Electronic nicotine delivery systems: overheating, fires and explosions

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ABSTRACT

Background Electronic nicotine delivery system (ENDS)-associated overheating, fire or explosion (OH/F/EXP) events have occurred since at least 2009.

Objective To identify the number and nature of ENDS OH/F/EXP events in the USA.

Methods Center for Tobacco Products (CTP) scientists searched for event reports among five US federal agencies, scientific literature and media outlets.

Findings 100 reference sources identified 92 OH/F/EXP events in the USA, of which 45 (49%) injured 47 people, and 67 (73%) involved property damage beyond the product. Events were identified in media outlets (n=50; 54%) and reported to four agencies (n=42; 46%). The report rate peaked at an average of six reports per month in late 2013 with a smaller peak of three to four reports per month in the second quarter of 2015. All reports were incomplete and events exhibited variability. International events in three countries are mentioned, and international responses to events are summarised.

Conclusions The scope, causes and trajectory of ENDS OH/F/EXP events remain incompletely defined. Some events have resulted in life-threatening injury, permanent disfigurement or disability, and major property damage, suggesting the need for ongoing surveillance and risk mitigation. More comprehensive reporting could assist future analyses and may help to identify root causes and contributors to the OH/F/EXP events.

BACKGROUND

The US Food and Drug Administration (FDA), Center for Tobacco Products (CTP) began to receive voluntary reports of electronic nicotine delivery system (ENDS)-associated overheating, fire or explosion (OH/F/EXP) events in 2011, and began to identify these events in media reports in 2012. In 2014, a US firefighter sent the FDA a number of media stories of e-cigarette F/EXP events along with his conclusion, 'A significant risk of death and/or serious injury exists. Immediate action is needed.' (United States Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. Safety Reporting Portal. Report of City Fire Department Deputy Fire Marshal from California to FDA. Report date 8 May 2014. (Unpublished data)) In the same year, following an airline incident, a US firefighter wrote to the Consumer Product Safety Commission (CPSC) stating, "I am very concerned that these heat generating devices can be turned on through normal handling of luggage, causing a fire at any moment. If this fire had started in the cargo luggage area and was

undetected while the plane was in flight a major tragedy could have occurred...It is apparent that if these e-cigarettes could start a fire in the skies, they may also be able to start fires in other settings, such as homes and businesses." (United States Consumer Product Safety Commission. Letter from Fire Marshal to CPSC Chairman re: E-cigarette Airport Luggage Fire. Letter date 15 Oct 2014. Incident date 9 Aug 2014. (Unpublished data)) Indeed, ENDS use has been documented in many settings that put users and non-users at risk for injury if the ENDS were to explode or catch fire, including medical settings,^{1–3} schools,^{4–5} multiunit housing,^{6–8} workplaces, restaurants and bars,^{9–11} jails,¹² while driving,¹³ and on public transit systems,¹⁴ including an airborne passenger plane.¹⁵ The FDA/CTP has proposed to regulate ENDS as tobacco products for the protection of public health;¹⁶ hence, CTP explored the number and nature of OH/F/EXP events to evaluate their public health impact and to inform any potential future regulatory action.

METHODS

In 2012, CTP scientists launched an exploratory search among US federal agencies, the scientific literature and news media outlets to identify ENDS OH/F/EXP events, with results herein concluding 30 September 2015. Database search terms employed singular, plural, synonyms and other derivatives for ENDS products and their parts, and included event-related and injury-related terms, customised for the coded versus narrative data or syntax relevant to each database. The search terms evolved with our knowledge of products, events and the consumer vernacular. Online supplementary table S1 details the search strategy.

Five US federal agencies received relevant reports: the FDA, the Federal Aviation Administration (FAA),¹⁷ the CPSC,¹⁸ the US Coast Guard (USCG)¹⁹ and the US Fire Administration (USFA).²⁰ Our knowledge of US federal agency jurisdictional authorities and interagency communications led us to identify these five agencies. The USFA receives firefighter-reported data about fire incidents. However, we utilised the USFA's publicly posted analysis of 25 media events to glean their perspective because they state that their National Fire Incident Reporting System (NFIRS) did not "...collect information... specific enough to provide accurate analysis of the frequency or impact of e-cigarette fires."²¹

Reports were reviewed by at least two staff scientists who consulted other experts as needed. Minimum inclusion criteria were for a plausible event occurring in the USA involving an ENDS product or part. We excluded events originating

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from drills or exercises and battery incidents that did not identify the device intended for use with the battery. We manually reviewed event date and location, description and personally identifiable information (when available), to identify duplicate and follow-up reports in each incoming report batch, and then reviewed this data retrospectively for the entire set. The coauthors did not contact injured parties, investigators, media outlets or reporters to obtain additional or clarifying information.

FINDINGS

Overview of ENDS OH/F/EXP Events in the US

Scientists identified 92 discrete OH/F/EXP events reported in the USA (table 1). Forty-five reports (49%) described injury of 47 people. Sixty-seven reports (73%) described property damage beyond the product. FDA/CTP authors briefly had described 21 events previously.^{22–24} The scientific literature yielded no additional events. Fifty events^{25–80} were identified from media outlets and 42 from reports to four US Federal government agencies by consumers/concerned citizens (n=24), healthcare professionals (n=7), air transportation industry workers (n=6) and fire fighters (n=5) (United States Consumer Product Safety Commission. Letter from Fire Marshal to CPSC Chairman re: E-cigarette Airport Luggage Fire. Letter date 15 Oct 2014. Incident date 9 Aug 2014. (Unpublished data)); United States Department of Transportation, Federal Aviation Administration, Office of Security and Hazardous Materials Safety. National Aeronautics and Space Administration Aviation Safety Reporting System Telecon. Report 1263077. Report date 9 Jul 2015. (Unpublished data); United States Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. Personal Communication from Fire Marshal to CTP Tobacco Product Surveillance Team. Event date 3 Nov 2013. Report date 12 Nov 2013. (Unpublished data); United States Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. *Safety Reporting Portal*. Problem start date 26 Mar 2014. Report date 26 Mar 2014. (Unpublished data); United States Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. *Personal Communication from Concerned Citizen to CTP Ombudsman*. Event date not reported. Report date 30 Apr 2014. (Unpublished data); United States Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. *Safety Reporting Portal*. Problem start date 7 Aug 2014. Report date 7 Aug 2014. (Unpublished data); United States Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. *MedWatch*. Event date 14 Apr 2015. Report date 17 Apr 2015. (Unpublished data); United States Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. *Safety Reporting Portal*. Problem start date 19 Jun 2015. Report date 20 Jun 2015. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 29 Mar 2013. Report date 1 Apr 2013. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 18 Sep 2013. Report date 14 Oct 2013. (Unpublished data); United States Consumer Product Safety Commission.

SaferProducts.gov Report. Incident date 25 Nov 2013. Report date 24 Mar 2014. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 20 Dec 2013. Report date 14 Apr 2014. (Unpublished data); United States Consumer Product Safety Commission. Hospital report to CPSC. Unique ID 131254591. Treatment date 24 Dec 2013 (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 9 Jan 2014. Report date 14 Jan 2014. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 15 Jan 2014. Report date 20 Feb 2014. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 15 Nov 2013. Report date 20 Feb 2014. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 25 Jan 2014. Report date 27 Feb 2014. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 26 Jan 2014. Report date 28 Jan 2014. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 24 Feb 2014. Report date 25 Feb 2014. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 28 Feb 2014. Report date 28 Feb 2014. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 21 Mar 2014. Report date 24 Mar 2014. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 20 Apr 2014. Report date 29 Apr 2014. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 6 Aug 2014. Report date 12 Aug 2014. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 22 Apr 2015. Report date 5 Jun 2015. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 9 May 2015. Report date 9 May 2015. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 9 Jun 2015. Report date 11 Jun 2015. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 12 Jul 2015. Report date 24 Jul 2015. (Unpublished data); United States Consumer Product Safety Commission. *SaferProducts.gov Report*. Incident date 21 Jul 2015. Report date 23 Jul 2015. (Unpublished data)).^{81–97} The report rate peaked at an average of six reports per month in late 2013 with a smaller peak of three to four events per month in the second quarter of 2015 (figure 1). Reports to the government and the media are qualitatively similar in themes and extent of details, and so are discussed as one data set. Case summaries appear in online supplementary table S2.

Summary of ENDS OH/F/EXP Events in the US

The 47 injured comprise 34 users, 5 non-users and 8 of unclear user status. Injuries overall included chemical (n=4) and thermal burns (n=33), smoke inhalation (n=4), fractured neck vertebrae (n=2), fractured palate and finger (n=1), loss, displacement or damage of one or more teeth (n=3), lacerations (n=5), bruising (n=1), psychological distress (n=3), sensory disturbances (n=3), nicotine overdose (n=1) and oral discolorations (n=1). Treatments overall ranged from first aid (n=5) to hospitalisation for burn unit care (n=7) or surgical foreign body removal (n=1). Permanent effects (n=5 users) involved

ⁱChen²² described one; Yang *et al*²³ described 19, including Chen's; Durmowicz *et al*²⁴ described three, including one of Yang *et al*'s.

Table 1 US ENDS overheating/fire/explosion events by primary report recipient and year

Calendar year	Number of FAA	Number of FDA	Number of Media	Number of CPSC	Number of USCG	Total number of US reports
2009	1	0	0	0	0	1
2010	0	0	0	0	0	0
2011	0	1	0	0	0	1
2012	0	1	4	0	0	5
2013	0	5	24	7	0	36
2014	2	4	10	9	0	25
January 2015—September 2015	3	2	12	*5	2	24
Total	6	13	50	21	2	92

CPSC, USA Consumer Product Safety Commission; ENDS, electronic nicotine delivery system; FAA, USA Department of Transportation/Federal Aviation Administration; FDA, USA Department of Health & Human Services/Food & Drug Administration; USCG, USA Coast Guard/National Response Center.

The Primary Report Recipient represents the initial entity that received the report. For events reported to more than one entity, only the initial recipient is counted herein.

*Events reported by hospitals to CPSC were not yet available for 2015.

Tallies are for dates available from the primary report recipients as follows:

- ▶ FAA: date, not otherwise specified—based on one reliable corroborating reference (USA Consumer Product Safety Commission. Letter from Fire Marshal to CPSC Chairman re: E-cigarette Airport Luggage Fire. Letter date 15 Oct 2014. Incident date 9 Aug 2014. (Unpublished data)), five appear to be incident dates, one is a report date (USA Department of Transportation, Federal Aviation Administration, Office of Security and Hazardous Materials Safety. National Aeronautics and Space Administration Aviation Safety Reporting System Telecon. Report 1263077. Report date 9 Jul 2015. (Unpublished data)).
- ▶ FDA: event date or problem start date when available; otherwise the report date.
- ▶ Media: exact or approximate event date when available; otherwise the date the story was first published.
- ▶ CPSC: incident date when available; otherwise treatment date.
- ▶ USCG: incident date.

disfigurement and disability. Non-user injuriesⁱⁱ included minor hand burns (n=2), multiple burns (n=1 toddler) and hospitalisation for smoke inhalation (n=3) or burns (n=2). Two events involved youth of unknown user status: a 17-year-old sustained hand lacerations from product explosion, and two high school students ‘messing with’ an e-cigarette were uninjured from explosion.

Reports claimed property damage that ranged from minimal to US\$100 000 and ‘loss of use of home’. Indoor settings were predominant (n=57 (62%); residential=46). OH/F/EXP events occurred during charging (n=44 (48%); residential=32), when handling after charging (n=4), while inhaling or between puffs (n=20; 22%), while holding (n=3) or wearing the product in a pocket (n=4), during transport (n=5) and in storage (n=4). Of eight events in automobiles, five were explosions in occupied or moving cars. Five passenger air-transportation events involved fire in a checked bag in an airport, fire in a checked and loaded bag before take-off, and baggage emissions on scheduled landing consisting of smoke (n=1) or ‘acid’ (n=1) from carry-on bags and smoke from a checked bag as it was being off-loaded. There were two associated airplane evacuations. Three commercial transportation events involved one fire in stowed air cargo on scheduled landing and fires in two ground sort centers—one after international air shipment. Other public settings for events were multiunit housing (n=5), workplaces (n=4), medical settings (n=3; two near medical oxygen), bars or restaurants (n=2) and a school.

Events involved a range of products at varied points in their lifespan. Most were e-cigarettes or parts; one was a ‘pipe-shaped device’ and another was a ‘cigar-sized device’. Four events involved disposable e-cigarettes: two overheated and one exploded during use, and one exploded as its original package was opened. Fifty-five events (60%) involved products described as rechargeable or placed on charge. Partially-identified batteries were ‘lithium ion’ (n=7) ‘lithium’ rechargeable (n=4; including one ‘Ultrafire protected’), ‘lithium’ (n=5), ‘lithium metal’ (n=2), ‘nickel cadmium’ (n=1) and other (n=8). Incomplete

charger/power source descriptors included: universal serial bus (USB)/computer (n=11), USB/wall (n=2), USB/car (n=1), USB (n=1), wall (n=7), car (n=6) and cell phone (n=2). Events have occurred with the product-specific and substitution chargers. Time on charge before F/EXP events (n=16) ranged from ‘under 2 min’ to 5 h. One product exploded during its first charge. Product ages (n=13) ranged from never used to 16 months.

Fire typically accompanied (n=45), but twice preceded explosion. Seven reports plausibly described fire without explosion; seven plausibly described explosion without fire. Six reports described OH during use without progression to F/EXP, alleging failure of the activation button/battery to turn off (n=2), and failure of the ‘between-puff’ shut-off mechanism in several devices (n=1 report). Reports further described OH during intermittent use over 1 week (n=1) and 3 months (n=1). Three additional OH reports described one product sitting idle, attended, on a counter for 20–30 min, and two in carry-on bags. Two OH reports described prompt actions taken to cool the device.

OH/F/EXP events have occurred both when following and in the absence of instructions. User actions that were possibly causative or contributory included: using a substitution charger, charging a non-rechargeable battery, using a recalled or incorrect battery and use near oxygen. Perceived harbingers (n=18) were noises, odours, battery leakage, device motion, a flash or sparkling and smoke.

RELEVANT LITERATURE FINDINGS

Summary of ENDS OH/F/EXP events outside of the USA

The media have reported over 100 F/EXP events in the UK, with an event rate of over one per week in late 2014.⁹⁸ Listings of 19 UK cases show themes resembling those in US cases.⁹⁹ Since late 2013, a Canadian fire with patient injury,¹⁰⁰ two F/EXP-related deaths in the UK^{101–103} and the first reported Australian F/EXP¹⁰⁴ involved ENDS use around medical oxygen.

Responses to OH/F/EXP events

Consumer responses have included identical product replacement (thrice with a similar or worse event), obtaining a different ENDS, seeking information, warning others, requesting a

ⁱⁱThree were earlier described by Durmowicz *et al.*²⁴

Figure 1 ENDS overheating/fires/explosions in the US, 2009–30 September 2015. ENDS, electronic nicotine delivery system.

refund or compensation, filing lawsuits, returning to combusted cigarettes and pursuing cessation.

Retailer or manufacturer responses have included selling blast bags¹⁰⁵ and safety storage or carrying boxes, retailer product quality checks, point-of-sale consumer education, apologising, collecting damaged product, offering refunds or replacements, inventory control, product recalls,^{106 107} blaming counterfeit products and product improvements in labelling and design.

Public health responses have included incident reporting guidance for US fire departments;¹⁰⁸ Health Canada's Consumer Product Update warning of the fire risk of e-cigarette use around oxygen;¹⁰⁹ and international aviation authority issuances toward banning e-cigarette use on commercial aircraft,^{110–113} requiring passengers to carry ENDS and spare batteries separately and exclusively in the cabin^{113 117} and banning ENDS product recharging aboard aircraft.^{113 117} Public posting of US events has occurred,^{17–19 118} and consumer safety advice has emerged from public health authorities and commercial entities.^{119–123}

DISCUSSION

Limitations

Because of the well-known long-standing phenomenon of under-reporting for adverse events, as well as search methodology issues, data such as compiled herein cannot be used to calculate incidence or prevalence. Case reports may be inaccurate or incomplete and skewed towards reporting the more sensational events. Our analysis relied primarily on written text, as images were often unavailable or irrelevant. Event 'investigations' were inconsistent and incompletely detailed; some were challenged by lack of device identifiers and device damage. Thirty-four reports came from questionnaires structured for public safety surveillance, including four from the CTP Safety Reporting Portal's tobacco-specific questionnaire;¹²⁴ 58 reports came from unstructured sources. The varied data sources may have affected data reporting and analysis and may account for some of the observed event variability. Despite our best efforts, undetected duplicate cases may remain. Owing to the nature of the search and voluntary reporting to many sources, this compilation likely under-represents the true number of OH/F/EXP events.

General discussion

Although the actual number of ENDS OH/F/EXP events is unknown, rates appear to be low overall in relation to ENDS use rates. The event rate has fluctuated over time (figure 1) despite a steady annual increase in ENDS use in the USA.¹²⁵ US

adult 'ever use' of e-cigarettes has grown from 0.6% to 12.6% of the population between 2009 and 2014,¹²⁶ with 3.7% of US adults reporting e-cigarette use every day or some days in 2014.¹²⁷ Decreased event rates may be related to voluntary product design and labelling improvements, consumer awareness and education or local and organisational bans on product use in various settings.^{9 11 14 110 111 113 128} Increased event rates may be related to the increasing numbers of users with accompanying use or product presence in high-risk medical (United States Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. *Safety Reporting Portal*. Problem start date 19 Jun 2015. Report date 20 Jun 2015. (Unpublished data)) and air travel (United States Department of Transportation, Federal Aviation Administration, Office of Security and Hazardous Materials Safety. National Aeronautics and Space Administration Aviation Safety Reporting System Telecon. Report 1263077. Report date 9 Jul 2015. (Unpublished data))^{85 86 96 97} settings. The peaks and valleys in events between 2013 and 2015 (figure 1) do not correspond to our changes in search strategies. Drivers for fluctuations in reporting rates for tobacco product-associated adverse events are unknown.

In one explosion event reported to FDA (United States Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. Personal Communication from Fire Marshal to CTP Tobacco Product Surveillance Team. Event date 3 Nov 2013. Report date 12 Nov 2013. (Unpublished data)), the Fire Marshal had identified the involved device as being among those recalled by a Chinese retailer due to a 'serious risk' of explosion during charging.¹⁰⁶ To explore further for potential contributors to event rates we searched for current and historical ENDS product recalls in the scientific, business and consumer literature and in USA¹²⁹ and global¹⁰⁷ public product recall repositories, as detailed in online supplementary table S1. No recalls were found in the US repository, while the global repository had posted nine relevant recalls in English between 2012 and 2015. The recalls were for 'serious' electrical hazards of e-cigarettes or their electrical parts involving four European countries. Only one of the global recalls identified how many incidents had occurred (n=1), and none provided data on how many products had been sold or were being recalled. Identified hazards included electric shock, fire or burns related to inadequate insulation of the charger, lack of a cut-off to avoid overcharging, insufficient clearance/cree-page distances between the primary and secondary windings of the power supply, tip overheating while charging, insufficient internal connections and failure to comply with four European

electrical product standards.^{130–133} Recall actions involved withdrawing the product from the market (n=3), recalling the product from end users (n=2) or both (n=4). It is unclear if these recalls may have affected the US market. Seven of the recalls occurred in April–November, 2014, corresponding directly to a time of a precipitous decline followed by a low-level of OH/F/EXP events in the USA (figure 1). Searching the events listed in online supplementary table S2 for involved products, we found three with similar product identifiers and relevant outcomes that predated two of the recalls by 4–6 months (United States Consumer Product Safety Commission. SaferProducts.gov Report. Incident date 25 Jan 2014. Report date 27 Feb 2014. (Unpublished data); United States Consumer Product Safety Commission. SaferProducts.gov Report. Incident date 26 Jan 2014. Report date 28 Jan 2014. (Unpublished data); United States Consumer Product Safety Commission. SaferProducts.gov Report. Incident date 24 Feb 2014. Report date 25 Feb 2014. (Unpublished data)).

The benefits and drawbacks of various battery types and their failure modes, as well as standards relevant to battery and electronic device safety and transportation, have been presented elsewhere by engineers and other experts in the private¹³⁴ and government sectors internationally.^{116 117 135 136} Two published analyses specific to e-cigarettes suggest preventive and corrective actions. After analysing 25 F/EXP news reportsⁱⁱⁱ in which 80% of events occurred during charging, the USFA concluded that battery failure rates are low compared to e-cigarette sales, but are likely to increase with sales, unless offset by design improvements. The USFA recommends user education on safe charging practices, strong warnings and product design changes to eliminate USB electrical connections, and to include electrical protection circuits.¹³⁷ CTP engineers' systematic review of 2004–2013 e-cigarette products/designs from a systematic search including literature (n=14), patents (n=16), conferences (n=3) and websites (n=2), suggested that overcharge protection, thermal power cut-offs and internal overpressure relief mechanisms could mitigate some battery failures.¹³⁸ Whether ENDS products present any novel failure modes remains to be determined.

ENDS products are largely unregulated in the USA. Although some states, localities and organisations have laws or policies restricting sales or use in certain locations, the application of available risk mitigation knowledge and standards in ENDS design, manufacture, sales and use is largely voluntary. US consumers expect safety and predictability in the use and performance of electronic products and to be warned of associated risks. This expectation is reflected by at least six US F/EXP events resulting in legal proceedings and another seven events in which users reported of absent or misleading instructions for use or absent warnings. In October 2015, a US jury awarded \$1.9 million to a woman who claimed physical and emotional 'scarring for life' related to a 2013 ENDS product explosion. The jury found the US distributor, wholesaler and retailer at fault for being 'involved in the distribution of a product that failed to conform to any kind of reasonable safety expectation—battery chargers should not explode-and failed to warn about known dangers.'¹³⁹

US consumers also are accustomed to the correction of product problems identified. For example, the largest-ever consumer electronics safety recall was for Dell computers in 2006,

when 'several' OH/F incidents resulted in the recall of 4.1 million laptops.¹⁴⁰ In 2013, Hewlett Packard recalled 145 000 laptop chargers after receiving nine reports of overheating and melting during use that included one minor burn injury and one minor property damage complaint.¹⁴¹ In 2015, a singular OH event of a lithium-ion powered electronic credit card reader on a US airplane, with no associated injuries, led the manufacturer to recall an undisclosed number of 'all similar models'.^{142–144} Accurate and complete sales data for specific brands and models of ENDS products in the USA are not available. However, it appears that the ENDS product sector may be lagging behind the mobile consumer electronics product sector in addressing this consumer safety risk.

CONCLUSIONS

Dispersed and rudimentary reporting in the USA has challenged efforts to identify and analyse ENDS OH/F/EXP events. Including a core information set in every report, such as fields shown in online supplementary table S2, may facilitate and improve future analyses. The use of complete product descriptors with standardised terminology for products and parts could further aid analyses. CTP's Safety Reporting Portal can accept complete event reports, including images and follow-up information.¹²⁴

ENDS OH/F/EXP events are occurring internationally. The scope, causes and trajectory of events in the US remain incompletely defined. Despite increasing efforts by various authorities outside FDA to limit or control the settings in which ENDS may be used, in 2015 events have continued to occur in high-risk medical and air-transportation settings. The identified events vary in the involved products, parts, people, device-user interactions, environments, surrounding circumstances, and outcomes, which have included life-threatening injury, permanent disfigurement and disability, and major property damage. These findings suggest a need for ongoing surveillance, along with strategies to prevent and mitigate events such as: failure mode analyses; attention to device design; good manufacturing practices; educating consumers, industry and public health professionals about risk, prevention and event reporting; and continued regulatory efforts. Data on ENDS OH/F/EXP may inform clinical counselling, informed consent in clinical research, consumer best practices, product labelling, organisational and public health system policies and regulation.

What this paper adds

- ▶ This is the largest compilation of US electronic nicotine delivery system (ENDS) overheating/fire/explosion (OH/F/EXP) events analysed and published to date.
- ▶ The causes, numbers and trajectory of ENDS OH/F/EXP events remain incompletely defined.
- ▶ This limited data set provides information to support exploration of strategies to prevent or mitigate ENDS OH/F/EXP events for the protection of public health.

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ⁱⁱⁱAll of the USFA-identified events are included in this paper's 92 events.

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Contributors SFR directed or conducted the literature and report searches, was the primary event analyst, drafted and revised the paper. BD was a secondary event analyst, reviewed and edited the paper.

Competing interests None declared.

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Data sharing statement Reports posted to CTP's public Freedom of Information Act (FOIA) Electronic Reading Room may move (have a new web address) in the future. The reports can be located on the FDA public website <http://www.fda.gov> by searching the term "CTP FOIA Electronic Reading Room." Unpublished reports to the FDA can be acquired by submitting a FOIA request. Instructions are posted to <http://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeaFOIARequest/ucm2007229.htm>. FOIA requests should be submitted in writing to: Food and Drug Administration, Division of Freedom of Information, Office of the Executive Secretariat, OC, 5630 Fishers Lane, Room 1035, Rockville, MD 20857, Phone: 301 796 3900, FAX 301 827 9267. Online FOIA Requests to the FDA can be submitted via <http://www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm>. Unpublished reports to the CPSC can be acquired by submitting a FOIA request to: FOIA Requester Service Center, US Consumer Product Safety Commission, 4330 East West Highway, Room 820, Bethesda, MD 20814, Tel. 301-504-7923 and Fax. 301-504-0127, E-mail: cpsc-foia@cpsc.gov, Or contact the CPSC FOIA Public Liaisons: Deborah Acosta, dacosta@cpsc.gov, Tel. 301-504-6821. Lynn Carter, lcarter@cpsc.gov, Tel. 301-504-6890. The latest guidelines on making a CPSC FOIA request are posted to <http://www.cpsc.gov/en/Newsroom/FOIA/Make-a-FOIA-Request/>. Unpublished reports to the FAA can be acquired by submitting a FOIA request online via: https://www.faa.gov/foia/email_foia/index.cfm?region=hq. For further information, contact: Federal Aviation Administration, Douglas Taylor, National Freedom of Information Act Staff, AFN-140, 800 Independence Avenue, SW, Washington, DC 20591, Phone: (202) 267-7799, Fax: (202) 267-6514.

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