

# Regulating E-Cigarettes

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## Health harm

- E-cigarettes deliver lower levels of carcinogens than cigarettes
- expose users to high levels of ultrafine particles and other toxins
- may increase cardiovascular and non-cancer lung disease risks - account for more than half of all smoking-caused deaths
- e-cigarettes are reducing smoking cessation rates
- increasing the nicotine market by attracting youth (Glantz et al, 2018)



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## Safety of e-cigarettes

- Responsibility for demonstrating safety or harm has fallen on the health sector
- E-cigarettes came to market without any good data showing effect on smoking cessation
- Sold on concept of “Harm reduction”



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## Registration of e-cigarettes

- Not tobacco products so do not fall under Tobacco Products Control Act
- Medicines and Related Substances Act of 1965 (“Medicines Act”), nicotine-containing e-cigarettes that are sold as a substitute for tobacco products (or as a medicinal aid to quit smoking) must be registered with the Medicines Control Council for lawful sale, and may only be sold in pharmacies, on prescription.



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# A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy

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**Table 2. Abstinence Rates at Different Time Points and Smoking Reduction at 52 Weeks.\***

Outcome	E-Cigarettes (N = 438)	Nicotine Replacement (N = 446)	Primary Analysis: Relative Risk (95% CI) <sup>†</sup>	Sensitivity Analysis: Adjusted Relative Risk (95% CI)
Primary outcome: abstinence at 52 wk — no. (%)	79 (18.0)	44 (9.9)	1.83 (1.30–2.58)	1.75 (1.24–2.46) <sup>‡</sup>
Secondary outcomes				
Abstinence between wk 26 and wk 52 — no. (%)	93 (21.2)	53 (11.9)	1.79 (1.32–2.44)	1.82 (1.34–2.47) <sup>§</sup>
Abstinence at 4 wk after target quit date — no. (%)	192 (43.8)	134 (30.0)	1.45 (1.22–1.74)	1.43 (1.20–1.71) <sup>¶</sup>
Abstinence at 26 wk after target quit date — no. (%)	155 (35.4)	112 (25.1)	1.40 (1.14–1.72)	1.36 (1.15–1.67) <sup>‡</sup>
Carbon monoxide–validated reduction in smoking of ≥50% in participants without abstinence between wk 26 and wk 52 — no./total no. (%)	44/345 (12.8)	29/393 (7.4)	1.75 (1.12–2.72)	1.73 (1.11–2.69) <sup>  </sup>



## Efficacy of e-cigarettes as a quit tool

- Among participants with 1-year abstinence:
  - 80% (63 of 79) were using e-cigarettes at 52 weeks in the e-cigarette group
  - 9% (4 of 44) were using nicotine replacement in the nicotine replacement group



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# Public health organisations statements

- A 2016 European Public Health Association statement “The health risks associated with e-cigarettes remain uncertain, but they cannot be considered safe. What is certain is that statements that they are some percentage safer than conventional cigarettes are so far unjustified”.



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## Public health organisation statements

- The European Respiratory Society (2019) treats e-cigarettes exactly the same as cigarettes
- Recommends they are not used
- Apply the same membership restrictions regarding conflicts of interest for e-cigarettes as for cigarettes



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## Public health organisation statements on e-cigarettes

- Lancet 2019: No e-cigarettes have been tested or launched as smoking cessation products;
- All sold directly to the consumer as tobacco, not medicinal, products.
- No solid evidence base supports marketing claims that e-cigarettes are healthier than cigarettes or that they can support quitting
- Lax regulation has allowed e-cigarette manufacturers to position e-cigarettes as healthy



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## WHO statement on e-cigarettes, 2014

- Health risks evident for both users and non-users
- Efficacy as a quit tool not certain
- Interferes with existing tobacco control efforts and undermines the implementation of the FCTC



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## Areas of concern

- Nicotine is a highly addictive substance
- Gateway for adolescents to tobacco products
- Contain propylene glycol - known irritant when inhaled. 2018 study with mice shows severe health impact even when non-nicotine products are used
- Poorly regulated
- No convincing evidence for smoking cessation
- **Other safer and researched smoking cessation options are available**



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## E-cigarette regulation globally

- 98 countries with national/federal laws regulating e-cigarettes including laws related to
- Sale (including minimum age)
- advertising, promotion, sponsorship, packaging (child safety packaging
- health warning labeling and trademark)
- product regulation (nicotine volume/concentration, safety/hygiene, ingredients/flavors)
- reporting/notification
- classification of e-cigarettes
- use (vape-free) and taxation ([www.globaltobaccocontrol.org](http://www.globaltobaccocontrol.org))



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## Draft Tobacco Bill

- Proposes regulation exactly as cigarettes are regulated
- Marketing
- Ban on indoor public use
- Graphic health warnings
- Plain packaging



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