorities have used drugs and poisons regulations to impose an effective ban on the sale of vaping products that contain nicotine [6]. As will be shown below, both policies enjoy the strong support of key stakeholders in each country. There is a minority of dissenters within the public health communities in each country, with the dissident view in the United Kingdom the dominant view in Australia and vice versa.

This paper explores the historical reasons for these striking policy differences. We begin by giving a detailed description of the policies towards ENDS in England and Australia and briefly explain how policymakers have justified these policies in each country. We then describe the origins of these policies in the history of tobacco control in each country, highlighting the important role played by influential policy actors and major research and policy networks. We briefly describe the 'pre-history' of attitudes towards the concept of 'safer smoking' within networks of researchers and public health advocates in leading national institutions and the differing levels of support for the use of nicotine to assist smoking cessation. We outline the roles that anti-smoking activist networks have played in each country and at regional level. We also discuss the extent to which personnel involved in harm reduction responses to drugs and HIV have, or have not, provided support for the use of ENDS in tobacco harm reduction in each country.

OUR APPROACH TO ANALYSIS

Our approach focused on the methodology of historians, using contemporary history approaches, primarily the use of documentary sources. One difference from social science disciplines is that historians do not start out with a hypothesis which they are testing. The approach is inductive through interaction with the source material [7–9].

In each country, we reviewed the arguments and evidence cited in major reports and policy statements by government agencies and in submissions to parliamentary inquiries. A detailed content analysis of one of these parliamentary inquiries has been published elsewhere [2]. We also examined public statements made by leading public health bodies and non-government organizations (e.g. cancer councils, medical organizations and heart foundations) in each country [10]. We supplemented these data with

arguments presented for and against ENDS policies in media stories and in the leading medical journals in each country.

We focused upon key time-points for developments in ENDS policy and the justifications that were provided for these policies by key policy actors. We also paid attention to the concept of pre-history and its impact as developed through work on HIV/AIDS [11,12]. This approach argues that contextual issues, the existence of networks, approaches and structures powerfully affect responses to new but related policy problems. We drew upon histories of tobacco control policy in each country to understand the pre-history of these differences in policy approaches to ENDS between the two countries. Commonalities and differences across countries were compared in a multi-day face-to-face meeting between the investigators. The meeting arrived at a consensus through discussion on key commonalities and divergences in historical approaches to nicotine policy in Australia and the United Kingdom. Summaries of the policy situation in each country were prepared and these were used to produce this paper. There have been different policy views in constituent countries of the United Kingdom, notably England and Scotland, which is why England is our main focus. Some agencies are UK-wide and European Union (EU) regulation applies to the whole of the United Kingdom, so at times a UK policy perspective is taken.

ENDS POLICIES IN THE UNITED KINGDOM

The United Kingdom primarily regulates ENDS as tobacco-related consumer products. ENDS may also be licensed as medicines, but no licensed products have been marketed. When ENDS first came onto the market as consumer products they were subject to product safety regulations. In June 2013, on advice from the Medicines and Healthcare Products Regulatory Agency (MHRA), a UK-wide agency, the government proposed to regulate all non-tobacco nicotine products, including ENDS, as medicines. The government later decided against policy for a number of reasons, the major one being that membership of the EU required the United Kingdom to comply with the regulations mandated under the EU Tobacco Products Directives (TPD). These regulations also fitted with the preference of the Cameron government (on the advice of its Behavioural Insights Team, the 'nudge unit') for the use of 'light touch' regulation to encourage smokers to use ENDS as cessation aids and long-term smoking substitutes [13].

The European Commission had also intended to use medicinal licensing as the entry route for ENDS, but this approach was voted down by the European Parliament on 8 October 2013. The Parliament decided instead that

ENDS would be regulated like tobacco. The policy change in the parliament was purported to be brought about by an alliance of vapers, who made good use of social media, to obtain the support of Conservative and other MEPs, particularly those from Italy and Germany. In 2014, passage of the European TPD (2014/40/EU) placed limits on the sale and merchandising of tobacco and tobacco-related products in the EU. In 2016, a revised TPD updated regulations on tobacco products and set new regulations. These required medical licensing if therapeutic claims were made for ENDS products or if they contained more than 20 mg/ml of nicotine. They also placed limits on the sale and merchandising of tobacco and tobacco-related products in the EU. The European Parliament approved these regulations in February 2014. They prohibited the use of health or cessation claims when advertising ENDS, and set limits on the maximum concentration of nicotine allowed in liquids (less than 20 mg), and the maximum volumes of liquid that could be sold. They also required: child-proof packaging of e-liquids, specified purity of ingredients, devices that delivered consistent doses of vapour and disclosure of ingredients and nicotine content. Regulators were empowered to act if these regulations were not met [14]. The Tobacco Products Directive prohibits all forms of advertising capable of crossing borders. In England, the Committee on advertising practice has produced guidelines which balance the protection of minors and the promotion of new low-risk products to consumers. From 2015 restrictions on age of sale (18 years) and advertising were introduced with the support of researchers.

Leading tobacco control researchers supported the change in ENDS policy in a series of reports. This included Public Health England (PHE), a new organization covering England only, that was created when the government devolved public health to local authorities and out of National Health Service (NHS) control in 2013. PHE produced a series of reports and evidence updates in 2015 [5] and 2018 [15]. PHE also published a joint statement: 'E cigarettes: an emerging public health consensus' [16], that was supported by the following public health bodies: Action on Smoking and Health (ASH); Association of Directors of Public Health; British Lung Foundation; Cancer Research UK; Faculty of Public Health; Royal College of Physicians; the Royal Society for Public Health; the UK Centre for Tobacco and Alcohol Studies; and the UK Health Forum.

The Royal College of Physicians Tobacco Advisory Group (RCPTAG) has been an influential supporter of ENDS. Its 2000 report on nicotine addiction called for the creation of a nicotine regulatory authority [17] and RCPTAG advocated for tobacco harm reduction in 2007 and 2018 [18,19]. In its 2016 report, 'Nicotine without smoke: tobacco harm reduction', it concluded that ENDS were likely to benefit public health in the United Kingdom [20]. They argued that smokers should be encouraged to

use them and the public reassured that ENDS were much safer than smoking cigarettes. The British Medical Association supported the use of ENDS for cessation in 2017 [21] and 2018 National Institute for Health and Care Excellence (NICE) guidelines on smoking and harm reduction supported their use for cessation, if other methods had failed [22].

In 2017, the House of Commons Science and Technology Committee examined the evidence on the impact of ENDS on human health (including their effectiveness for smoking cessation), the suitability of regulations guiding their use and the financial implications of a growing market on business and the NHS. Its report supported ENDS as a form of tobacco harm reduction. The Committee concluded that: 'Some aspects of the regulatory system for e-cigarettes appear to be holding back their use as a stop smoking measure' and recommended that ENDS regulations be liberalized [23].

PUBLIC HEALTH OPPOSITION TO ENGLISH ENDS POLICY

Some leading public health figures have criticized ENDS policy. Martin McKee and Simon Capewell [24,25] criticized PHE's claim that ENDS were 95% safer than smoking cigarettes. They argued that the estimate was based on a 2013 publication that could not be trusted, because its funders and some authors had links to the ENDS and tobacco industries. They highlighted the potential adverse health effects of chemicals in e-liquids and the risk that ENDS would serve as a gateway to cigarette smoking in young people. In their view, ENDS should only be available as approved medical devices. A similar stance was adopted by the then president of the Faculty of Public Health, John Ashton [26].

THE DEVELOPMENT OF ENDS POLICY IN AUSTRALIA

In Australia, the sale of nicotine vaping liquid has been banned as a consequence of classifying nicotine as a Schedule 7 'dangerous poison'. Nicotine can only be sold if one of the following exemptions applies: (a) it is in preparations for animal treatment (with 3% or less nicotine); (b) it is in preparation for human therapeutic use; or (c) it is in tobacco prepared and packed for smoking. Nicotine as a smoking cessation aid is included under exemption (b). These products are classified as Schedule 4 (prescription-only medicine) unless they are delivered through the oral mucosa or transdermally, in which case they are available without a prescription [27].

In Australia, medicines and other therapeutic goods must be listed on the Australian Register of Therapeutic Goods (ARTG) before they can be used as medicines. A

listing on the ARTG requires evidence that ENDS are safe and effective in clinical trials for smoking cessation and meet other requirements for a therapeutic good, such as conformity with therapeutic goods manufacturing standards. The financial resources required to meet these requirements are major disincentives to manufacturers applying to have ENDS approved as a medicine in the small Australian market.

Nicotine e-liquids can be obtained in Australia as unapproved medicines if individuals have a medical prescription. This allows nicotine e-liquid to be imported for personal use or to have it compounded by a pharmacist. Vaporizers can be sold in all states apart from Western Australia (which has banned their sale). Vaping liquids that do not contain nicotine can be sold as consumer products, under the same restrictions that apply to tobacco products. Smoke-free legislation applies to ENDS, and these laws are enforced by state health departments. Several ENDS vendors have been prosecuted and fined and e-liquids imported for personal use have been seized [28]. ENDS users are understandably confused about the laws covering the use of vaping products with and without nicotine [29].

In Australia, a series of national tobacco strategies to guide tobacco control policymaking have been produced by an inter-governmental committee in consultation with government and non-government stakeholders, such as health and medical organizations. ENDS emerged during the period covered by the 2004–2009 national tobacco strategy, which anticipated the development of new non-medicinal nicotine products that were referred to in the strategy as ‘tobacco substitutes’, ‘other nicotine products’ and ‘alternative nicotine delivery systems’. Objective 4 of the strategy supported harm-reduction approaches (‘where feasible, to reduce harm associated with continuing use of, and dependence on, tobacco and nicotine’), which were also described as one of the three pillars of Australian tobacco control policy, together with supply and demand reduction strategies. Examples of how to achieve this policy objective were provided, including the development of a framework that ‘would coordinate regulation of tobacco products and products designed to replace tobacco products by:

- forcing the pace of innovation towards less harmful and, if feasible (and if deemed desirable), less addictive tobacco products;
- controlling the price and the accessibility of tobacco products and products that would replace tobacco products consistent with inherent harmfulness; and
- creating incentives to market tobacco products and products that would replace tobacco products in ways that minimize overall population harm’ [30].

In the 2007 federal election the Labor party, led by Kevin Rudd, was elected to replace the Liberal National Coalition government. The Rudd government established

an Australian National Preventative Health Agency in 2009 and a National Preventative Health Taskforce, chaired by Rob Moodie and Mike Daube, to develop a National Preventive Health Strategy. Mike Daube chaired the Taskforce’s tobacco expert advisory group. The next National Tobacco Strategy (2012–18) retained objective 4 from the previous strategy, but was much more negative about lower-risk products than the previous strategy. It identified ‘a need to better understand the potential risks and/or benefits of these products, determine whether there is a need to increase restrictions on their availability and use, and identify the most appropriate policy approach for Australia’. No evaluation of the 2004–09 NTS was published, so there is no public explanation for the change in policy direction.

There was very little public input into the formulation of Australian ENDS policy. State and federal officials developed policy on the advice of tobacco control advocates and health and medical organizations [31]. The Commonwealth Health Department commissioned reviews of the policy in 2012 and 2014 but did not solicit public submissions and did not publish either report [31].

In 2014, agitation by Australian vaper organizations prompted state and federal governments to commission inquiries into ENDS, some of which invited submissions [31]. The majority of submissions came from vapers who reported that ENDS had assisted them to quit smoking and who wanted easier access to ENDS. By contrast, submissions from public health and medical organizations all supported the ENDS sales ban. They emphasized that allowing ENDS to be sold as consumer products would increase youth uptake of smoking and argued that ENDS would be used by the tobacco industry to discourage smokers from quitting and recruit youth to smoking [31].

Australian ENDS policy enjoys bipartisan support from the Liberal National coalition government and the Labor opposition. A minority of centre-right Australian politicians have argued that ENDS should be sold as consumer products. These include free market advocates within the Liberal party, a member of a libertarian party and independent MPs [31,32]. The Australian Greens support supervised injecting rooms, drug checking and the legalization of recreational cannabis use, but they have not supported more liberal ENDS policies.

A House of Representatives inquiry into e-cigarettes in 2017 attracted a large number of submissions from public health researchers, medical organizations and the public [33]. Nearly all (97%) of the 259 public submissions from vapers wanted to legalize access to ENDS products that contain nicotine. Public health and medical organizations overwhelmingly supported the ban on the sale of ENDS. A sales ban was supported by all State and Federal Health Departments, state and national cancer councils, the National Heart Foundation, the Thoracic Society of

Australia and New Zealand and the Australian and New Zealand Public Health Association. The Royal Australian and New Zealand College of Psychiatrists, RANZCP, was a notable exception, arguing that medicinal regulation or regulation as tobacco products would restrict access to ENDS for people with mental illnesses who have a high prevalence of cigarette smoking. A few public health researchers (including two of the authors, C.G. and W.H.) made submissions in support of the sale of ENDS to adults (under more restrictive regulations than tobacco products) [34].

In 2018, the Committee's majority report supported the sales ban on ENDS and recommended an even more restrictive national approach to regulating nicotine-free vaping products [33]. The majority argued that there was insufficient evidence that ENDS were effective cessation aids, and that the possibility that ENDS may serve as a gateway to smoking among young people justified a sales ban in keeping with a precautionary principle. Two dissenting reports from three members of the Liberal Party recommended that nicotine in ENDS should be regulated as consumer products, with 'restrictions based on those in place in the EU' [33].

The historical origins of ENDS policies in the United Kingdom and Australia

In the remainder of the paper, we offer some provisional historical explanations for why such divergent ENDS policies were adopted in Australia, and specifically England, within the United Kingdom despite their shared history of tobacco control policies.

The failure of the safer cigarette and the rejection of tobacco harm reduction

The pre-history of tobacco control might have led one to expect that Australia and the United Kingdom would have developed similar policies towards e-cigarettes. Both had a pre-history of rejecting 'safer smoking' and both have adopted stringent public health policies towards tobacco smoking. Public health policy in both Australia and the United Kingdom between the 1950s and the 1970s had supported research to produce a safer smoking product by identifying and removing the harmful constituents in tobacco. This strategy failed in the case of low-tar cigarettes because of compensatory smoking [35–38], and the public health community largely abandoned tobacco harm reduction and banned the sale of oral snuff in the United Kingdom and of chewing tobacco and oral snuff in Australia [31]. Some leading figures in tobacco control cite this history as a major reason for their opposition to ENDS [39].

In both countries, leading tobacco control advocates successfully campaigned for policies to reduce the demand for tobacco by: raising tobacco taxes, banning tobacco

advertising, educating smokers about the risks of smoking (via cigarette pack warnings and mass media campaigns) and restricting places where cigarettes could be smoked [35,40,41].

The major actors in the policy networks that successfully campaigned for these policies have been influential opponents of ENDS. In Australia they include Mike Daube and Simon Chapman, who have publicly supported the sales ban on ENDS [39,42]. Daube was the second director of ASH in the United Kingdom in the 1970s and he has since held senior roles in the Australian Council on Smoking and Health, the Public Health Advocacy Institute of Australia and the Australian Government's National Preventive Health Agency [35,43]. Chapman is an Emeritus Professor of public health who also has a long history as an anti-smoking activist, including as a proud founding member of BUGAUP in Australia, which spray-painted anti-smoking graffiti on cigarette advertising billboards [44]. He was also a member of the National Preventive Health Taskforce tobacco expert advisory group chaired by Daube. McKee in the United Kingdom shares their views, and the three have co-authored editorials and parliamentary submissions [42,45]. Based on the pre-history of safer smoking alone, one might have expected both countries to be hostile to e-cigarettes.

TOBACCO HARM REDUCTION NETWORKS IN ENGLAND AND AUSTRALIA

However, there was one crucial aspect of the pre-history of the tobacco issue on which the two countries radically differed: the level of support for the use of nicotine in tobacco harm reduction.

An influential tobacco policy network was established in London at the Institute of Psychiatry in the 1970s that adopted a more positive view of tobacco harm reduction using nicotine. It was led by the psychiatrist Michael Russell, in the Addiction Research Unit, who set out to develop safer forms of smoking to help those who could not quit because of nicotine dependence. Russell's advocacy of harm reduction using safer forms of nicotine was not popular in mainstream public health, but the psychologists he trained later became influential actors in UK policy on ENDS; namely, Ann McNeill, Robert West, Martin Jarvis and Peter Hajek [35,46]. Their views later received support from the Royal College of Physicians, and a leading academic and tobacco control expert, John Britton, a respiratory physician who influenced the policy advice that the 'nudge unit' gave to David Cameron [13].

In Australia, by contrast, psychiatrists and psychologists have not been as involved in tobacco control or smoking policy until very recently, when the RANZ College of Psychiatrists supported the use of ENDS to reduce the

high prevalence of heavy smoking among their patients. This reflected an increased focus upon improving the physical health of people living with a mental illness, such as the Equally Well Consensus Statement [47]. A minority of prominent Australian tobacco control advocates, Nigel Gray and Ron Borland, advocated for tobacco harm reduction using less harmful nicotine products [48,49]. Both worked for the Cancer Council of Victoria (CCV) (Gray as the Director 1968–95 and Borland as a researcher 1986–2019). The CCV has since strongly supported the ENDS sales ban [50]. For these reasons, a tobacco harm reduction network was not as well developed in Australia as in England.

The pre-history of nicotine for cessation and harm reduction

In England, another crucial difference was a pre-history of the use of nicotine in cessation treatment in a well-established network of stop smoking services.

Michael Russell & Ove Ferno (the manufacturer of nicotine gum) introduced nicotine-assisted cessation into the United Kingdom [35]. By the mid-1990s, the nicotine nasal spray and gum could be prescribed on the NHS, advertising of gum was allowed in 1998 and NRT was sold to the public in two strengths and transdermal patches. In 2006, an MHRA committee on nicotine regulation concluded that: ‘Overall, the benefits of quitting smoking clearly outweighed any risk there may be with NRT’ [51]. In 2006, NRT was licensed for temporary abstinence and for long-term use in 2009 [46]. Specialized NHS smoking cessation services were established from the 1970s/80s and developed expertise in helping heavy smokers to quit [35]. In 1999 globally unique comprehensive stop smoking services were set up with a major financial investment as part of the Labour government’s tobacco control strategy.

In Australia, by contrast, NRT was only made a subsidized medicine in 2011, although bupropion and varenicline were subsidized in 2001 and 2008, respectively. Formal quitting assistance has largely been provided by free telephone Quitlines in each state/territory supported by the provision of self-help materials on government and non-governmental organization (NGO) websites. Simon Chapman has questioned the need for medication-assisted cessation services, arguing that unassisted quitting is the most effective method to quit smoking [52]. Unlike England, NRT has not been recommended for long-term harm reduction use by Australian smokers.

The influence of illicit drug harm reduction

Harm reduction influences from the drugs field and a cross-over of personnel also had more of an influence in England than in Australia.

In the United Kingdom, harm reduction in the illicit drug field, where Scotland was also a prominent player, provided an early stimulus for discussions of harm reduction in the tobacco field. In 1997 Ann McNeill gave a paper on tobacco harm reduction to the Society for the Study of Addiction (SSA). A more direct connection was formed between ENDS and drugs harm reduction after PHE was created by combining the National Treatment Agency (from the alcohol and drugs field) with the Health Protection Agency and other agencies and covering England only. Trends within the drug field impacted upon tobacco. The transfer of a tobacco post to PHE from the Department of Health enabled liaison between tobacco and the drug and alcohol treatment sectors. The appointment of Martin Dockrell was important because he had been policy director of ASH, and in the 1980s and 1990s worked on injecting drug use and harm reduction in various organizations. His appointment helped a harm reduction approach to ENDS to flourish in England in the health bureaucracy and among networks of researchers.

In Australia, those involved in harm reduction for drugs had few connections with the tobacco field. A researcher–clinician, Alex Wodak, who pioneered harm reduction in the illicit drugs field, has publicly supported tobacco harm reduction and some individuals and organizations that work in the addictions field made submissions to the House of Representatives inquiry advocating ENDS as a way to reduce the high prevalence of smoking in their patient populations [33]. Other influential public health figures who supported illicit drug harm reduction policies in the 1990s have opposed the use of ENDS for harm reduction [53].

The role of activist organizations

The role of anti-smoking activism has historically been extremely important in the tobacco field, and this was again the case with e-cigarettes in England but not in Australia.

Support for vaping came from English ASH, a long-established, anti-tobacco health activist organization [35]. ASH opposed tobacco harm reduction in the 1970s (under Mike Daube) but changed its stance in the late 1990s, first under Clive Bates as Director, and later under Deborah Arnott (Director from 2004), with input from Martin Dockrell. ASH first supported tobacco harm reduction using NRT and later the use of ENDS [54].

Vaper activists also played an important role in developing UK’s ENDS policy in Europe. Prosmoking groups in the past were primarily tobacco industry-funded, but the vaping activists who formed the New Nicotine Alliance initially avoided affiliating with or receiving any funding from the tobacco industry, although they may have later accepted funding from Philip Morris International’s Smoke Free World Initiative.

Vaper activist groups formed in Australia but have been much less influential in policy. The now defunct Australian arm of the New Nicotine Alliance (NNA AU) made submissions to government inquiries and unsuccessfully applied to the TGA to have nicotine vaping products exempted from Schedule 7 of the Poisons Standard. An Australian Tobacco Harm Reduction Association (ATHRA), led by a general practitioner who specializes in tobacco cessation, Colin Mendelsohn, has advocated for smokers to have easier access to nicotine vaping products. The public impact of these advocacy groups has been limited by the success of public health opponents of ENDS in portraying supporters of ENDS as affiliated with the tobacco industry (or vaping companies which are equated with the tobacco industry) [55]. NNA AU stated that they have not taken any funding from the tobacco or vaping industry. ATHRA accepted funds from vaping companies to establish its website, but it has since adopted a policy of not accepting funding from the vaping industry.

An Australian branch of ASH was created in the 1980s (with Mike Daube as Director) but it was disbanded in 2013 largely because the policies it advocated for had been implemented [56]. Its advocacy role has been taken on by state and federal cancer councils and the Australian Medical Association, all of which have supported the ban on ENDS sales. Australia did not, as a result, have an organization such as English ASH that supports tobacco harm reduction.

LIMITATIONS

A major limitation of our analysis of the origins of policy in Australia was that we had to rely largely upon public documents. Australian ENDS policy was made by officials with no public input and commissioned reviews of the policy have not been published. We were unable to access government archival material, as this is covered by the 30-year rule in England. Interviews were carried out in England, but have not been used in this paper for the purposes of consistency in methodology. As a result, the paper is necessarily a first pass at an analysis of some of the major historical factors that contributed to the striking difference in policy directions between Australia and the United Kingdom. Further research is clearly warranted as more documents are made public and when policymakers, who may be reluctant to discuss policies decided in confidence, are prepared to be interviewed about the origins of these policies.

CONCLUSION

A recent editorial in *Nature* predicted that 'policies on e-cigarettes will be built on evidence and collaboration' [57]. Our analysis suggests that this may be an optimistic

view, because the evidence has been, and is likely to continue to be, evaluated very differently by the very different research and policy networks in Australia and England. For example, proponents and opponents of harm reduction using ENDS have disagreed about the strength of the evidence on the effectiveness of ENDS for smoking cessation. They also fiercely disagreed on whether ENDS is already serving, or will in future serve, as a gateway to cigarette smoking in young people. These divergent understandings of the contested evidence have been refracted through policy networks, national government structures and institutions that, for historical reasons, have given very different priority to the goals of promoting cessation among smokers and preventing the youth uptake of smoking. They have also given different emphasis to the role of nicotine in smoking cessation. These historical factors have produced the highly divergent ENDS policies in Australia and the United Kingdom that are evident today.

Declaration of interests

The three Australian authors (C.G., K.M. and W.H.) have published articles in favour of the regulated sale of ENDS in Australia and have been critical of Australian policy in submissions to parliamentary inquiries. They have not received any funding from the tobacco or ENDS companies. Their work on ENDS has been funded by the National Health and Medical Research Council and VicHealth, a government agency in Victoria that funds public health research.

Acknowledgements

The research for the production of this paper was funded by the Wellcome Trust's Humanities programme with a grant made to the English author (V.B.), grant reference 209524Z/17/Z. An early version of the paper was given by V.B. at the E-cigarette summit in London in December 2018.

Author contributions

Virginia Berridge: Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; supervision. **Wayne Hall:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration. **Suzanne Taylor:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration. **Coral Gartner:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration. **Kylie Morphet:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration.

References

- Chapman S. The UK is hopelessly smitten with e-cigarettes. *BMJ* 2018; **361**: k2279.
- Erku A. D., Morphet K., Steadman J. K., Gartner E. C. Policy debates regarding nicotine vaping products in Australia: a qualitative analysis of submissions to a government inquiry from health and medical organisations. *Int J Environ Res Public Health* 2019; **16**: 4555.
- Hall W., Gartner C. E., Forlini C. Ethical issues raised by a ban on the sale of electronic nicotine devices. *Addiction* 2015; **110**: 1061–7.
- Levy D. T., Yuan Z., Li Y., Alberg A. J., Cummings K. M. A modeling approach to gauging the effects of nicotine vaping product use on cessation from cigarettes: what do we know, what do we need to know? *Addiction* 2019; **114**: 86–96.
- McNeill A., Brose L. S., Calder R., Hitchman S. C., Hajek P., McRobbie H. E-cigarettes: An Evidence Update. A report commissioned by Public Health England. 2015. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/E-cigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf (accessed 16 July 2020).
- Douglas H., Hall W., Gartner C. E-cigarettes and the law in Australia. *Aust Fam Physician* 2015; **44**: 415–8.
- Berridge V. Introduction to history in health. In: Green J., Brown J., editors. *Principles of Social Research*. New York: Open University Press; 2005, pp. 145–55.
- Gorsky M., Mold A. Documentary analysis. In: Mays N., Pope C., editors. *Qualitative Methods in Health Research*. Hoboken, NJ: Wiley Blackwell; 2020, pp. 83–96.
- James M. Historical research methods. In: McConway K., Basiro D., editors. *Studying Health and Disease*. London: Open University Press; 2001; 36–48.
- Erku D. A., Kisely S., Morphet K., Steadman K. J., Gartner C. E. 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. *Int J Drug Policy* 2020; **78**: 102699.
- Berridge V. *Making Health Policy: Networks in Research and Policy After 1945*. Amsterdam: Rodopi; 2007.
- Berridge V., Strong P. *AIDS and Contemporary History*. Cambridge: Cambridge University Press; 1993.
- Halpern D. *Inside the Nudge Unit: How Small Changes Can Make a Big Difference*. London: WH Allen; 2015.
- European Union. Directive 2014/40/EU of the European Parliament and of the Council. Official Journal of the European Union 2014. Available at: https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf (accessed 16 July 2020).
- McNeill A., Brose L., Calder R., Bauld L., Robson D. Evidence Review of E-Cigarette and Heated Tobacco Products 2018: A report commissioned by Public Health England. London: Public Health England. 2018. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf (accessed 16 July 2020).
- Public Health England. E-cigarettes: An Emerging Public Health Consensus. 2015. Available at: <https://www.gov.uk/government/news/e-cigarettes-an-emerging-public-health-consensus> (accessed 16 July 2020).
- Royal College of Physicians (RCP). Nicotine Addiction in Britain. RCP. 2000. Available at: <https://shop.rcplondon.ac.uk/products/nicotine-addiction-in-britain?variant=6633984645> (accessed 16 July 2020).
- Royal College of Physicians (RCP) Tobacco Advisory Group. Harm reduction in nicotine addiction. Helping people who can't quit. RCP. 2007. Available at: <https://shop.rcplondon.ac.uk/products/harm-reduction-in-nicotine-addiction-helping-people-who-cant-quit?variant=6509405637> (accessed 16 July 2020).
- Royal College of Physicians (RCP) Tobacco Advisory Group. Hiding in Plain Sight: Treating tobacco dependence in the NHS: RCP; 2018. Available at: <https://www.rcplondon.ac.uk/projects/outputs/hiding-plain-sight-treating-tobacco-dependency-nhs> (accessed 16 July 2020).
- Royal College of Physicians (RCP). Nicotine Without Smoke: Tobacco harm reduction. RCP 2016. Available at: <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0> (accessed 16 July 2020).
- British Medical Association. E-cigarettes: Balancing Risks and Opportunities: British Medical Association. 2017. Available at: <https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/tobacco/e-cigarettes> (accessed 16 July 2020).
- National Institute for Health and Clinical Excellence (NICE). Stop Smoking Interventions and Services: NICE guideline. UK: NICE; 2018. Available at: <https://www.nice.org.uk/guidance/ng92> (accessed 16 July 2020).
- House of Commons Science and Technology Committee. E-cigarettes. 2017. Available at: <https://publications.parliament.uk/pa/cm201719/cmselect/cmsstech/505/505.pdf> (accessed 16 July 2020).
- McKee M., Capewell S. Evidence about electronic cigarettes: a foundation built on rock or sand? *BMJ* 2015; **351**: h4863.
- McKee M., Capewell S. Electronic cigarettes: we need evidence, not opinions. *Lancet* 2015; **386**: 1239.
- Ashton J. R. Regulation of electronic cigarettes. *BMJ* 2014; **349**: g5484.
- Australian Therapeutic Goods Association. Poisons Standard June 2018. Available at: <https://www.legislation.gov.au/Details/F2018L00625> (accessed 16 July 2020).
- Irby R. Liquid nicotine 'poison' lands man in court: NewsMail 2017. Available at: <https://www.news-mail.com.au/news/liquid-nicotine-an-honest-mistake/3220549/> (accessed 16 July 2020).
- Saw K. E. S., Morphet K., Puljević C., Bromberg M., Gartner C. The medium is not the message: a content analysis of public information about vaping product regulations in Australia. *Drug Alcohol Rev* 2019; **38**: 569–78.
- Ministerial Council on Drug Strategy *National Tobacco Strategy, 2004–2009*. Canberra: Commonwealth of Australia; 2004.
- Gartner C. E., Bromberg M. One does not simply sell e-cigarettes in Australia: an overview of Australian e-cigarette regulations. In: Gruszczynski L., editor. *The Regulation of E-cigarettes: International, European and National Challenges*. Cheltenham: Elgar Online; 2019; 249–79.
- Griffiths P., Magnusson P. Good laws create freedom, not a nanny state. Sydney Morning Herald 2015. Available at: <https://www.smh.com.au/opinion/good-laws-create-freedom-not-a-nanny-state-20151013-gk7k71.html> (accessed 16 July 2020).
- House of Representatives Standing Committee on Health, Aged Care and Sport. Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia: Commonwealth of Australia 2018.

- Available at: http://parlinfo.aph.gov.au/parlInfo/download/committees/reportrep/024115/toc_pdf/ReportontheInquiryintotheUseandMarketingofElectronicCigarettesandPersonalVaporisersinAustralia.pdf;fileType=application%2Fpdf (accessed 16 July 2020).
34. Gartner C. E., Hall W. Submission 282 to the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia 2017. Available at: https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes/Submissions (accessed 16 July 2020).
 35. Berridge V. *Marketing Health: Smoking and the Discourse of Public Health in Britain 1945–2000*. Oxford, UK: Oxford University Press; 2007.
 36. Berridge V., Starns P. The ‘invisible industrialist’ and public health: The rise and fall of ‘safer’ smoking in the 1970s. In: Berridge V., Loughlin K., editors. *Medicine, the Market and the Mass Media: Producing Health in the Twentieth Century*. Abingdon, UK: Routledge; 2005, pp. 172–91.
 37. Jarvis M. J., Russell M. A. Comment on the Hunter Committee’s second report. *BMJ* 1980; **280**: 994–5.
 38. King W., Carter S. M., Borland R., Chapman S., Gray N. The Australian tar derby: the origins and fate of a low tar harm reduction programme. *Tob Control* 2003; **12**: iii61.
 39. Chapman S. Should electronic cigarettes be as freely available as tobacco cigarettes? No. *BMJ* 2013; **346**: f3840.
 40. Chapman S. *Public Health Advocacy and Tobacco Control: Making Smoking History Carlton*. Malden, MA: Blackwell Publishing; 2007.
 41. Institute for Government. Reducing smoking rates policy reunion; 2011. Available at: https://www.instituteforgovernment.org.uk/sites/default/files/policy_seminar_report_smoking.pdf (accessed 16 July 2020).
 42. Mckee M., Daube M., Chapman S. E-cigarettes should be regulated. *Med J Aust* 2016; **204**: 331.
 43. Berridge V. New social movement or government funded voluntary sector? ASH (Action on Smoking and Health), science and tobacco activism in the 1970s. In: Pelling M., Mandebrote S., editors. *The Practice of Reform in Health, Medicine and Science 1500–2000: Essays for Charles Webster*. London: Ashgate; 2005, pp. 333–48.
 44. Chapman S., Wakefield M. Tobacco control advocacy in Australia: reflections on 30 years of progress. *Health Educ Behav* 2001; **28**: 274–89.
 45. Chapman S., Daube M., Bareham D., Peters M. Submission to the Standing Committee on Health, Aged Care and Sport on Electronic Cigarettes and Vapourisers (submission no. 0313) 2017. Available at: https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes/Submissions (accessed 16 July 2020).
 46. Berridge V. The art of medicine: electronic cigarettes and history. *Lancet* 2014; **383**: 2204–5.
 47. National Mental Health Commission (NMHC). Equally Well Consensus Statement: Improving the Physical Health and Wellbeing of People Living With Mental Illness in Australia. Sydney: NHMC; 2016. Available at: <https://www.equallywell.org.au/wp-content/uploads/2018/12/Equally-Well-National-Consensus-Booklet-47537.pdf> (accessed 16 July 2020).
 48. Borland R. Paying more attention to the ‘elephant in the room’. *Tob Control* 2016; **26**: e35–e36.
 49. Gray N. J. Nicotine yesterday, today, and tomorrow: a global review. *Nicotine Tob Res* 2014; **16**: 128–36.
 50. Cancer Council Australia. Position statement—Electronic cigarettes. 2016. Available at: http://wiki.cancer.org.au/policy/Position_statement_-_Electronic_cigarettes (accessed 16 July 2020).
 51. Medicines and Healthcare Products Regulatory Agency. Report of the Committee on Safety of Medicines Working Group on Nicotine Replacement Therapy: MHRA; 2006. Available at: https://www.hri.global/files/2011/07/13/MHRA_-_Report_on_Nicotine_Replacement_Therapy.pdf (accessed 16 July 2020).
 52. Chapman S., Mackenzie R. The global research neglect of unassisted smoking cessation: causes and consequences. *PLOS Med* 2010; **7**: e1000216.
 53. Moore M., McKee M., Daube M. Harm reduction and e-cigarettes: distorting the approach. *J Public Health Policy* 2016; **37**: 403–10.
 54. Action on Smoking and Health (ASH). Briefing: Electronic Cigarettes. London, UK: ASH; 2018. Available at: https://ash.org.uk/wp-content/uploads/2019/04/E-Cigarettes-Briefing_PDF_v1.pdf (accessed 16 July 2020).
 55. Han E. Secret industry funding of doctor-led vaping lobby group laid bare. The Sydney Morning Herald 2018. Available at: <https://www.smh.com.au/healthcare/secret-industry-funding-of-doctor-led-vaping-lobby-group-laid-bare-20180823-p4zcc5.html> (accessed 16 July 2020).
 56. Australian Medical Association. Ash butts out [2 December 2013]. 2013. Available at: <https://ama.com.au/ausmed/ash-butts-out> (accessed 16 July 2020).
 57. The debate over e-cigarettes demands stronger evidence of their value [Editorial]. *Nature* 2019; **570**: 415.