



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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1st. March 2021

Deputy John McGuinness
TD
Dail Eireann
Kildare Street
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PQ 10127/21: To ask the Minister for Health the supports that are available from the HSE for a person who was vaccinated with the HPV vaccine on 28 September 2020, and had serious health issues after receiving the vaccine and was admitted to hospital on 6 October 2020 and diagnosed with postural orthostatic tachycardia syndrome; if a long-term plan is in place to support those affected in this way; the reason the possible adverse side effects were not outlined on the information leaflet for parents; the action taken by the Health Products Regulatory Authority relative to this issue; and if he will make a statement on the matter.

Dear Deputy McGuinness,

The above PQ has been forwarded to my Department for direct response to you on same.

The HSE cannot comment on individual cases.
However, there is no evidence that HPV vaccine causes POTS.

Please see studies below this have found no association between HPV vaccine and POTS.

1. Study found no increased rates of hospital records related to pain, fatigue, or circulatory symptoms in girls exposed to HPV vaccine versus unexposed girls. Furthermore, at the Danish population level, rates of these hospital records steadily increased over time in both girls and boys-unrelated to the timing of introduction of HPV vaccination Hospital Records of Pain, Fatigue, or Circulatory Symptoms in Girls Exposed to Human Papillomavirus Vaccination: Cohort, Self-Controlled Case Series, and Population Time Trend Studies <https://scanner.topsec.com/?r=None&t=9ee603a7d8c70c81725b7d7b3ec002ffa9289187&d=1527&u=https%3A%2F%2Facademic.oup.com%2Faje%2Farticle%2F189%2F4%2F277%2F5695267> January 2020

2. In September 2019 the American Autonomic Society finds that there are no data to support a causal relationship between HPV vaccination and CRPS, chronic fatigue, and postural tachycardia syndrome to other forms of dysautonomia.

Certain conditions are prevalent in the same populations that are vaccinated with the HPV vaccine (peri-pubertal males and females). This association, however, is an insufficient proof of causality.

Human papillomavirus (HPV) vaccine and autonomic disorders: a position statement from the American Autonomic Society

<https://scanner.topsec.com/?r=None&t=27cd10b2779a66b378b840e04a7b3a2d071c81a3&d=1527&u=https%3A%2F%2Fdoi.org%2F10.1007%2Fs10286-019-00608-w>

3. In October 2018 Dutch research showed no causal link between the HPV vaccine and chronic fatigue symptoms in girls.

Current findings of epidemiological research in the Netherlands correspond with the results of previous international studies.

"No evidence found for an increased risk of long-term fatigue following human papillomavirus vaccination of adolescent girls"

<https://scanner.topsec.com/?r=None&t=bb6d07bd551fd78947026022f352527afda75b7c&d=1527&u=https%3A%2F%2Fwww.sciencedirect.com%2Fscience%2Farticle%2Fpii%2FS0264410X18312684>

4. In October 2017 a Norwegian study aimed to ascertain if any association existed between HPV vaccination and chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME).

Over 176,000 girls who were eligible for HPV vaccination were included in the study. No indication of increased risk of CFS/ME following HPV vaccination was observed among girls who were vaccinated.

HPV vaccination and risk of chronic fatigue syndrome/myalgic encephalomyelitis: A nationwide register-based study from Norway.

5. In January 2016 the EMA issued a final report on the review of HPV vaccines. This report found no evidence the vaccine was linked to chronic fatigue like conditions.

Please see link for full details at

<https://scanner.topsec.com/?r=None&t=b8010e2f4c50386bb95978bb2421c570c2fb261c&d=1527&u=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fnews%2Fpreview-concludes-evidence-does-not-support-hpv-vaccines-cause-crps-pots>

The European Commission endorsed the conclusion of the EMA.

6. In 2013 the UK medicines' regulatory authority, the MHRA conducted a large study in the UK which showed no link between HPV vaccines and illnesses such as chronic fatigue syndrome and fibromyalgia, see information at

<https://scanner.topsec.com/?r=None&t=c04596028b591fcffa8dab1077ffb47834d9879b&d=1527&u=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpubmed%2F24001935>

Since 2006 the Global Advisory Committee on Vaccine Safety of the World Health Organization, the US Centers for Disease Control and Prevention (CDC), the FDA and the European Medicines Agency (EMA) have continually reported that controlled clinical trials on thousands of individuals and post licensure monitoring of millions of individuals have found no causal association between HPV vaccination and any long term medical condition.

The World Health Organization (WHO) Global Advisory Committee for Vaccine Safety (GACVS) has reviewed all the worldwide evidence on the safety of Gardasil vaccine 9 times, in 2007, and subsequently in 2008, 2009, 2013, 2014, 2015, 2017, 2019 (twice reported in 2020).

WHO has never reported safety concerns with HPV vaccines. WHO reported in July 2017 that HPV vaccines are considered to be extremely safe.

Further information can be found at

https://scanner.topsec.com/?r=None&t=b458b920b032b75e64e5899599844f4cf942968d&d=1527&u=http%3A%2F%2Fwww.who.int%2Fvaccine_safety%2Fcommittee%2Ftopics%2Fhpv%2Fen%2F All the WHO reports on HPV vaccine safety are available at this website.

I trust this clarification will be of assistance to you.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Kevin Kelleher', with a horizontal line underneath.

DR. KEVIN KELLEHER, FFPHM, FFPHMI
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