

# Australian Public health Investigation: Side effects of flu vaccine worse than the disease

By [Amy Corderoy](#)

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*Professor Collignon questioned the TGA's independence and transparency because some of its advisers had worked for drug companies.*

PUBLIC health experts have called for an independent body to monitor drug safety after it emerged that young children were more likely to end up in hospital because of side effects from a flu vaccine than they were from the disease itself.

The analysis contradicts government safety advice that the harm did not outweigh the risk and raises concerns about the Therapeutic Goods Administration's assessment of the vaccine.

More than 1000 adverse responses in children under five were reported to the TGA by June this year, including nearly 100 instances of febrile convulsions, a seizure which in a small number of cases has been associated with long-term adverse health outcomes.

Side effects were linked to one of the three seasonal flu vaccines, Fluvax and Fluvax junior, from the drug company CSL, but the TGA maintained despite that, that "the overall risk-benefit balance of both products remains positive".

The Commonwealth Chief Medical Officer claims the advice was intended to indicate the drug should not be withdrawn from the market but said the government would reassess it in light of the research.

But research published yesterday in the journal Eurosurveillance showed Fluvax might have caused two to three hospital admissions due to seizure for every admission from flu it prevented.

The chief executive of the Public Health Association of Australia, Michael Moore, said further examination of risks was needed, at arm's length from the TGA. The government should consider creating an independent centre.

"There is a concern ... that the TGA is the body that approves vaccines and is also the body that determines what the risks and benefits are when concerns are raised," he said.

Peter Collignon, an infectious diseases expert at the Australian National University, said the vaccination program in children under five did more harm than good. "The TGA made that decision [about risk-benefit] without any evidence to back it up."

The Chief Medical Officer, Jim Bishop, said the risk-benefit claim indicated the drug should not be withdrawn. The TGA had recommended other vaccines besides Fluvax be used for children under five. He defended the TGA's independence: "There is no evidence the TGA is obligated to drug companies and they have a number of ways to make sure their advice is independent," he said.

"I feel comfortable about our investigation [of the vaccine, but] the fact of the matter is there is now new information available and the regulator will take that into account".

Heath Kelly, the study leader and an honorary associate professor at the University of Melbourne, said the government should check for vaccine side effects – not wait for reports.

There should also be a national insurance scheme to compensate people if they had a bad reaction.

"On very rare occasions, things can go wrong in vaccination programs. The community that recommended and promoted vaccination [should] provide support for any child who suffers serious adverse consequences."

Robert Booy, an infectious diseases expert at the Children's Hospital, Westmead, said that while the rate of seizures was unacceptably high, it was important to remember that continuing complications from them were extremely rare.

While this study indicated there would be more hospital admissions from seizures than would be prevented by the vaccine, children tolerated the other two vaccines well.

A spokeswoman for CSL said: "Extensive investigations are ongoing with international collaborators". It supported recommending that Fluvax should not be used in children under five until it could be confident of preventing problems.

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