National E-cigarette Monitoring and Evidence Consortium: Supporting informed research, policy and practice in Australia

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Background

Electronic cigarettes (e-cigarettes), electronic nicotine and non-nicotine delivery systems, or vaping goods/products, are a diverse and rapidly changing range of battery-powered devices that heat a liquid to deliver an aerosol that is inhaled.[1,2] Internationally, and in Australia, most e-cigarettes deliver nicotine.[3–7] Other substances—including various cannabis-based products—may be added to e-cigarettes by the user.[8] Heated tobacco products (HTPs), that heat tobacco leaves, are generally considered a separate product category from e-cigarettes.[9]

In keeping with the World Health Organization's recommendations, e-cigarettes are regulated in Australia with the goal of maximising the protection of public health.[10] Australia's model of e-cigarette access is unique worldwide and has evolved over time, supported by federal and varying state and territory legislation.[11–13] At the time of writing, a range of goals regarding e-cigarettes is outlined in the current laws, regulations and guidelines in Australia. Additionally, various policy reforms to strengthen and address deficiencies in regulations have been announced, highlighting the rapidly changing policy landscape. These reforms support the Australian Government's objective to significantly reduce tobacco use and nicotine addiction by 2030, as outlined in the National Tobacco Strategy 2023–2030.[14]

The December 2020 changes to the scheduling of nicotine when used in e-cigarettes[15] state that the final decision was based on the need to balance consumer demand for nicotine e-cigarettes to support smoking cessation and the need to minimise and prevent initiation among non-smokers, particularly among adolescents. Up until recently, nicotine-delivering e-cigarettes were only legal in Australia when prescribed for therapeutic use (smoking cessation or management of nicotine dependence) and when supplied in pharmacy settings.[11] From 1 October 2024, e-cigarettes may only be supplied in pharmacies, by a registered pharmacist, to individuals aged 18 and over.[12] No e-cigarette has yet been approved for inclusion on the Australian Register of Therapeutic Goods by the Therapeutic Goods Administration, so their use is as an "unapproved" product.[13]

The Therapeutic Goods Administration has developed product standards that stipulate minimum safety and quality requirements for therapeutic vaping products.[16–18] The objectives of Therapeutic Goods Order 110[16,18] and Medical Device Standard Order 2023[17] are to help health practitioners and consumers have accurate information about product contents; prohibit ingredients/substances with known, demonstrable health risks associated with inhalation; prohibit active ingredients other than nicotine; specify a maximum nicotine concentration; and minimise the health and safety risks of accidental exposure and/or ingestion.[11] In addition, the only flavours allowed in therapeutic vaping products are components or ingredients that produce the smell or taste of mint, menthol or tobacco.[16] Therapeutic Goods Order 110 notes the following risks of e-cigarettes: poisoning, severe burns, respiratory disease, seizures and dependence, and the possibility that vaping may negatively impact tobacco control and population health.[18]

Minimising population harm related to e-cigarettes requires high-quality evidence and coordinated activities from multiple stakeholders. Monitoring multiple aspects of e-cigarettes and their regulation—including legislation/regulation, enforcement activities, product types, availability, price, promotion, knowledge/attitudes/beliefs, use and health and other outcomes (**Figure 1**)—is also needed to ensure policy goals are met and to inform evidence gaps regarding their impacts at individual and population levels. Evidence,

[a]Details listed at end of paper.
[b]The views expressed in this paper do not necessarily reflect the views of the listed organisations.

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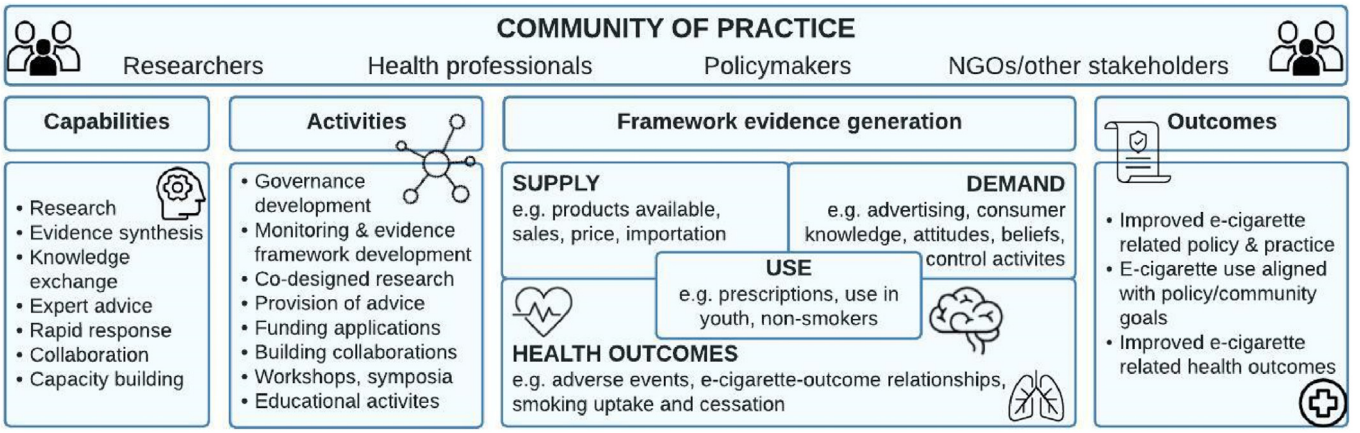
Figure 1: The National E-cigarette Monitoring and Evidence Consortium conceptual framework.



while currently limited, is accruing rapidly across multiple areas. The tobacco and nontherapeutic e-cigarette industries are active in promoting commercial interests, including aggressive marketing of e-cigarettes to young people[10,19,20] and undermining research.[21,22] E-cigarette-related research activities are currently not coordinated and visibility of research activities is limited. There is also a lack of coordinated mechanisms for research end users to engage and work in partnership with the research community and to ensure timely dissemination of findings.

The Australian National E-cigarette Monitoring and Evidence Consortium (NEMEC) was conceived in 2021 in recognition of the need for activities that support the strategic coordination of research efforts and the engagement of research stakeholders on e-cigarettes. This includes identifying research gaps, facilitating knowledge exchange (especially between policymakers and researchers), encouraging collaboration, building capacity and supporting monitoring. The Consortium's first meeting was held in December 2021. This document outlines the background, aims and approach of NEMEC.

Aims

The overarching aim of the Consortium is to improve health by informing policy and practice on e-cigarettes, nationally and internationally. To achieve this, it applies the conceptual framework outlined in Figure 1 and has the following core objectives:

1. **Create and sustain a community of practice** on e-cigarette monitoring and evidence generation that connects and harnesses the collective capabilities of researchers, policymakers, health practitioners and other stakeholders, independent of tobacco and e-cigarette industry influence.
2. **Support knowledge exchange** on e-cigarette monitoring, research activities, data and policy and practice needs.
3. **Support leadership, strategic coordination, expertise and advice** on e-cigarette monitoring, evidence generation and evidence-based decision-making.
4. **Facilitate collaboration and establish projects, programs and systems** to monitor and generate evidence on e-cigarettes, including identifying evidence gaps and needs.
5. **Support capacity building** for e-cigarette monitoring and evidence generation.

Approach

Values

The Consortium is guided by a set of agreed values and principles:

- Transparency;
- Independence;
- Equity;
- Excellence;
- Collaboration;
- Conscientiousness;
- Fairness;
- Integrity; and
- Trustworthiness.

Members and participants

The Consortium aims to build an effective community of practice comprising researchers, health practitioners, members of non-government organisations (NGOs) and policymakers independent of tobacco and related nicotine industry interests. It is led by the chair, currently based at the National Centre for Epidemiology and Population Health at The Australian National University, and is supported by a steering group and a secretariat.

Individuals and organisations may join the Consortium as a 'member' or as a 'participant'. Members may be named as individuals (with their organisational/departmental affiliation) on its webpage,[23] in other NEMEC forums, and on outputs in its name in the future, but have the option to have their details withheld. Participants are generally from government organisations and have as a default that their organisation/department is named, without them being named as individuals on its webpage, in other NEMEC forums and on outputs that are in its name in the future. However, participants may opt to be named as individuals (with their organisational/departmental affiliation).

Membership and participation are limited to individuals based ordinarily in Australia who are members of bona fide academic institutions, government, NGOs or other relevant policy institutions

and who have no conflicts of interest with the tobacco or e-cigarette industries.

Nominations for membership and participation can be made to the NEMEC secretariat, steering group or chair, with a short description of the nominee's relevant expertise and a statement regarding potential conflicts of interest (see below). Membership of or participation in the Consortium does not constrain member or participant contribution to any policy or research forum in their own capacity, independent of NEMEC. Additional details regarding the governance of NEMEC are available at the NEMEC webpage.[23]

Conflicts of interest

Approval of membership or participation is contingent on accurately declaring actual, perceived, or potential conflicts of interest to the Consortium and maintaining independence from industry influence. A conflict of interest is generally agreed to be the direct or indirect lifetime receipt of financial or in-kind support from entities or individuals associated with a vested interest in e-cigarettes or tobacco. The current conflict of interest declaration is:

> *To the best of your knowledge, have you, an immediate family member, or your organisation received any support, whether financial or non-financial, direct or indirect, from any parties involved in the production, distribution, or sale of tobacco, nicotine, or vaping products?*
>
> *Please provide details of that support, including: (a). the nature of that support; (b). the amount or value provided; (c). the name of the entity or person providing it; (d). years the support was received; and (e). any other related information.*

The Consortium recognises that conflicts of interest occupy a spectrum, and accordingly they are assessed on a case-by-case basis. Members and participants have an ongoing responsibility to inform the steering group of any changes to their conflicts of interest. Membership/participation may be reconsidered if a conflict of interest is deemed to not align with the Consortium's values and objectives.

Activities

To achieve its stated objectives, the Consortium does the following:

- **Meets regularly to share information, support collaboration and progress work on shared goals.**

  Meetings actively support knowledge exchange, including showcasing current research activities, policies and programs and evidence needs. The Consortium also identifies areas to work on as a group or as part of working groups.

- **Acts as a point of contact for expertise on e-cigarettes.**

  The Consortium serves as a point of contact for people and organisations seeking expertise and engagement on e-cigarettes. This includes an online presence and directory of researchers and other experts accessible to academic and non-academic audiences.

- **Supports policy- and practice-relevant research and implementation.**

  The Consortium works to connect research and monitoring data end users and researchers to ensure that research is responsive to the needs of policy and practice, and to increase the awareness and use of research findings. This is done through chair, steering group and member and participant activities in engaging with stakeholders including through formal and informal meetings, presentations, briefing notes, publications and reports.

A range of additional activities are planned, such as capacity building, shared projects and educational activities (Figure 1), which are contingent on funding.

Progress, activities to date and discussion

The Consortium held its first meeting in December 2021 and has grown to >105 members and participants from >40 universities, healthcare and research institutions, NGOs, federal, state, territory and local health departments and other government agencies. Membership has increased via invitations to researchers active in the field and word-of-mouth.

Since its inception, the Consortium has met approximately six-monthly and has provided a forum for presentations on monitoring and research evidence, research that is underway, stakeholder evidence needs, national and regional tobacco control and progress on regulatory reforms in relation to e-cigarettes. The NEMEC chair and secretariat have also been contacted by stakeholders to link to expertise on specific areas of e-cigarette research needs. For example, policymakers have contacted the chair to request expertise in the environmental effects of e-cigarettes and toxicology. NEMEC has received some initial start-up funding as a policy and practice engagement component of two research projects (see Funding section).

As well as recruitment of members and participants, regular meetings and knowledge exchange, early work of the Consortium has focused on establishment of its goals, governance and ways of working, creation of the webpage and the collaborative scoping of options for e-cigarette monitoring frameworks, with application of these options to a logic model for integrated e-cigarette and tobacco use monitoring in youth. All of these activities, along with serving as a pool of expertise and knowledge, are designed to support e-cigarette monitoring. Consortium members are actively seeking funding to support its work and as further funding is obtained, its activities will evolve to include greater numbers of those outlined in Figure 1.

Research and policy related to e-cigarettes are challenging for several reasons. In particular, e-cigarette products are diverse, recently introduced and rapidly changing, contributing to major gaps in evidence and the need for decision-making in the face of uncertainty. Globally, regulations and policies regarding e-cigarettes are heterogeneous. The impacts and concerns span a broad array of disciplines, including public health, clinical medicine, epidemiology, toxicology, taxation, border control, law, behavioural science, pharmacy/pharmacology, education and environmental science. NEMEC members and participants reflect these disciplines and conduct a wide range of activities including qualitative research, clinical trials, large-scale epidemiological projects, education-related research and policy development. They comprise experts who have made substantive and long-term contributions to tobacco control in Australia and internationally, including providing evidence to support recent reforms. The tobacco and e-cigarette industries are highly active in marketing products and promoting commercial interests, including through front groups and attempts to influence research and policy. As with other commercial determinants of health, working on e-cigarette-related research topics is especially demanding, with high levels of community concern and media interest and frequent hostility directed towards researchers, politicians and

policymakers—especially in response to adverse findings and precautionary approaches.

Another major consideration is the need to maintain a focus on comprehensive tobacco control, while also appropriately addressing—and not being distracted by—e-cigarettes and other emerging nicotine and tobacco products. NEMEC is committed to integrated tobacco, e-cigarette and other tobacco and nicotine product control. Hence, the group also considers monitoring of measures beyond e-cigarettes, including those relating to tobacco smoking and to other products as they emerge (e.g. nicotine pouches).

These factors make linking research end users (e.g. policymakers, program designers) with an independent, multidisciplinary, multisector Consortium of researchers particularly important. A supportive community of practice improves researcher, policymaker and practitioner capacity to manage the challenges presented by e-cigarettes. It also seeks to reduce unnecessary duplication of efforts and to enhance synergies between research and policy initiatives.

National E-cigarette Monitoring and Evidence Consortium (correct as at 30 June 2024)

Steering group

Emily Banks AM, The Australian National University (Chair); Becky Freeman, The University of Sydney; Coral Gartner, The University of Queensland; Michelle Scollo AM, Cancer Council Victoria, Quit Victoria.

Members

Renee Bittoun, Avondale University, The University of Notre Dame Australia; Alecia Brooks, Cancer Council NSW; Sinan Brown, The Australian National University; Gary Chan, The University of Queensland; Louisa Collins, QIMR Berghofer Medical Research Institute; Mike Conway, The University of Melbourne; Emma Dean, Cancer Council Victoria, Quit Victoria; Anita Dessaix, Cancer Council NSW; Jo Dono, South Australian Health and Medical Research Institute; Angela Gazey, The University of Notre Dame Australia; Tracey Greenberg, St Vincent's Health Network; Elizabeth Greenhalgh, Cancer Council Victoria; Deepali Gupta, Queensland Health; Alys Havard, University of New South Wales (Sydney); Christina Heris, The Australian National University; Laura Hunter, Australian Council on Smoking and Health; Jonine Jancey, Curtin University; Michelle Jongenelis, The University of Melbourne; Sarah Khanlari, NSW Ministry of Health; Alexander Larcombe, Curtin University, Telethon Kids Institute; Carmen Lim, The University of Queensland; Natalia Lizama, Cancer Council WA; Raglan Maddox, The Australian National University; Guy Marks, University of New South Wales (Sydney); Kahlia McCausland, Curtin University; James McLennan, St Vincent's Health Network; Caroline Miller, South Australian Health and Medical Research Institute, The University of Adelaide; Kylie Morphett, The University of Queensland; Megan Passey, The Daffodil Centre; Matthew Peters, Concord Hospital, Macquarie University; Simone Pettigrew, The George Institute for Global Health, University of New South Wales (Sydney); Darren Roberts, NSW Poisons Information Centre; Robert Roseby, Monash Health, Monash University; Maree Scully, Cancer Council Victoria; Abby Smith, Cancer Council Tasmania, The University of Sydney; Colleen Smyth, Macquarie University, Queensland Health, The University of Queensland; Jessamine Soderstrom, Royal Perth Hospital; Daniel Stjepanović, The University of Queensland; Matthew Tuson, The University of Notre Dame Australia; Moya Vandeleur, The Royal Children's Hospital; Amy Villarosa, The Australian National University; Christina Watts, The Daffodil Centre; Marianne Weber, The Daffodil Centre; Luke Wolfenden, The University of Newcastle, Australia; Lisa Wood, The University of Notre Dame Australia; Amelia Yazidjoglou, The Australian National University; Serene Yoong, Deakin University.

Organisations of members and participants

ACT Health; Australian Council on Smoking and Health; Australian Government Department of Health and Aged Care; Australian Institute of Health and Welfare; Australian Medical Association; Avondale University; Cancer Council NSW; Cancer Council Tasmania; Cancer Council Victoria; Cancer Council WA; Concord Hospital; Curtin University; Deakin University; Macquarie University; Monash Health; Monash University; NSW Ministry of Health; NSW Poisons Information Centre; QIMR Berghofer Medical Research Institute; Queensland Health; Quit Victoria; Royal Perth Hospital; South Australian Health and Medical Research Institute; St Vincent's Health Network; Tasmanian Department of Health; Telethon Kids Institute; The Australian National University; The Daffodil Centre; The George Institute for Global Health; The Royal Children's Hospital; The University of Adelaide; The University of Melbourne; The University of Newcastle, Australia; The University of Notre Dame Australia; The University of Queensland; The University of Sydney; University of New South Wales (Sydney); Victorian Health Promotion Foundation (VicHealth).

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Conflicts of interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Becky Freeman reports a relationship with Cancer Council NSW that includes: funding grants and travel reimbursement. Emily Banks and Becky Freeman report a relationship with World Health Organization that includes: consulting or advisory and travel reimbursement. Becky Freeman reports a relationship with Public Health Association of Australia Inc that includes: travel reimbursement. Becky Freeman reports a relationship with NSW Ministry of Health that includes: consulting or advisory. Becky Freeman, Emily Banks and Michelle Scollo report a relationship with Australian Government Department of Health and Aged Care that includes: funding grants. Becky Freeman reports a relationship with Cancer Institute NSW that includes: consulting or advisory. Coral Gartner reports financial support was provided by Australian Research Council. Member of the Public Health Association of Australia (Coral Gartner). Emily Banks is a member of PHAA. Michelle Scollo reports a relationship with VicHealth that includes: funding grants. Michelle Scollo reports a relationship with Cancer Council Victoria that includes: funding grants. Michelle Scollo is an expert member of the Tobacco Issues Committee of Australian Cancer Councils and reports that the major project which funds her salary is financed by state and territory cancer councils. The authors declare that they have no

known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Ethics approval

No ethics approval was required for this article.

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