# No substantial link between swine flu vaccine and Guillain-Barre syndrome, confirm experts

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Adjuvanted vaccines used during the 2009 swine flu pandemic did not increase the risk of Guillain-Barré syndrome substantially, if at all, finds a large Europe-wide study published in the *British Medical Journal* today. An adjuvant is a substance added to a vaccine to stimulate the immune system to respond to the vaccine.

The study provides reassurance about potential risks of adjuvanted pandemic influenza vaccines. It also exemplifies the use of a newly available infrastructure in Europe, which may help to provide reliable risk assessments related to future concerns.

Guillain-Barré syndrome is a rare disorder in which a person's own immune system damages the nerve cells, causing muscle weakness and sometimes paralysis.

In 1976, a vaccine used during a US flu pandemic was linked with the syndrome and vaccination was stopped abruptly. Since then, studies have shown no or only slight increases in risk but, to date, the role of flu vaccines as a trigger in Guillain-Barré syndrome remains controversial.

Therefore, the European Centre for Disease Prevention and Control (ECDC) requested and funded a consortium of European researchers (VAESCO) to estimate the risk of Guillain-Barré syndrome following pandemic influenza A (H1N1) 2009 vaccination.

The study published in BMJ today was carried out in a population of 50 million people across five European countries which vaccinated people during the 2009 swine flu pandemic. A total of 104 cases of Guillain-Barré syndrome (and its variant Miller Fisher syndrome) were matched to one or more controls.

After adjusting for recognised risk factors, such as influenza-like illness or upper respiratory tract infection, and seasonal influenza vaccination, the researchers could find no association between pandemic flu vaccination and Guillain-Barré syndrome. The consistent pattern across countries also provides reassurance about the findings, they add.

However, they point out that they cannot rule out the possibility of a small increased risk remaining.

Based on these results, they estimate this risk to be less than three excess cases of Guillain-Barré syndrome for every million individuals protected by the vaccination.

They conclude: "This study provides reassurance that adjuvanted pandemic influenza A (H1N1) 2009 vaccines did not increase the risk of Guillain-Barré syndrome substantially, if at all." They also say that larger studies, using different techniques to minimise bias, are currently underway that will give a clearer picture of the link between flu vaccines and Guillain-Barré syndrome.

This view is supported in an accompanying editorial by US researchers, who say the risk of Guillain-Barré syndrome, if any, is considerably smaller than that seen with the 1976 swine flu vaccines. They add that safety findings on adjuvanted flu vaccines are important if such vaccines become more common in future, whether in seasonal flu vaccines or for the next pandemic.