Electronic cigarettes: analysis of FDA adverse experience reports in non-users

The US Food and Drug Administration (FDA) Center for Tobacco Products (CTP) receives and reviews voluntary reports from consumers, healthcare professionals and members of the public on adverse experiences (AEs) associated with tobacco products. Reports from consumers and concerned citizens have described AEs not only in users, but also in non-users of e-cigarettes.[1 2]

AE reports received by FDA between 1 January 2012 and 31 December 2014 were reviewed to evaluate AEs associated with e-cigarettes in non-users. The reports were received via the Safety Reporting Portal, MedWatch, mail and email. Of 136 reports related to e-cigarette AEs, 40 involved non-users (table 1).

Thirty-five reports were related to passive aerosol exposure (typically in indoor spaces). Respiratory symptoms (n=26) were most common and included asthma exacerbations, bronchitis, cough, difficulty breathing and pneumonia. Additional passive aerosol exposure symptoms included eye irritation (n=8), headache (n=8), nausea (n=6), sore throat/irritation (n=6), dizziness (n=5) and racing/irregular heart rate (n=5). Eleven reports identified recurrent problems associated with repeat exposure (positive rechallenge) and six reports described AEs in multiple individuals. Six cases reported seeking medical attention; three of which reported prescription of medications, two reported self-treatment and one reported hospitalisation. Of 27 reports providing information about pre-existing conditions, 11 indicated a history of respiratory or allergic conditions and nine of those AEs may have been related to the underlying condition.

The remaining five non-user reports included three reports of burns (due to contact with an overheated device (n=2) and to device explosion (n=1) while recharging),[i] one report of lip cheilitis (after kissing an e-cigarette user) and one report of infant death after choking on an e-liquid cartridge.[ii]

Table 1 Tobacco product adverse experience reports submitted to FDA*

Year	Total number of reports	Total number of e-cigarette reports	Total number of e-cigarette AE reports	Number of non-user e-cigarette AE reports	Non-user AE e-cigarette report categories		
					Passive aerosol exposure	Burn	Other
2012	29	23	16	1	0	0	1
2013	69	61	41	10	8	1	1
2014	138	109	79	29	27	2	0
Total Reports	236	193	136	40	35	3	2

*All tobacco product reports submitted to FDA are voluntary.
AE, adverse experience; FDA, US Food and Drug Administration.

The majority of non-user reports (n=36) were in adults. The four reports in children included the infant death (above), burns in a 3-year-old following an e-cigarette explosion and breathing problems in a 3-year-old and 'raspy' voice in a 4-year-old after passive aerosol exposure.

Although small in number, e-cigarette AE reports submitted to FDA are increasing. Twenty-nine per cent (40/136) of the e-cigarette AE reports received January 2012–December 2014 involved non-users and included symptoms related to passive aerosol exposure and device overheating or explosion. Additional e-cigarette risks in non-users, especially young children, include unintentional exposure to e-cigarette components and e-liquids resulting in choking associated injuries and nicotine toxicity.[3]

The AEs may provide important information about the potential impact of e-cigarettes on public health. However, because reporting AEs associated with tobacco products to FDA is voluntary, the reports received likely under-represent the true number and types of AEs associated with e-cigarettes and the AEs reported may not have a causal relationship to product exposure. Therefore, data cannot be used to calculate incidence (occurrence) rates or estimate risk. In addition, the January 2014 launch of CTP's web-based safety reporting portal[iii] may have influenced reporting rates and report content.

Research evaluating e-liquids, e-cigarette devices, exhaled aerosol constituents and their impact on health effects in users and non-users will be important to better understand their impact on public health.

[i]Of note, FDA has also received reports of burns in e-cigarette users during use and nonuse situations, such as recharging.
[ii]This AE was also reported by Chen who described e-cigarette AEs reported to FDA through first-quarter 2012.[1]

[iii]Link to Safety Reporting Portal: http://www.safetyreporting.hhs.gov.

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