



Vaccine Safety

Narcolepsy Following 2009 Pandemrix Influenza Vaccination in Europe

An increased risk of narcolepsy was found following vaccination with Pandemrix, a monovalent 2009 H1N1 influenza vaccine that was used in several European countries during the H1N1 influenza pandemic. This risk was initially found in Finland, and then other European countries also detected an association.

Background

Narcolepsy is a central nervous system disorder characterized by excessive daytime sleepiness (EDS) and abnormal manifestations of rapid eye movement (REM) sleep. This disorder is caused by the brain's inability to regulate sleep-wake cycles normally, but it can be treated with medication and behavior modification.

[About narcolepsy and other sleep disorders.](#)

Pandemrix is manufactured by GlaxoSmithKline in Europe and was specifically produced for pandemic 2009 H1N1 influenza. It was not used before 2009, and has not been used since the influenza pandemic season (2009-2010). It contains an oil-in-water emulsion adjuvant called ASO3. Adjuvants are substances added to a vaccine to increase the body's immune response to that vaccine. [More about adjuvants.](#)

Pandemrix was not licensed for use in the United States.

CDC Vaccine Safety Efforts and Research

In response to the events in Europe, CDC reviewed data from the U.S. [Vaccine Adverse Event Reporting System \(VAERS\)](#) and the [Vaccine Safety Datalink \(VSD\)](#) and found no indication of any association between U.S.-licensed H1N1 or seasonal influenza vaccine and narcolepsy.

In 2014, CDC published a study to assess the occurrence of narcolepsy following vaccination with 2009 H1N1 influenza vaccine or 2010-2011 seasonal influenza vaccine, both of which contained the 2009 H1N1 virus strain (more about [types of influenza viruses](#)). The analysis included more than 650,000 people who received the 2009 pandemic flu vaccine and over 870,000 people who received the 2010-2011 seasonal flu vaccine. The study found that vaccination with influenza vaccines containing the 2009 H1N1 virus strain used in the United States was not associated with an increased risk for narcolepsy.

Source: [Narcolepsy and influenza A \(H1N1\) pandemic 2009 vaccination in the United States \[Neurology. 2014\]](#) [↗](#)

In 2018, a study team including CDC scientists analyzed and published vaccine safety data on adjuvanted pH1N1 vaccines (arenaprix-AS03, Focetria-MF59, and Pandemrix-AS03) from 10 global study sites. Researchers did not detect any associations between the vaccines and narcolepsy.

- Incidence rate study data did not show a rise in the rate of narcolepsy following vaccination except in the one signaling country included (Sweden, which used Pandemrix).
- Case-control analyses for Arepanrix-AS03 did not show evidence of an increased risk of narcolepsy.
- Case-coverage analysis for Pandemrix-AS03 in children in the Netherlands did not show evidence of an increased risk of narcolepsy, but the number of exposed cases was small (N=7).
- Cases-control analysis for Focetria-MF59 did not show evidence of an increased risk of narcolepsy.

Source: [Narcolepsy and adjuvanted pandemic influenza A \(H1N1\) 2009 vaccines – Multi-country assessment \[Vaccine. 2018\]](#) [↗](#)

Talk with your healthcare provider about vaccines.

They can answer questions and offer advice based on your specific health needs.

CDC recommends influenza vaccination as the best way to protect from influenza disease and its complications. [See CDC influenza vaccine recommendations.](#)

Related Scientific Articles

Weibel D, Sturkenboom M, et al. [Narcolepsy and Adjuvanted Pandemic Influenza A \(H1N1\) 2009 Vaccines – Multi-country Assessment](#) [↗](#) *Vaccine*. 2018 Oct 1;26(41):6202-6211.

Duffy J, Weintraub E, Vellozzi C, DeStefano F; Vaccine Safety Datalink. [Narcolepsy and influenza A\(H1N1\) pandemic 2009 vaccination in the United States](#) [↗](#) . *Neurology*. 2014 Nov 11;83(20):1823-30.

European Centre for Disease Prevention and Control. [Narcolepsy in association with pandemic influenza vaccination \(a multi-country European epidemiological investigation\)](#) [↗](#) . *Stockholm: ECDC*; September 2012.

Eurosurveillance editorial team. [Swedish Medical Products Agency publishes report from a case inventory study on Pandemrix vaccination and development of narcolepsy with cataplexy](#) [↗](#) . *Euro Surveill*. 2011;16(26).

Miller E, Andrews N, Stellitano L, Stowe J, Winstone AM, Shneerson J, et al. [Risk of narcolepsy in children and young people receiving AS03 adjuvanted pandemic A/H1N1 2009 influenza vaccine: retrospective analysis.](#) [↗](#) *BMJ*. 2013;346:f794

Nohynek H, Jokinen J, Partinen M, Vaarala O, Kirjavainen T, Sundman J, et al. [AS03 adjuvanted AH1N1 vaccine associated with an abrupt increase in the incidence of childhood narcolepsy in Finland](#) [↗](#) . *PLoS One*. 2012;7(3):e33536.

Partinen M, Saarenpää-Heikkilä O, Ilveskoski I, Hublin C, Linna M, Olsén P, et al. [Increased incidence and clinical picture of childhood narcolepsy following the 2009 H1N1 pandemic vaccination campaign in Finland](#) [↗](#) . *PLoS One*. 2012;7(3):e33723.

More Information

[Safety Information on Flu Vaccines](#)

The latest safety information on flu vaccines: safety studies, common side effects, vaccine package inserts, and more.

[Narcolepsy Fact Sheet – NINDS](#) [↗](#)

Fact sheet on narcolepsy from the National Institute of Neurological Disorders and Stroke (NINDS) – National Institute of Health (NIH)

[How Vaccine Safety Works](#)

Current vaccine safety programs in the United States, their history, and how they work.

[Seasonal Influenza Vaccine Safety: A Summary for Clinicians](#)

Information for clinicians about the different seasonal influenza vaccinations available.

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