



Australian Government
Department of Health and Ageing

**INVESTIGATION INTO FEBRILE CONVULSIONS IN YOUNG CHILDREN AFTER
SEASONAL INFLUENZA VACCINATION**

LATEST FINDINGS AND RECOMMENDATIONS 30 JULY 2010

Recommendation

Currently there is a suspension of the use of trivalent influenza vaccine for health children under 5. This restriction can now be lifted provided the trivalent influenza vaccines Vaxigrip[®] or Influvac[®] are used. This is based on additional data confirming low rates of fever with convulsions similar to that documented for trivalent influenza vaccine in previous years.

Although Fluvax[®] remains a registered trivalent influenza vaccine for use in children aged less than 5 years, the accumulated data on increased rates of fever and febrile convulsions within 24 hours of immunisation with the 2010 Fluvax[®] in children less than 5 years of age has led to a recommendation for the use of alternative available influenza vaccines in this age group.

On 23 April 2010, the use of seasonal influenza vaccine in children less than 5 years of age was temporarily suspended in Australia, pending investigation into the causes of an apparent increase in febrile convulsions after seasonal influenza vaccination first reported in Western Australia (WA).

An investigation has been undertaken by the Therapeutic Goods Administration (TGA) and the Australian Technical Advisory Group on Immunisation (ATAGI) in collaboration with the National Centre for Immunisation Research and Surveillance (NCIRS) and state and territory health authorities. This Fact Sheet provides the results from this investigation.

The investigation has included extensive laboratory testing of the seasonal influenza vaccine, review of the clinical case notes of all the cases of febrile convulsions reported from WA, review of adverse events following seasonal and pandemic influenza vaccines reported from all states and territories, review of clinical trial data, liaison with international regulators, consultation with expert advisers and an epidemiological analysis of the adverse events. On 2 July 2010 the TGA published a report of these investigations on the TGA website: <http://www.tga.gov.au/alerts/medicines/flu vaccine-report100702.htm>

The report concluded that there was an increased risk of fever and febrile convulsions associated with vaccination with Fluvax[®] and Fluvax[®] Junior but no evidence of a similar safety signal from the two other seasonal influenza vaccines available in Australia, Influvac[®] and Vaxigrip[®]. However TGA noted that numbers of administered doses of Influvac[®] and Vaxigrip[®] in Australia were too small to be certain at that time.

Since that report, further data from New Zealand have confirmed low rates of fever and febrile convulsions in children vaccinated with Vaxigrip[®]. These rates are similar to those seen with seasonal trivalent influenza vaccination in previous years. In New Zealand there was wide distribution of all three vaccines. A study from the University of Auckland confirmed the finding of substantially increased febrile reactions in the first 24 hours after administration of Fluvax[®] with no increase noted with the other seasonal influenza vaccines.

No biological, clinical or epidemiological factors have been identified to explain these higher than expected rates of febrile convulsions. Vaccine testing both in Australia and in collaboration with the US Centers for Disease Control and Prevention in Atlanta has shown no abnormalities thus far, however further more sensitive tests are continuing and we will be providing further advice regarding these continuing TGA coordinated laboratory investigations.

Convulsions occur following fever due to any cause (most commonly an infection) in 2 to 3 in every 100 children by the age of 5 years. Up to 1 in 5 children hospitalised with natural influenza experience a febrile seizure, more than double the rate for other respiratory viruses.

Previous studies have found that convulsions associated with fever occur within 24 hours of administration of trivalent influenza vaccine to children less than 5 years of age at a rate of less than 1 per 1,000 doses. In 2010, febrile seizures were reported in approximately 1 in 100 in children aged between 6 months to less than 5 years of age in the first 24 hours after receipt of Fluvax[®] or Fluvax[®] Junior.

Trivalent influenza vaccine offers protection against three strains of influenza: the pandemic H1N1 influenza A strain, a second influenza A strain H3N2, and an influenza B strain. It is unknown what proportion of influenza strains circulating in 2010 will be H1N1 versus H3N2 or B however all strains have been reported thus far in the 2010 season with a higher proportion of H3N2 and B seen in recent isolates. Thus there is a need to cover these strains in the population. In some previous years such as in 2008 the flu season has begun in late July or August therefore an adjustment in recommendations is still relevant.

The TGA considers that, overall, the balance of benefits and risks of Fluvax[®] and Fluvax[®] Junior continues to be positive but has required a new warning to be inserted in the product information for these vaccines to alert clinicians to the increased rate of high fever and febrile convulsions with their use in children less than 5 years of age.

Therefore, the suspension of the use of the 2010 trivalent influenza vaccines Vaxigrip[®] and Influvac[®] for healthy children less than 5 years of age can be lifted and these vaccines safely given due to their low and acceptable rates of fever with convulsion, similar to that seen in previous years.

Although 2010 Fluvax[®] remains a registered trivalent influenza vaccine for use in children aged less than 5 years, the accumulated data on increased fever with convulsions within 24 hours of vaccination has led to a recommendation for the use of alternative TIV vaccines.

Immunisation providers should use clinical judgement to evaluate the risks and benefits for the individual child and agree the best clinical management with the child's parent or guardian. Despite the documented increase with Fluvax[®], febrile convulsions after influenza

vaccination continue to be uncommon events, and parents should be made aware of this side effect and the child should be monitored for fever. Paracetamol and physical methods can be used to reduce fever.

All seasonal influenza vaccines for those aged 5 years and over are safe and effective and can continue to be recommended especially to high risk populations such as those with underlying medical conditions, Indigenous populations, those aged 65 years and over and pregnant women.