

01 SEP 2015

Freyberg Building  
20 Aitken Street  
PO Box 5013  
Wellington 6145, New Zealand  
T +64 4 496 2000

[REDACTED]  
Risk & Policy Adviser  
[REDACTED]

Ref: H201503277

Dear [REDACTED]

### Response to your request for official information

Thank you for your request of 04 August 2015 under the Official Information Act 1982 (the Act) for

*“Can I have copies of the three causality assessments undertaken in relation to the three deaths associated with Gardasil (and any others that may not have been mentioned to date), a copy of the original ADR reports (with personal details other than age/gender removed) and related correspondence, reports, meeting records, etc ad correspondence with Merck or any other external source related to the decision-making process.*

*Can I also have details of all the ADR reports related to Gardasil that have been deemed non-causal and not loaded into the on-line database”.*

The information relating to this request is itemised below, with copies of documents attached. Some of the information you request is already in the public domain (see below).

There have been four reports made to the Centre for Adverse Reactions Monitoring (CARM) in which a person vaccinated with Gardasil was later noted to have died.

#### Case 87237

The details for this case have been made public ([www.beyondconformity.org.nz/hilarys-desk/part-five-jasmine-the-tip-of-the-iceberg](http://www.beyondconformity.org.nz/hilarys-desk/part-five-jasmine-the-tip-of-the-iceberg)). Medsafe and CARM have no additional information. Medsafe and CARM are awaiting the results of the coroner's inquest.

#### Case 84614

The details for this case are publically available ([www.stuff.co.nz/national/health/5229088/Leukaemia-boy-Chace-needs-a-miracle](http://www.stuff.co.nz/national/health/5229088/Leukaemia-boy-Chace-needs-a-miracle)). Medsafe and CARM have no additional information.

#### Case 90322

In this case the vaccinator saw the name of a girl they had vaccinated in the death notices in the paper. On follow up the death was found to be a suicide. No further details were provided.

Case 109290

This 16 year old girl was found dead in bed the day after vaccination. The case has been referred to the coroner.

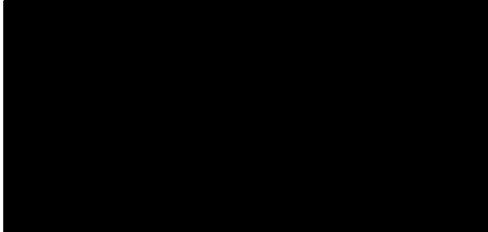
The collection of reports of suspected adverse reactions to medicines is contracted by Medsafe, Ministry of Health, CARM. CARM analyses these reports for causality based on the WHO guidelines. The following association outcomes are possible: certain, probable, possible, unlikely and unclassified. The assessment is a clinical deductive process, there is no documented checklist. The assessment for all four cases was unclassified.

I have decided under sections 9(2)(a) and 9(2)(ba)(i) of the Act to withhold information in order to protect the privacy of natural persons and to protect information which is subject to an obligation of confidence where the making available of the information would be likely to prejudice the supply of similar information. I have also decided to withhold information that is outside the scope of your request.

<b>Request</b>	<b>Response</b>
<i>Copies of the three causality assessments undertaken in relation to the three deaths associated with Gardasil (and any others that may not have been mentioned to date)</i>	This is a deductive process based on there being in the first instance sufficient information to define the clinical event and its nature and other factors such as a clear temporal association, biological plausibility/mechanism, exclusion or consideration of confounding factors, consideration of potential alternative explanations, evidence from other accepted cases that are the same/similar. The assessment for all four cases was unclassified.
<i>A copy of the original ADR reports (with personal details other than age/gender removed)</i>	As you are aware, the provision of copies of ADR reports is subject to an investigation by the ombudsman. Medsafe will not release copies of ADR reports until the outcome of this investigation is known. Details of the cases are outlined above
<i>Related correspondence, reports, meeting records and correspondence with Merck or any other external source related to the decision making process.</i>	The related correspondence is attached. I have withheld information in this correspondence under sections 9(2)(a) and (9)(2)(ba)(i).
<i>Details of all the ADR reports related to Gardasil that have been deemed non-causal and not loaded into the on-line database</i>	This information has been requested in OIAs H201502464 and H201503369 and has been/will be provided in the response to these requests.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely



Acting Group Manager  
Medsafe

Subject: Fw: PM prelim results

Greetings

Please see message from the pathologist.

----- Original Message -----

From:

Sent: 19/12/2013 03:05 p.m. ZE12

To:

Subject: PM prelim results

· can u pass this message from the pathologist who conducted the PM on to all those involved.  
He sent it thru yesterday.

Thanks

Re Pm

Histology inconclusive, no anatomical cause of death. If toxicology (pending) negative will proceed with molecular analysis for cardiac conduction defect.

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OFFICIAL INFORMATION ACT

17/05/2012 03:02 p.m.

Subject: RE: CARM- Medsafe teleconference HPV - AML Update

Follow-up on the Gardasil Med Error in a 6/52 old.

I have now had a look at this report more carefully and see that it IS in fact the report was in the media last year. It seems that the mother has now decided to submit the details of the report to us. At the time we assessed the report in 2009 there were no further follow-up details other than the fact of the error and the immediate actions of the practice.

When the story became the media issue in April 2011, we picked it up when asked us if we knew of it and through that follow-up at the time established that it was linked to the case we had on file for the 2009 event and added the AML aspect hence my recollection that we possibly had another. At the time the MOH for the DHB, the Immunisation Programme and IMAC were involved in the follow-up.

When I raised this today I had misread the AML diagnosis date of March 2011 as 2012 hence thinking it's a new case. I don't understand why the parent has now decided to submit the case, but at least suggests that it understandably remains uppermost in the parent's minds and could signal new attention on the issue. Possibly it is a straightforward matter of the parent ensuring that it is recorded in the CARM system. My response will be along the lines of us having received the initial notification of the error at the time and then the subsequent diagnosis when it was discovered and highlighted in the media.

With best wishes

**Subject:** CARM- Medsafe teleconference

17 May 2012

Present:

Cases of Interest

- HPV vaccine and AML - child given HPV at 6 weeks instead of Infanrix, report of the medication error was received in 2009. Mother has provided follow up that child experienced flu-like symptoms following the error, was then diagnosed with ITP and then AML.\*

\* Medsafe investigation suggests that this is the case widely reported in the media earlier in the year and not a second case.

PharmacoVigilance,  
Clinical Risk Management  
Medsafe  
Ministry of Health  
DDI:

<http://www.medsafe.govt.nz>

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Hi :

Thank you for your request. I have attached a spreadsheet which shows the numbers and rates of acute myeloid leukaemia registrations and deaths from 1994 to 2008.

I hope this helps. Please contact me if you have any questions.

Cheers

Analytical Services, Ministry of Health

phone: 06 478 5700

fax: 06 478 5700

e-mail: [medsafe@medsafe.govt.nz](mailto:medsafe@medsafe.govt.nz)



CancerLeukaemia\_AcuteMyeloid.xls

----- Forwarded by

p.m.-----

From:

To: [data-enquiries@moh.govt.nz](mailto:data-enquiries@moh.govt.nz)

Date: 17/05/2012 11:14 a.m.

Subject: Request from Medsafe

---

Hi

I would be grateful if you could provide me with some information on the incidence of Acute Myeloid Leukaemia over the last 10 years and by age.

Please let me know if you need any further information from me.

Best Regards

Medsafe

Ministry of Health

DDI:

<http://www.medsafe.govt.nz>

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Hello .

When the media issue came up , we looked at WHO and did not identify anything. We did find that the report had been made to CARM at the time as a Medication Error and is recorded in the database as such.

The CARM database was searched and filtered for age <9years:

There are only 2 reports:

- 84614 - the report you are referring to, received on 29 May 2009
- 86446 - a similar situation with HPV given in error

For other Neoplasm or Leukaemia:

There is one report in the CARM database of a 17yr old girl who received both the HPV1 and HPV2 ( ) who was diagnosed with leukaemia ( ) and was reported to CARM in Jan 2010 \ . The reporter (Programme Vaccinator) stated that the report was submitted as documentation for why the HPV



vaccine was not going to be completed and not because of any potential association.

I have now also had another look at the WHO for HPV vaccine: (Appended))

No Reports for Leukaemia

No Reports for any terms in the System Organ Class (SOC) "Blood and Lymphatic organs"

No reports for SOC "Neoplasm's Benign and Malignant"

Centre for Adverse Reactions Monitoring

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MARC REPORT  
March 2010

Patient: F - 18

Report No. 87237

Report Received: 12.11.2009

Source: Practice Nurse

Suspect Medicine(s): HPV 3  
Medroxyprogesterone

MARC Reason: Death

Reactions	Severity	Relationship	Labelled
Paraesthesia	Severe	Unclassified	No
Cognition abnormal	Severe	Unclassified	No
Muscle weakness	Severe	Unclassified	No
Night sweats	Severe	Unclassified	No
Sudden death	Severe	Unclassified	No

Medicine	Dose	Route	Start Date	End Date	Indication
Gardasil		IM	18.09.08		Immunisation
Depo Provera			03.11.08		
Gardasil		IM	18.11.08		Immunisation
Depo Provera			26.01.09		
Gardasil		IM	17.03.09		Immunisation
Depo Provera			17.04.09		
Depo Provera			10.07.09		

Onset Date: 22.09.09

Duration to Onset: 6 months following HPV3

Event description:

Initial report from GP reporting sudden death on 22 /09/09 with an HPV immunisation date of 17/3/08, and that the case was under investigation by Coroner

*Synopsis of event summary reported by Parent from follow-up information*

18.09.08 - HPV1

*20.04.08 - Developed hand warts and rough skin on the webbing between fingers. Temperament changed.*

03.11.08 - Depot injection

18.11.09 - HPV2 - GP note: "no problems after last injection"

January 09 - Warts returned - under nails.

*Bouts of dizziness, Pins & needles in hand, Bursts of memory lapses, abdominal pains.*

26.01.09 - Depot injection

17.03.09 - HPV3

*"Immediately after" temperament changed and became more agitated. Intermittent weak arm and daytime tiredness with daytime naps. Pins & needles increased. Started dropping things. Appetite increased, but not putting on weight.*

17.04.09 - Depot injection

*Night sweats enough to soak bed began in period post Depot*

*June 09 onwards - became clumsy, knocking over things and dropping items.*

*Thinking abnormal - forgetting how to use common objects, what decisions to make in daily living.*

*Intermittent chest pain and racing heart*

*14.08.09 - URTI - Rx'd Otrivin spray and Brufen*

*URTI never improved (still had rhinorrhoea until day before death).*

*Headaches, more pimples than normal. Still eating more than normal*

*22.09.09 - Died in sleep overnight*

**Outcome:** Death - Cause unknown  
**Follow-up information:** Received from parent included in Event description above  
**Other Medical Conditions:** None stated

### ASSESSMENT REPORT

**CARM data:** HPV N=236 - no other reports of death

**Literature:** Literature supports the overall safety profile of the HPV vaccine and that national monitoring systems are prone to receive reports that may be co-incidental events. One recent report highlights a case where a co-incidental event could have been incorrectly attributed to HPV immunisation.

1. Agorastos T, Chatzigeorgiou K, Brotherton JM, Garland SM. Safety of human papillomavirus (HPV) vaccines: a review of the international experience so far. *Vaccine*. 2009 Dec 9;27(52):7270-81. Epub 2009 Sep 30.
2. O'Dowd A. Teenager who died after having HPV vaccine had a malignant chest tumour. *BMJ*. 2009 Oct 1;339:b4032.
3. Slade BA, et al. Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine. *JAMA*. 2009 Aug 19;302(7):750-7.

**Comment:** Cause of death as yet unknown and still in process of Coronial review. Death occurred 6 months following the last (HPV3) immunisation, although follow-up report describes the earlier onset of unusual neuro-psychiatric events more prominently evident about 2 months following the HPV2 and apparently more marked in the period following the HPV3. She had also received Depo (medroxyprogesterone) before and during the course of HPV immunisation. The presence of night sweats and persistence of progressive neuropsychiatric signs as well as the report of chest pain and palpitations are very unusual in the context of immunisation and are difficult to collectively explain as a consequence of immunisation. The autopsy and Coronial findings will provide a basis from which to more adequately evaluate this report.

**Recommendation:** Review following the receipt of the autopsy and Coronial findings

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Serious AEFIs in Children under 18 years.....continued

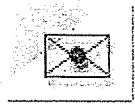
REPORT	DATE	Severe	REACTIONS	VACCINE	AGE	SEX	OUTCOME
109290	DEC2013	Yes	SUDDEN DEATH	HPV VACCINE (HPV-2) ETHINYLLOESTRADIOL LEVONORGESTROL	16	F	Died

Case Summary:

CARM Comment:

This report is unable to be assessed for potential causal association and only has a temporal link with HPV-2 vaccination

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Thank

**From:**  
**Sent:** 09/12/2013 11:24 p.m. GMT  
**To:**  
**Subject:** FW: AEFI

Hi as discussed this is the information I have received from our DHB Imms Co-ordinator. I'll let you know as and when I receive any update

Thanks,

Good Morning

Thanks for talking to me.

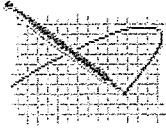
I received a phonecall from [redacted] 1000. The practice had just been visited by the local Police.

[redacted] (dob [redacted] '97) – 16year old [redacted] n – had 1<sup>st</sup> Gardasil. Dose 2 administered at [redacted] yesterday by [redacted] y. No problems with previous vaccine. Full informed consent taken. Patient found to be dead in bed this am. Had seen GP prior to receiving the vaccine for repeat of OCs. Patient for post-mortem and Coroner's inquest.

I have spoken to the nurse to offer support and debrief.

Thanx

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Sent by:

18/02/2014 11:11 a.m.

Subject: RE: HPV death last year for March MARC

Hi

I have added the HPV report to the AEFI table for MARC. I meant to pass this onto you on Friday for look-see and just recalled that I hadn't done so. It's the last one in the list. It didn't get on the list in the first place because the information we had was so scant making assessment impossible, but its these instances that we need to consciously remember to consider including – there will only be the very occasional one every now and again.

There is limited detail on this report so there isn't much I could write about other than what I have included. I don't think any of what I have written may be misinterpreted or contentious at this point. We are still awaiting the ongoing investigations. Note the references to the COC's - this is all we know – it may well be the components of a brand of COC.

With Best Wishes

I  
New Zealand Pharmacovigilance Centre / Medical Assessor: CARM  
NZPhvC, PO Box 913, Dunedin 9054, New Zealand | Tel: 03 479 7150 | Fax: 03 479 7150

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**Subject:** Re: HPV death last year

Hi

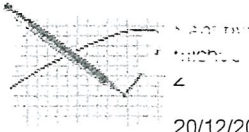
Thanks for the heads up.

Just to let you know, this case will be presented to the MARC at the next meeting in March.

Kind regards

Principal  
Clinical Risk Management  
Medsafe  
Ministry of Health

<http://www.medsafe.govt.nz>



20/12/2013 12:21 p.m.

Subject: RE: rate of unexplained deaths

Hi :

Thanks for this

I have not had much success with [redacted], but have been in touch with the Mortality Review Group themselves (they are located here in the Dunedin School of Med- Paediatrics). The clinical head of the Unit is away until early Jan, but the Analyst pointed me to this annual review of last year which he thought may be helpful. It has endless tables and graphs, but here are drill downs for the teenager and slightly older which I have extracted in the attached file. Apparently they can do more specific analysis but that has to go through the Head and [redacted] and then their Committee, but looking at these tables I am not sure how helpful that may be.

I guess we would be wanting to know the figures for unexplained death in these age groups and you will see from these tables, the "Unspecified" or Natural/Environmental" may be the groups of interest. There aren't any in the 15-19 unspecified and wondered if the unexplained deaths could be part of the "Natural" group, but I don't see a definition of Natural/Environmental and hopefully can get this when the Head is back. I suspect this definition may be part of the some Census/Statistics grouping. Anyway it's a starting point and will pick this up again in the New Year.

With Best Wishes and a great Holiday time and New Year

Dr [redacted] | Tel: [redacted] | Fax: 03 479 7150  
New Zealand Pharmacovigilance Centre / Medical Assessor: CARM  
NZPhvC, PO Box 913, Dunedin 9054, New Zealand

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**Subject:** rate of unexplained deaths

Rates of sudden unexplained death in the US are 5-14yrs 0.2/100,000 per year  
15-24 yrs 1.3/100,000

Population size in NZ is around 600,000 for 5-14 yrs - estimate 1 per year  
and around 660,000 for 15-14 yrs- estimate around 8 per year

if the rate is the same/similar as US



13/01/2014 01:18 p.m.

Subject: update on Unexplained sudden death

Hi All

Please see the update from [redacted] on the unexplained sudden death [redacted]

Kind regards

Programme manager  
Immunisation  
Sector Capability and Implementation  
Ministry of Health

<http://www.moh.govt.nz>  
mailto:



From:  
To:  
Cc:

Date: 13/01/2014 12:48 p.m.  
Subject: RE: Unexplained sudden death

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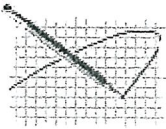
Fyi, I've received the post mortem report on the 16 year old young woman who died at home in [redacted] approximately 24 hours after receiving her second dose of HPV vaccine. The pathologist's conclusion is "no obvious cause of death is found".

He has referred the case to the Inherited Cardiac Diseases Unit for them to rule out the possibility of any congenital cardiac conduction defects.

Thanks,

Medical Officer of Health





Sent by:

To:

cc:

bcc:

17/12/2013 04:05 p.m.

Subject: HPV 109290

Hi

Today we have received the AEFI report for the death in the context of HPV vaccination from the GP (nurse).

I have responded to the reporter saying that this is not an expected outcome with vaccination in general or HPV specifically and that there is no evidence to suspect that HPV vaccination imposes any increased risk of death further supported by the absence of such signals from its considerable use in diverse countries. Also that we carefully review any report of death with therapeutic agents including vaccines and that this one will undergo such consideration. To this end I have requested that any additional information that may be available or become available would be valuable in this review and should be forwarded to CARM.

I have spoken with the practice to establish some communication update conduit,

The GP involved was not available and the one nurse I did speak to who seemed to know about the case mentioned that she thinks all their data is being passed to IMAC through the school based programme (and that I should get it from there...). I hope this isn't the making of a situation of updates variably being sent to diverse avenues. The GP will apparently be getting back to me. Perhaps this is a reason to have a quick VSEAG meeting, or maybe more appropriate to directly ask the Immunisation people (MoH & IMAC) to pass on whatever they may get.

I thought I would contact the Child and Youth Mortality Review Committee for background data on Sudden Death in adolescence to contribute some contextual data that may assist in further evaluation including through the VSEAG. As you will know I haven't advised VSEAG yet that we now formally have this report

With Best Wishes

Dr: New Zealand Pharmacovigilance Centre / Medical Assessor: CARM  
NZPhvC, PO Box 913, Dunedin 9054, New Zealand | Fax: 03 479 7150

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109290.pdf



Sent by:  
11/12/2013 03:02 p.m.

To:  
cc:  
bcc:

Subject: Fw: sudden death

As discussed. Preliminary info from PM today.

**From:** [redacted]  
**Sent:** 11/12/2013 01:40 a.m. GMT  
**To:**  
**Subject:** sudden death

Hi [redacted] as discussed I have just spoken with [redacted], the pathologist who completed the post mortem this morning in [redacted]

[redacted] said he detected a slight petechial rash over the chest but there were no gross signs of the meninges being infected. Otherwise the post mortem was unremarkable. He has taken samples of csf, blood, and various tissues for further testing including to rule out meningococcal disease, other bacteria, viruses, cardiac arrhythmias (including prolonged QT), illicit substances and other drugs.

[redacted] was aware of the concern related to the case having been vaccinated with Gardasil the day prior to her death and he said he would let me know as soon as he had any results to report. He added he would also let the family know as soon as he had any meaningful results.

Regards, [redacted]

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13/12/2013 03:31 p.m.

Subject: RE:

Hi , I've just had a follow up conversation with , the pathologist who did the post mortem. He confirmed he has not received any lab results; one significance of this being that had any specimens been positive for meningococcal disease we would very likely have known by now. He anticipates he will have some of the histology reports early next week, but toxicology is likely to take another week or two.

I've relayed this information on to ' said he has not spoken with the family of the deceased since

Thanks,

**From:**

**Sent:** Thursday, 12 December 2013 1:47 p.m.

**To:**

**Cc:**

**Subject:**

Kia ora all,

I just wanted to let you all know that I have spoken with and he is very comfortable to remain the local interface at this stage.

I have also spoken with She informs me that they are holding the last remaining dose from that vaccine pack in their vaccine fridge presently - awaiting further instructions.

is as I understand. He has had initial contact with the family 2 days ago on learning of the tragedy, and the practice intends to send a sympathy card as part of their standard process for patients of theirs who pass away. It may be opportune for call the family again to inform them of the initial post mortem findings, and that we would not expect an interim report from the pathologist until later next week, but that he has undertaken to pass on any important results as information comes to hand. This might also be an opportunity to ask the family if they have any particular questions or concerns at this time. I am happy for family or health professionals to call me directly on my cellphone if there are questions that people are seeking answers for.

n, the pathologist who performed the post-mortem examination yesterday advises that he has not spoken with the family at all (and would usually not do so unless the family requested this). He would expect to have an interim report available - likely by late next week - and this will be made available to family as soon as it is available. In the interim he is happy for the family to be advised that the initial examination has not revealed any obvious cause of death.

Chief Advisor