

Gardasil – Regional data

These data are being provided in response to concerns regarding Gardasil from the media and consumers

Role of the Centre for Adverse Reactions Monitoring

The Centre for Adverse Reactions Monitoring (CARM) is contracted by the Ministry of Health (Medsafe) to collect reports of *suspected* adverse reactions to medicines including vaccines. CARM

review these reports to determine whether there is an association between the medicine/vaccine and the reaction/events (causality assessment). In some situations CARM is unable to make a final assessment, for example due to lack of information or an unknown cause of death. These reports are still included in the CARM database.

Number of reports to CARM of suspected adverse reactions/events after Gardasil vaccination, per region: 1 September 2008 to 30 June 2015

Region according to District Health Board (DHB)	Number of girls who received 1st dose	Number of girls who received 2nd dose	Number of girls who completed 3 doses	Total doses given	Number of reports submitted to CARM
Waitemata	26,534	25,581	22,124	74,239	
Auckland	23,087	22,376	19,909	65,372	
Counties Manukau	33,609	31,563	27,384	92,556	
Total for Auckland DHBs	83,230	79,520	69,417	232,167	140
Lakes	6,667	6,379	5,636	18,682	
Bay of Plenty	10,964	10,435	8,917	30,316	
Total for Bay of Plenty DHB	17,631	16,814	14,553	48,998	68
Canterbury	25,667	24,200	21,739	71,606	50
Capital & Coast	16,033	15,046	13,444	44,523	
Hutt Valley	8,293	7,779	6,847	22,919	
Total for Wellington DHBs	24,326	22,825	20,291	67,442	36
Hawkes Bay	9,574	9,131	8,048	26,753	15
MidCentral	8,668	8,417	7,385	24,470	16
Nelson Marlborough	6,043	5,660	5,032	16,735	25
Northland	8,412	7,481	7,065	22,958	14
South Canterbury	2,829	2,744	2,504	8,077	9
Southern	16,465	15,961	14,165	46,591	76
Tairāwhiti	3,211	3,091	2,673	8,975	8
Taranaki	5,611	5,395	4,715	15,721	17
Waikato	19,768	19,078	16,266	55,112	50
Wairarapa	2,418	2,366	2,080	6,864	11
West Coast	1,189	1,130	1,012	3,331	9
Whanganui	3,945	3,764	3,292	11,001	9
National	238,987	227,577	200,237	666,801	553

Understanding these data

The number of girls who have received Gardasil was obtained from the National Immunisation Register (NIR). Gardasil vaccination is only funded for girls. The numbers of girls are those who have been vaccinated up to 30 June 2015. More girls have had the first dose than the second or third dose. Some girls are part-way through the vaccination course and some did not complete the course.

As of 30 June 2015, CARM had received 568 reports of suspected adverse reactions to Gardasil. The number of girls involved is lower as a separate report may have been submitted after more than one dose for some girls.

Ten reports were submitted prior to the start of the funded vaccination programme. These reports have been excluded from the table as the number of girls being vaccinated before 1 September 2008 is unknown.

Five further reports were excluded as the region in which the patient lived was unknown.

Understanding spontaneous reporting

Spontaneous reports are submitted to CARM by healthcare professionals or the public. These reports describe a suspicion that a medicine caused an adverse reaction. Not all adverse reactions are reported. Some regions report

more than others. These reports are used to identify possible safety concerns. Other sources of information are used to confirm or refute the safety concern.

An overview of all the reports sent to CARM about Gardasil is published on the Medsafe website (www.medsafe.govt.nz/publications/OIAContents.asp).

Safety concerns linked to Gardasil have been reviewed by the Medicines Adverse Reactions Committee. Further information on these discussions is published on the Medsafe website (www.medsafe.govt.nz/profs/MARC/Minutes.asp).

To date the Committee has not verified a new safety concern with Gardasil.

More information on vaccine safety is published on the Medsafe website (www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Vaccine-safety.asp).

Conclusion

Medsafe and CARM continue to monitor the safety of Gardasil. The benefits of immunisation with Gardasil continue to outweigh any risk of harm. More information can be found in the data sheet and CMI.

Please continue to report all suspected adverse reactions to medicines/vaccines to CARM (nzphvc.otago.ac.nz/report/).



New Zealand Government