



Direct Healthcare Professional Communication

27 January 2020

E-cigarette use or vaping: reporting suspected side effects, including lung injury, to MHRA

Summary

- Severe and fatal cases of lung injury suspected to be associated with e-cigarette use or vaping have been reported in the USA
- Currently, the volume and pattern of adverse respiratory events reported in association with e-cigarette use or vaping in the UK do not seem to reflect the trends emerging from the USA
- As of January 2020, MHRA is aware of two potential fatal cases of e-cigarette or vaping associated lung injury in the UK (one reported directly as a Yellow Card)
- MHRA is requesting healthcare professionals report any suspected side effects with e-cigarettes and the e-liquids used for vaping to the Yellow Card Scheme <http://www.mhra.gov.uk/yellowcard>
- Have a high index of suspicion for lung injury in patients with respiratory symptoms who have a history of e-cigarette use in the past 30 days
- Case definitions are provided in this letter to facilitate identification of probable or possible cases of e-cigarette or vaping associated lung injury
- Routinely ask all patients about e-cigarette use or vaping as you would about cigarette smoking (see page 3)

E-cigarette use or vaping associated lung injury

The US Centers for Disease Control and Prevention (CDC) is investigating cases of lung injury suspected to be associated with e-cigarettes and vaping. For the latest information on the US investigation, see the [CDC page](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html): (https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html) and a description of US cases in the accompanying Drug Safety Update article from January 2020 <https://www.gov.uk/drug-safety-update/e-cigarette-use-or-vaping-reporting-suspected-adverse-reactions-including-lung-injury>

Most patients had non-specific respiratory symptoms such as cough, dyspnoea (shortness of breath), and chest pain, often with associated gastrointestinal symptoms, fever, chills, and weight loss. Radiological findings include pulmonary infiltrates on chest X-rays and bilateral ground glass infiltrates on CT thorax.

Currently, the volume and pattern of adverse respiratory events reported in association with e-cigarette use or vaping in the UK do not seem to reflect the trends emerging from the USA.

Reporting probable or possible cases of e-cigarette or vaping associated lung injury or other suspected events without delay to the [Yellow Card Scheme](#) will assist the MHRA to take action as necessary to protect public health in case a similar situation emerges as in the USA.

MHRA is responsible for the UK notification scheme for e-cigarettes and e-liquids.

What to report – Case definitions

No gold-standard diagnostic criteria exist for e-cigarette or vaping associated lung injury. On the basis of expert advice we have devised UK case definitions to facilitate identification of probable or possible cases.

Cases should be considered **probable** if they meet ALL of the following criteria:

1. Using an e-cigarette or vaping in 30 days prior to symptom onset
- AND
2. Pulmonary infiltrate, such as opacities on plain film chest X-ray, or ground glass opacities on CT chest
- AND
3. Absence of respiratory infection. Minimum criteria to be excluded:
 - Negative respiratory viral screen (eg, influenza, adenovirus, rhinovirus, coronavirus)
 - Negative testing for all other clinically-indicated respiratory infectious diseases (eg, urine antigen for Streptococcus pneumoniae and Legionella, sputum culture, bronchoalveolar lavage culture, blood culture and opportunistic respiratory infections if appropriate)
- AND
4. No evidence of alternative diagnosis (eg, cardiac, autoimmune, malignancy)

Cases should be considered **possible** if they meet criteria 1, 2 and 4, but a respiratory infection is identified via culture or PCR, and the clinical team believes infection is not the only cause of underlying lung injury OR the minimum criteria to exclude infection are not met due to testing not having been performed and the clinical team believes the infection is not the only cause of the underlying lung injury.

Cases that do not strictly meet the criteria, for example if use of e-cigarette or vaping stopped more than 30 days before symptom onset, are still of interest and should still be reported to the MHRA as below.

How to report suspected side effects to the Yellow Card Scheme

Report any suspected side effects or safety concerns with e-cigarettes and the e-liquids used for vaping via the [e-cigarette reporting tool for the electronic Yellow Card Scheme](#). Reporting cases to the MHRA will assist with further evaluation of risk. Information provided to the Yellow Card Scheme is kept safe, secure and confidential.

If you report a case of e-cigarette or vaping associated lung injury (EVALI), please specify if it meets the criteria for a probable or possible case and provide full details of the vaping product, vaping history, and other potentially relevant clinical details, including combustible cigarette smoking history, and investigation results. If a product sample is available for analysis, please also specify this via the Yellow Card report.

In response, we may contact you to collect further details regarding the case via [a form](#). Providing further information is important as this will assist with case confirmation and evaluation. The form should be returned to yellowcard@mhra.gov.uk or to Freepost Yellow Card Scheme (no other address details or postage required).

Routinely document e-cigarette history

As part of routine clinical practice clinicians are requested to ask about and document use of e-cigarettes or vaping devices. Routine documentation will facilitate any future study using medical records on long-term effects of e-cigarettes or vaping.

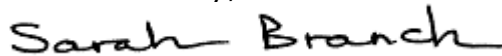
Clinicians should routinely document:

- Name or brand of product used
- Type of product (if known)
- Duration and frequency used
- Substances vaped (eg, nicotine or recreational substances)
- Strengths of substances.

For **further information** please consult the Drug Safety Update article from January 2020 <https://www.gov.uk/drug-safety-update/e-cigarette-use-or-vaping-reporting-suspected-adverse-reactions-including-lung-injury>

Informing us of your suspicions regarding e-cigarette or vaping use as a possible cause of lung injury is important for evaluation of a potential public health risk. Thank you for your contribution.

Yours faithfully,



Dr Sarah Branch

Interim Director

Vigilance and Risk Management of Medicines Division

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

info@mhra.gov.uk

020 3080 6000