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Risk versus regulation: an update on the state of e-cigarette control in Australia

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Abstract

E-cigarettes are increasingly common around the world, particularly among youth. Ingestion of nicotine-containing e-liquid, while relatively rare, is the major toxicological risk associated with their use. Current Australian regulation has nicotine for use in e-cigarettes listed as a dangerous poison in Schedule 7, with its supply or sale illegal in all states and territories, while regulation on the sale of e-cigarettes and accessories varies by state. However, with increasing evidence that e-cigarettes produce far fewer toxic by-products than their combustible counterparts perhaps it is time to review this regulation.

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Risk versus regulation: an update on the state of e-cigarette control in Australia

Jody Morgan, Andreas Breitbarth and Alison Jones

Electronic cigarettes, more commonly referred to as e-cigarettes or “vape pens”, work by heating a liquid, which often contains nicotine, to form a vapour that can be inhaled into the lungs in a process colloquially referred to as ‘vaping’. E-cigarette awareness and use has grown rapidly since its development in 2003, expanding into the global market with United States (US) retail sales expected to approach \$10 billion by 2017;¹ presenting a challenge for tobacco regulatory bodies and health departments.

Where do the risks lie?

From a toxicological perspective the key potential area of risk associated with the use of e-cigarettes is the nicotine-containing e-liquid which poses a risk of accidental nicotine ingestion, particularly by children. Oral ingestion of nicotine e-cigarette fluid has been noted in numerous attempted suicides² and was the method of at least two documented successful suicides, with an additional suicide following intravenous injection of e-liquid (**Table 1**). There has also been at least one reported death following accidental ingestion of nicotine e-liquid in a 15-month old.³ The child ingested 5 ml (50 mg) of liquid nicotine and despite immediately vomiting the patient developed cardiopulmonary arrest and hypoxic brain damage.³ The lethal adult oral dose of nicotine is often quoted as 30-60 mg (corresponding to an oral LD₅₀ of around 0.8 mg/kg), however, a 2014 paper by Mayer states that this dose is based upon dubious 19th-century data and should be revisited with more recent overdose survival data suggesting the lethal dose of oral nicotine is more than 0.5 g or an LD₅₀ of 6.5 mg/kg.⁴ There are also two cases in the literature detailing burns caused by the spontaneous explosion of the battery in e-cigarettes.²

In contrast, there are several reported benefits associated with the use of e-cigarettes. General consensus is that e-cigarettes are less harmful than traditional cigarettes, largely due to the absence of combustion and therefore no inhalation of the carcinogens associated with tars.¹ Analysis of e-cigarette vapour has found that while toxicants are present, they are orders of magnitude lower than the levels found in combustible cigarettes.⁸ A cross-sectional study found that long-term (>6 months) e-cigarette-only users had substantially reduced exposure to carcinogens compared with combustible cigarette users and dual users.⁸ While there are no studies that can unequivocally state that e-cigarettes are entirely free from risk, there are many that determine they are less harmful than combustible cigarettes and thus provide a possible alternative to combustible cigarettes, with particular focus upon their use as a harm minimisation tool to aid current combustible cigarette smokers wishing to quit.⁹

One of the most controversial issues relating to the use of e-cigarettes is their role in the initiation of smoking among teens, particularly as experimentation with e-cigarettes without a prior history of smoking is rare among adults but increasingly common among youth.¹ Statistics suggest that e-cigarette use among youth is on the increase, particularly in countries where e-cigarette regulation is less stringent than Australia, with rates of e-cigarette ever-use (18.5%) in Wales among high school (age 11-16) students now higher than that of combustible cigarette ever-use (10.5%).¹⁰ This can be compared with the 7.1% of Australian youth (age 12-17) that have used e-cigarettes.⁹ Wolfenden et al stated that meta-analyses of current research suggests that youth who use e-cigarettes are two to five times more likely to subsequently take up combustible cigarettes.⁹ However, as pointed out in a recent review of youth e-cigarette use by Gartner (2017) it is difficult from these studies to determine how many of these students would have taken up use of traditional cigarettes regardless of their e-cigarette usage and a large number of these studies took place in countries with little regulation upon the sale of e-cigarettes to users under 18 years of age.¹¹ Additional research is required to determine

if there is a definitive causation between youth e-cigarette smoking as a pathway to combustible cigarettes.

Current state of regulation

The World Health Organisation has recommended that e-cigarettes be regulated in the same way as tobacco products. However regulation varies greatly between countries.¹² In Australia, the current state of regulation for e-cigarettes is complex,¹³ with Federal scheduling of nicotine, dependant on its intended use, and State-controlled regulation of the sale of e-cigarette devices and accessories.

Nicotine in traditional cigarettes and some smoking cessation devices, including gums, transdermal patches and mouth sprays are currently exempt from scheduling under Australian law.¹⁴ However, nicotine for use in e-cigarettes is currently in Schedule 7, listed as a dangerous poison. As such, the sale or supply of nicotine for use in e-cigarettes is currently illegal in all Australian states and territories. Interestingly, analysis of several nicotine-free e-cigarette liquids, currently available for sale through tobacco stores, have been shown to contain nicotine, contravening the current laws.¹⁵

While nicotine containing e-liquids are illegal in all states and territories other regulations vary significantly by state. The various regulations imposed by the states are summarised in **Table 2**. Of particular interest is the fact that in Queensland it is illegal to be in possession of e-liquid containing fluid¹⁶ and in Western Australia it is illegal to purchase an e-cigarette but not illegal to use one.¹⁷

A survey of Australian e-cigarette users back in 2015 showed that 89% of users purchased their e-cigarettes, accessories and refill solutions mostly from online stores.¹² In all Australian states and territories, except Queensland, Australians are able to legally import e-cigarette liquids containing nicotine, provided they have a prescription from an Australian registered medical practitioner, for use as an unapproved therapeutic via the TGA's personal importation scheme.¹² The importer can only

import a maximum of 3 months' supply at any one time with the total quantity imported in a 12-month period not allowed to exceed 15 months' at the maximum recommended dose. Individuals in Queensland are unable to take advantage of this system due to regulations imposed prohibiting the possession of any e-liquid containing nicotine with or without a prescription.

For those not wishing to import their nicotine-containing e-liquids there are now several Australian-based online websites which provide individuals with both a prescription and product formulation via a compounding pharmacy. The ordering process through all of these sites is similar: 1) register on the website; 2) complete a questionnaire detailing smoking and medical history, including previous attempts to quit; 3) a doctor will review the questionnaire and write a prescription for nicotine; 4) the compounding pharmacy will prepare the nicotine according to the prescription; 5) the product will then be delivered. Some of these compounding pharmacies will also allow individuals to bring their own prescription from their personal practitioner. These compounding pharmacies have a variety of flavours and strengths available and while they are more expensive than equivalent products ordered from overseas they are still significantly cheaper than combustible cigarettes.

The price of combustible cigarettes in Australia is ever-increasing, with the most recent tax price rise in September 2017 adding an extra 13% to the tobacco excise. The average pack-a-day smoker now spends in excess of \$12,000 a year on cigarettes. In contrast, the average ex-pack-a-day vaper consumes 3 – 5 ml of nicotine-containing e-liquid per day. While the prices of e-liquid vary significantly by source and flavour option (\$5.60 - \$24.99 per 30 ml), even taking the upper end of this scale with 5 ml of consumption per day the annual cost would be approximately \$1500 per year, a saving of more than \$10,000 a year.

The most recent appeal to the TGA in Australia to change the scheduling of nicotine for use in e-cigarettes was rejected in March 2017 despite the fact that precautions, including: a maximum of 900

mg of nicotine per container; a nicotine concentration of less than 3.6%; and ensuring all containers were made with child-resistant packaging, would have gone a long way to reconciling most of the risks outlined above. Overseas importers and compounding pharmacies, currently providing nicotine-containing e-liquids, do not have to abide by these suggested regulations, with high concentrations available and no specific requirement for child proof packaging which has the potential to lead to a higher number of toxic ingestions of nicotine, particularly among children.

E-cigarettes have been shown to generate fewer toxic products than combustible cigarettes, providing a useful tool for adults already addicted to nicotine. Future changes to regulation need to protect Australian youth from possible risks associated with e-cigarettes as a possible pathway to combustible cigarettes. Regulations also need to ensure that children are protected from risk of nicotine overdose with focus on appropriate packaging and low (<3.6%) nicotine concentrations. We believe that nicotine-containing e-liquids should be regulated as a medical product which will allow a high level of quality control for nicotine concentration as well as appropriate packaging with usage specifically targeted at current and ex-combustible cigarette smokers.

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Table 1: Summary of literature case reports of fatal intoxications with nicotine sourced from e-liquids.

Ref.	Patient	E-liquid Consumed	Outcome
⁵	34 yr old male; suicide	Oral consumption ~150 ml of 72 mg/ml nicotine concentrate	Death; Medical autopsy found significant nicotine concentrations in femoral blood (5 mg/L) and gastric contents (3,950 mg)
⁶	24 yr old female; suicide	Oral consumption ~30 ml of 100 mg/ml nicotine concentrate	Cardiac arrest and anoxic brain injury; plasma nicotine concentration >1 mg/L; death 3 days post-ingestion
⁷	29 yr old male; suicide	Intravenous injection with e-cig refill fluid (no volume/concentration data provided)	Ventricular fibrillation, tonic-clonic seizures, anoxic encephalopathy; Serum nicotine concentration 2 mg/L; death 5 days post-injection
³	15 month old female; accidental ingestion	Oral consumption ~5 ml of 10 mg/ml nicotine e-cig refill fluid	Cardiac arrest and anoxic brain injury; severe cerebral oedema; no nicotine concentrations published; death 44 days post-ingestion

Table 2: E-cigarette regulations across the Australian states and territories as of May 2018. **✗** = use/possession illegal under the conditions listed; **✓** = use/possession legal under the conditions listed; **?** = No current legislation in place; **?✓** OR **?✗** = Legislation proposed but not yet passed through parliament; *while it is currently legal to use e-cigarettes in public places in NSW this will change on 1 July 2018 to more closely align with the majority of the other states and territories.

	NSW ¹⁵	VIC ¹⁸	QLD ¹⁶	TAS ¹⁹	SA ²⁰	WA ¹⁷	NT ²¹	ACT ²²
Sale of nicotine-containing e-liquids legal without prescription	✗	✗	✗	✗	✗	✗	✗	✗
Sale of nicotine containing e-liquids legal with a prescription	✓	✓	✗	✓	✓	✓	✓	✓
Sale of non-nicotine containing e-liquids legal	✓	✓	✓	?✓	?✓	✓	?	✓
Sale of e-cigarette style devices is legal	✓	✓	✓	?✓	?✓	✗	?	✓
E-cigarette/e-liquid sale incorporated in states' tobacco legislation	✓	✓	✓	✓	?✓	✓	?	✓
E-cigarette use permitted in public locations	✓*	✗	✗	✗	?✗	✓	✓	✗