

Increased risk of sleep disorder in children who received swine flu vaccine

February 26 2013

A study published in *BMJ* today finds an increased risk of narcolepsy in children and adolescents who received the A/H1N1 2009 influenza vaccine (Pandemrix) during the pandemic in England.

The results are consistent with previous studies from Finland and Sweden and indicate that the association is not confined to Scandinavian populations. However, the authors stress that the risk may still be overestimated, and they call for longer term monitoring of the cohort of children and [adolescents](#) exposed to Pandemrix to evaluate the exact level of risk.

In 2009, [pandemic influenza](#) A (H1N1) virus spread rapidly, resulting in millions of cases and over 18,000 deaths in over 200 countries. In England the vaccine Pandemrix was introduced in October 2009. By March 2010, around one in four (24%) of healthy children aged under 5 and just over a third (37%) aged 2-15 in a [risk group](#) had been vaccinated.

In August 2010 concerns were raised in Finland and Sweden about a possible association between narcolepsy and Pandemrix. And in 2012 a study from Finland reported a 13-fold increased risk in children and young people aged 4-19.

But a lack of reported cases in other countries led to speculation that any possible association might be restricted to these Scandinavian populations.

Narcolepsy is a [chronic disorder](#) of excessive daytime sleepiness, often accompanied by sudden muscle weakness triggered by strong emotion (known as cataplexy). To evaluate the risk after vaccination in England, a team of researchers reviewed case notes for 245 children and young people aged 4-18 from sleep centres and child neurology centres across England.

Of these, 75 had narcolepsy (56 with cataplexy) with onset after 1 January 2008. Eleven had been vaccinated before onset of symptoms; seven within six months.

After adjusting for clinical conditions, vaccination at any time was associated with a 14-fold increased risk of narcolepsy, whereas vaccination within six months before onset was associated with a 16-fold increased risk.

In absolute numbers, this means that one in 52,000 to 57,500 doses are associated with narcolepsy, say the authors.

They write: "The increased risk of [narcolepsy](#) after vaccination with AS03 adjuvanted pandemic A/H1N1 2009 vaccine indicates a causal association, consistent with findings from Finland. Because of variable delay in diagnosis, however, the risk might be overestimated by more rapid referral of vaccinated children."

While further use of this [vaccine](#) for prevention of seasonal flu seems unlikely, they say their findings "have implications for the future licensure and use of AS03 adjuvanted pandemic vaccines containing different subtypes such H5 or H9."

And they conclude: "Further studies to assess the risk, if any, associated with the other A/H1N1 2009 vaccines used in the pandemic, including those with and without adjuvants, are also needed to inform the use of

such vaccines in the event of a future pandemic."

More information: www.bmj.com/cgi/doi/10.1136/bmj.f794

Provided by British Medical Journal

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