A critique of 'E-cigarettes linked to severe lung illness'

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A critique of 'E-cigarettes linked to severe lung illness'

> **'All Australian governments are united in maintaining <u>a precautionary approach</u> to the marketing and use of e-cigarettes'**

Response

The precautionary principle holds that if there are uncertainties about a new product it is best to delay introduction until those concerns are resolved. It requires a *full risk assessment* of the potential consequences of BOTH adopting and rejecting the new product

In the case of vaping, the harms from withholding vaping (and denying smokers a safer alternative) are far greater than harms of introducing it (potential long-term risk, uptake by young people).

Being cautious to prevent harm sounds like a virtuous approach but in this case it will actually increase harm. Although there are uncertainties about the long-term risks of vaping, the risks of NOT adopting vaping are much greater, as cigarettes are substantially more harmful. (UK House of Commons Science and Technology Committee report)

This application of the precautionary principle for vaping demands a much higher standard of proof of safety than we apply to other products. If we applied this standard in other areas, no new medicines would be introduced until we had long-term safety data after 20-30 years of use. However, the evidence will never be available until products are released onto the market.

In practice, we do not wait for decades for absolute certainty before introducing new products. We make decisions on the weight of evidence. According to the evidence available, the risks of delaying vaping outweigh the risks of introducing it.

According to the eminent English epidemiologist Sir Austin Bradford Hill, 'All scientific work is incomplete - whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, to postpone action that it appears to demand at a given time.'

> **'There is growing evidence implicating e-cigarettes in a range of harms to individual and population health'.**

Response

Vaping is not harmless. Nothing is. However, the overwhelming scientific evidence is that it is much less harmful than smoking. Comprehensive reviews by Public Health England and the UK Royal College of Physicians have concluded that vaping is unlikely to be more than 5% of the risk of smoking. While there is evidence of changes in cell and in animal studies, there is little evidence of significant harms in humans.

Vaping is a harm reduction strategy. It aims to reduce (not eliminate) harm for smokers who cannot quit by substituting a lower-risk product for combustible tobacco. THR is a complementary strategy to existing tobacco control strategies and is one of the three pillars of the Australian National Tobacco Strategy.

According to the US National Academies of Sciences, Engineering and Medicine (NASEM), 'There is substantial evidence that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems'. (Conclusion 18.2)

> **'E-cigarettes are relatively new products and the long-term safety and health effects associated with their use are unknown.'**

Response

The precise long-term health effects of vaping have yet to be established. However, based on current knowledge of the ingredients of vapour, the risk is certain to be much less than smoking. Vaping nicotine has been in widespread use for around ten years and currently around 45 million people vape. There have been so far no documented serious health effects from vaping nicotine and no deaths.

According to the UK Royal College of Physicians, 'the hazard to health arising from **long-term** vapour inhalation from the e-cigarettes available today is unlikely to exceed 5% of the harm from smoking tobacco'.

Like all new products it will probably be more than 30 years before the exact risks of vaping are known. This means that we must make judgements now based on the known constituents of the vapour, taking into account both the dose and toxicity of the chemicals. We have more than enough information now to make that decision.

The requirement for evidence of long-term safety is not applied to other consumer goods or medicines. There is no reason why a much higher standard should apply to vaping.

Some harm from sustained exposure to low levels of toxins over many years may yet emerge, but the magnitude of these risks relative to those of sustained tobacco smoking is likely to be small. (RCP p79)

> **'Health effects associated with and exposure to secondhand vapour are unknown'**

Response

The risk from exposure to second-hand vapour is likely to be minimal. Concentrations of chemicals are extremely low and the liquid droplets evaporate quickly. The review by Public Heath England concludes ''ENDS release negligible levels of nicotine into ambient air with no identified health risks to bystanders'. The UK Royal College of Physicians concludes 'There is, so far, no direct evidence that such passive exposure is likely to cause significant harm.' (p84)

> **'International evidence is emerging of a possible link between the use of e-cigarettes and lung disease. This includes severe lung disease requiring intensive care support and, as at 11 September 2019, at least six fatalities being linked with vaping in the United States. No single substance or product has been consistently associated with illness, although many patients have reported use of cannabinoids, such as tetrahydrocannabinol (THC).'**

Response

The outbreak of clusters of an acute respiratory illness in the US since June 2019 has affected 380 people (confirmed and probable cases) and caused six deaths as of 12 September 2019. The pattern of this outbreak is typical of what occurs when a bad batch of illegal drugs hits the streets.

The investigation is ongoing, but it is increasingly clear that the outbreak is due to illicit street drugs and has nothing to do with vaping nicotine products from reputable suppliers. Not one case has been linked to nicotine vaping.

Where a cause has been identified, almost all cases are linked to THC liquid contaminated with vitamin E acetate. This oily thickening agent has recently started to be used by black market suppliers, mostly in states where THC is illegal.

Many cases are described as lipoid pneumonia or pneumonitis, which is consistent with the inhalation of oil-based liquid into the lungs. Nicotine e-liquid is alcohol-based and does not contain oily ingredients.

The statement from the Australian health authorities uses the terms 'e-cigarettes and vaping' which imply vaping nicotine as a substitute for smoking and is very misleading and incorrect.

According to the US Food and Drug Administration (FDA) on 13 September 2019, '**Many of the samples tested by states or by the FDA as part of this ongoing investigation have been identified as vaping products containing THC, and further, most of those samples with THC tested also contained significant amounts of vitamin E acetate'**.

In a case series of 53 patients published in the New England Journal of Medicine, 84% of cases had used THC. In regard to the other cases, the authors say 'patients may be reluctant to report illicit drug use.' In Wisconsin, the Department of Health Services said that 24 of the 27 individuals with confirmed lung injuries in the state reported vaping oil with THC. In California, 21 of 21 cases were linked to vaping illicit THC oil. The New Mexico Department of Health reported that 8 out of 8 cases were confirmed to be associated with THC oil. The most recent cases were this week in Georgia and all 3 patients had vaped with THC.

A commentary in the British Medical Journal reported that The New York State Department of Health found 'very high vitamin E acetate levels in all cannabis samples analysed' and 'at least one vape product containing vitamin E acetate has been linked to each patient who submitted a product for testing.

Former Director of the Food and Drug Administration Dr Scott Gottlieb stated recently 'the current belief is the illnesses are linked to **illegal vapes containing vitamin E oil** — used as an emulsifying agent and dangerous when inhaled.'

According to Professor Peter Hajek, from Queen Mary University of London, 'The mystery seems to have been resolved now, with cases being traced to a **contaminated marijuana extract**. Although the scare is being used to put smokers off switching from cigarettes to much less risky vaping, it has nothing to do with e-cigarettes as they are normally used in this country'.

Some illegal operators using this ingredient to make THC oils have now been arrested. Companies that market and sell vitamin E acetate oil as a thickening agent are being subpoenaed, for example by the New York Department of Health.

Leading researcher Dr Konstantinos Farsalinos explains from an epidemiological perspective why the outbreak is extremely unlikely to be caused by conventional nicotine vaping. These cases are acute, within a short period of time, in a specific geographical region, in a specific age group and have never occurred previously in vapers. There are about 45 million vapers worldwide.

Vaping nicotine liquid is not without risk, but it has never been linked to any serious respiratory harm according to a recent comprehensive review. The review by NASEM concluded 'There is no available evidence whether or not e-cigarettes cause respiratory diseases in humans'. (Conclusion 1.1)

'At a population level, there continues to be insufficient evidence to promote the use of e-cigarettes for smoking cessation'

Response

Studies in the US and England have found a significant benefit from vaping at the population level. Smokers who use vaping to quit have significantly higher quit rates than those who do not. (Zhu; Johnson; Beard; Jackson) Quit attempts and quit rates have been increasing since vaping became popular.

An English study of 19,000 smokers compared the real-world effectiveness of quitting aids used in the most recent quit attempt. (Jackson) Those who used vaping devices had the highest quit rate compared to all other treatments including varenicline and nicotine replacement products.

A US study of nearly 23,000 smokers also found that those who used a vaping device were 73% more likely to quit than non-users (8.2% v 4.8%) and were also more likely to make a quit attempt. (Zhu) Similar results were found in a study of 60,000 25-45-year-olds in the US: smokers who were vaping were 65% more likely to have quit smoking in the last 12 months than smokers who were not. (Johnson)

Furthermore, in countries that allow vaping, increased vaping is increasing population quit rates. The decline in smoking in the United States and United Kingdom, for example, has accelerated over the period that vaping has become widespread. Given that vaping is widely used and can be effective it is likely to be contributing to this rapid decline although it is not possible to prove cause and effect from time trends in prevalence.

Furthermore, several modelling studies (Levy; Warner; Cherng; NASEM) concluded that allowing e-cigarettes to be regulated as consumer goods produced a net public health benefit. Only one such study found no benefit. (Soneji).

'Unlike any e cigarette product, all smoking cessation products lawfully available for sale in Australia have been evaluated for safety and efficacy and have been registered with the Therapeutic Goods Administration (TGA). To date, the TGA has not approved any e-cigarette product as a therapeutic good to help smokers quit.'

Response

TGA regulation is not appropriate for vaping products. Vaporisers are consumer goods used almost exclusively as a less harmful substitute by smokers who can't quit smoking or nicotine. Vaping should be regulated by the ACCC under consumer law. The ACCC ensures that consumer products are safe, fit for purpose and comply with all legal requirements. Vaporisers do not make therapeutic claims and should not fall under TGA jurisdiction.

It does not make sense to require the highest standards of research and quality for nicotine vaporisers when they are replacing a far more harmful product, lethal cigarettes.

Not a single vaping product globally has been assessed by a national regulator and gone to market in any country.

The practical outcome of TGA regulation would be the decimation of the vaping market. Every device and e-liquid and every future modification would require a detailed, costly and onerous application that only tobacco companies could afford. Most small to medium companies would be driven out of business.

'The liquids used in e-cigarettes can contain nicotine, but also flavourings and harmful substances such as heavy metals, volatile organic compounds and cancer-causing chemicals.'

Response

There are low doses of chemicals in vapour. However, the risk to human health is determined by the dose of the exposure. According to Public Health England

- the constituents of cigarette smoke that harm health – including carcinogens – are either absent in e-cigarette vapour or, if present, they are mostly at levels much below 5% of smoking doses (mostly below 1% and far below safety limits for occupational exposure)
- the main chemicals present in e-cigarettes only have not been associated with any serious risk

According to NASEM 'There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes'. (Conclusion 18.1)

A review of the chemicals in vapour concluded that the risk of cancer from vaping was <0.5% that of smoking tobacco.

'Anyone using e-cigarette products or who is exposed to e-cigarette emissions and/or e liquids is potentially at risk.'

Response

Vaping products are used almost exclusively by either smokers or former smokers. The small, potential risks from vaping should be compared to the known substantial risk of tobacco smoking, which kills two in three long-term users.

Risk to health depends on the dose and toxicity of the chemicals involved. According to the report by NASEM, 'There is substantial evidence that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes'.

> *'Smokers or vapers attempting to quit should use evidence-based treatments. Smoking cessation medication (approved by the Therapeutic Goods Administration) combined with behavioural intervention provides smokers with the best chance of quitting for good.'*

Response

Most smokers try and fail repeatedly to quit, even with the best available treatment. An Australian study found that 'the average 40-year-old smoker who started in their teens has made more than 20 failed quit attempts'.

Conventional treatments have only very modest success rates. In clinical trials, drug treatments have long-term success rates of 5-15% greater than placebo. Results in real world trials are considerably lower.

The latest research suggests that vaping is the most effective quit aid.

- A high-quality randomised controlled trial in the UK (n=886) found that smokers allocated to vaping were nearly twice as likely to quit after 12 months compared to those using nicotine patches and gums (18% vs 9.9%).
- A recent RCT in New Zealand (n=1184) found that the combination of vaping and a nicotine patch was three times more effective than the patch alone after 6 months (7% vs 2%).
- A real-world English study of 19,000 smokers found that, in their most recent quit attempt, those who used vaping devices had the highest quit rate compared to no treatment (OR 1.95) followed by varenicline (OR 1.82) and prescribed NRT (OR 1.34) Over-the-counter NRT had no significant effect.

Furthermore, many smokers do not use smoking cessation therapies to quit and do not seek medical help. Vaping is the most popular quitting aid globally, so its reach is much greater. It is unscientific and immoral to deny addicted smokers a legitimate aid to quitting or long term harm reduction.