

Issues presented in TV3 news on Saturday 5th February from US CBS news item.

This item presents the case of a young woman who developed neurological problems following administration of the Gardasil® vaccine.

- Whenever a new vaccine is introduced there is increased awareness and therefore reporting of adverse events following immunization. There is more reporting of common minor reactions such as injection site pain and swelling as well as more reporting of any event following the immunisation, whether it was caused by the vaccine or not. This is also seen in New Zealand - every time a new vaccine is introduced the Centre for Adverse Reaction Monitoring receives increased rates of reports. This is a normal and positive phenomenon, increased awareness and reporting should be encouraged.

- The National Vaccine Information Center is the anti-immunisation lobby in the United States. They are well known for their role as anti-immunisation advocates. They do not use scientific evidence in their claims.

- This 'research' reported on CBS is not actually research, it is unscientific and does not provide any meaningful information. This is scaremongering. Here is why.
 - The 'analysis' is based on Vaccine Adverse Event Reporting System (VAERS) reporting – VAERS is the US equivalent of CARM. VAERS takes all the reports that health providers and parents send through. Reporting is 'passive' i.e. based on who chooses to report and what they choose to report. A report to VAERS does not mean the vaccine caused the event, it just means the reporter noted an event that happened after the vaccine was delivered. It is not cause and effect. The purpose of VAERS reporting is a warning sign system to note if any unusual or unexplained events are reported that may be vaccine-related. If a new event is noted that could possibly be vaccine-related then proper research is needed to be undertaken to compare vaccinated with unvaccinated.
 - The VAERS system does not tell us how many doses of vaccine have been given (i.e. the denominator). There could have been tens of millions of doses given or only 10 doses. VAERS cannot provide this information. Therefore VAERS cannot tell how common an event is.
 - This reported 'analysis' compared the number of reports received at VAERS after the delivery of Menactra – a meningococcal conjugate vaccine routinely given as a single

dose to 11-12 year old adolescents in the US with the number of reports received from Gardasil® vaccine given to girls aged 11 – 12 years in a 3 dose regime and in catch up programmes.

- It does not report how many doses were given of Gardasil® compared to Menactra: One would assume many more doses of Gardasil® have been given than Menactra hence more reported events
 - It makes no comment of the well recognised phenomenon that new vaccines generate more publicity therefore more reports. Menactra is well established on the US schedule, whereas Gardasil® is a newly introduced vaccine with a lot of publicity.
- A proper analysis of whether an event is vaccine related or not requires an intervention group (the group given the vaccine) and a comparator control group (not given the vaccine) and to compare rates of events in both groups. If an event is very rare it requires large numbers to determine if there is a link.
 - For potentially rare events the USA can undertake comparative data using large linked databases where hundreds of thousands of people have both their primary care and hospital data linked. These systems have been used to show there does not appear to be any link to vaccines and conditions such as autism, brain damage etc.
 - The US authorities continue to have no major safety concerns around Gardasil®. This ‘analysis’ has not raised any concerns. To date there are no known severe safety risks with Gardasil® except the risk of anaphylaxis.

Illustrative examples

- Imagine you unknowingly ate chicken contaminated with salmonella on Tuesday night. On Thursday you received the Gardasil® vaccine. On Friday you began vomiting with diarrhea lasting a week. You go to see your doctor who reports this to the Centre for Adverse Reaction Monitoring as occurring following Gardasil® vaccine.
- Eighteen year old Casey receives Gardasil® at school on Friday. On Saturday she goes out with her friends. A drunk driver hits their car and tragically Casey is killed. This is a death following vaccination and the Adverse Event Reporting System will record it as such.

Key points

- The “research” reported by CBS news is not scientific in any way.
- There are no current concerns about the safety profile of Gardasil® vaccine. The most common reaction is local injection site pain. In 2/100 vaccinees this can be quite painful although self limiting.
- This news item is scaremongering and as such has the potential to cause unnecessary anxiety. The Immunisation Advisory Centre is disappointed that New Zealand television chose to air this item.