Australian Government
Department of Health
Therapeutic Goods Administration

Nicotine vaping products, the UK smoking cessation experience

Practical tips for Australian prescribers

Panel

Julia Robson, Tobacco Control Programme Manager, Office for Health Improvement & Disparities, Department of Health & Social Care, UK
Paul Aveyard, Professor of Behavioural Medicine, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK
Jamie Hartmann-Boyce, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Chair

Adj Professor John Skerritt, Therapeutic Goods Administration, Department of Health
Martin Dockrell, Tobacco Control Lead, Office for Health Improvement and Disparities (OHID) UK

TGA Health Safety Regulation

20 October 2021

Welcome

- This webinar is being recorded
- Slides will be made available on the TGA website
- Questions – please use the **Q&A** tool when I open this function
  - Q&A will occur after todays presentation
  - Your questions are only visible to the panel
- If you need to contact the moderator – please use the **'Chat'** function
- Relevant links will be sent to you via the chat function box
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Nicotine vaping products, the UK smoking cessation experience

Practical tips for Australian prescribers

Panel from UK

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Paul Aveyard, Professor of Behavioural Medicine, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Jamie Hartmann-Boyce, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

TGA Health Safety Regulation

20 October 2021

Australian Government
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Welcome and introduction

Adjunct Prof John Skerritt
Deputy Secretary,
Australian Department of Health

Martin Dockrell
Tobacco Control Lead,
Office for Health Improvement and Disparities (OHID)

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Meet the panel

Julia Robson

Julia Robson is a clinician by background (nurse and midwife) and currently a Tobacco Control Programme Manager at OHID (was PHE) involved in policy work around smoking cessation services, pregnant smokers and e-cigarettes. She brings practical, frontline experience of delivering support to quitters using e-cigarettes, having lead a large stop smoking service for over 15 years before moving to PHE. This service was one of the first in England to introduce a specific vaping voucher programme in 2016 to increase access to e-cigarettes for smoking cessation.

Professor Paul Aveyard

Paul is a practising GP and Professor of Behavioural Medicine at Oxford University. He brings extensive experience from the Primary Care perspective, in addition to research in this context including the role of primary care in smoking cessation and use of e-cigarettes. Optimising standard care smoking cessation advice from Health Care Assistants, Practice Nurses and GPs in the Management of Smoking in Primary Care (MaSC) trial

Jamie Hartmann-Boyce

Jamie is part of the Cochrane Collaboration and leads on the Cochrane Living Review on e-cigarettes Electronic cigarettes for smoking cessation - Hartmann-Boyce, J - 2021 | Cochrane Library and runs a monthly podcast on recent research related to e-cigarettes.

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Nicotine vaping products, the UK smoking cessation experience

Supporting smokers to quit tobacco

Julia Robson
Tobacco Control Programme Manager
Office for Health Improvement and Disparities
Department of Health and Social Care, UK

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Office for Health Improvement & Disparities

E-cigarettes: English Stop Smoking Service Experience.

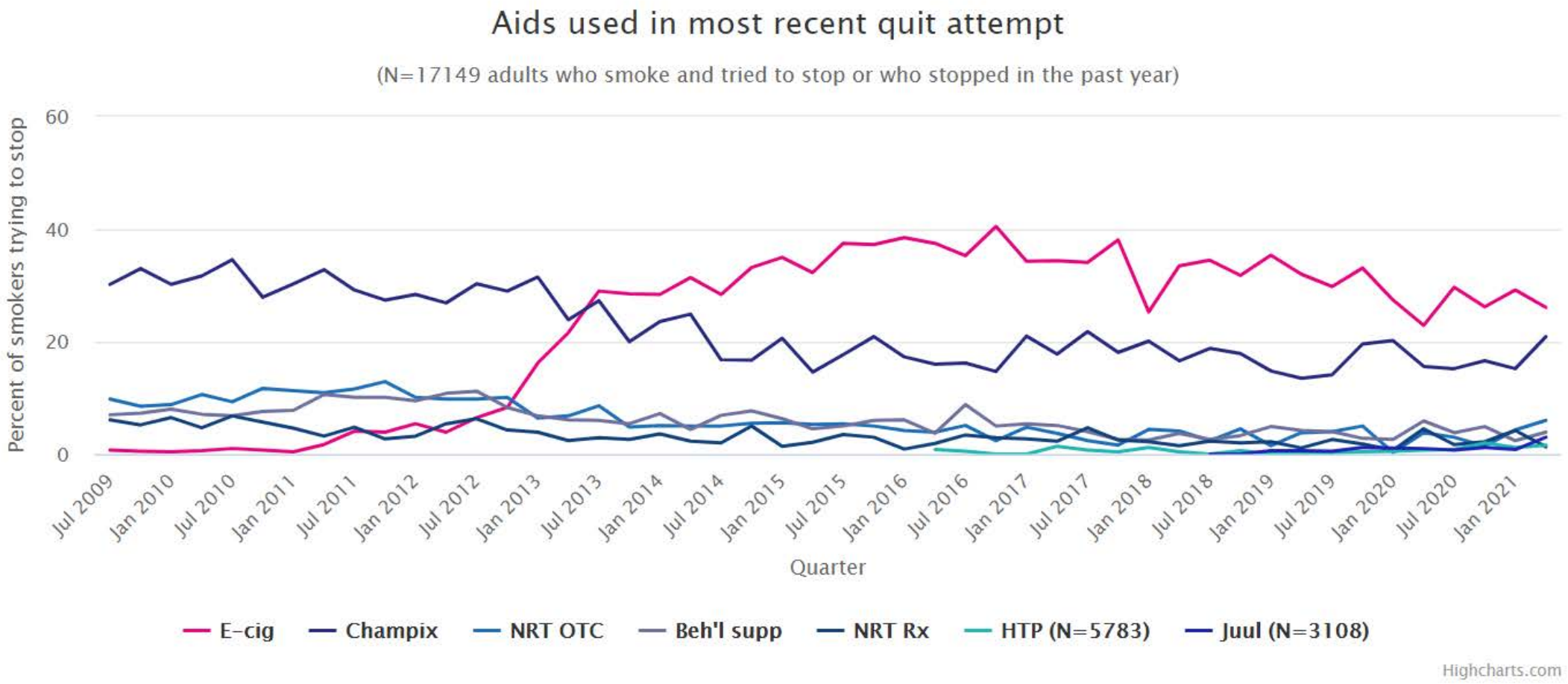
Supporting smokers to quit tobacco

20/10/2021

Agenda:

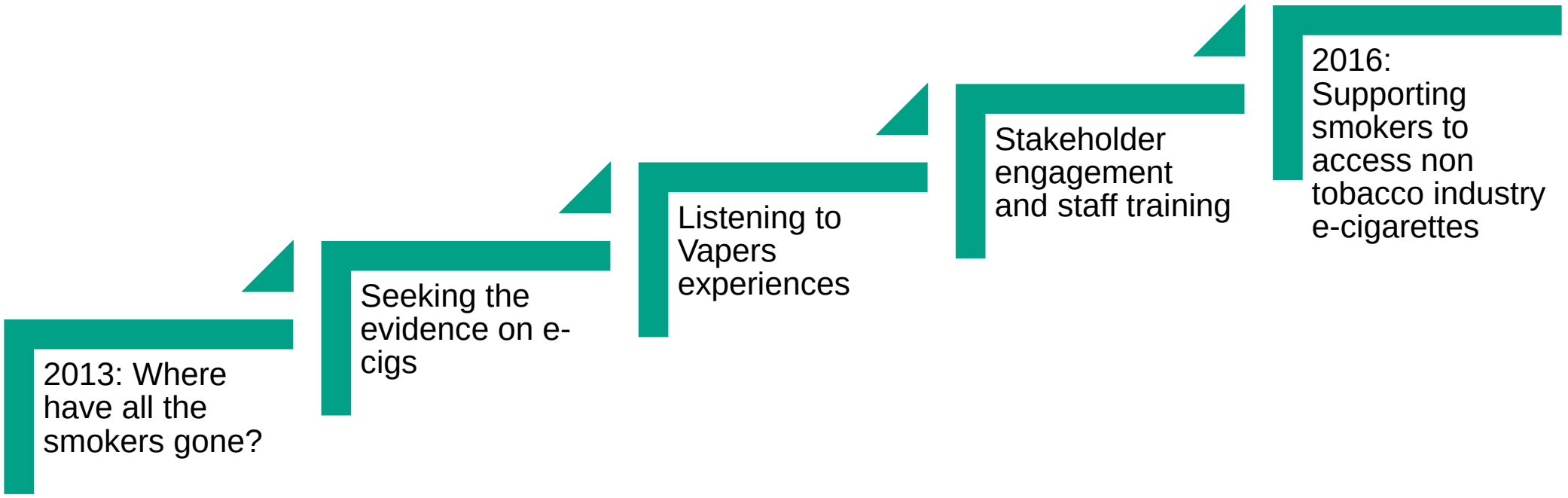
- **English Stop Smoking Services experience of e-cigarettes 2013 - 2021**
- **Nicotine and Flavours**
- **Advice on supporting 1st time e-cigarette users**

2013: E-cigs became the most popular quit aid in England



[E Cigarettes Latest Trends - Graphs - Smoking in England]

A journey to becoming an e-cig friendly stop smoking service



2013 - Listening to Vapers: Quitting was easy!

Other Vapers helped me get the right device

"I tried everything to quit and then I was given an e-cig and I just stopped smoking!"

It just worked!!

The e-cig just gave me everything I needed to quit smoking tobacco. Quitting felt great!

I was going to use it to help me cut down but 2 days later I had quit tobacco completely.

It took a bit of practising but so did smoking!

2021: E-cigarettes use in English Stop smoking services

- **Nearly 6% of clients** across all English stop smoking services make a quit attempt using an e-cigarette

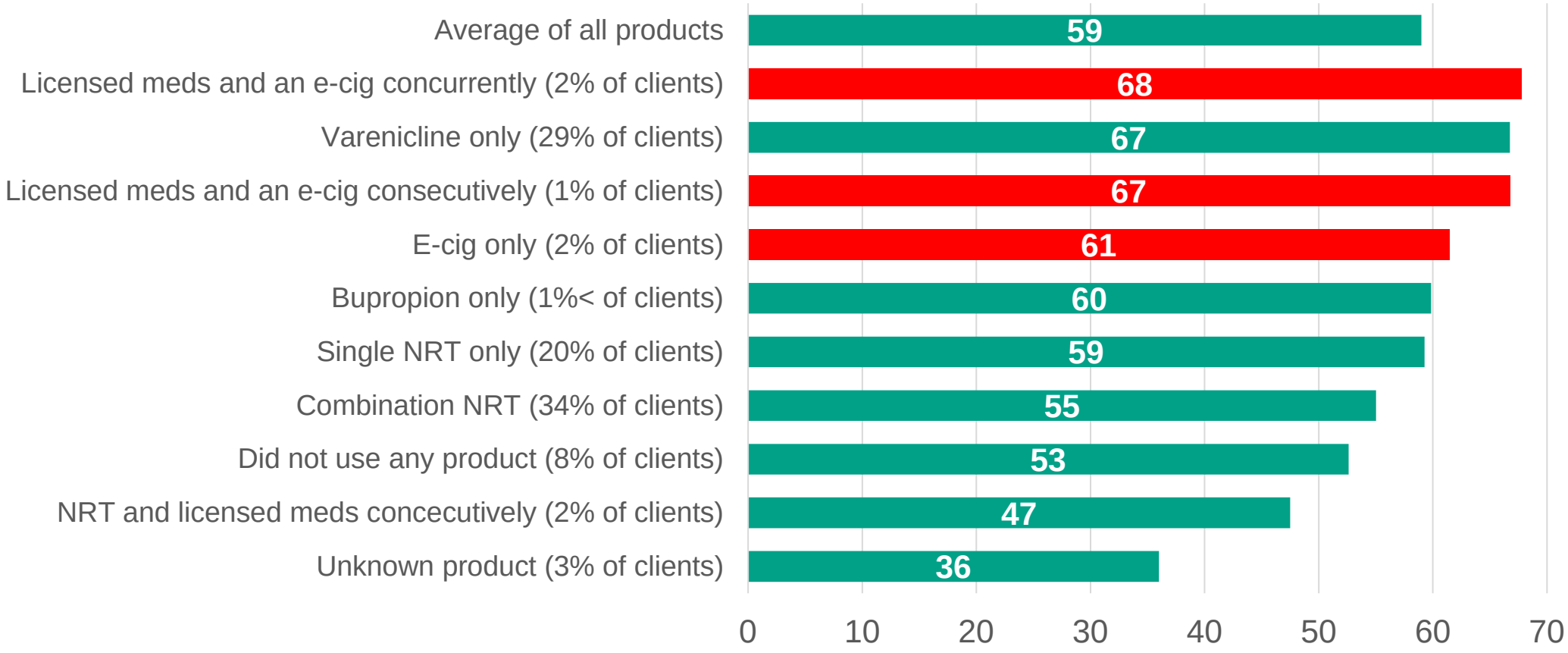
(concurrently or consecutively with other pharmacotherapy or as single product)

- E-cig use across individual services shows variation from **0% to 34% of users**

- Some services have models to support easier access to e-cigarettes and behavioural change support through voucher schemes or direct supply

2021: Pharmacotherapy success rates in stop smoking services

4-week self-reported quit success rates (%) in English Stop Smoking Services by pharmacotherapy type used (2020-21)



Supporting the use of E-cigarettes:

1st time Users

Nicotine and Flavours

Advice for 1st time e-cig users

1. **Start simple** – try a closed system
2. **Good nicotine level** – higher nicotine levels for more dependent smokers
3. **Encourage vapers to contact other vapers**

    - independent forms and community networks

    - vaping buddy

5. **Practice – vaping is different to smoking**. Suggest trying different inhalation styles, devices, VG/PG mix and to **remember that first cigarette!**

Vapers: Experts by Experience!

Nicotine levels in e-cigs: How much?

- Both smokers and vapers self titrate and can control their nicotine levels

- There are many factors that affect the nicotine absorbed when vaping e.g.
  - freebase nicotine or nicotine salts (salts = smoother, faster nicotine hit)
  - resistance level of atomiser (lower resistance = greater vaper and throat hit)
  - power of device (higher power = greater throat hit and nicotine levels)
  - vaping technique and frequency – Mouth To Lung and Direct Lung

- Higher tobacco nicotine dependency = higher nicotine mg/ ml to manage withdrawal

- Too low a nicotine level could result in compensatory, heavier vaping to manage withdrawal, with an associated increase in expedients

‘Real-world’ compensatory behaviour with low nicotine concentration e-liquid: subjective effects and nicotine, acrolein and formaldehyde exposure - Dawkins - 2018 - Addiction

Quitting with an E-cig: Using flavours

- Many clients switched to tobacco flavour initially then moved to other flavours
- Leaving tobacco flavour behind completely is often part of gaining a new identity as an Ex Smoker and supports relapse prevention
- Experimenting with flavours can be part of the quitting process

Julia Robson
Tobacco Control Programme Manager
Office for Health Improvement and Disparities
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Nicotine Vaping Products (NVP), the UK smoking cessation experience; practical tips for Australian prescribers

The latest Cochrane evidence

Jamie Hartmann-Boyce
Nuffield Department of Primary Care Health Sciences
University of Oxford, UK

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Cochrane Tobacco Addiction

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E-cigarettes for smoking cessation

The latest Cochrane evidence

Jamie Hartmann-Boyce*, Hayden McRobbie, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodoulou, Caitlin Notley, Nancy A Rigotti, Tari Turner, Ailsa Butler, Thomas Fanshawe, Peter Hajek

*Centre for Evidence-Based Medicine and Cochrane Tobacco Addiction Group, Nuffield Department of Primary Care Health Sciences, University of Oxford. Jamie.hartmann-boyce@phc.ox.ac.uk

October 2021

Funded by CANCER RESEARCH UK

Funded by NHS National Institute for Health Research

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Acknowledgements and funding

The work presented today has been supported by Cancer Research UK and the National Institute for Health Research (NIHR).

Within the past 3 years, I have received funding from Cancer Research UK, the NIHR, the British Heart Foundation, Cochrane, and the University of Oxford.

The views and opinions expressed therein are those of myself (and for the paper results, my co-authors) and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, National Health Service (NHS) or the Department of Health.

I have never received industry funding and have no conflicts of interest to declare.

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Our author team

About Cochrane

WHAT?

- Gathers and combines the best evidence from research to determine the benefits and risks of treatments/interventions

HOW?

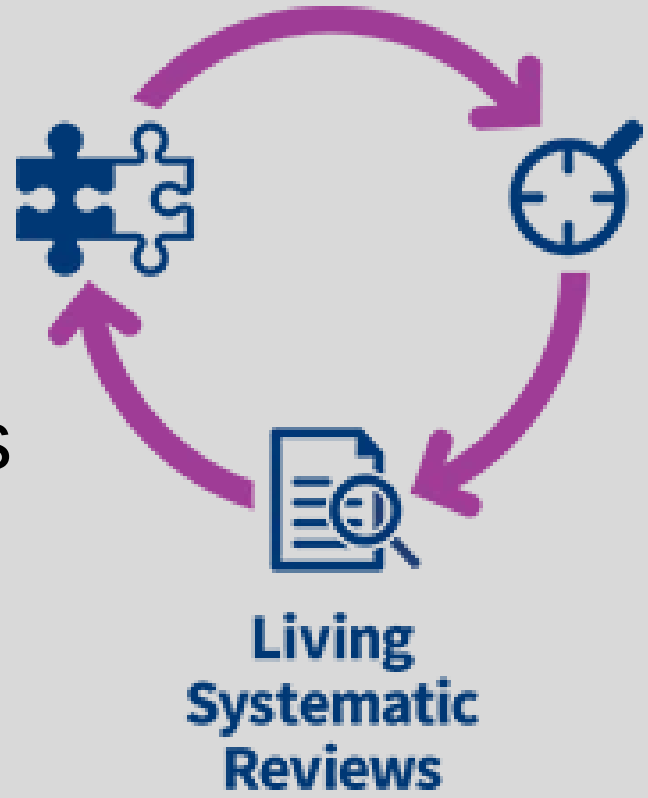
- By systematically reviewing the available evidence, with strong emphasis on quality assessment
- Cochrane methods considered gold-standard

WHY?

- To help healthcare providers, patients, carers, researchers, funders, policy makers, guideline developers improve their knowledge and make decisions

Living systematic review (LSR)

- Search for new evidence monthly
- Publish links to new evidence monthly
- Update full review when new data emerges that changes, strengthens, or weakens existing conclusions, or relates to new comparisons or outcomes



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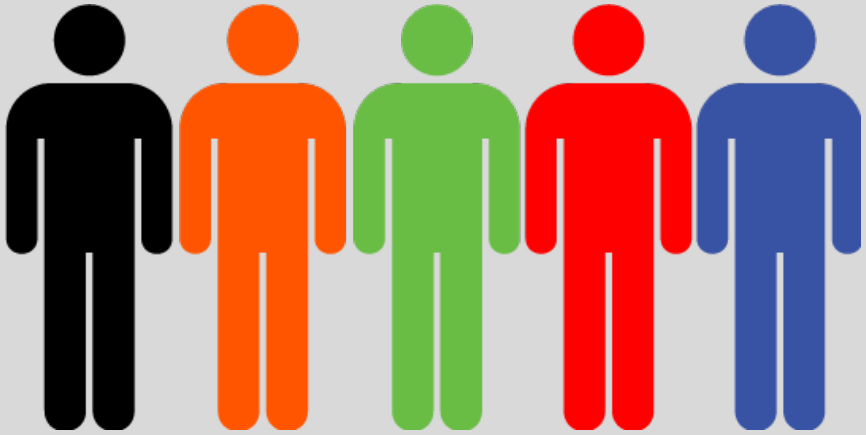
Also as part of the living systematic review project…

Review update published Sept 2021

Latest searches 1 May 2021

Sept 2021 update: included studies

- 61 studies in adults who smoke given an EC intervention (34 of which were RCTs)
- 16,759 participants



Primary comparisons

- Nicotine e-cigarette versus NRT
- Nicotine e-cigarette versus behavioural support only/no-support
- Nicotine e-cigarette versus non-nicotine e-cigarette

Outcomes

Cessation*	Adverse events (AE)*	Serious adverse events (SAE)*	Changes in relevant biomarkers	*new outcome* Product use
• 6 months+ • Intention to treat • Strictest definition of abstinence • Biochemically verified where available • (as per standard Cochrane methods)	• One week or longer of EC use • Defined as any undesirable experience associated with the use of a medical product in a patient	• One week or longer of EC use • Any AE where the patient outcome is death; life-threatening; hospitalization; disability; birth defect; or requires intervention to prevent any of the above	• One week or longer of EC use • Known carcinogens and toxicants • Exhaled carbon monoxide • Airway and lung function • Blood oxygen levels	• 6 months or longer • Proportion of participants still using assigned study product (EC or medication) at longest follow-up • Added as part of LSR process at request from multiple policymakers

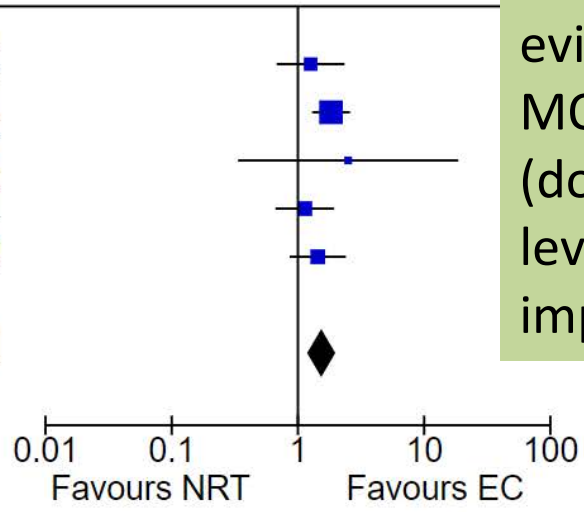
*primary outcome

Nicotine e-cigarette versus NRT:

Quitting at 6+ months

Study or Subgroup	EC Events	EC Total	NRT Events	NRT Total	Weight	Risk ratio M-H, Fixed, 95% CI
Bullen 2013	21	289	17	295	16.5%	1.26 [0.68 , 2.34]
Hajek 2019	79	438	44	446	42.8%	1.83 [1.30 , 2.58]
Lee 2018	5	20	1	10	1.3%	2.50 [0.34 , 18.63]
Russell 2021 (1)	34	140	15	70	19.6%	1.13 [0.66 , 1.94]
Russell 2021 (2)	44	145	15	71	19.8%	1.44 [0.86 , 2.40]
Total (95% CI)		**1032**		**892**	**100.0%**	**1.53 [1.21 , 1.93]**
Total events:	183		92			

Heterogeneity: Chi² = 2.90, df = 4 (P = 0.58); I² = 0%
Test for overall effect: Z = 3.60 (P = 0.0003)
Test for subgroup differences: Not applicable

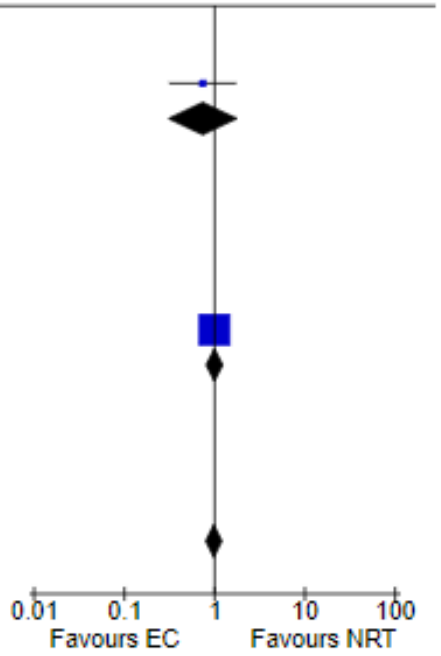


GRADE certainty of evidence: MODERATE (downgraded one level due to imprecision)

Footnotes
(1) FBNPs EC arm; control group split to avoid double-counting
(2) NSP EC arm; control group split to avoid double-counting

Nicotine e-cigarette versus NRT: Adverse events at 1+weeks

Study or Subgroup	Nicotine EC Events	Total	NRT Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.2.1 4 weeks						
Lee 2018 (1)	7	19	5	10	6.1%	0.74 [0.31 , 1.73]
Subtotal (95% CI)		**19**		**10**	**6.1%**	**0.74 [0.31 , 1.73]**
Total events:	7		5			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.70 (P = 0.48)						
1.2.2 6 months						
Bullen 2013	107	241	96	215	93.9%	0.99 [0.81 , 1.22]
Subtotal (95% CI)		**241**		**215**	**93.9%**	**0.99 [0.81 , 1.22]**
Total events:	107		96			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.05 (P = 0.96)						
Total (95% CI)		**260**		**225**	**100.0%**	**0.98 [0.80 , 1.19]**
Total events:	114		101			
Heterogeneity: $Chi^2 = 0.45$, df = 1 (P = 0.50); $I^2 = 0\%$						
Test for overall effect: Z = 0.21 (P = 0.83)						
Test for subgroup differences: $Chi^2 = 0.45$, df = 1 (P = 0.50), $I^2 = 0\%$						



Footnotes

(1) Data at 4 weeks post-operation; time from baseline not defined and likely to differ between participants

GRADE certainty of evidence: MODERATE (downgraded one level due to imprecision)

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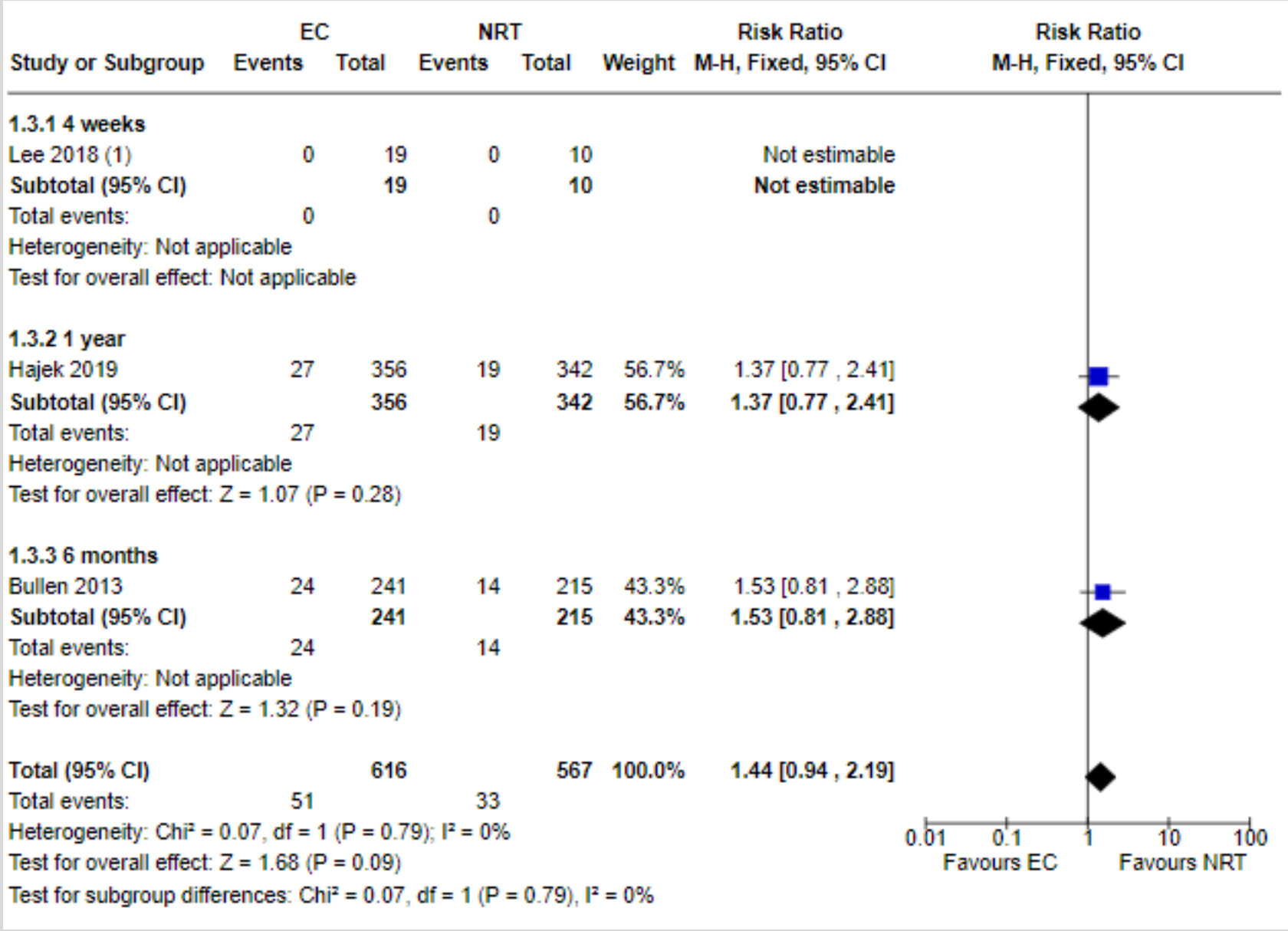
Nicotine e-cigarette versus NRT:

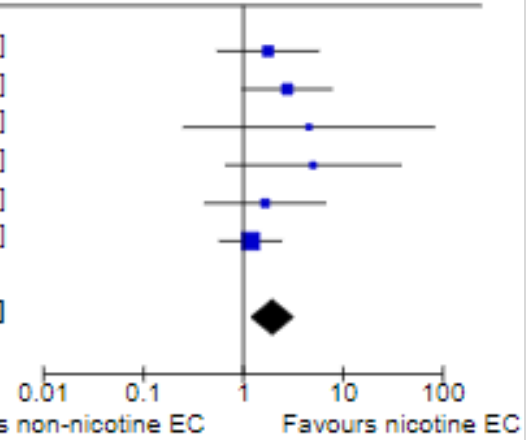
Serious adverse events at 1+weeks

GRADE certainty of evidence: LOW (downgraded two levels due to imprecision)



Nicotine e-cigarette versus non-nicotine e-cigarette: Quitting at 6+ months

Study or Subgroup	Nicotine EC Events	Total	Non-nicotine EC Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bullen 2013	21	289	3	73	18.3%	1.77 [0.54 , 5.77]
Caponnetto 2013a	22	200	4	100	20.4%	2.75 [0.97 , 7.76]
Cobb 2021 (1)	4	130	0	65	2.5%	4.53 [0.25 , 82.96]
Cobb 2021 (2)	10	130	1	65	5.1%	5.00 [0.65 , 38.22]
Eisenberg 2020	5	128	3	127	11.5%	1.65 [0.40 , 6.77]
Lucchiari 2020	13	70	11	70	42.1%	1.18 [0.57 , 2.46]
Total (95% CI)		**947**		**500**	**100.0%**	**1.94 [1.21 , 3.13]**
Total events:	75		22			



Heterogeneity: Chi² = 3.44, df = 5 (P = 0.63); I² = 0%
Test for overall effect: Z = 2.74 (P = 0.006)
Test for subgroup differences: Not applicable

Footnotes
(1) 8 mg/nl arm; control group split to avoid double-counting
(2) 36 mg/nl arm; control group split to avoid double-counting

GRADE certainty of evidence: MODERATE (downgraded one level due to imprecision)

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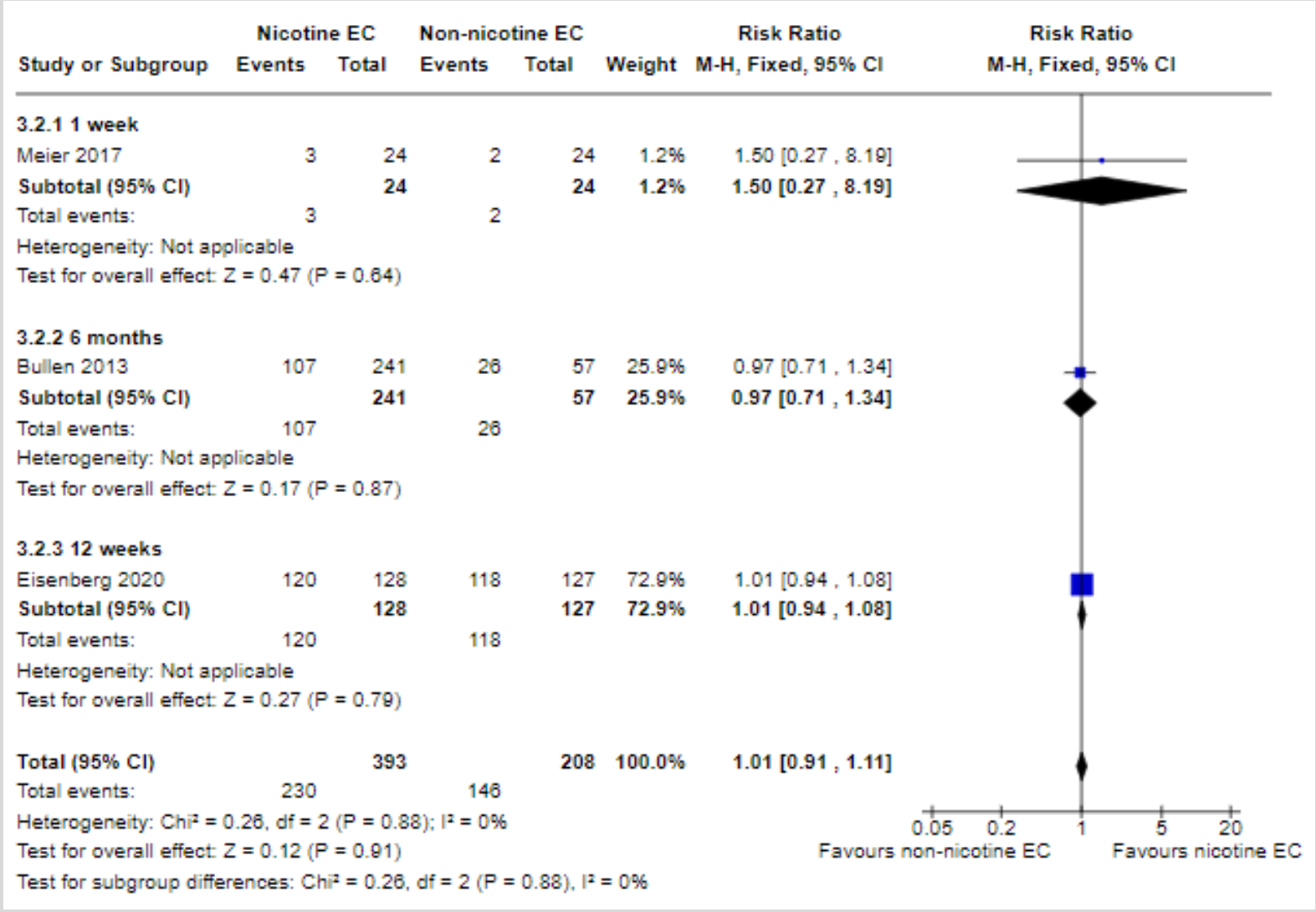
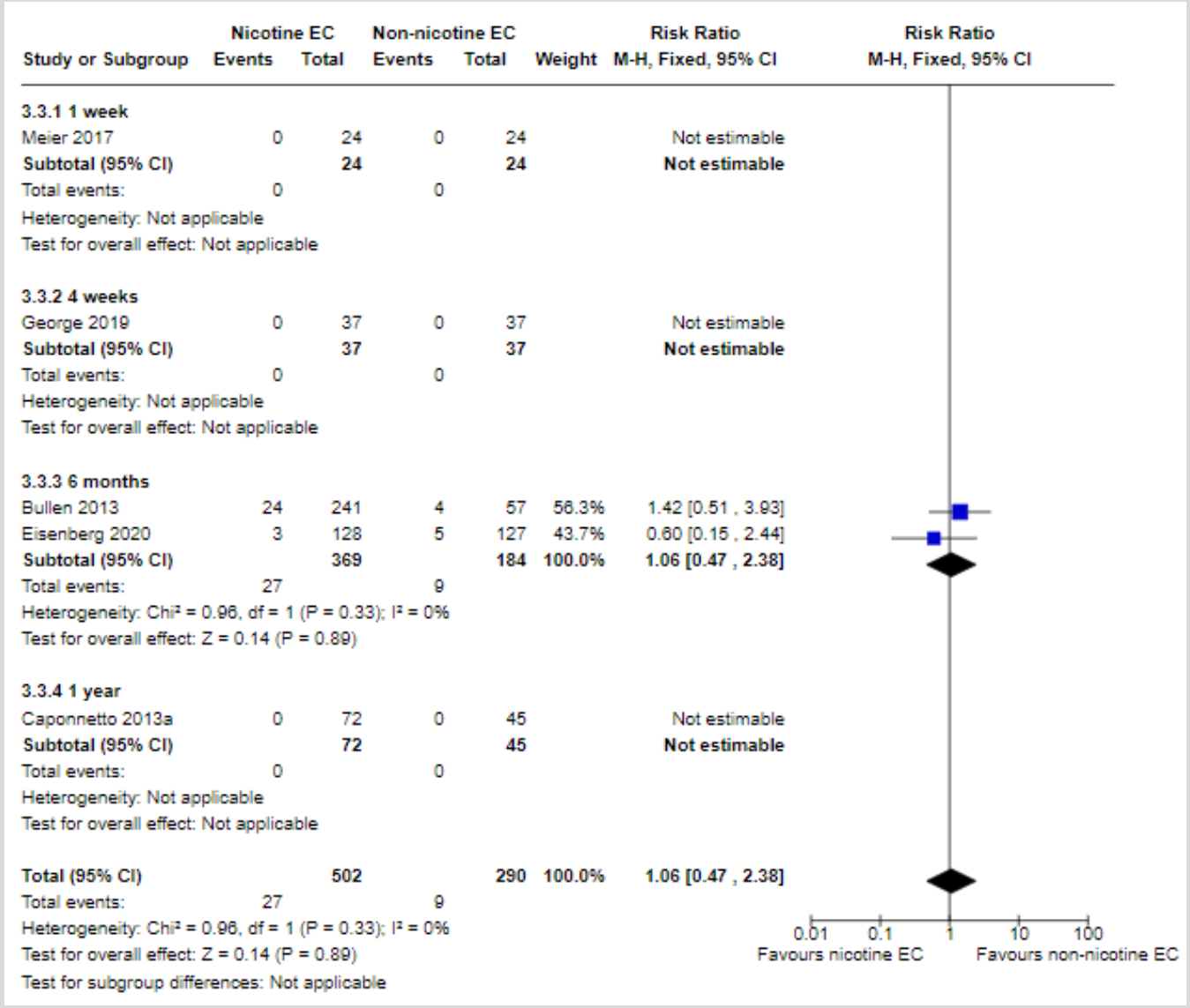
Nicotine e-cigarette versus non-nicotine e-cigarette: Adverse events at 1+ weeks

GRADE certainty of evidence: LOW (downgraded two levels due to imprecision)



Nicotine e-cigarette versus non-nicotine e-cigarette: Serious adverse events at 1+weeks

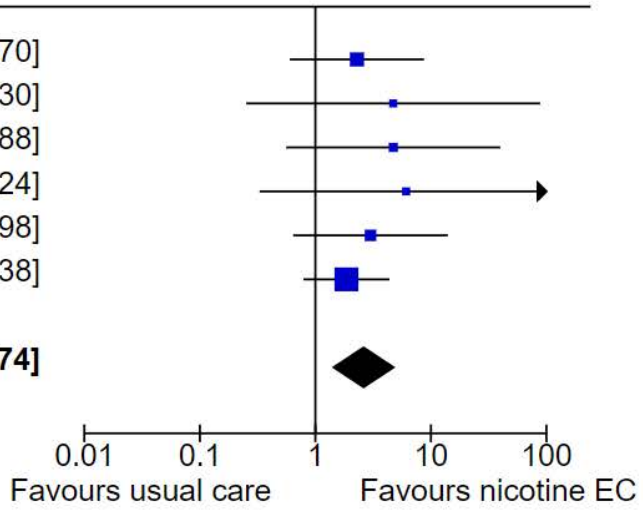
GRADE certainty of evidence: LOW (downgraded two levels due to imprecision)



Nicotine e-cigarette versus behavioural support only/no support: Quitting at 6+ months

Study or Subgroup	Nicotine EC Events	Total	Usual care Events	Total	Weight	Risk ratio M-H, Fixed, 95% CI
Begh 2021	7	164	3	161	21.2%	2.29 [0.60 , 8.70]
Dawkins 2020	3	48	0	32	4.2%	4.71 [0.25 , 88.30]
Eisenberg 2020	5	128	1	121	7.2%	4.73 [0.56 , 39.88]
Halpern 2018	4	1199	0	813	4.2%	6.11 [0.33 , 113.24]
Holliday 2019 (1)	6	40	2	40	14.0%	3.00 [0.64 , 13.98]
Lucchiari 2020	13	70	7	70	49.1%	1.86 [0.79 , 4.38]
Total (95% CI)		**1649**		**1237**	**100.0%**	**2.61 [1.44 , 4.74]**
Total events:	38		13			

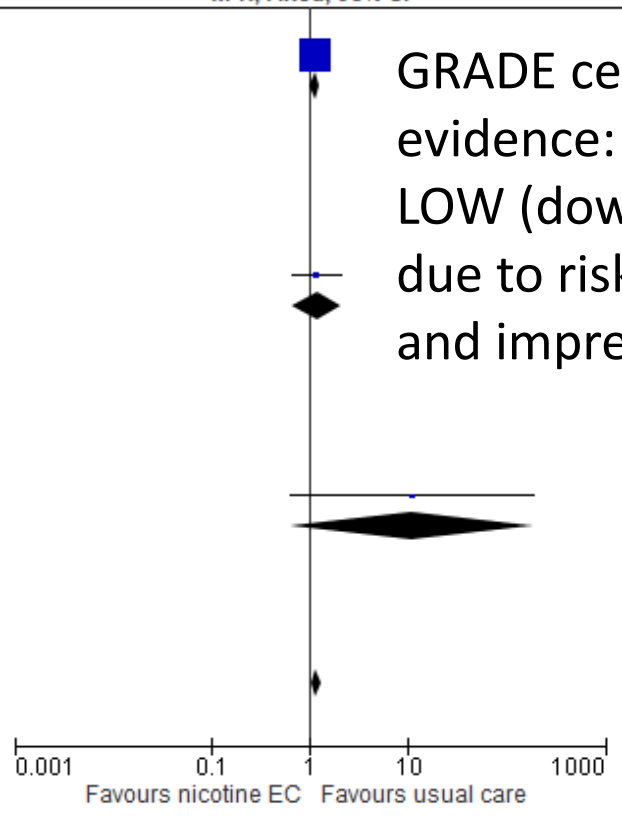
Heterogeneity: Chi² = 1.46, df = 5 (P = 0.92); I² = 0%
Test for overall effect: Z = 3.16 (P = 0.002)
Test for subgroup differences: Not applicable



GRADE certainty of evidence: VERY LOW (downgraded two levels due to risk of bias; one level due to imprecision)

Nicotine e-cigarette versus behavioural support only/no support: Adverse events at 1+weeks

Study or Subgroup	Nicotine EC Events	Total	Usual care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
4.2.1 12 weeks						
Walele 2018	271	306	80	102	91.3%	1.13 [1.01, 1.26]
Subtotal (95% CI)		**306**		**102**	**91.3%**	**1.13 [1.01, 1.26]**
Total events	271		80			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.18 (P = 0.03)						
4.2.2 16 weeks						
Carpenter 2017 (1)	20	34	8	16	8.3%	1.18 [0.67, 2.07]
Subtotal (95% CI)		**34**		**16**	**8.3%**	**1.18 [0.67, 2.07]**
Total events	20		8			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.56 (P = 0.57)						
4.2.3 6 months						
Holliday 2019 (2)	5	29	0	29	0.4%	11.00 [0.64, 190.26]
Subtotal (95% CI)		**29**		**29**	**0.4%**	**11.00 [0.64, 190.26]**
Total events	5		0			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.65 (P = 0.10)						
Total (95% CI)		**369**		**147**	**100.0%**	**1.17 [1.04, 1.31]**
Total events	296		88			
Heterogeneity: Chi² = 2.79, df = 2 (P = 0.25); I² = 28%						
Test for overall effect: Z = 2.71 (P = 0.007)						
Test for subgroup differences: Chi² = 2.46, df = 2 (P = 0.29), I² = 18.8%						



Footnotes

(1) 24mg EC arm included here; 16mg data reported elsewhere

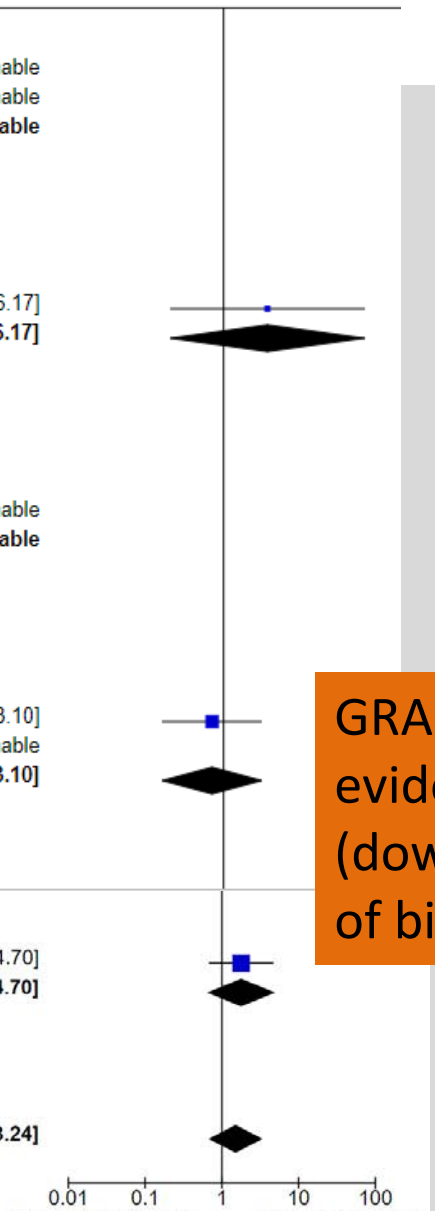
(2) Participants offered choice of nicotine or no-nicotine EC; all chose nicotine-containing EC

GRADE certainty of evidence: VERY LOW (downgraded due to risk of bias and imprecision)

Nicotine e-cigarette versus behavioural support only/no support:

Serious adverse events at 1+wks

Study or Subgroup	Nicotine EC Events	Nicotine EC Total	Usual care Events	Usual care Total	Weight	Risk Ratio M-H, Fixed, 95% CI
4.3.1 4 to 6 weeks						
George 2019	0	37	0	40		Not estimable
Pulvers 2020	0	115	0	54		Not estimable
Subtotal (95% CI)		**152**		**94**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
4.3.2 12 weeks						
Walele 2018	5	306	0	102	6.8%	3.69 [0.21 , 66.17]
Subtotal (95% CI)		**306**		**102**	**6.8%**	**3.69 [0.21 , 66.17]**
Total events:	5		0			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.89 (P = 0.38)						
4.3.3 16 weeks						
Carpenter 2017 (1)	0	34	0	16		Not estimable
Subtotal (95% CI)		**34**		**16**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
4.3.4 6 months						
Eisenberg 2020	3	128	4	121	37.6%	0.71 [0.16 , 3.10]
Holliday 2019 (2)	0	29	0	29		Not estimable
Subtotal (95% CI)		**157**		**150**	**37.6%**	**0.71 [0.16 , 3.10]**
Total events:	3		4			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.46 (P = 0.65)						
4.3.5 8 months						
Begh 2021	11	148	6	144	55.6%	1.78 [0.68 , 4.70]
Subtotal (95% CI)		**148**		**144**	**55.6%**	**1.78 [0.68 , 4.70]**
Total events:	11		6			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.17 (P = 0.24)						
Total (95% CI)		**797**		**506**	**100.0%**	**1.51 [0.70 , 3.24]**
Total events:	19		10			
Heterogeneity: Chi² = 1.49, df = 2 (P = 0.47); I² = 0%						
Test for overall effect: Z = 1.06 (P = 0.29)						
Test for subgroup differences: Chi² = 1.48, df = 2 (P = 0.48), I² = 0%						



GRADE certainty of evidence: VERY LOW (downgraded due to risk of bias and imprecision)

Comparisons between nicotine ECs

- Three trials provided data comparing **different doses of nicotine**; only Cobb 2021 (low risk of bias) looked at quit rates, which were higher in the 36 ml arm than 8ml, but the 95% CI included no difference (RR 2.50, 95% CI 0.80 to 7.77). No evidence re differences in safety outcomes.

- One study compared **nicotine salt and free-base nicotine** (Russell 2021, unclear risk of bias). Quit rates were similar between arms (RR 1.25, 95% CI 0.85 to 1.83). Safety outcomes were not reported.

Implications for practice

- Evidence suggesting nicotine EC can aid in smoking cessation is consistent across several comparisons. There was moderate certainty evidence, limited by imprecision, that EC with nicotine increased quit rates at six months or longer compared to non-nicotine EC and compared to NRT. There was very low certainty evidence that EC with nicotine increased quit rates compared to behavioural support only or no support.
- The effect of nicotine EC when added to NRT was unclear.
- None of the included studies (short- to mid-term, up to two years) detected serious adverse events considered possibly related to EC use.
- The most commonly reported adverse effects were throat/mouth irritation, headache, cough, and nausea, which tended to dissipate over time. In some studies, reductions in biomarkers were observed in people who smoked who switched to vaping consistent with reductions seen in smoking cessation.

See full review for

- More detail on everything that's been presented
- Secondary outcomes
- Other comparisons
- Data from uncontrolled studies
- Comparison with other reviews

Updates to and information on the living systematic review: https://www.cebm.ox.ac.uk/research/electronic-cigarettes-for-smoking-cessation-cochrane-living-systematic-review-1

Nicotine Vaping Products (NVP), the UK smoking cessation experience; practical tips for Australian prescribers

Professor Paul Aveyard
Professor of Behavioural Medicine
Nuffield Department of Primary Care Health Sciences
University of Oxford, UK

Website and link references | Nicotine Vaping Products (NVP)

Nicotine vaping products	https://www.tga.gov.au/nicotine-vaping-products
Information for prescribers	https://www.tga.gov.au/nicotine-vaping-products-information-prescribers
Frequently Asked Questions	https://www.tga.gov.au/nicotine-vaping-products-frequently-asked-questions
Guidance for use of NVP for smoking cessation	https://www.tga.gov.au/guidance-use-nicotine-vaping-products-smoking-cessation
New NVP users	https://www.tga.gov.au/sites/default/files/nicotine-vaping-products-flow-chart-university-wollongong.pdf

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