

My original enquiry to CANSA:

Submitted on 2015/08/09 at 16:43

Could you please let me know why CANSA is supporting the use of the HPV vaccines when these are now proven to be deadly? Several hundred young women have died because of this vaccine and thousands more are permanently disabled or battling with chronic health problems. This vaccine has NEVER been proven to prevent cervical cancer. Many countries have banned these vaccines because they are not just useless, they are dangerous – why is South Africa using them? And why does your web page not list the potential side effects?

CANSA's first reply

From: Info [<mailto:info@cansa.org.za>]
Sent: 13 August 2015 01:53 PM
To: [sarah](#)
Subject: RE: Ask CANSA Cervical Cancer and HPV vaccines

Dear Sarah,

Thank you for contacting the CANSA information Centre, please review the response from our clinical specialist Prof Michael Herbst regarding the HPV vaccines.

If you have any further inquiries please feel free to contact Pro Michael Herbst at mherbst@cansa.org.za

Kind regards,

Radiah Sadan
Information Co-ordinator

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The following three pages is the attachment that was sent as a 'reply'

CANSA : attachment with first reply

Med J Armed Forces India. 2015 Apr;71(2):171-7. doi: 10.1016/j.mjafi.2015.02.006. Epub 2015 Mar 13.

HPV vaccine: Current status and future directions.

Kumar S1, Biswas M2, Jose T3.

Author information

Abstract

HPV Vaccine was introduced to prevent cervical cancer known to be caused by infection with one or more of the high risk subtypes of the Human papilloma virus (HPV). Since introduction, trials have proven its efficacy in preventing Cervicalintraepithelial neoplasia (CIN) beyond doubt and its effectiveness in preventing cervical cancer though presumptive is reasonably certain as per mathematical modelling. It also prevents other HPV related anogenital and oropharyngeal malignancies in both sexes. HPV vaccines have courted many controversies related to its efficacy, safety, ideal age of vaccination, use in HPV infected individuals and use in males. The currently available vaccines are based on L1 Viral like particles (VLP) and hence highly species specific, thermolabile, costly and are purely prophylactic. The quest for a cheaper, thermostable and broad spectrum vaccine has led to many newer prophylactic vaccines. Therapeutic vaccines were born out of the inescapable necessity considering high HPV related morbidity projected in the non HPV naïve population. Therapeuticvaccines would immediately reduce this burden and also help in the management of HPV related cancers alone or as part of combination strategies. Ongoing research is aimed at a total control over HPV related malignancies in the near future.

KEYWORDS:

Cervical cancer; Cervical intraepithelial neoplasia; Humoral immune response; Papillomavirus vaccines; Viral like particles

Clin Exp Vaccine Res. 2014 Jul;3(2):168-75. doi: 10.7774/cevr.2014.3.2.168. Epub 2014 Jun 20.

Current status of human papillomavirus vaccines.

Kim KS1, Park SA1, Ko KN1, Yi S1, Cho YJ1.

Author information

Abstract

Cervical cancer is a malignant neoplasm arising from cells that originate in the cervix uteri. It is the second most prevalentcancer among women. It can have several causes; an infection with some type of human papillomavirus (HPV) is the greatest risk factor for cervical cancer. Over 100 types of HPVs have been identified, and more than 40 types of HPVs are typically transmitted through sexual contact and infect the anogenital region. Among these, a number of HPVs types, containing types 16 and 18, are classified as "high-risk" HPVs that can cause cervical cancer. The HPVs vaccine prevents infection with certain species of HPVs associated with the development of cervical cancer, genital warts, and some less common cancers. Two HPVs vaccines are currently on the global market: quadrivalent HPVs vaccine and bivalent HPV vaccine that use virus-like particles as a vaccine antigen. This review discusses the current status of HPVs vaccines on the global market, clinical trials, and the future of HPVs vaccine development.

KEYWORDS:

Clinical trial; Papillomavirus vaccines; Uterine cervical neoplasms; Virus-like particle vaccines

Vaccine. 2013 Dec 31;31 Suppl 7:H71-9. doi: 10.1016/j.vaccine.2013.04.086.

Cost-effectiveness of cervical cancer prevention in Central and Eastern Europe and Central Asia.

Berkhof J1, Bogaards JA2, Demirel E2, Diaz M3, Sharma M4, Kim JJ4.

Author information

Abstract

We studied the cost-effectiveness of cervical cancer prevention strategies in the Central and Eastern Europe and Central Asia (CEECA) region. The cost-effectiveness of human papillomavirus (HPV)16/18 vaccination of 12 year-old girls was calculated for 28 countries, under the assumption that vaccination prevents 70% of all cervical cancer cases and that cervical cancer and all-cause mortality rates are stable without vaccination. At three-dose vaccination costs of I\$ 100 per vaccinated girl (currency 2005 international dollars), HPV16/18 vaccination was very cost-effective in 25 out of 28 countries using the country's gross domestic product (GDP) per capita as cost-effectiveness threshold (criterion by World

CANSA : attachment with first reply

Health Organization). A three-dose vaccination cost of I\$ 100 is within the current range of vaccine costs in European immunization programs, and therefore our results indicate that HPV vaccination may be good value for money. To evaluate the cost-effectiveness of cervical cancerscreening combined with vaccination, we calibrated a published simulation model to HPV genotype data collected in Slovenia, Poland, and Georgia. The screening interval was varied at 3, 6, and 10 years starting at age 25 or 30 and ending at age 60. In Slovenia and Poland, combined vaccination and 10-yearly HPV (DNA) screening (vaccination coverage 70%, screening coverage per round 70%) was very cost-effective when the cost of three-dose vaccination was I\$ 100 per vaccinated girl. More intensive screening was very cost-effective when the screening coverage per round was 30% or 50%. In Georgia, 10-yearly Pap screening was very cost-effective in unvaccinated women. Vaccination combined with 10-yearly HPV screening was likely to be cost-effective if the three-dose vaccination cost was I\$ 50 per vaccinated girl. To conclude, cervical cancer prevention strategies utilizing both HPV16/18 vaccination and HPV screening are very cost-effective in countries with sufficient resources. In low-resource settings, low vaccine pricing is essential for strategies of combined vaccination and screening to be cost-effective. This article forms part of a regional report entitled "Comprehensive Control of HPV Infections and Related Diseases in the Central and Eastern Europe and Central Asia Region" Vaccine Volume 31, Supplement 7, 2013. Updates of the progress in the field are presented in a separate monograph entitled "Comprehensive Control of HPV Infections and Related Diseases" Vaccine Volume 30, Supplement 5, 2012.

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KEYWORDS:

Central Asia; Central Europe; Cost effectiveness; Eastern Europe; HPV; Mathematical model; Screening; Vaccination

Eur J Cancer Prev. 2014 May;23(3):206-24. doi: 10.1097/CEJ.0b013e328364f273.

Review of the current knowledge on the epidemiology, pathogenesis, and prevention of humanpapillomavirus infection.

Asiaf A1, Ahmad ST, Mohammad SO, Zargar MA.

Author information

Abstract

Human papillomavirus (HPV) infection is a central and necessary, although not sufficient, cause of cervical cancer. Besides HPV, the additional multiple risk factors related with the onset of cervical cancer are early-age sexual activities; high number of sexual partners, which is the most salient risk factor; suppression and alteration of the immune status; long-term use of oral contraceptives; and other hormonal influences. The tumor-suppressor proteins p53 and pRb are degraded and destabilized through ubiquitination by viral oncoproteins E6 and E7. Over 95% of cervical cancer cases worldwide test positive for oncogenic HPV DNA. Although cervical screening procedures have been successful in reducing the disease burden associated with HPV infection because of lack of resources or inadequate infrastructure many countries have failed to reduce cervical cancer mortality. Therefore, prevention may be a valuable strategy for reducing the economic and disease burden of HPV infection. At present, two successful prophylactic HPV vaccines are available, quadrivalent (HPV16/18/6/11) 'Gardasil' and bivalent (HPV16/18) 'Cervarix' for vaccinating young adolescent girls at or before the onset of puberty. Recent data indicate that vaccination prevents the development of cervical lesions in women who have not already acquired the vaccine-specific HPV types. Moreover, several therapeutic vaccines that are protein/peptide-based, DNA-based, or cell-based are in clinical trials but are yet to establish their efficacy; these vaccines are likely to provide important future health benefits. The therapeutic vaccination mode of prevention is a promising area of research, as revealed in preclinical trials; however, clinical trials based on large populations are warranted before reaching a valid conclusion. This review summarizes the studies on the epidemiology of HPV infection, the pathogenesis of viral oncoproteins in the oncogenesis of cervical cancer, the economic and health burden of HPV-related diseases, and, finally, focuses on the results of recent clinical vaccination trials.

CANSA : attachment with first reply

J Adolesc Health. 2013 May;52(5 Suppl):S69-75. doi: 10.1016/j.jadohealth.2012.09.020.

Hispanic mothers' and high school girls' perceptions of cervical cancer, human papilloma virus, and the human papilloma virus vaccine.

Morales-Campos DY1, Markham CM, Peskin MF, Fernandez ME.

Author information

Abstract

PURPOSE:

Cervical cancer incidence and mortality are higher for Hispanic women than for women in other population groups. However, the incidence could be reduced if teenaged Hispanic girls received the human papillomavirus (HPV) vaccine before they become sexually active. Unfortunately, few Hispanic girls receive this vaccine, which prevents cervical cancer. This study assessed Hispanic mothers' and girls' perceptions about cervical cancer, HPV, and the HPV vaccine. Results show factors that affect whether Hispanic high school girls receive the vaccine.

METHODS:

Twenty-four Hispanic mothers and 28 Hispanic girls from an urban school district in southeast Texas each participated in one of eight focus groups. Bilingual moderators facilitated the mothers' groups in English and Spanish and the girls' groups in English. We analyzed transcripts of the discussions and identified themes using the grounded theory approach.

RESULTS:

Our analysis found several themes that affect whether Hispanic girls get the HPV vaccine: gaps in knowledge; fears and concerns about the vaccine; sociocultural communication practices; and decision-making about HPV vaccination. Both mothers and girls had limited knowledge about cervical cancer, HPV, and the vaccine. Some girls who received the vaccine said they wished their mothers had involved them in making the decision.

CONCLUSIONS:

Findings may help in developing school or community-based educational programs for Hispanic families. Such programs should provide information on the HPV vaccine and the link between HPV and cervical cancer, and they should assist mothers and girls in communicating to make informed decisions about the vaccine.

From: Sarah
 Sent: 16 August 2015 09:02 PM
 To: mherbst@cansa.org.za
 Cc: 'Info'
 Subject: RE: Ask CANSA Cervical Cancer and HPV vaccines

Dear Radiah, many thanks for passing on Prof Herbst's email to me and for responding.

Dear Prof Herbst

Thank you for the document containing various abstracts to papers on the subject of HPV. With all due respect, these are obviously of zero value in terms of answering the questions that I put to CANSA.

My specific questions are:-

Why is CANSA supporting the use of the HPV vaccines when these are now proven to be deadly and when they have NEVER been proven to prevent cervical cancer?

Both India and Japan have stopped giving this vaccine because of the severe side effects – why is South Africa ignoring the glut of data that shows this vaccine is dangerous?

<http://articles.mercola.com/sites/articles/archive/2010/12/29/why-india-has-stopped-giving-hpv-vaccines.aspx>
 As at 29th December 2010: “The reported death toll for the HPV vaccine now stands at 89, and the first male death has also been reported. A young boy died just eight days after being vaccinated with Gardasil.
 As of November 3, 2010, there were also 20,575 adverse reactions, the Age of Autism reports, and 352 reports of abnormal pap smears post vaccination. Keep in mind however, that it has been estimated that only 1 to 10 percent of all vaccine adverse events are ever reported, which means there could actually be millions of vaccine injuries related to Gardasil, and perhaps thousands of deaths.
 Shockingly, the vaccine is now also related to infant deaths.”
 The death toll from Gardasil/Cervarix as at June 2015 is 232 : <http://sanevax.org/> This is according to the CDC VAERS reporting system. The total adverse events are 39,685. This includes 693 life-threatening cases. And it must be noted that it is widely acknowledged that only between 1 and 10% of all adverse events are reported. So this number could be as much as 400,000 adverse events.

<http://nsnbc.me/2013/07/28/uk-drug-safety-agency-falsified-vaccine-safety-data-for-6-million/> This report confirms that Japan are no longer recommending the HPV vaccine because of the poor safety record. What is worse is that the UK drug safety agency covered up the reporting of adverse events:
 How UK Health Officials Tampered With the Adverse Reaction Reporting Systems
 In the UK the Medicines Healthcare Products Regulatory Agency [MHRA] first interference was to encourage health professional not to report adverse reactions. This was done in formal advice issued in the name of Chief Executive Professor Sir Kent Woods telling health professionals that reactions can be “psychogenic” – or in simpler terms a figment of 12 year old schoolgirls' imaginations and nothing to do with the vaccines [see more below for full details].

Why does CANSA not warn parents and young girls of the potential side effects of this vaccine?
 Is CANSA aware that the HPV vaccines contain strains of HPV which are not normally carried by black people?
 This vaccine has not been properly studied and has not been properly studied on black Africans. The benefits are not proven. Between 90 and 94% of the individuals who were studied were not of black African descent. It has been reported that black Africans carry different strains of HPV from other race groups and that these strains are NOT covered in the vaccine. Therefore, the potential benefit for South African blacks is even further restricted.
 Surely CANSA has a duty to investigate whether or not this vaccine is suitable for the population of South Africa?

In terms of giving credibility to any industry-sponsored studies or trials, attached is a short report on the statement made by Mr Richard Horton, Editor-in-Chief of the Lancet who said “much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness”.
<http://www.collective-evolution.com/2015/05/16/editor-in-chief-of-worlds-best-known-medical-journal-half-of-all-the-literature-is-false/>

Furthermore, Dr Marcia Angell, a physician and longtime Editor in Chief of the New England Medical Journal (NEMJ), which is considered to another one of the most prestigious peer-reviewed medical journals in the world, makes her view of the subject quite plain: "It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of the New England Journal of Medicine" (source)

So in other words, please forgive me if I don't accept the abstracts CANSA sent me. In return, I am attaching a list of 200 papers showing the adverse effects of vaccines.

We could swap "studies" all day long, but the truth is still that in the CDC VAERS reporting system young girls are dead and injured because of this vaccine. Here are just a few reported cases to illustrate what can happen:

<http://vaccineimpact.com/2015/13-year-old-world-championship-karate-student-forced-to-quit-after-gardasil-vaccine/>

<http://healthimpactnews.com/2014/gardasil-vaccine-one-more-girl-dead/>

<http://fox4kc.com/2014/08/08/girl-with-sore-throat-gets-hpv-vaccine-dies-hours-later/>

<http://sanevax.org/i-want-my-daughters-life-back-the-way-it-was-before-gardasil/>

It is clear that a number of countries are now dealing with protests against this vaccine.

<http://healthimpactnews.com/2015/parents-of-hpv-vaccine-victims-protest-in-the-streets-of-colombia/>

<http://healthimpactnews.com/2014/gardasil-vaccine-spain-joins-growing-list-of-countries-to-file-criminal-complaints/>

One only has to search on "gardasil lawsuits" to get the following information:

<https://www.google.com/search?q=gardasil+lawsuits&ie=utf-8&oe=utf-8>

What we do need to do is look at the reported adverse events and to ask the pertinent questions regarding the safety of this vaccine. No manufacturer is going to admit (unless forced to by a court of law) that their product is either defective or deadly.

If anyone purports to be a caring physician and who wishes to help the community defend itself against deadly diseases, then surely that person needs to look at both sides of the argument? It is completely unacceptable simply to point towards the manufacturer and trust that their data is 100% accurate. Attached is a document that lists many of the criminal activities of (and fines handed down to) various pharmaceutical companies. These are the reasons why a good proportion of the general public does not trust the pharmaceutical industry.

Patients have a right to know the risks and benefits of any medical treatment offered to them. Attached is a document that gives pertinent information for South Africans, including the issue of informed consent. This information should be made known to the patient BEFORE the administration of this vaccine.

I therefore respectfully ask that you go through the above information and then kindly answer my questions.

Thank you very much indeed for your time.

Kind regards

Sarah

From: Sarah
 Sent: 16 August 2015 10:06 PM
 To: 'mherbst@cansa.org.za'
 Subject: RE: Ask CANSA Cervical Cancer and HPV vaccines

Dear Prof Herbst

This report from the Daily Mail came to my attention a few moments ago:

<http://www.dailymail.co.uk/news/article-2908963/Judges-demand-answers-children-die-controversial-cancer-vaccine-trial-India.html#ixzz3iS3GKJmw>

Judges demand answers after children die in controversial cancer vaccine trial in India

- Tribal girls were given shots of cervical cancer vaccines during trial
- Children given Merck's Gardasil and Cervarix vaccines
- Petitioners also asked judges to investigate trials of new drug Gardasil 9
- Drug has allegedly caused side-effects in children as young as nine
- Investigation claims children were used as unwitting human guinea pigs
- Supreme Court has given the government one month to provide answers

Read more: <http://www.dailymail.co.uk/news/article-2908963/Judges-demand-answers-children-die-controversial-cancer-vaccine-trial-India.html#ixzz3j0fS3ab7>

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This is not the only vaccine that has been used in India and which has caused vaccine injuries. The polio vaccine has also been reported to cause acute flaccid myelitis. But that's another story....

Here is another report on the payment of \$6million to victims of Gardasil:

<http://www.washingtontimes.com/news/2014/dec/31/us-court-pays-6-million-gardasil-victims/?page=all>

By Peter Lind - - Wednesday, December 31, 2014

WASHINGTON, April 10, 2013 - Gardasil, the vaccine for HPV (human papillomavirus), may not be as safe as backers claim.

Judicial Watch announced it has received documents from the Department of Health and Human Services (HHS) revealing that its National Vaccine Injury Compensation Program (VICP) has awarded \$5,877,710 dollars to 49 victims in claims made against the highly controversial HPV (human papillomavirus) vaccines. To date 200 claims have been filed with VICP, with barely half adjudicated.

Surely CANSA cannot be turning a blind eye to all of these reports? Surely CANSA must take responsibility to investigate these issues? Is CANSA prepared to risk these types of injury compensation claims in South Africa?

Kind regards

Sarah

From: Michael Herbst (Prof) [mailto:mherbst@cansa.org.za]
 Sent: 17 August 2015 08:07 AM
 To: Sarah
 Subject: RE: Ask CANSA Cervical Cancer and HPV vaccines

Dear Sarah

Upon opening your first e-mail, I noticed that you are referring to a clinical trial that was conducted in India. A clinical trial is exactly what the term says: it is the testing (a trial) of a new drug or medicine (or vaccine) to see the effectiveness, safety, etcetera of a new drug.

It is very dangerous to compare vaccine clinical trials with an already proven vaccine campaign.

The trial conducted in India was the testing of a new vaccine which covers nine (9) of the Human Papilloma Viruses (HPVs). The previous vaccines covered either 2 or 4 of the HPVs. South Africa currently uses the bivalent HPV vaccine which is effective against the two most dangerous HPV's namely HPV 16 & 18.

Kind Regards
 Michael C

From: Sarah
 Sent: 17 August 2015 09:24 PM
 To: 'Michael Herbst (Prof)'
 Subject: RE: Ask CANSA Cervical Cancer and HPV vaccines

Dear Michael

Thank you very much indeed for your reply.

I do have a modicum of understanding with regard to what a clinical trial is. I also understand that the participants in such a trial are supposed to be made aware of what they have agreed to be a part of. It would seem from the reports that this specific trial in India is surrounded in accusations of gross misconduct on the part of the manufacturer of the vaccine as well as the Indian government.

'It is a very encouraging development that the judges are now discussing accountability and not just accountability but also compensation, so the tone of the hearing today was very positive for us because it's clear from all the parties, including from government reports, that there were, at best, serious irregularities and, at worst, gross violations of fundamental human rights,' said Kerry McBroom, one of the lawyers.

Read more: <http://www.dailymail.co.uk/news/article-2908963/Judges-demand-answers-children-die-controversial-cancer-vaccine-trial-India.html#ixzz3j6JkVJ15>

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On the subject of trials, I would like to point out the following (this information was in the PDF file I sent you – Vaccination – HPV information document):-

“The most disconcerting part of this new vaccine is it doesn't include HPV 35, 66 and 68, three of the strains of HPV of which African-American women are getting the most,” said study co-author, Cathrine Hoyo. “We may want to rethink how we develop these vaccines, given that African-Americans tend to be underrepresented in clinical trials.”

Shouldn't these studies and questions confirm that at the very least, black populations should refrain from HPV vaccines until further evidence is provided that they are safe and effective?

Ref: The findings, presented on Oct. 28, 2013, at the 12th annual International Conference on Frontiers in Cancer Prevention Research hosted by the American Association for Cancer Research. The research was supported by the National Cancer Institute (R01CA142983 and R01CA142983-02S1). The authors reported no conflicts of interest. http://www.dukehealth.org/health_library/news/hpv-strains-affecting-african-american-women-differ-from-vaccines

Has any research been carried out in South Africa to determine the most prevalent strains of HPV?

Notwithstanding all of the above, I look forward to receiving your response on all the other information that I sent you and in particular the response to the adverse events and deaths which are attributed to the use of HPV vaccines.

Thank you again for your time, I really do appreciate it.

Kind regards

Sarah

From: Sarah
Sent: 19 August 2015 06:29 AM
To: 'Michael Herbst (Prof)'
Cc: 'Izak Mahali'
Subject: RE: Ask CANSA Cervical Cancer and HPV vaccines

Dear Michael

Following on from our recent correspondence, herewith are yet more articles on the effects of the Gardasil vaccine:-

<http://healthimpactnews.com/2013/truth-and-gardasil-doctor-discusses-premature-menopause-in-16-year-old-after-gardasil-vaccine/>

<http://www.washingtontimes.com/news/2014/dec/31/us-court-pays-6-million-gardasil-victims/?page=all>

Here is a quote from the above article:

US Court pays \$6million to Gardasil victims

The facts appear to contradict the FDA's safety statements. The adverse reaction reports detail 26 new deaths reported between September 1, 2010 and September 15, 2011 as well as incidents of seizures, paralysis, blindness, pancreatitis, speech problems, short term memory loss and Guillain-Barré Syndrome. The documents come from the FDA's Vaccine Adverse Event Reporting System (VAERS) which is used by the FDA to monitor the safety of vaccines.

That's 26 reported deaths of young, previously healthy, girls after Gardasil vaccination in just one year.

My questions are these : Is every effect going to be dismissed as 'coincidence' and all the effects ignored? Or are these damaged girls going to be taken seriously in South Africa? Clearly the VAERS system had no option but to pay out nearly R80,000,000 to these victims. Is South Africa prepared to accept this liability for a vaccine that has not even been tested on black Africans?

I look forward to your comment on this as well as a reply to my earlier emails.

Many thanks again for your time, I do appreciate it.

Kind regards

Sarah

From: Debbie van Wyk [<mailto:webmaster@cansa.org.za>]

Sent: 20 August 2015 11:35 AM

Subject: Your Comment on the CANSA Website

Dear Sarah

Thank you for your query. I have followed up for you with CANSA's Head of Health.

Please find a response from Professor Michael Herbst (CANSA's Head of Health) below:

Dear Sarah

Thank you for your questions regarding the Human Papilloma Virus Vaccine.

Please forward to CANSA any scientific evidence (unbiased peer-reviewed research) / scientific reference that supports and proves that:

- HPV vaccines are deadly
- That several hundred women have died as a direct result of the vaccine (please reference country / countries where women have died & number of women who have died)
- That the HPV vaccine was directly responsible for the disability / disabilities that are claimed to result from HPV vaccine (include disability type, numbers affected and country)
- That there is a direct link between HPV vaccine and the chronic health problems you refer to (specific chronic conditions, numbers affected and country)

Please forward scientific information regarding the banning of HPV vaccine by different countries together with the scientific grounds on which the vaccine was banned – please also identify the countries by name.

Find attached a few abstracts of peer-reviewed scientific research which categorically state that HPV vaccine prevents cervical cancer and Google 'PubMed' and then the key words "HPV vaccine Cervical Cancer Prevention" and read further scientific evidence supporting this.

Please also find our Fact Sheet regarding the Human Papilloma Virus Vaccine here:

<http://www.cansa.org.za/files/2015/05/Fact-Sheet-Human-Papilloma-Virus-Infection-Cancer-May-2015.pdf>

Kind Regards

Professor Michael C Herbst
Head of Health
Cancer Association of South Africa (CANSA)

Sarah to CANSA : attachment is my 100 page document/research

On 13 September 2015 at 17:29, Sarah > wrote:

Dear Debbie/Prof Herbst

Many thanks indeed for your email and the questions that you posed.

As you will see from the attached document I have spent a considerable amount of time compiling information, references and sources on the HPV vaccines. I sincerely hope that you will do me the honour of reading through all the information and answering the questions where posed.

I look forward to your reply in due course.

Yours in health

Sarah

On 15 September 2015 at 08:48, Sarah wrote:

Dear Debbie

Please could you send one more link to Prof Herbst?

This is an account of a presentation to the UK Parliament by HPV vaccine damaged girls from the Cervarix vaccine.

<http://sanevax.org/uk-parliamentary-meeting-families-girls-injured-hpv-vaccines/>

As it says at the bottom of the report : 'There are only so many times you can say that this is a coincidence'.

Many thanks indeed.

Kind regards

Sarah

15 September 2015

Dear Sarah

I have done so and also included CANSA's Head of Research, Melissa Wallace.

Kind regards

Debbie Van Wyk
CANSA Webmaster

From: Sarah
 Sent: 11 October 2015 09:45 PM
 To: 'Debbie van Wyk'
 Subject: FW: Feedback on Customer Query from MSD Gardasil and tolerability

Dear Debbie

Following on from previous correspondence, I thought I would send you this email.

I can also apply the first paragraph to CANSA but I do acknowledge that the document I sent is a lengthy one.

I do hope to receive a reply from CANSA very shortly.

Many thanks again for your time.

Kind regards

Sarah

From: Sarah
 Sent: 11 October 2015 09:22 PM
 To: 'Lizeth Kruger' - DIS-CHEM
 Cc: 'Tanya Booyens'; 'Brian Epstein';
 Subject: FW: Feedback on Customer Query from MSD Gardasil and tolerability

Dear Lizeth

Further to our correspondence below, I am a little disappointed that I have not yet received a response. I do realise that the document I sent you (an updated one is attached) is very lengthy but I would have thought that four weeks would be sufficient to at least get an acknowledgement and some answers to my questions concerning the administration of this vaccine and follow-up procedures.

Besides following up on my correspondence to you, I wish to raise a further query concerning the misleading article that Dis-Chem has published in your "Benefits" magazine (Issue 51 – Spring edition), written by Dr Karen Koch.

At this point I also wish to express disappointment that it would appear you have not forwarded either my queries or the attached document to Dr Koch prior to the publication of the article. Alternatively, if you have forwarded it to Dr Koch it would appear that it has been totally ignored.

The title of the article is "Get the Jab on Cancer : HPV Vaccination", with a sub heading "Vaccines save lives. But for the first time in history a vaccine will protect your child from cancer. What's not to love?".

I take serious issue with this article on many levels:-

1. First of all, HPV vaccines have not been proven to prevent one single case of cervical cancer. Not one. I challenge you yet again to provide me with absolute proof that any HPV vaccine has been documented to prevent cervical cancer. Please don't provide me with studies that show a decreased incidence of abnormal PAP smears or prevention of CIN1 or CIN2 or even CIN3. This is not proof that cervical cancer has been prevented. As you will see in section 6 (page 14) of my attached document, the reasons why HPV vaccines have not been proven to prevent cervical cancer are clearly listed.

2. The phrase "what's not to love?" cannot go unchallenged because, if you take the time to read my attached document, there is a whole lot NOT to love, including the hundreds of deaths and

destroyed lives of healthy young women who have been misinformed about the safety and efficacy of these vaccines.

3. Let me now turn to the article itself and reference paragraph 2. Please show me the research that demonstrates that the circulating HPV strains in South Africa, and in particular in young black women, are strains 16 and 18. As you will see from section 9 in my document (page 22), the strains which were found to be circulating in African American females are 35, 66 and 68. It is also worth noting that Africans are grossly under-represented in the clinical trials for this vaccine.

4. Also in paragraph 2, there is absolutely zero evidence that the mere existence of the HPV strain is the actual cause of cervical cancer and therefore it cannot be stated that “two particular strains of Human Papilloma Virus (16 and 18) cause 70% of all cervical cancer”. If you go to the top of page 6 in my document you will see that the FDA actually stated :

"Based on new scientific information published in the past 15 years, it is now generally agreed that identifying and typing HPV infection DOES NOT BEAR A DIRECT RELATIONSHIP TO STRATIFICATION OF THE RISK FOR CERVICAL CANCER. " [my capitals and underscore for emphasis]

Furthermore, if you go to page 25 of my document, you will see the question “why would only 1 in 10,000 women 'infected' with HPV go on to get cervical cancer?”

5. Staying in paragraph 2, there is zero science behind the claim “... preventing 93% of users from cervical cancer”. Again, please provide scientific proof to support this claim. This claim is grossly misleading and is going to lead the reader to believe that the vaccine has an efficacy rate of 93%, something which is absolutely unproven.

6. Under the title “How does the vaccine work?” please provide me with the scientific evidence of the Gardasil 25,000 13-country trial showing 100% prevention of cervical cancer. Likewise with the Cervarix trial on 30,000 females from 10 to 55 years of age.

7. Under the title “Can I get vaccinated?” the article states “if you are over the age of 26, vaccination will be technically off-label but this doesn't mean you won't benefit from it”. If something is “technically off-label” then it is “off-label” and, according to my research, this is illegal if promoted by the manufacturer. It doesn't take too long to find records of pharmaceutical companies being heavily fined for promoting drugs off-label : <http://www.justice.gov/archive/opa/pr/2009/January/09-civ-038.html> . Is Dis-Chem seriously going to promote the dubious practice of off-label drug use for a vaccine that is not proven safe in the older age category and for which any “benefit” has not been proven?

8. Also under this heading, it is stated that the vaccine protection [sic] lasts up to eight years. So in other words, if a 9 year old girl is given this vaccine it gives protection [sic] until she is 17. How many 17 year olds are developing cervical cancer in South Africa? All the research points to the fact that cervical cancer mostly occurs in women over 20 and is very rare under 20. Various sources including the one below confirm that this cancer “occurs in mid-life”.
<http://www.cancer.org/cancer/cervicalcancer/detailedguide/cervical-cancer-key-statistics> As stated in your article, it is not yet certain whether booster shots will be needed. Presumably when the vaccine fails to prevent cervical cancer there will be a call for booster shots, the safety of which will not have been proven and which again will expose vulnerable young girls to the serious adverse effects of these vaccines.

9. As stated in the attached document, page 52, if a female has already been exposed to a vaccine strain HPV virus, she is 44.6% more likely to develop cervical cancer. So it is understandable why the manufacturers want to catch young girls very early. However, as asked in my document, where is the screening for the HPV virus before administration of the vaccine? And, if booster shots will be required, will screening be compulsory to determine if the female has been exposed to the vaccine

strain HPV virus?

10. The very fact that PAP smears are still required when vaccinated absolutely negates the requirement for HPV vaccines. At a cost of R4.6 billion (yes, that's BILLION – see my calculations on page 24) for the South African HPV vaccination program in order to prevent [sic] 2100 HPV cervical cancer deaths, then the cost to prevent each death is R1,890,000. Where is the funding going to come from for this vaccination program and where is the proposed program to get all these young girls/women into a regular PAP smear testing program? The PAP smear test has already been proven (on its own) to be biggest THE single factor in the prevention of cervical cancer. Why do we need to spend R4.6 billion on an unproven and dangerous vaccine when we should be spending money on a well-proven, perfectly safe and very effective PAP smear testing program?

11. The last section of the article “Is it Safe?” has completely ignored the wealth of information and data flowing in on the serious adverse effects of these vaccines. In my document attached there are dozens of references from various sources which is conclusive evidence of the dangers of these vaccines – please see 13 pages of evidence in Appendix C and Appendix D which any sane, rational person would be hard pushed to ignore. Show this to any woman contemplating getting vaccinated and most women would probably say “no”. But of course, the pharmaceutical companies don't want that to happen, hence the deliberate withholding of this evidence?

12. The last question in the article “is it safe NOT to vaccinate?” has to be a resounding YES!!! It is far safer to remain in a PAP smear testing program than it is to get the vaccine. PAP smears are non-toxic, perfectly safe, have zero adverse effects or serious adverse effects and have been proven to save thousands upon thousands of women's lives. The same cannot be said for HPV vaccines.

13. This matter is serious. Very serious. The comment in the article that “the anti-vaccination group will be hard pressed to find fault with this vaccine” is completely erroneous. I invite all the recipients of this email to watch this 4 minute report on the Irish Parliament where Senator Paschal Mooney, on 8th October 2015, addressed the Irish Parliament on the issue of HPV vaccine damaged young women who have formed their own support group called www.regret.ie. <https://www.youtube.com/watch?v=OSpu0XLV9sl&feature=youtu.be> . He states that there are young women who have been “confined to their beds and admitted to hospital psychiatric wards, who are suffering from almost terminal fatigue, who have had their sporting careers disrupted to the point where they can no longer play their games – all because of this vaccination”. He refers to a minister to whom he addressed this issue and who has refused to respond to the questions raised. He refers to the medical profession which is protecting the pharmaceutical companies, who are denying that there are these adverse side effects. He further states that the HSC (in his opinion) is acting “disgracefully” by not supplying the information leaflet for the patients.

How many South African patients have been given the product information leaflet for the HPV vaccine? How many have been given true 'informed consent'? How many parents are shown the product information leaflet?

Senator Mooney goes on to say that the more he delved into this situation the more he believes that this is a “national disgrace”. He also refers to the fact that this vaccine is having serious adverse effects worldwide.

This is not some “anti-vaccination group”, this is a senator in the Irish Parliament who – thankfully – has listened the young girls and women who have been seriously damaged by these vaccines. This has got nothing to do with being anti-anything – this is raising the awareness that something is seriously wrong with this vaccine. He is not alone in his attempts to raise awareness – there are numerous doctors, scientists and researchers worldwide trying to bring this to the attention of the general public but are being thwarted by governments and organisations who are heavily influenced by the pharmaceutical companies.

In response to Dr Koll's comment (in the article) that "it's tragic that women are hesitant to vaccinate". As a woman who has been through the treatment for pre-cancerous cells of the cervix, and who has thoroughly investigated this vaccine, I personally would not go anywhere near this vaccine and I would advise any woman to do the same. It's an absolute disgrace that the serious adverse effects of this vaccine are being deliberately hidden from the general public. It is no wonder that women are "hesitant to vaccinate" once they start investigating this vaccine. Any woman of sound mind would draw the same conclusion as I have.

It is also an absolute disgrace that Dis-Chem, CANSA and Discovery Health appear to be not just refusing to fully inform the general public of the potential dangers of this vaccine (and/or refusing to investigate the serious adverse effects), they are actively promoting it as "safe and effective".

Unless you inform me to the contrary, I will have to accept that my last paragraph is the truth.

Kind regards

Sarah

Note: As at 16th December 2015, neither Dis-Chem nor Dr Koll has responded.

From: Sarah
Sent: 15 November 2015 09:50 PM
To: 'Izak Mahali'
Subject: FW: Feedback on Customer Query from MSD Gardasil and tolerability

For the attention of Prof Herbst

I am sorely disappointed to note that I have not received a response from CANSA.

It would appear that there is collusion amongst various organisations and companies to ignore the mounting evidence of serious adverse effects of the HPV vaccines.

Why is CANSA ignoring my queries?

I consider it completely unacceptable that CANSA refuses to answer me.

Is CANSA not aware of the increasing number of petitions being made to various governments and health departments by victims of the very serious adverse effects of these vaccines? Here are links to two very recent enquiries made in the Irish Parliament and the Scottish Parliament:-

https://www.youtube.com/watch?v=g7m35_1FN8U&feature=youtu.be&t=3580
(Scottish Public Petitions Committee)

<https://www.youtube.com/watch?v=OSpu0XLV9sl&feature=youtu.be>
(Irish Parliament)

I am pursuing this and will shortly be going public with the truth about how I have been treated with regard to this matter.

Thank you for your attention and I look forward to hearing from you very soon.

Yours sincerely

Sarah

From: Michael Herbst (Prof) [<mailto:mherbst@cansa.org.za>]
Sent: 16 November 2015 09:25 AM
To: Radiah Sadan
Subject: RE: Feedback on Customer Query from MSD Gardasil and tolerability

Dear Radiah
Attached please find my response.
Regards
Michael C

From: Info [<mailto:info@cansa.org.za>]
Sent: 17 November 2015 10:14 AM
To:
Subject: FW: Feedback on Customer Query from MSD Gardasil and tolerability

Dear Sarah,

Please find Prof Herbst response below.

Thank you for your time and patience.

Kind regards,

Radiah Sadan
Information Co-ordinator

Tel: +27 (0)21 689 5381
Cell: +27 (0)81 322 5870
Fax2Email: +27 (0)86 512 8521
Follow CANSA on [Facebook](#) | [Twitter](#) | [Pinterest](#)

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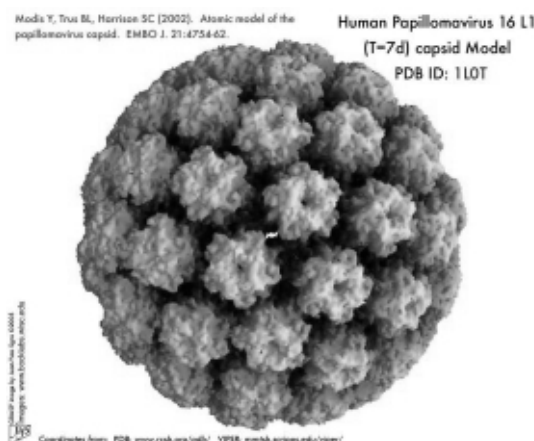
Cancer Association of South Africa (CANSA)

Fact Sheet On Human Papilloma Virus Infection and Cancer

Introduction

The human papillomavirus (HPV) is a DNA virus from the papillomavirus family that is capable of infecting humans. Like all papillomaviruses, HPVs establish productive infections only in keratinocytes of the skin or mucous membranes. While the majority of the known types of HPV cause no symptoms in most people, some types can cause warts (verrucae), while others can – in a minority of cases – lead to cancers of the cervix, vulva, vagina, penis, oropharynx and anus. Recently, HPV has also been linked to an increased risk of cardiovascular disease. In addition, HPV 16 and 18 infections, apart from being responsible for cervical cancer, are strongly associated with an increased risk of oropharyngeal (throat) cancer (Wikipedia).

[Picture Credit: HPV-16]



Human papillomavirus (HPV), specifically cancer-related types, is likely associated with myocardial infarction or stroke among women, according to a *Journal of the American College of Cardiology (JACC)*. The study, which is based on data from 2 450 women between the ages of 20 and 59 enrolled in the National Health and Nutrition Examination Survey between 2003 to 2006, is the first-ever to look at the correlation between cardiovascular disease and HPV. According to the study, 60 women (2,5 percent) reported having cardiovascular disease (CVD). Of those, the study results found that HPV and CVD still persevered after adjustment for health/sex behaviours, medical conditions, and cardiovascular risk burden and management. "[This indicates] that conventional risk factors cannot fully explain the relation of HPV to CVD and that presence of HPV infection, especially cancer-associated genotypes, is a strong and independent correlate for CVD," study authors said. (American College of Cardiology).

More than 30 to 40 types of HPV are typically transmitted through sexual contact and infect the anogenital area. Some sexually transmitted HPV types may cause genital warts. Persistent infection with 'high-risk' HPV types - different from the ones that are responsible for causing skin warts - may progress to precancerous lesions and invasive cancer. HPV infection is a cause of nearly all cases of cervical cancer (Wikipedia).

High and Low Risk Human Papilloma Viruses

Most people infected with HPV never develop any symptoms, however, there are a number of conditions that can result from an HPV infection.

HPV Research Scientists have separated HPV types into those that are more likely to develop into cancer and those that are less likely. The so-called 'high-risk' types are more likely to lead to the development of cancer, while 'low-risk' viruses rarely develop into cancer.

The sexually transmitted varieties of 'high-risk' HPV types include:

HPV-16	HPV-18	HPV-31	HPV-33	HPV-35	HPV-39
HPV-45	HPV-51	HPV-52	HPV-56	HPV-58	HPV-59
HPV-68	HPV-69				

A few other HPV types are also sometimes included on this list. These 'high-risk' HPV types cause growths that are usually flat and nearly invisible as compared to the warts caused by types HPV-6 and HPV-11.

Up to 70% of cervical cancer cases are caused by HPV-16 and HPV-18.

'Low-risk' HPV types can cause no symptoms or may cause conditions such as genital warts, but do not cause cervical cancer. Warts can form weeks, months, or even years after sexual contact with a person who has genital HPV. It is also possible that warts may never appear. In fact, most people with 'low-risk' HPV types never know they are infected because they do not get warts or any other symptoms.

The following table lists various conditions along with their associated types of HPV:

Disease	HPV Type
Cervical cancer	16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58
Precancerous changes	16, 18, 34, 39, 42, 55
Laryngeal papillomas	6, 11, 30
Genital Warts	6, 11, 30, 40, 41, 42, 43, 44, 45, 51, 54
Common warts	1, 2, 4, 26, 27, 29, 41, 57
Flat warts	3, 10, 27, 28, 41, 49
Plantar warts	1, 2, 4

(eMedTV).

HPV Type and Disease Association according to Eileen M Burd:

Disease	HPV type
Plantar warts	1, 24, 63
Common warts	2, 1, 4, 26, 27, 29, 41, 57, 65, 77, 1283, 4, 10,
Flat warts	3, 10, 26, 27, 28, 38, 41, 49, 75, 76
Other cutaneous lesions (e.g., epidermoid cysts, laryngeal carcinoma)	6, 11, 16, 30, 33, 36, 37, 38, 41, 48, 60, 72, 73
Epidermoid dysplasia verruciformis	2, 3, 10, 5, 8, 9, 12, 14, 19, 52, 017, 212, 223, 24, 25, 36, 37, 38, 47, 50
Recurrent respiratory papillomatosis	6, 11
Focal epithelial hyperplasia of Heck	13, 32

Disease	HPV type
Conjunctival papillomas/carcinomas	6, 11, 16
Condyloma acuminata (genital warts)	6, 11, 30, 42, 43, 45, 51, 54, 55, 70
Cervical intraepithelial neoplasia	
Unspecified	30, 34, 39, 40, 53, 57, 59, 61, 62, 64, 66, 67, 68, 69
Low risk	6, 11, 16, 18, 31, 33, 35, 42, 43, 44, 45, 51, 52, 74
High risk	16, 18, 31, 33, 35, 39, 42, 44, 45, 51, 52, 56, 58, 66
Cervical carcinoma	16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 66, 68, 70

Burd, E.M. 2003. Human papillomavirus and cervical cancer. Clin Microbiol Rev. Jan; 16(1):1 -17. Doi: 10.1128/CMR.16.1.1-17.2003
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC145302/table/t1/>

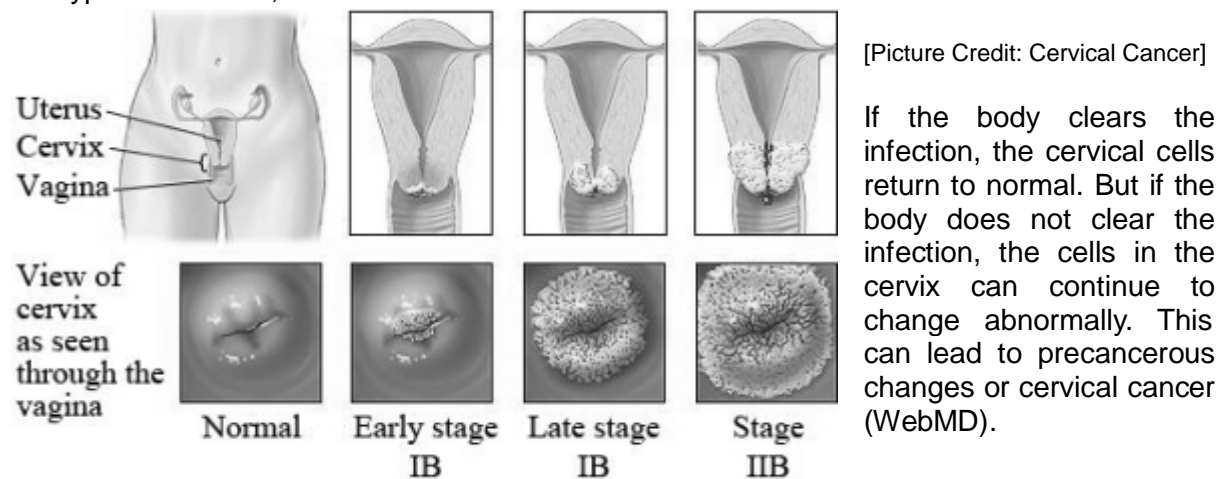
HPV Infection

Genital human papillomavirus (also called HPV) is the most common sexually transmitted infection (STI). There are more than 40 types of HPVs that can infect the anogenital areas of males and females. These HPV types can also infect the mouth and throat.

HPV can cause serious health problems, including genital warts and certain cancers. There is no certain way to tell who will develop health problems from HPV and who will not. In most cases HPV goes away by itself before it causes any health problems, and most people who become infected with HPV do not even know that they have it.

HPV is not the same as herpes or HIV (the virus that causes AIDS). Both viruses can be passed on during sexual contact but they have different symptoms and cause different health problems (Centers for Disease Control and Prevention).

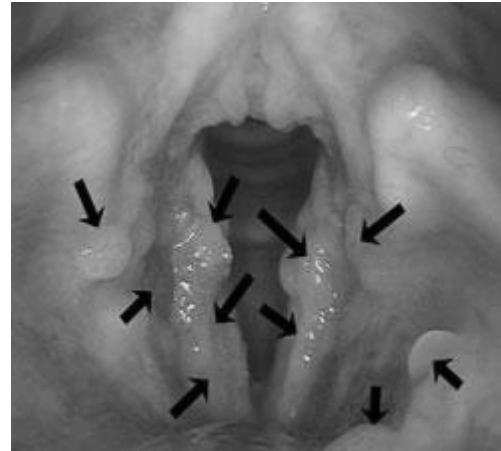
Cervical Cancer – the presence of ‘high-risk’ HPV types may lead to abnormal cell changes and can cause genital cancers: cervical cancer as well as cancer of the vulva, anus, and penis. In fact, researchers say that virtually all cervical cancers - more than 99% - are caused by these ‘high-risk’ HPV viruses. The most common of the high-risk strains of HPV are types 16 and 18, which cause about 70% of all cervical cancers.



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Please refer to CANSA's Fact Sheet on Cervical Cancer.

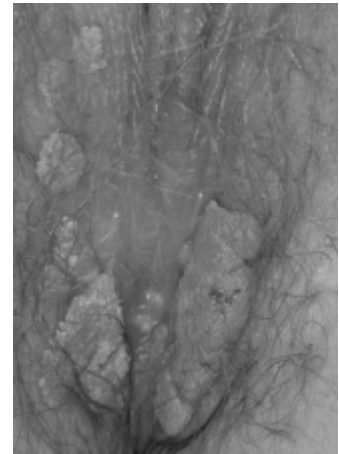
Laryngeal Papillomas – papillomas are benign epithelial tumours that are caused by infection with the human papilloma virus (HPV). They are the most common benign neoplasms affecting the larynx and upper respiratory tract. Malignant degeneration to squamous cell carcinoma can occur, but is very rare. Laryngeal papillomas are similar to verrucae on the skin (common wart) and *condyloma acuminatum*, or genital warts. Infection with the virus is ubiquitous (universal).



[Picture Credit: Laryngeal papilloma]

Why some infected people develop clinical expression of papilloma (respiratory, genital, or cutaneous) and some people never develop clinical disease remains uncertain. The reality is that some individuals appear to be susceptible to the virus and others do not. Although some individuals can acquire the virus through intimate contact, the virus can be transmitted from mother to foetus and laryngeal (respiratory) papillomatosis is not considered a sexually transmitted infection (Center for Voice and Swallowing).

Genital warts - a genital wart is an infection of the skin, in genital or anal area, as well as the mucous membranes of the rectum, cervix and vagina. Genital warts are also known as venereal warts or *condylomata acuminata*. Genital warts are one of the most common kinds of sexually transmitted infections (Medical News Today).



[Picture Credit: Female Genital Warts]

HPV virus infection in men can also cause health problems. It is important for men to understand how to reduce the risks of HPV infection. HPV infection can increase a man's risk of getting genital cancers, although these cancers are not common. HPV can also cause genital warts in men, just as in women.



[Picture Credit: Male Genital Warts]

Warts are caused by viruses and can appear anywhere on the body. Those that show up in the genital area are caused by the human papillomavirus, commonly called HPV and are easily transmitted by sexual contact. HPV infection is one of the most common sexually transmitted infections. More than half of men who are sexually active will have HPV at some time in their life. Often, a man's body will clear the virus on its own with no health problems (WebMD).

Penile Cancer – Penile cancer is a disease in which malignant (cancer) cells form in the tissues of the penis.

[Picture Credit: Penile Cancer due to HPV Infection]

- x Risk factors for developing penis cancer include human papillomavirus (HPV) infection, not being circumcised, being age 60 or older, phimosis (narrowing of the foreskin), poor personal hygiene, many sexual partners, and tobacco use
- x Signs and symptoms of penile cancer include sores, redness, irritation, discharge, bleeding, or a lump on the penis
- x A biopsy may be taken to determine if one has penile cancer
- x Treatments for penile cancer include surgery, radiation therapy, and chemotherapy
- x Prognosis and treatment options depend on the stage of the cancer, the location and size of the tumour, and whether the cancer has just been diagnosed or has recurred.



(Medicine.Net).

Common warts - common warts are small, grainy skin growths that occur most often on the fingers or hands. Rough to the touch, common warts also often feature a pattern of tiny black dots - sometimes called seeds - which are small, clotted blood vessels.

[Picture Credit: Common Warts]

Common warts are caused by a virus and are transmitted by touch. Children and young adults are more likely to develop common warts, as are people who have weakened immune systems. Common warts usually disappear on their own, but many people choose to remove them because they find them bothersome or embarrassing (Mayo Clinic).



Plantar warts - plantar warts are noncancerous skin growths on the soles of the feet caused by the human papillomavirus (HPV), which enters the body through tiny cuts, breaks or other vulnerable sites on the skin of the feet. Plantar warts often develop beneath pressure points in the feet, such as the heels or balls of the feet. This pressure also may cause a plantar wart to grow inward beneath a hard, thick layer of skin (callus).

[Picture Credit: Plantar Warts]

Most plantar warts are not a serious health concern and may not require treatment. However, plantar warts can be bothersome or painful. If self-care treatments for plantar warts do not work, one may need to see one's doctor to have them removed (WebMD).



Round warts - In most cases, the body's immune system defeats an HPV infection before it has a chance to create any warts. When warts do appear, they may vary in appearance depending on which variety of HPV is involved. Flat warts are flat-topped, slightly raised lesions darker than your regular skin colour. They usually appear on the face, neck, hands, wrists, elbows or knees. HPV infections that cause flat warts usually affect children, adolescents and young adults (Mayo Clinic).



[Picture Credit: Round Warts]

Anal Cancer - 95% of anal cancers are caused by the human papillomavirus (HPV). There are many types of HPV. Some HPV types cause benign warts, but some cause lesions (also called dysplasia) that can progress to invasive cancer. HPV-16 and HPV-18 are the high-risk strains responsible for the majority of HPV-associated cancers. Nearly 80% of sexually active people will have a genital HPV infection at some point in their lives.



[Picture Credit: Anal Cancer due to HPV Infection]

Men who have sex with men (MSM) are especially at risk of anal cancer due to HPV infection.

Risk Factors for HPV Infection

HPV infections are common. Risk factors for HPV infection include:

- o Number of sexual partners - the greater your number of sexual partners, the more likely you are to contract a genital HPV infection. Having sex with a partner who has had multiple sex partners also increases your risk
- o Age - common warts occur most often in children and adolescents. While plantar warts may occur in adults, they're more likely to initially surface during childhood. Genital warts occur most often in adolescents and young adults
- o Weakened immune systems - people who have weakened immune systems are at greater risk of HPV infections. Immune systems can be weakened by HIV/AIDS or by immune system-suppressing drugs used after organ transplants
- o Damaged skin - areas of skin that have been punctured or opened are more prone to develop common warts. For example, people who bite their fingernails are more likely to develop warts around their fingernails
- o Personal contact - touching someone's warts or not wearing protection before contacting surfaces that have been exposed to HPV - such as public showers or swimming pools - may increase one's risk of HPV infection

(Mayo Clinic).

Treatment for HPV

There is currently no medical treatment for HPV infection. Infection with some HPV types may cause changes to cells in the cervix which can lead to cervical cancer. These are classified as 'high-risk' HPV types.

If one is infected with a 'high-risk' type of HPV, one will usually have no symptoms whether man or woman.

In most women, infection with HPV causes no harm because the immune system clears up the initial infection. This is particularly the case for women who are under 30 and who tend to have many HPV infections. Most women with an HPV infection do not go on to develop cervical cancer.

In men, at present there is no reliable test to detect HPV infection and it is often very difficult to diagnose.
(NHS.UK).

One important way to prevent cervical cancer is through regular screening with the Pap smear test. An HPV test can also be used at the same time as the Pap smear test for women 30 years and older. The Pap smear and HPV tests can find early problems that could lead to cervical cancer over time. These tests do NOT:

- o Check for early signs of other cancers
- o Check your fertility (ability to get pregnant)
- o Check for all HPV types –The HPV test only checks for specific HPV types that are linked to cervical cancer.
- o Check for other sexually transmitted infections (STIs).

Experts recommend HPV testing for women who are:

- o Age 30 or older - as part of regular screening, with a Pap test, or
- o Age 21 or older - for follow-up of an abnormal Pap test result

One must request a HPV test.

A HPV test is normally not recommended as part of regular screening for younger women and teens. HPV is very common in women under age 30. It is not useful to test women under age 30 for HPV, since most HPV that is found in these women will never cause them health problems. Most young women will fight off HPV within a few years.

HPV is less common in women over the age of 30, who are at increasing risk for cervical cancer. HPV is also more likely to signal a health problem for these women, who may have had the virus for many years. Doctors may use the HPV test with the Pap smear test to tell if these women are more likely to get cervical cancer in the future and if they need to be screened more often.

Getting regular Pap smear tests, even without the HPV test, is still a good way to prevent cervical cancer - for both younger and older women (Centers for Disease Control and Prevention).

Please refer to CANSA's Fact Sheet on Cervical Cancer as well as to CANSA's Position Statement on Cervical Cancer.

Common Questions and Answers Regarding HPV Vaccination

Why are HPV vaccines needed?

Certain HPV types cause cancer, including cervical, vulvar, vaginal, penile, anal, and oropharyngeal (base of the tongue, tonsils and back of throat) cancers. Certain HPV types also cause most cases of genital warts in both men and women.

HPV is a common virus that is easily spread by skin-to-skin contact during sexual activity with another person. It is possible to have HPV without knowing it, so it is possible to unknowingly spread HPV to another person.

HPV vaccine is a strong weapon in prevention. These vaccines are available to protect individuals against some of the most common HPV types and the health problems that the virus can cause.

How common are the health problems caused by HPV?

HPV is the main cause of cervical cancer. It is estimated that about 1 in 100 sexually active adults have genital warts at any given time. HPV infection is responsible for 80% of cases of penile cancer. It is also a major cause of anal cancer.

What HPV vaccines are available in the South Africa?

Two HPV vaccines are available in South Africa. These vaccines are:

- o Cervarix, a bivalent vaccine made by GlaxoSmithKline
- o Gardasil, a quadrivalent vaccine made by Merck.

What vaccine is used by the National Department of Health in South Africa?

The National Department of Health in South Africa makes use of the bivalent vaccine in its HPV vaccination programme for school girls.

How are the two HPV vaccines similar?

- o Both vaccines are very effective against diseases caused by HPV types 16 and 18 - HPV 16 and 18 cause most cervical cancers, as well as other HPV associated cancers
- o Both vaccines have been shown to prevent cervical pre-cancers in women
- o Both vaccines are said to be safe following trials
- o Both vaccines are made with a very small part (in this case, the protein outer coat) of the human papillomavirus (HPV) that cannot cause infection
- o Both vaccines are given as injections and usually require 3 doses

It has since been established that two (2) doses of the bivalent vaccine is just as effective as the three (3) prescribed doses.

How are the two HPV vaccines different?

The quadrivalent vaccine protects against HPV types 6, 11, 16 and 18 - the types that cause most genital warts

Only the quadrivalent vaccine has been tested and licensed for use in males

The bivalent vaccine protects against HPV types 16 and 18

The vaccines have different adjuvants—a substance that is added to the vaccine to increase the body's immune response

Who should get HPV vaccine?

Cervarix and Gardasil are licensed, and said to be safe, and effective for females ages 9 through 26 years. The Centers for Disease Control and Prevention (CDC) in the United States recommends that all 11 or 12 year old girls get the 3 doses (shots) of either brand of HPV vaccine to protect against cervical cancer. Gardasil also protects against most genital warts, as well as some cancers of the vulva, vagina and anus. It is further recommended that girls and young women ages 13 through 26 should get HPV vaccine if they have not received any or all doses when they were younger.

Gardasil is also licensed, and said to be safe, and effective for males ages 9 through 26 years. The Centers of Disease Control and Prevention (CDC) in the United States recommends Gardasil for all boys aged 11 or 12 years, and for males aged 13 through 21 years, who did not get any or all of the three recommended doses when they were younger.

All men may receive the vaccine through age 26, and should speak with their doctor to find out if getting vaccinated is right for them.

The vaccine is also recommended for gay and bisexual men (or any man who has sex with men) and men with compromised immune systems (including HIV) through age 26, if they did not get fully vaccinated when they were younger.

Why is HPV vaccine recommended at an early age?

For the HPV vaccine to work best, it is very important for preteens to be vaccinated long before any sexual activity begins. It is possible to be infected with HPV the very first time one has sexual contact with another person. Also, the vaccine produces higher antibody that fights infection when given at this age compared to older ages.

In South Africa the ideal age for administration of the HPV vaccine has been determined to be nine (9) years of age or older based on the onset of puberty among South African girls.

What is the recommended schedule (or timing) of the 3 HPV doses (shots)?

3 doses (shots) are recommended over six months. CDC recommends that the second dose be given one to two months after the first, and the third dose be given six months after the first dose.

It has since been established that two (2) doses of the bivalent vaccine is just as effective as three (3) doses of the vaccine.

Are the HPV vaccines safe and effective?

Both the vaccines as said to be safe and effective. Both vaccines were tested in thousands of people around the world. These studies showed no serious side effects. Common, mild side effects included pain where the shot was given, fever, headache, and nausea. As with all vaccines, CDC and FDA continue to monitor the safety of these vaccines very carefully.

Do people faint after getting HPV vaccines?

People faint for many reasons. Some individuals may faint after any medical procedure, including receiving vaccines. It is possible for falls and injuries to occur after fainting. Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and related injuries.

Can HPV vaccines treat HPV infections, cancers, or warts?

HPV vaccines will not treat or get rid of existing HPV infections. Also, HPV vaccines do not treat or cure health problems (like cancer or warts) caused by an HPV infection that occurred before vaccination. It is important for adult women to still get cervical cancer screening even if they have completed the HPV vaccine series.

How important is it to get HPV vaccine?

The HPV vaccines are important tools to help prevent cervical cancer and other HPV related cancers and genital warts.

Why are HPV vaccines not recommended for people older than 26?

Both vaccines were studied in thousands of people from 9 through 26 years old and found to be safe and effective for these ages.

Should pregnant women be vaccinated?

HPV vaccine should only be administered to girls before they become sexually active – once infected with HPV, the vaccine has no role to play in preventing cervical cancer.

Pregnant women are not included in the recommendations for HPV vaccines. Studies show neither vaccine caused problems for babies born to women who got the HPV vaccine while they were pregnant. Getting the HPV vaccine when pregnant is not a reason to consider ending a pregnancy. Thus, to be on the safe side until even more is known, pregnant women should not be given HPV vaccines until their pregnancy is completed. (Centers for Disease Control and Prevention).

Is Parental/Legal Guardian Consent Required?

Parental/legal guardian consent is required before any child will be given a HPV vaccination in South Africa. This also applies to the HPV programme of the National Department of Health and National Department of Education in South African public schools.

FDA approves first human papillomavirus test for primary cervical cancer screening

The US Food and Drug Administration recently approved the first FDA-approved HPV DNA test for women 25 and older that can be used alone to help a health care professional assess the need for a woman to undergo additional diagnostic testing for cervical cancer. The test also can provide information about the patient's risk for developing cervical cancer in the future.

Using a sample of cervical cells, the cobas HPV Test detects DNA from 14 high-risk HPV types. The test specifically identifies HPV 16 and HPV 18, while concurrently detecting 12 other types of high-risk HPVs.

Based on results of the cobas HPV Test, women who test positive for HPV 16 or HPV 18 should have a colposcopy, an exam using a device that illuminates and magnifies the cervix so a physician can directly observe the cervical cells. Women testing positive for one or more of the 12 other high-risk HPV types should have a Pap test to determine the need for a colposcopy. Health care professionals should use the cobas HPV Test results together with

other information, such as the patient screening history and risk factors, and current professional guidelines.

“Today’s approval offers women and physicians a new option for cervical cancer screening,” said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health at the FDA’s Center for Devices and Radiological Health. “Roche Diagnostics conducted a well-designed study that provided the FDA with a reasonable assurance of the safety and effectiveness when used as a primary screening tool for cervical cancer.”

The FDA first approved the test, called the cobas HPV Test in 2011 for use in conjunction with or as a follow-up to a Pap test (cell cytology), which examines cervical cells for changes that might become cervical cancer.

Today’s approval expands the use of the test to include use as either a co-test or as a primary cervical cancer screening test, however; it does not change current medical practice guidelines for cervical cancer screening. These guidelines are developed, reviewed and modified by groups other than the FDA.

Genital HPVs are a group of more than 40 related viruses and, according to the Centers for Disease Control and Prevention (CDC), are the most common sexually transmitted infections. Approximately 14 ‘high-risk’ HPV types are associated with cervical cancer.

In most cases, a high-risk HPV infection goes away on its own and does not cause any health problems. However, about 10 percent of women infected with high-risk HPV develop a persistent infection which may put them at risk of cancer. Virtually all cervical cancers are caused by HPV infections, with just two types, HPV 16 and HPV 18, responsible for approximately 70 percent of cervical cancers.

Data supporting the use of the cobas HPV Test as a primary screening test for cervical cancer included a study of more than 40,000 women 25 years and older undergoing routine cervical exams. Women who had a positive Pap test or whose cervical cells screened positive for HPV, as well as a subset of women whose Pap and HPV tests were both negative, underwent a colposcopy and cervical tissue biopsy. All biopsy results were compared to the Pap and cobas HPV Test results. Data from this study, which included three years of follow-up on women who went to colposcopy, showed that the cobas HPV Test is safe and effective for the new indication for use.

The cobas HPV Test is manufactured by Roche Molecular Systems, Incorporated, Pleasanton, Calif. (US Food and Drug Administration).

Medical Disclaimer

This Fact Sheet is intended to provide general information only and, as such, should not be considered as a substitute for advice, medically or otherwise, covering any specific situation. Users should seek appropriate advice before taking or refraining from taking any action in reliance on any information contained in this Fact Sheet. So far as permissible by law, the Cancer Association of South Africa (CANSA) does not accept any liability to any person (or his/her dependants/estate/heirs) relating to the use of any information contained in this Fact Sheet.

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Sources and References

American College of Cardiology

<http://www.cardiosource.org/News-Media/Publications/Cardiology-Magazine/HPV-and-CVD.aspx>

Anal Cancer Due to HPV Infection

<http://www.theaidsreader.com/articles/changing-face-anal-cancer>

Centers for Disease Control and Prevention

<http://www.cdc.gov/std/hpv/stdfact-hpv.htm>

<http://www.cdc.gov/std/hpv/pap/>

<http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm>

Center for Voice and Swallowing

<http://www.ucdvoice.org/papilloma.html>

Common Warts

https://www.google.co.za/search?q=flat+genital+warts&source=Inms&tbn=isch&sa=X&ei=gR7UqW4E8-VhQfp-YDQAw&ved=0CAcQ_AUoAQ&biw=1366&bih=600#facrc=_&imgdii=_&imgrc=6qOXsptBHK_7_M%3A%3BvfeTuRENCUU3BM%3Bhttp%253A%252F%252Fmedstation.yale.edu%252Fpedres%252Fwww%252Fwarts_clip_image002_0000.jpg%3Bhttp%253A%252F%252Fmedstation.yale.edu%252Fpedres%252Fwarts.html%3B593%3B417

eMedTV

<http://hpv.emedtv.com/hpv/types-of-hpv.html>

Female Genital Warts

https://www.google.co.za/search?q=female+genital+warts&source=Inms&tbn=isch&sa=X&ei=-IN7Us-CN46thQfxuYDYDA&sqi=2&ved=0CAcQ_AUoAQ&biw=1366&bih=600#facrc=_&imgdii=_&imgrc=_vS16h6qaYE9NM%3A%3BPIK-qGhhJLLP-M%3Bhttp%253A%252F%252Fwww.genital-warts-medication.com%252Fcondyloma-hpv-genital.gif%3Bhttp%253A%252F%252Fgenitalwartsnaturalremedy.com%252F340%252Fget-rid-of%252Fflaser-treatment-for-genital-warts-pills%3B398%3B557

HPV-16

https://www.google.co.za/search?q=hpv&source=Inms&tbn=isch&sa=X&ei=Vjh7UtX7BcSUhQfCmlHwDg&sqi=2&ved=0CAcQ_AUoAQ&biw=1366&bih=643#facrc=_&imgdii=FdNzY3s8kZaNGM%3A%3BdYI2EmOdxZ7kkM%3BFdNzY3s8kZaNGM%3A&imgrc=FdNzY3s8kZaNGM%3A%3B3o2xBd3_A1uwLM%3Bhttp%253A%252F%252Fwww.bristol.ac.uk%252Fbiochemistry%252Fgaston%252FHPV%252Fhpv_in1.jpg%3Bhttp%253A%252F%252Fwww.bristol.ac.uk%252Fbiochemistry%252Fgaston%252FHPV%252Fhpv_information.htm%3B281%3B256

Laryngeal Papilloma

https://www.google.co.za/search?q=laryngeal+papillomatosis&source=Inms&tbn=isch&sa=X&ei=1HN7UsqIFo-ThgfUh4CYBg&sqi=2&ved=0CAcQ_AUoAQ&biw=1366&bih=643#facrc=_&imgdii=_&imgrc=yrxxZIMI5kcPUM%3A%3BPqbJ0UFYn40ooM%3Bhttp%253A%252F%252Fprofessionalvoice.org%252Fimages%252Fmultiple_papilloma_resized.jpg%3Bhttp%253A%252F%252Fprofessionalvoice.org%252FHPV-Papilloma.aspx%3B245%3B225

Mayo Clinic

<http://www.mayoclinic.com/health/common-warts/DS00370>
<http://www.mayoclinic.com/health/hpv-infection/DS00906/DSECTION=symptoms>
<http://www.mayoclinic.com/health/hpv-infection/DS00906/DSECTION=risk-factors>

Medicine.Net

http://www.medicinenet.com/penis_cancer/article.htm#penis_cancer_facts

Medical News Today

<http://www.medicalnewstoday.com/articles/155236.php>

NHS.UK

<http://www.nhs.uk/chq/Pages/2383.aspx?CategoryID=118>

Penile Cancer Due to HPV Infection

<http://www.consultantlive.com/urologic-diseases/penile-cancer-squamous-cell-carcinoma-situ/page/0/3>

Round Warts

https://www.google.co.za/search?q=round+genital+warts&source=lnms&tbm=isch&sa=X&ei=_IR7Uq-RPJDxhQfFyYCYAQ&ved=0CAcQ_AUoAQ&biw=1366&bih=600#facrc=_&imgdii=iHvNpHP3byxYBM%3A%3B3glYDTr7ZY6YeM%3BiHvNpHP3byxYBM%3A&imgrc=iHvNpHP3byxYBM%3A%3BZQBy4OSYUQjcm%3Bhttp%253A%252F%252Fshs.osu.edu%252Fposts%252Fimages%252Fverruca-vulgaris-big.jpg%3Bhttp%253A%252F%252Fshs.osu.edu%252Fblog%252Fcan-a-wart-on-my-finger-spread-to-my-genitals%3B369%3B276

US Food and Drug Administration

<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm394773.htm>

WebMD

<http://www.webmd.com/sexual-conditions/hpv-genital-warts/cervical-cancer-hpv-what-women-girls-should-know>
<http://www.webmd.com/sexual-conditions/hpv-genital-warts/hpv-virus-men>
<http://www.mayoclinic.com/health/plantar-warts/DS00509>

Wikipedia

http://en.wikipedia.org/wiki/Human_papillomavirus

From: Sarah
 Sent: 06 December 2015 05:56 PM
 To: 'Michael Herbst (Prof)'
 Cc: 'Izak Mahali'
 Subject: RE: Feedback on Customer Query from MSD Gardasil and tolerability

Dear Prof Herbst

Thank you for the email from Radiah but there was no response from you to my questions. Attached was a document that is merely standard information and which contains gross inaccuracies such as:-

Are the HPV vaccines safe and effective?

Both the vaccines as said to be safe and effective. Both vaccines were tested in thousands of people around the world. These studies showed no serious side effects. Common, mild side effects included pain where the shot was given, fever, headache, and nausea. As with all vaccines, CDC and FDA continue to monitor the safety of these vaccines very carefully.

Clearly the above is not a response from you but is just a regurgitation from the manufacturer.

Where is the scientific evidence behind "both the vaccines are said to be safe and effective"? Who said they are "safe and effective"? Where is the evidence to back up this claim?

Attached is a report from VAERS which shows that the HPV vaccines are producing startling numbers of adverse effects. The total as at October 2015 is 41,773 adverse effects, including 234 deaths, 8007 did not recover and serious at 5595. Each single number of these events relate to real people, real girls. Each serious event has devastating effects on a young life. We must never forget this.

Here is a link to various studies conducted by GSK which show serious adverse effects:

https://clinicaltrials.gov/ct2/show/results/NCT00546078?term=hpv%2Bsafety&recr=Closed&no_unk=Y&rslt=With&rank=13§=X30156#evnt

	Cervarix™ 4-Dose Group	Cervarix™ 3-Dose Group
Total, serious adverse events		
# participants affected / at risk	1/65 (1.54%)	1/50 (2.00%)
Hepatobiliary disorders		
Cholecystitis * 1		
# participants affected / at risk	1/65 (1.54%)	0/50 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Pulmonary embolism * 1		
# participants affected / at risk	0/65 (0.00%)	1/50 (2.00%)

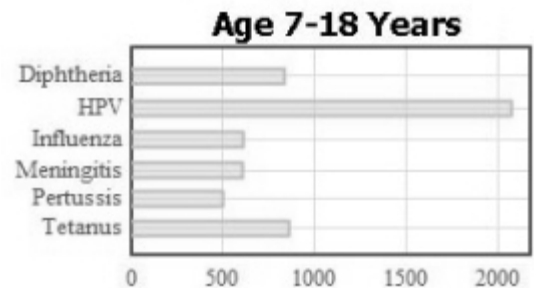
Complete list:

https://clinicaltrials.gov/ct2/results?term=hpv%2Bsafety&recr=Closed&no_unk=Y&rslt=With&type=&cond=&intr=&titles=&outc=&spons=&lead=&id=&state1=&cntry1=&state2=&cntry2=&state3=&cntry3=&locn=&gndr=&rcv_s=&rcv_e=&lup_s=&lup_e=

Plus more links concerning serious adverse events:

<http://www.infectagentscancer.com/content/8/1/6>
 Tomljenovic – list the questions.....

<http://www.nvic.org/Vaccines-and-Diseases/hpv.aspx>
 References for serious adverse events



I still want answers to the questions as laid out in my document that I sent to you. Why is CANSA refusing to answer me?

Kind regards

Sarah

From: Michael Herbst (Prof) [mailto:mherbst@cansa.org.za]
Sent: 06 December 2015 08:36 PM
To: Sarah
Cc: info@cansa.org.za
Subject: RE: Feedback on Customer Query from MSD Gardasil and tolerability

Dear Ms XXXX

March 12, 2014 Global Advisory Committee on Vaccine Safety Statement on the continued safety of HPV vaccination As with all new vaccines, the Global Advisory Committee on Vaccine Safety has been reviewing the safety of HPV vaccines since they were first licensed in 2006. The World Health Organization (WHO) recommends the introduction of HPV vaccination into national immunization programmes where prevention of cervical cancer is a public health priority and the introduction is programmatically feasible [1]. While early detection of pre- and cancerous cells through screening programs has helped decrease incidence rates of cervical cancer in women aged 25-45 in the UK, for example [2], that decrease has plateaued in the past decade. While safety concerns about HPV vaccines have been raised, these have systematically been investigated: to date, the GACVS has not found any safety issue that would alter any of the current recommendations for the use of the vaccine.

The purpose of this update is to summarize the work of GACVS over the past six years in reviewing the safety of HPV vaccines. It is important to highlight and reiterate this work because a number of national immunization programs have been facing real and potential public losses of confidence in their programs as a result of increased negative publicity, even from safety issues that have been addressed.

To date, the GAVCS has reviewed evidence related to syncope, anaphylaxis, venous thromboembolism, adverse pregnancy outcomes, Guillain Barre Syndrome, and stroke [3]. It also examined concerns around the aluminium adjuvant used in HPV vaccines, with considerations around the toxicology of aluminium adjuvants and studies by investigators claiming that aluminium in the quantities used in vaccines are associated with adverse health outcomes [4]. Finally the Committee also reviewed the question of autoimmune disease, specifically around multiple sclerosis (MS), cerebral vasculitis, and an evolving concern over cases of complex regional pain syndrome (CRPS) and/or other chronic pain conditions following vaccination that have surfaced.

With respect to aluminium, the GACVS has had occasion to review the safety of the adjuvant on several occasions, beginning in 1999. At that time, deltoid muscle biopsies performed in France on a number of patients with a variety of complaints revealed in a small number the presence of a minute inflammatory focus of macrophages with associated necrosis. These localized lesions, called macrophagic myofasciitis (MMF), have been shown to contain aluminium salts [5, 6]. Since the location of the lesions in the deltoid muscle coincides with the usual site of injection for vaccines, these microscopic lesions may appear to be related to immunization. The investigators from the "Groupe d'études et de recherche sur les maladies musculaires acquises et dysimmunitaires" (GERMAAD) have suggested that vaccination and localized MMF lesions might be associated with a multi-system disorder. The GACVS has reviewed evidence regarding MMF on several occasions since that time and continues to reaffirm that, while MMF is clearly linked to a vaccination "tattoo" among some patients who have received an aluminium containing vaccine, the associated systemic symptoms related to that finding have never been scientifically proven. Statements about MMF were published in 1999, 2002 and 2004 [4]. While there have never been any published reports of MMF in recipients of HPV vaccines, there is no plausible reason to suspect that any reports of MMF would be associated with systemic symptoms following aluminium containing HPV vaccines any more than the finding of the histological lesion of MMF following hepatitis B vaccine and clinical symptoms.

In 2012, the GACVS reviewed two studies claiming an association between aluminium in vaccines and autism spectrum disorder [7, 8]. It found serious flaws in the two studies that limited their value even for hypothesis generation. In December 2013, the GACVS reviewed evidence related to HPV vaccine and autoimmune disease, specifically multiple sclerosis [3]. While there remain case reports in the literature, multiple epidemiologic studies have not demonstrated any increased risk of autoimmune diseases, including MS, in studies, some of which have included girls who have received HPV vaccine compared to those who had not [9, 10, 11, 12].

Several papers have also been published pertaining to the finding of HPV L1 gene DNA fragments in clinical specimens following HPV vaccination [13, 14]. These papers claimed an association with clinical events of an inflammatory nature, including cerebral vasculitis. While the GACVS has not formally reviewed this work, both the finding of DNA fragments in the HPV vaccine and their postulated relationship to clinical symptoms, have

been reviewed by panels of experts. First, the presence of HPV DNA fragments has been addressed by vaccine regulatory authorities who have clearly outlined it as an expected finding given the manufacturing process, and not a safety concern [15]. Second, the case reports [13] of adverse events hypothesized to represent a causal association between the HPV L1 gene DNA fragments and death were flawed in both clinical and laboratory methodology [16]. The paper described 2 fatal cases of sudden death in young women following HPV vaccine, one after 10 days and one after 6 months, with no autopsy findings to support death as result of cerebral vasculitis or an inflammatory syndrome. Thus the hypotheses raised in these papers are not supported by what is understood about the residual DNA fragments left over following vaccine production [17]: given the extremely small quantities of residual HPV DNA in the vaccine, and no evidence of inflammation on autopsy, ascribing a diagnosis of cerebral vasculitis and suggesting it may have caused death is unfounded.

In June 2013, the GACVS reviewed the concerns arising in Japan in regard to reports described as CRPS in a few cases, and other chronic pain conditions following HPV vaccine. At the time, GACVS found no evidence to suggest a causal link with the HPV vaccine, and recommended careful documentation of each case and definition of diagnostic criteria to guide management and causality assessment. The Committee has meanwhile continued to monitor the HPV vaccine and considered further issues during their meeting in December 2013 [3]. In Japan, an expert advisory committee has continued to meet and review the situation but has not yet reached a conclusion. It is acknowledged that the HPV vaccine may be a more painful injection, leading to frequent complaints of pain, which, in some settings, may trigger additional non-specific complaints [18, 19]. As to Complex Regional Pain Syndrome, this entity has been described following various forms of trauma, including injury, surgical procedures and injections. It is therefore plausible that CRPS could develop following the injection of any vaccine (however, such cases have been very rarely described in the literature [20]).

In summary, the GACVS continues to closely monitor the safety of HPV vaccines and, based on a careful examination of the available evidence, continues to affirm that its benefit-risk profile remains favorable. The Committee is concerned, however, by the claims of harm that are being raised on the basis of anecdotal observations and reports in the absence of biological or epidemiological substantiation. While the reporting of adverse events following immunization by the public and health care providers should be encouraged and remains the cornerstone of safety surveillance, their interpretation requires due diligence and great care. As stated before, allegations of harm from vaccination based on weak evidence can lead to real harm when, as a result, safe and effective vaccines cease to be used. To date, there is no scientific evidence that aluminium-containing vaccines cause harm, that the presence of aluminium at the injection site (the MMF “tattoo”) is related to any autoimmune syndrome, and that HPV DNA fragments are responsible for inflammation, cerebral vasculitis or other immune-mediated phenomena.

References

1. World Health Organization. Human papillomavirus vaccines. WHO position paper. *Wkly Epidemiol Rec* 2009;84:118--31.
2. Foley, GA, Alston, RA, Geraci, MA, Brabin, LB, Kitchener, HB, Birch, J. Increasing rates of cervical cancer in young women in England: An analysis of national data 1982-2006. *British Journal of Cancer*. Volume 105, Issue 1, 28 June 2011, pp 177-184
3. Statements and reports on HPV vaccine 2013 - GACVS Safety update on HPV Vaccines December, 2013 – Published in *WER* vol. 89, 7, 14 Feb 2014, pp 58–60 2013 - GACVS Safety update on HPV Vaccines June, 2013 – Published in *WER* vol. 88, 29, 19 Jul 2013, pp 309–312 2009 – GACVS Report of meeting June 2003 – Published in *WER* vol. 84, 32, 7 Aug 2009, pp 328–329 2008 – GACVS Report of meeting December 2002 – Published in *WER* vol. 84, 5, 30 Jan 2009, p 39 2007 – GACVS Report of meeting June 2007 – Published in *WER* vol. 82, 28/29, 20 Jul 2007, pp 255–256
4. Statements and reports on aluminium-containing vaccines and MMF 2012 – GACVS Report of meeting Jun 2012 – Published in *WER* vol. 87, 30, 27 Jul 2012, pp 282–283 2004 – GACVS Report of meeting December 2004 – Published in *WER* vol. 79, 3, 16, Jan 2004, .p 20 2002 – GACVS Report of meeting June 2002 – Published in *WER* vol. 77.47 22, Nov 2002, pp 392-393 1999 – GACVS Report of meeting June 1999 – Published in *WER* vol. 74, 41, 15 Oct 1999, pp 337-348 Statement from the Global Advisory Committee on Vaccine Safety on aluminium-containing vaccines http://www.who.int/vaccine_safety/committee/topics/aluminium/statement_112002/en/ Questions and answers about MMF http://www.who.int/vaccine_safety/committee/topics/aluminium/questions/en/
5. Gherardi RK, Coquet M, Cherin P, Belec L, Moretto P, Dreyfus PA, Pellissier JF, Chariot P, Authier FJ. Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminium hydroxide in muscle. *Brain*. 2001 Sep;124(Pt 9):1821-31.
6. Authier FJ, Cherin P, Creange A, Bonnotte B, Ferrer X, Abdelmoumni A, Ranoux D, Pelletier J, Figarella-Branger D, Granel B, Maisonnobe T, Coquet M, Degos JD, Gherardi RK. Central nervous system disease in patients with macrophagic myofasciitis. *Brain*. 2001 May;124(Pt 5):974-83.

7. Tomljenovic L, Shaw CA. Do aluminium vaccine adjuvants contribute to the rising prevalence of autism? *Journal of Inorganic Biochemistry*, 2011; 105: 1489–1499.
 8. Tomljenovic L, Shaw CA. Aluminium vaccine adjuvants: are they safe? *Current Medicinal Chemistry*, 2011; 18(17):2630–2637.
 9. Siegrist CA. Autoimmune diseases after adolescent or adult immunization: what should we expect? *CMAJ*. 2007 Nov 20;177(11):1352-4.
 10. Arnheim-Dahlström L, et al. Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: cohort study. *BMJ*. 2013 Oct 9; 347.
 11. Chao C et al. Surveillance of autoimmune conditions following routine use of quadrivalent human papillomavirus vaccine. *J Intern Med*. 2012 Feb;271(2):193-203.
 12. Slade BA, Leidel L, Vellozzi C, Woo EJ, Hua W, et al. Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine. *JAMA*. 2009 Aug 19;302(7):750-7. doi: 10.1001/jama.2009.1201
 13. Tomljenovic L, Shaw CA. Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental? *Pharmaceut Reg Affairs* 2012, S12:001
 14. Lee, SH. Detection of human papillomavirus L1 gene DNA fragments in postmortem blood and spleen after Gardasil® vaccination—A case report. *Advances in Bioscience and Biotechnology*, 2012, 3, 1214-1224
 15. FDA Information on Gardasil – Presence of DNA Fragments Expected, No Safety Risk. October 21, 2011 <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm276859.htm>
 16. CISA Technical report: http://www.cdc.gov/vaccinesafety/Activities/cisa/technical_report.html
 17. NZ Immunisation Advisory Centre:
http://www.nzdoctor.co.nz/media/2003295/response_to_theories_by_lee_and_shaw_final_180912.pdf
 18. Gold MS, Buttery J, McIntyre P. Human papillomavirus vaccine safety in Australia: experience to date and issues for surveillance. *Sexual Health* 2010;7:320-324
 19. Buttery JP, Madin S, Crawford NW, Elia S, La Vincente S, Hanieh S, Smith L, Bolam B. Mass psychogenic response to human papillomavirus vaccination. *Med J Australia* 2008;189(5):261-262
 20. Genc H, Karagoz A, Saracoglu M, Sert E, Erdem HR. Complex regional pain syndrome type-I after rubella vaccine. *Eur J Pain*. 2005 Oct;9(5):517-20.
- http://www.who.int/vaccine_safety/committee/topics/hpv/GACVS_Statement_HP_V12_Mar_2014.pdf

From: Sarah
 Sent: 07 December 2015 08:30 PM
 To: 'Michael Herbst (Prof)'
 Cc: 'Izak Mahali'
 Subject: RE: Feedback on Customer Query from MSD Gardasil and tolerability

Dear Prof Herbst

Thank you once again for your email.

It greatly concerns me that CANSA appears to have no thoughts of its own and instead relies on statements from organisations who have a vested interest in pursuing vaccination programs and maintaining "public confidence".

Upon reading the GACVS statement, anyone who had not investigated this matter would think that this vaccine is perfectly safe, yet the truth is far from that as can be seen by the various protest groups, lawsuits, representations to governments and other actions being taken by victims of the HPV vaccines. If the vaccine was perfectly safe, why are SO many victims stepping forward and why are many, many doctors, scientists and health professionals trying to get their message heard about the dangers of these vaccines?

In the CERVARIX product packaging it states:

"There is the possibility that broad use of CERVARIX could reveal adverse reactions not observed in clinical trials."

"In addition to reports in clinical trials, worldwide voluntary reports of adverse events received for CERVARIX since market introduction (2007) are listed below."

https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Cervarix/pdf/CERVARIX-PI-PIL.PDF

So in other words, the manufacturers are relying on voluntary reports to reveal adverse reactions 'post marketing'. What format are these reports? How would a recipient of an HPV vaccine report an adverse reaction? Presumably these are personal reports via a doctor, VAERS or other type of notification system.

In the GACVS statement it says :

"The Committee is concerned, however, by the claims of harm that are being raised on the basis of anecdotal observations and reports in the absence of biological or epidemiological substantiation."

So in other words, the only way that a recipient of an HPV vaccine can report an adverse reaction is via 'anecdotal observation' yet these are being dismissed by GACVS because they are 'anecdotal!! In reality, ANY report of ANY adverse event is automatically dismissed by GACVS because they have already determined that this is without 'epidemiological substantiation'.

At what point will these anecdotal reports be taken seriously – if ever? How many lawsuits must be filed before the medical profession realises the dangers of this pharmaceutical product?

There are 1300 girls being investigated in Denmark because of adverse reactions to the HPV vaccine. They do not accept the EMA report on the HPV vaccines, which has been heavily criticised. <http://www.justcancernews.com/chronic-symptoms-after-hpv-vaccination-danes-start-study/> (this link takes you to Medscape).

Are all these 1300 girls making up their stories? Why are they not being taken seriously?

Another extremely critical question remains unanswered with regard to studies showing the prevalence

of the particular HPV strains in South Africa. How do we know that CERVARIX has the correct strains of HPV that are circulating in South Africa? I would like an answer to this please.

Other questions also remain unanswered:

1. How are South African girls going to be followed up for adverse effects?
2. How are South African girls going to be placed into a proper PAP smear testing program?
3. Are South African girls and/or their parents being given true informed consent? Are they being told of the potential adverse effects?

Thank you for your patience with my questions and concerns.

Kind regards

Sarah

From: Michael Herbst (Prof) [<mailto:mherbst@cansa.org.za>]
Sent: 08 December 2015 06:23 AM
To: Sarah
Cc: Radiah Sadan
Subject: RE: Feedback on Customer Query from MSD Gardasil and tolerability

Dear Ms XXXXX

Thank you for your response. I wish to inform you that I am ending our discussion on HPV vaccination. If you have issues around HPV vaccination, I would like to suggest that you take it up with the National Department of Health, and not with the Cancer Association of South Africa.

Kind Regards

Prof Michael C Herbst
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From: Sarah
 Sent: 08 December 2015 08:02 PM
 To: 'Michael Herbst (Prof)'
 Cc: 'Radiah Sadan'
 Subject: RE: Feedback on Customer Query from MSD Gardasil and tolerability

Dear Prof Herbst

I am saddened and appalled at your response. I am a cancer survivor myself (malignant melanoma) and I am shocked that CANSA refuses to answer genuine concerns about a pharmaceutical product that is supposed to protect against cancer. The general public is led to believe that organisations like CANSA have the best interests of the public at heart but clearly this is not the case.

I therefore wish to place on record the following conclusions that I have drawn from the lack of response by CANSA:

1. CANSA has no interest in protecting the lives of females (or males, as young males are now also being drawn into the HPV vaccination program) in South Africa
2. CANSA is unwilling to properly investigate the flood of reports, scientific studies and documented evidence of the dangers of HPV vaccines
3. CANSA is not providing balanced information to the general public of the dangers of HPV vaccines and therefore has no interest in ensuring full informed consent
4. CANSA refuses to answer my concerns and questions
5. CANSA is putting the lives of all young South Africans at risk by failing to properly investigate the devastating serious adverse effects that are being reported all over the world

I leave you with this report where at least in Scotland they are sitting up and taking notice of the large numbers of serious adverse effects relating to the HPV vaccine:

http://www.sundaypost.com/how-safe-is-the-hpv-vaccine-thousands-of-adverse-reactions-to-cervical-cancer-jab-recorded-annually-1.914111?regType=social%C2%AE_success=true

But SNP MSP Chic Brodie, who sits on the petitions committee which has been considering the HPV campaign's bid to get the vaccine programme suspended, said he backed calls for a moratorium.

He explained: "I am delighted we have given this a good airing at the petitions committee because I think there is clearly a need for this to be investigated further, and that means we need a moratorium on the vaccine programme until we know more.

"The Scottish Government and the Scottish Medicines Consortium need to take a closer look at this. There is information from all around the world on this but we can lead the way in investigating the clear health concerns."

Also, the Irish government is being sued by a victim of the HPV vaccine:

http://www.naturalnews.com/052045_HPV_vaccines_cervical_cancer_vaccine_side_effects.html

A woman is suing the Irish government to compel it to withdraw the license for Merck's Gardasil brand HPV vaccine, alleging that her daughter suffered "horrendous adverse effects" after receiving the vaccine as recommended under the Irish school vaccination program.

My last question – which of course CANSA won't answer – is how many girls (or boys) in South Africa must either die or be seriously adversely affected by the HPV vaccine before something is done?

I also wish to state on record that I have tried my utmost to get CANSA to acknowledge the dangers of the HPV vaccine and that I have given you sufficient information and warnings yet you have chosen to ignore them.

I sincerely hope that CANSA will develop a conscience before it is too late.

In closing, I am going to be sharing this email thread with a group of us who are trying to raise awareness on the dangers of HPV vaccines as I believe that people should know CANSA's position on this matter.

Yours in health

Sarah

From: Michael Herbst (Prof) [<mailto:mherbst@cansa.org.za>]

Sent: 09 December 2015 06:16 AM

To: Sarah Subject: RE: Feedback on Customer Query from MSD Gardasil and tolerability

Dear Ms XXXXX

It is not CANSA that refuses to correspond with you – I regrettably do not have time to correspond with one particular individual on a topic which we clearly do not agree upon. I am here to represent the position of CANSA and that is what I am doing. CANSA is not responsible for the roll-out of HPV vaccination to school children – we do not participate in any form of treatment. Our Mission is to provide support to all individuals diagnosed and affected by cancer.

I only work three (3) days a week for CANSA and have a lot of things that need to be done.

The CANSA offices will be closing on the afternoon of the 15th December for the Festive Season and there is still a lot to be done before then.

I would like to repeat: if you have a particular issue with HPV vaccination, please take it up with the Department of Health as they are responsible, together with the Department of Basic Education for the HPV vaccination programme in schools.

Kind Regards

Prof Michael C Herbst

Health Specialist

[D Litt et Phil (Health Studies); D N Ed; M Art et Scien; B A Cur; Dip Occupational Health]

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Cancer Association of South Africa - Head Office

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From: Sin Hang Lee [mailto:shlee01@snet.net]
 Sent: 11 December 2015 08:47 AM
 To: 'Sarah mherbst@cansa.org.za; info@cansa.org.za'
 Subject: Sin Hang Lee's response to Professor Herbst's opinionated letter to Ms XXXX

December 11, 2015

Dear Professor Herbst:

Based on your 06 December 2015 letter addressed to Ms XXXXX on behalf of the Cancer Association of South Africa, you are obviously not a scientist, but are trying to dismiss a very important scientific issue which has affected the health of many teenagers worldwide. Since you are masquerading as a health specialist, acting as a spokesman in a cancer association and trying to discredit my scientific work on the finding of HPV L1 gene DNA in the vaccine Gardasil® while using your position to influence health policy decision making according to your agenda, your letter must not be allowed to pass without challenge.

The first exposure of your lack of understanding of the science involved in this matter is contained in your statement "Several papers have also been published pertaining to the finding of HPV L1 gene DNA fragments in clinical specimens following HPV vaccination [13, 14]. These papers claimed an association with clinical events of an inflammatory nature, including cerebral vasculitis."

You quoted as reference #13 a paper published by "Tomljenovic L, Shaw CA. Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental? Pharmaceut Reg Affairs 2012, S12:001". If you had understood what HPV L1 gene DNA fragments mean, you would not have made such an erroneous statement as you did because in their entire paper, Tomljenovic and Shaw never mentioned "HPV L1 gene DNA fragments" even once. These authors demonstrated HPV-16L1 VLPs, not DNA fragments in the blood vessel walls. You obviously do not understand the difference between HPV L1 VLPs and HPV L1 gene DNA fragments.

You quoted as reference #14 a paper published by "Lee, SH. Detection of human papillomavirus L1 gene DNA fragments in postmortem blood and spleen after Gardasil® vaccination—A case report. Advances in Bioscience and Biotechnology, 2012, 3, 1214-1224". You are basically putting your words into the author's mouth because I know the author did not claim cerebral vasculitis in this case report.

In an attempt to boost your credibility, you also wrote "...the case reports [13] of adverse events hypothesized to represent a causal association between the HPV L1 gene DNA fragments and death were flawed in both clinical and laboratory methodology [16]." For reference 16, you cite a CISA Technical report from a U.S. CDC webpage: http://www.cdc.gov/vaccinesafety/Activities/cisa/technical_report.html

However, in this CDC technical report, the unnamed authors of the document only questioned the HPV-16L1 particles, never HPV L1 gene DNA fragments. Therefore, it further confirms the fact that you really do not understand these two important and distinct chemicals in the HPV vaccine at all. And there is a Disclaimer following this document, stating: The information and conclusions in this report are those of the work group participants addressing this issue and do not necessarily represent the official position of CDC. So you blindly misquoted a technical report written by a team of ghost writers to dismiss a potential causal association between the HPV L1 gene DNA fragments and death.

You were unable to find a scientific publication published in a peer-reviewed journal to challenge the plausible mechanism leading to potential harm induced by residual HPV DNA left in the vaccine Gardasil®. So you had to use a blog written by a Dr Helen Petousis-Harris who knows even less than you do on this subject to support your opinion. In her blog (your reference #17), Dr Helen Petousis-Harris did not even cite a single publication of mine, and used some social media articles published on the Internet to attack me by character assassination. Although she had no personal experience on viral DNA research, she was brave enough to declare that the quantity of residual HPV DNA left in the vaccine Gardasil® has no health impacts on the vaccinees. It is unfortunate for the teenagers of this world to have people like you and Dr Helen Petousis-Harris to rely on selling your biased opinions without any scientific evidence of your own to influence health policy decision making. Neither of you has done any work to support your opinions. Neither of you knows what you are talking about. If you want to prove me wrong, please show me a report of the amount of HPV L1 gene DNA fragments (type 16, 11, 18 and 6) which are bound to the aluminum adjuvant, as found in the vaccine Gardasil®, that has been shown to be of no short-term or long-term risk to humans.

Since you have quoted in your reference #12, a paper published by Slade BA, Leidel L, Vellozzi C, Woo EJ, Hua

W, et al. Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine. JAMA. 2009 Aug 19;302(7):750-7. Let me point out to you that this CDC study shows that among 12,424 reported adverse events following Gardasil® vaccination from June 1, 2006 through December 31, 2008, there were 32 deaths with a mean age of 18 years old, who died 2 to 405 days after the last Gardasil® injection. Medical records and autopsy reports on 20 of the 32 deaths were available for review and confirmed there were 4 unexplained deaths and 6 cardiac-related deaths.

This same report also stated that syncope is the most common adverse reaction after Gardasil® injections and “The reporting rates per100 000 qHPV doses distributed were 8.2 for syncope;...” .

Syncope is defined as temporary loss of consciousness and posture, described as "fainting" or "passing out." It's usually related to temporary insufficient blood flow to the brain. It most often occurs when the blood pressure is too low (hypotension) and the heart doesn't pump a normal supply of oxygen to the brain.

In view of the high incidence of syncope developed among Gardasil® vaccinees, the FDA Prescribing Information for Gardasil® (qHPV) contains the following Warnings and Precautions:

“Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following vaccination with GARDASIL®. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.”

So why do Gardasil® vaccinees have a higher rate of syncope as compared to other vaccinees? The ugly truth that you and those agencies you have quoted to support your biased opinions would not like to face may be in the HPV L1 gene DNA fragments when the viral DNA fragments combine with the aluminum adjuvants in the vaccines. To understand this, you really have to spend time to study the history on the science of aluminum adjuvants in vaccination.

Aluminum salts have been used as adjuvants in vaccination empirically to boost immune responses of the host to the protein antigens for many decades. However, the mechanism of the adjuvant effects of aluminum salts has only been recently investigated at the molecular level. It is now generally agreed in the scientific community that aluminum salts used as adjuvants are toxic and always damage the cells of the host at the site of injection, causing a localized inflammation at the vaccination site. This initial cell damage by the aluminum salt is an essential and necessary step to initiate its adjuvant effects because the free host DNA molecules released from the aluminum salt-damaged host cells act as mediators to trigger augmented immune responses of the host [1, 2]. The free DNA molecules of the dying host cells, also referred to as damage-associated molecular patterns (DAMPs) [3] bind the aluminum salt adjuvant at the site of injection, and the resulting DNA/aluminum complexes are phagocytized by the antigen-presenting cells (APCs) and macrophages. It was known as early as 2003, that when bound to aluminum salts as nanoparticles, free DNA molecules undergo dramatic conformational changes and can be introduced into mammalian cells as a means of gene transfection [4]. In vaccination with aluminum adjuvants, the transfected host DNA activates the pathways that would increase their ability to interact productively with antigen-specific CD4 T cells to boost host immune responses [1, 2]. In plain language, free DNA derived from the dying host cells is needed to be carried by aluminum adjuvants into the APCs or macrophages to function as mediators for boosting immune responses in vaccination.

However, the presence of recombinant HPV L1-specific DNA fragments in the vaccine Gardasil® has disrupted this expected normal immunity response platform in vaccination. The HPV DNA molecules, being of a viral origin, are “non-self” microbial products, also referred to as pathogen-associated molecular patterns (PAMPs). The human body's defense system can distinguish the PAMPs from the DAMPs in order to mount an appropriate immune response to either the presence of a pathogen or a tissue damage [3].

The amorphous aluminum hydroxyphosphate sulfate (AAHS) nanoparticles which are expected to bind the free host DNA at the site of vaccine injection can also bind the fragments of HPV L1 gene DNA present in the vaccine Gardasil® [5] through a ligand exchange process between the phosphate groups of the DNA molecule and the hydroxyl groups on the aluminum adjuvant surface, similar to a reaction between phospholipids and AAHS in the recombinant hepatitis B vaccine [6]. In other words, Gardasil® has been furnished with a set of ready-made instant DNA immune “mediators” already in the adjuvant, in the form of a viral DNA/aluminum chemical compound, specifically an HPV L1 gene DNA/AAHS complex. The downstream events after transfection into the human macrophages of these viral DNA fragments which are rarely found in the human

genome [7] are quite different from those after the DNA of the dying host cells is introduced into the macrophages. Despite similarities between DNA molecules, mammalian cells have the remarkable ability to distinguish viral DNA from their own DNA. The human macrophages are able to recognize the HPV L1 gene DNA as a 'stranger' and a 'danger' signal, and in response produce many antiviral immune molecules, collectively referred to as type I interferons and pro-inflammatory cytokines [8-10].

Massive systemic production of these type I interferons and pro-inflammatory cytokines induces an antiviral state and protects the host, but it also can contribute to endotoxin lethality and autoimmune diseases [9]. Many of these cytokines are myocardial depressants. The two cytokines that show the greatest cardiovascular effects in animals and humans are tumor necrosis factor (TNF)- and IL-1 [11]. Administration of recombinant TNF- in animal models is known to cause hemodynamic changes and even death [11].

Injection of Gardasil® into animals has been shown to induce unusually early strong innate immune responses with quick releases of a variety of cytokines from the macrophages [12]. Injection of HPV DNA/AAHS complexes into the host is also known to induce a strong immune reaction and a strong CD8 T cell response [13]. Based on experiments with other viral DNA molecules, the recombinant HPV L1 gene DNA fragments transfected into human macrophages would also be recognized as "stranger" and "danger" signal, and invariably activate the macrophages to release numerous antiviral cytokines. Many of these cytokines, including TNF- and IL-1, are recognized myocardial depressants [14-18]. Hypotensive shock induced by TNF- has been well documented among animals [19, 20] and humans [21, 22].

This brief review of literature shows that there is a known molecular mechanism to explain why syncope occurs more often in people injected with Gardasil® than with other vaccines, and why certain predisposed vaccinees may suffer a sudden unexpected death as the result of Gardasil® vaccination. You and those who blindly dismiss the potential toxicity of aluminum adjuvant and in particular the toxicity of the newly created HPV L1 gene DNA/AAHS compound for marketing an HPV vaccine should be held responsible for intentionally ignoring the scientific evidence at the expense of public interest.

It is of interest that you mentioned that in June 2013, the GACVS reviewed the concerns arising in Japan in regard to reports described as CRPS in a few cases, and other chronic pain conditions following HPV vaccine. But you apparently purposely avoided mentioning the facts that the Japanese government has suspended its HPV vaccine recommendation since 2014 and that a December 10, 2014 Symposium held by the Japan Medical Association and the Japanese Association of Medical Sciences concluded that HPV vaccines should be promoted only after issues regarding vaccine safety are settled.

In summary, to protect the health of the young children there is an urgent need for open debate of the risks versus benefits of HPV vaccination being recommended or forced onto the 12-year old school girls and boys. A simple declaration of vaccine safety made by some armchair professor like you does not serve the interest of the public.

References

1. Marichal T, Ohata K, Bedoret D, Mesnil C, Sabatel C, Kobiyama K, Lekeux P, Coban C, Akira S, Ishii KJ, Bureau F, Desmet CJ. DNA released from dying host cells mediates aluminum adjuvant activity. *Nature Medicine* 2011;17: 996-1002.
2. McKee AS, Burchill MA, Munks MW, Jin L, Kappler JW, Friedman RS, Jacobelli J, Marrack P. Host DNA released in response to aluminum adjuvant enhances MHC class II-mediated antigen presentation and prolongs CD4 T-cell interactions with dendritic cells. *Proc Natl Acad Sci U S A.* 2013;110:E1122-31.
3. Paludan SR, Bowie AG. Immune sensing of DNA. *Immunity.* 2013;38:870-80.
4. Matsuzawa Y, Emi N, Kanbe T. Calcium Phosphate and Aluminum Hydroxide as Non-Virus Gene Carrier: The Morphology of DNA-salt Complex and the Effects It on DNA Transfection KAGAKU KOGAKU RONBUNSHU 2003; 29:680-4.
5. Lee SH. Detection of human papillomavirus (HPV) L1 gene DNA possibly bound to particulate aluminum adjuvant in the HPV vaccine Gardasil®. *J Inorg Biochem* 2012; 117:85–92.
6. Egan, P.M.; Belfast, M.T.; Giménez, J.A.; Sitrin, R.D.; Mancinelli, R.J. Relationship between tightness of binding and immunogenicity in an aluminum- containing adjuvant-adsorbed hepatitis B vaccine. *Vaccine* 2009; 27: 3175-80.
7. Sparwasser T, Miethke T, Lipford G, Erdmann A, Häcker H, Heeg K, Wagner H. Macrophages sense

- pathogens via DNA motifs: induction of tumor necrosis factor- α -mediated shock. *Eur J Immunol.* 1997;27:1671-79.
8. Orzalli MH, Knipe DM. Cellular sensing of viral DNA and viral evasion mechanisms. *Annu Rev Microbiol.* 2014;68:477-92.
 9. Yarilina A, Ivashkiv LB. Type I interferon: a new player in TNF signaling. *Curr Dir Autoimmun.* 2010;11:94-104.
 10. Unterholzner L. The interferon response to intracellular DNA: why so many receptors? *Immunobiology* 2013;218:1312–21.
 11. Fernandes CJ Jr, de Assuncao MS. Myocardial dysfunction in sepsis: a large, unsolved puzzle. *Crit Care Res Pract.* 2012;2012:896430.
 12. Herrin DM, Coates EE, Costner PJ, Kemp TJ, Nason MC, Saharia KK, Pan Y, Sarwar UN, Holman L, Yamshchikov G, Koup RA, Pang YY, Seder RA, Schiller JT, Graham BS, Pinto LA, Ledgerwood JE. Comparison of adaptive and innate immune responses induced by licensed vaccines for Human Papillomavirus. *Hum Vaccin Immunother.* 2014;10:3446-54.
 13. Caulfield MJ, Shi L, Wang S, Wang B, Tobery TW, Mach H, Ahl PL, Cannon JL, Cook JC, Heinrichs JH, Sitrin RD. Effect of alternative aluminum adjuvants on the absorption and immunogenicity of HPV16 L1 VLPs in mice. *Hum Vaccin.* 2007;3:139-45.
 14. Parrillo JE, Burch C, Shelhamer JH, Parker MM, Natanson C, Schuette W. A circulating myocardial depressant substance in humans with septic shock. Septic shock patients with a reduced ejection fraction have a circulating factor that depresses in vitro myocardial cell performance. *J Clin Invest.* 1985;76:1539-53.
 15. Kumar A, Paladugu B, Mensing J, Kumar A, Parrillo JE. Nitric oxide-dependent and -independent mechanisms are involved in TNF- α -induced depression of cardiac myocyte contractility. *Am J Physiol Regul Integr Comp Physiol.* 2007;292:R1900-6.
 16. Cauwels A, Van Molle W, Janssen B, Everaerd B, Huang P, Fiers W, Brouckaert P. Protection against TNF-induced lethal shock by soluble guanylate cyclase inhibition requires functional inducible nitric oxide synthase. *Immunity.* 2000;13:223-31.
 17. Cauwels A, Brouckaert P. Survival of TNF toxicity: dependence on caspases and NO. *Arch Biochem Biophys.* 2007;462:132-9.
 18. Cauwels A, Janssen B, Waeytens A, Cuvelier C, Brouckaert P. Caspase inhibition causes hyperacute tumor necrosis factor-induced shock via oxidative stress and phospholipase A2. *Nat Immunol.* 2003;4:387-93.
 19. Weinberg JR, Wright DJ, Guz A. Interleukin-1 and tumour necrosis factor cause hypotension in the conscious rabbit. *Clin Sci (Lond).* 1988;75:251-5.
 20. Turner CR, Esser KM, Wheeldon EB, Slivjak M, Smith EF 3rd. Cardiovascular and pulmonary effects of human recombinant tumor necrosis factor in the conscious rat. *Circ Shock.* 1989;28:369-84.
 21. Chapman PB, Lester TJ, Casper ES, Gabilove JL, Wong GY, Kempin SJ, Gold PJ, Welt S, Warren RS, Starnes HF, et al. Clinical pharmacology of recombinant human tumor necrosis factor in patients with advanced cancer. *J Clin Oncol.* 1987;5:1942-51.
 22. Brouckaert P1, Ameloot P, Cauwels A, Everaerd B, Libert C, Takahashi N, Van Molle W, Fiers W. Receptor-selective mutants of tumour necrosis factor in the therapy of cancer: preclinical studies. *Circ Shock.* 1994;43:185-90.

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 Director
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 2044 Bridgeport Avenue, Milford, CT 06460 USA
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From: Michael Herbst (Prof) [<mailto:mherbst@cansa.org.za>]
Sent: Friday, December 11, 2015 2:09 AM
To: shlee01@snet.net; Sarah ; Radiah Sadan
Subject: RE: Sin Hang Lee's response to Professor Herbst's opinionated letter to Ms XXXX

Dear Doctor Lee

I wish to thank you for your e-mail.

I wish to point out to you that I, at no stage, tried to discredit any of your scientific work. We work according to information received from organizations such as the World Health Organization and papers published in peer-reviewed publications. The Cancer Association of South Africa is not involved in any form of treatment – our mission is to provide support to all individuals diagnosed with cancer as well as providing support to all individuals affected by cancer.

The Cancer Association of South Africa is also not involved in the HPV vaccination programme in South Africa. This falls under the National Department of Health and the National Department of Basic Education.

I wish to thank you for the information provided by you. I undertake to include your counter arguments and other relevant information supplied by you in an updated version of CANSA's Fact Sheet on Human Papilloma Virus Infection and Cancer when our offices re-open on 4 January 2016 and will forward a copy of the updated document to you. I will also google your other research contributions in this regard. Our offices will be closing on Tuesday 15th December 2015.

I must admit, though, that I am rather disappointed in your personal attack on me.

Have a wonderful Festive Season and a blessed 2016.

Kind Regards

Michael C

From: Sin Hang Lee [mailto:shlee01@snet.net]
Sent: 11 December 2015 05:21 PM
To: 'Michael Herbst (Prof)'; 'Sarah 'Radiah Sadan'
Subject: RE: Sin Hang Lee's response to Professor Herbst's opinionated letter to Ms XXXX

Dear Professor Herbst:

Thank you for your prompt response to my letter.

Your statement “We work according to information received from organizations such as the World Health Organization and papers published in peer-reviewed publications” is not true. In your 06 December 2015 letter sent to Ms XXXX you wrote “Thus the hypotheses raised in these papers are not supported by what is understood about the residual DNA fragments left over following vaccine production [17]: given the extremely small quantities of residual HPV DNA in the vaccine,..”. As I pointed out, your reference #17 by Dr Helen Petousis-Harris was an internet blog of character assassination, not a peer-reviewed publication.

By quoting such a blog to support your opinion, you actually endorsed the act of character assassination against me in person.

You said you will also google my other research contributions in this regard. Then you will undoubtedly find other industry-paid character assassins' writings on the very top of your Google search list by a Professor David Gorski under the name of Orac. I suspect someone has been paying Google to place the Orac's smear attack on top of the Google search. The informed public will see how desperate the Gardasil industry is in suppressing dissenting scientific evidence.

Thank you for considering inclusion of my letter to you as the counter argument in CANSA's Fact Sheet on Human Papilloma Virus Infection and Cancer. I understand the Cancer Association's mission is to prevent cancers, not promoting HPV vaccines. For an article not representing the interest of the health care industry, please read the following linked paper.

<http://www.mdpi.com/2072-6694/6/4/2072>

Best,
S. H.

From: Sin Hang Lee [mailto:shlee01@snet.net]

Sent: 14 December 2015 05:02 PM

To: 'Michael Herbst (Prof)'; 'Sarah 'Radiah Sadan'

Subject: RE: Sin Hang Lee's response to Professor Herbst's opinionated letter to Ms Kalell

Dear Professor Herbst:

One of my colleagues sent me the following message and the copy of a partially blackened out official letter from a bureaucrat in the Japanese government with a comment:

“Going through some of the Japanese stuff again..... Nabae was doing exactly what Helen did in NZ.... don't present info formally so it can't be cross examined/scrutinised, but provide it after the inquiry so that the decision makers can be duly influenced by informal but 'expert' info... Very cunning... and corrupt.”

May I recommend the Cancer Association of South African dissociate from Helen Petousis-Harris and those from WHO GACVS in this global conspiracy to market HPV vaccines at the expense of public health interest.

This document was obtained through The Freedom of Information Act. Since you have quoted Helen Petousis-Harris and WHO as references to discredit my work, you may like to publish this document as well.

Best,
S. H.

On Feb 23, 2014, at 12:00 AM, 難波江 功二(nabae-koji) <nabae-koji@mhlw.go.jp> wrote:

Dear all,

Thank you so much for your time and commitment. The conference call was very useful for us.

I talked to my boss and we agree that it is better not to have WHO GACVS presence during the public hearing session [REDACTED] and there is no need to hurry for a statement. We are hoping the statement to come out a week or two weeks later so that our expert committee can refer to it when they finalize the report in March (or a bit later) (if things go smoothly).

Thank you so much for your help.

I look forward to meeting and talking to you later.

Warm regards,

Koji Nabae