

ITEM 7

AOB

Item 7.1 – Safety of HPV vaccination

Paper 7.1.1	Cover sheet	Page 5
Paper 7.1.2	Article in ‘The Independent’ and	Page 7
Paper 7.1.3	The ‘Toronto Star’ - Editor and Publisher’s comments on removal of a very similar story from their website	Page 13
Paper 7.1.4	List of HPV Yellow Card reports	Page 25
Paper 7.1.5	Case Reports of POTS in the UK, as held by MHRA	Page 43
Paper 7.1.6	Serious adverse reactions profile for HPV, Hepatitis B, inactivated influenza and Revaxis® vaccines	Page 53
Paper 7.1.7	FOI request to MHRA	Page 57
Annex A - Articles of note		
Paper 7.1.8	Arnheim-Dahlström <i>et al</i> (2013) Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus	Page 61

	vaccine in Denmark and Sweden: cohort study. BMJ 2013;347	
Paper 7.1.9	Blitshteyn (2013) Postural tachycardia syndrome following human papillomavirus vaccination Eur J Neurol	Page 73
Paper 7.1.10	Brinith <i>et al.</i> (2015) Suspected side effects to the quadrivalent human papilloma vaccine. Dan Med J 62/4	Page 79
Paper 7.1.11	Brinith <i>et al.</i> (2015) Orthostatic intolerance and postural tachycardia syndrome as suspected adverse effects of vaccination against human papillomavirus. Vaccine (article in press)	Page 85
Paper 7.1.12	Brotherton (2013) Safety of the quadrivalent human papillomavirus Vaccine: Now well established. BMJ 2013;347	Page 89
Paper 7.1.13	Nishioka <i>et al</i> (2014) Clinical features and preliminary diagnostic criteria of human papillomavirus vaccination associated with neuroimmunopathic syndrome (HANS). International Journal of Rheumatic Diseases 2014; 17 (Suppl. 2): 6–29	Page 91
Paper 7.1.14	Donegan <i>et al</i> (2013). Bivalent human papillomavirus vaccine and the risk of fatigue syndromes in girls in the UK. Vaccine 31 (2013) 4961– 4967	Page 93
Paper 7.1.15	Jarjour (2013) Postural Tachycardia Syndrome in Children and Adolescents. Semin Pediatr Neurol. 2013 Mar;20(1):18-26	Page 101

Paper 7.1.16	Kinoshita <i>et al</i> (2014) Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese Girls Following Immunization with the Human Papillomavirus Vaccine. Intern Med 53: 2185-2200	Page 111
Paper 7.1.17	Kizilbash <i>et al</i> (2014) Adolescent Fatigue, POTS, and Recovery: A Guide for Clinicians. Curr Probl Pediatr Adolesc Health Care 2014;44:108-133	Page 127
Paper 7.1.18	Martínez-Lavín (2015) Hypothesis: Human papillomavirus vaccination syndrome—small fiber neuropathy and dysautonomia could be its underlying pathogenesis. Clin Rheumatol	Page 153
Paper 7.1.19	Okamoto <i>et al</i> (2012) Neurohumoral and haemodynamic profile in postural tachycardia and chronic fatigue syndromes. Clinical Science (2012) 122, 183–192	Page 158

COVER SHEET
Item 7 – AOB
Issue
<p>Recent press articles have called into question the safety of HPV vaccine .</p>
Summary
<p>Item 7.1 – Safety of HPV vaccination</p> <p>Recent press articles have called into question the safety of HPV vaccine. .</p> <p>In particular, questions are being raised around a potential link between HPV vaccination and Postural Orthostatic Tachycardia Syndrome (POTS). According to available medical literature, POTS is becoming increasingly recognised as a syndrome in children and adolescents.</p> <p>Those with POTS typically present with an inability to tolerate standing up (with symptoms such as dizziness, chronic weakness and fatigue) and dysfunction of the autonomic nervous system, but also has a wide variety of clinical features (e.g. neurological, psychiatric and gastrointestinal) that affect the daily quality of life. Recent literature reviews indicate that POTS is four times more common in females. There also appears to be an overlap with many signs and symptoms of chronic fatigue syndrome (CFS) and fibromyalgia, which are also prevalent conditions in adolescence.</p> <p>While information available does indicate a temporal</p>

correlation between vaccination and onset of symptoms in a small number POTS diagnoses, EU regulators are reviewing cases as part of routine pharmacovigilance for HPV vaccines, and so far consider there is insufficient evidence to establish a causative link between HPV vaccination and POTS. The issue remains under review via the EMA.

Given the current press interest on this issue, the Secretariat has collated relevant documents for the Committee, including a series of relevant journal articles, and data from the MHRA on UK case reports.


A representative from the MHRA will provide regulatory context at the meeting.

Actions required by the Committee

1. To consider and comment on the information provided








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Thousands of teenage girls enduring debilitating illnesses after routine school cancer vaccination



'I had severe chest and abdominal pains, and breathing difficulties - one time, I couldn't move anything on one side of my body'

PAUL GALLAGHER Sunday 31 May 2015

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When Caron Ryalls was asked to sign consent forms so that her then 13-year-old daughter, Emily, could be vaccinated against cervical cancer, she assumed it was the best way to protect Emily’s long-term health.

Yet the past four years have turned into a nightmare for the family as Emily soon suffered side effects. Only two weeks after her first HPV injection, the teenager experienced dizziness and nausea.

“The symptoms grew increasingly worse after the second and third injections, and I went to A&E several times with severe chest and abdominal pains as well as difficulty breathing,” Emily, now 17, said. “One time I couldn’t move anything on one side of my body. I didn’t know what was happening.”

Emily is one of the thousands of teenage girls who have endured debilitating illnesses following the routine immunisation. She is yet to recover and has no idea when her health will return to normal. “Prior to the vaccination Emily had an ‘unremarkable’



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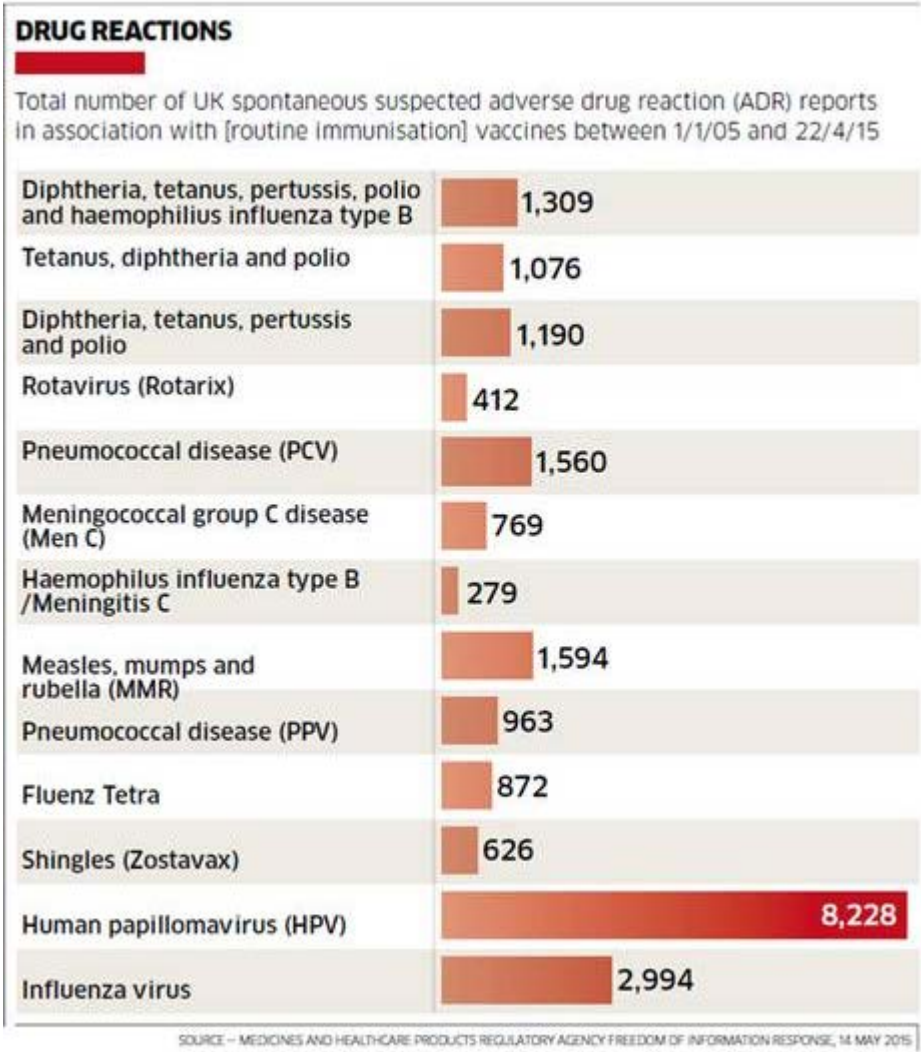
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medical history with no problems,” said Mrs Ryalls, 49, from in Ossett, West Yorkshire. “She was considered very healthy and represented the school at hockey, netball, athletics and was a keen dancer. She was also a high achiever at school, in the top sets for everything and predicted at least 10 GCSE with high grades. Her future was very bright.”

Mrs Ryalls reported Emily’s condition to the Medicines and Healthcare Products Regulatory Agency (MHRA). In the 10 years to April this year the agency received almost 22,000 “spontaneous suspected” adverse drug reaction (ADR) reports in 13 routine immunisation categories including flu, MMR, tetanus, diphtheria and polio, according to a Freedom of Information response released earlier this month.

In the HPV category alone, ADRs numbered 8,228, of which 2,587 were classified as “serious” – defined by several criteria,

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including whether it resulted in hospitalisation or was deemed life threatening.

The MHRA said that the figures did not reflect the true amount of ADRs because of an “unknown and variable level of under-reporting”. The agency estimates it receives about 10 per cent of all reports, suggesting the actual number of girls suffering ADRs could be tens of thousands. It also said that “many millions” of the vaccinations were administered in this time frame without any problems reported.

“Every visit to a doctor was met with rolled eyes,” said Mrs Ryalls. “Every mention of the HPV vaccination was met with hostility and ridicule. We were eventually referred to a local paediatrician who told her to push herself to get back to normal – ‘We all feel tired in the mornings, Emily’ was one of the remarks regarding her complete exhaustion.”

Health news: in pictures

Two years after falling ill, Emily was eventually referred to Dr Pradip Thakker at Queens Medical Centre in Nottingham; he used a tilt table test to diagnose PoTS (postural orthostatic tachycardia syndrome), a condition where moving from lying down to standing up causes an abnormally high heart rate. By this time Emily was able to manage only three to four hours of school a week. Mrs Ryalls, who had built up a small publishing company from scratch, was forced to close it and become Emily’s full-time carer.

Cancer Research UK points out that cervical cancer is the second most common cancer in women under the age of 35. In the UK, about 3,000 women a year are diagnosed with cervical cancer and it is estimated that about 400 lives could be saved every year as a result of vaccinating girls before they are infected with the human papilloma virus.

The NHS says that the vaccine, which was introduced as part of the routine immunisation programme in 2008, protects against the two HPV types that cause 70 per cent of the cases of cervical cancer. Screening is still needed to try to pick up cervical abnormalities caused by other HPV types that could lead to cancer.

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Since September 2014, girls have received only two injections; the second is taken six to 24 months after the first. The NHS says the programme has proved to be “very effective”. However, other countries are taking action following reports of increasing numbers of girls suffering side effects. A Danish TV documentary broadcast earlier this year highlighted the large number of girls who appear to have been affected following their HPV vaccination. Some, like those the Ryalls have met in the UK, are now wheelchair-bound.

Last year, Japan withdrew its recommendation for the HPV vaccine because of reported side effects.

In an article published last week in the Springer journal Clinical Rheumatology, Dr Manuel Martinez-Lavin, who has been treating people with chronic pain conditions for more than 30 years, said these illnesses are “more frequent after HPV vaccination”. He wrote: “Vaccination has been one of the most effective public health measures in the history of medicine. However, seemingly inexplicit adverse reactions have been described after the injection of the newer vaccines vs human papillomavirus (HPV). Adverse reactions appear to be more frequent after HPV vaccination when compared to other type of immunisations.”

Dr Martinez-Lavin said PoTS and fibromyalgia are among the diseases he believes have developed after HPV vaccination, and that clinicians should be aware of the possible association between HPV vaccination and the development of these “difficult to diagnose” painful syndromes.

Mrs Ryalls and about 80 families in similar situations across the UK are taking action. They have formed the Association for HPV Vaccine Injured Daughters (AHVID) to bring families with girls adversely affected by the HPV vaccine together.

She said: “We want to have a stronger voice and we are pushing hard for regional treatment and assessment centres along the lines of Denmark and Japan. We want increased reporting of adverse reactions, better educational support and greater transparency and information to enable parents to make an informed decision regarding consent to HPV vaccination.”

Mrs Ryalls also said the AHVID wants better research and treatment for the girls’ conditions and that treatment is currently “pot luck”, as too few doctors spot the signs of PoTS



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and other autoimmune conditions.

“I’m not anti-vaccination,” Mrs Ryalls said, “but it’s a big area with a lot of questions. I would never say to anyone don’t have it, because it has to be a personal choice. I would say do your own research and don’t just rely on the school leaflet.”

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Emily managed to return to school to complete enough GCSEs to move into the sixth-form college where she is now studying English language and photography. She hopes to study the latter at university.

The MHRA said it had no concerns on the numbers of ADRs related to the HPV vaccine and that the “expected benefits in preventing illness and death from HPV infection outweigh the known risks”.

The agency said: “The vast majority of suspected side effect reports for HPV vaccine relate to known risks of vaccination that are well described in the available product information. The reporting rate of suspected side effects, which are not necessarily proven to be caused by the vaccine, is influenced by many factors and expected to differ across vaccines. The greater number of reports for HPV vaccine does not necessarily mean that it is any less safe than other vaccines.

“Reports of PoTS following HPV vaccine remain under review by EU regulators. PoTS can occur naturally in adolescent girls and, at present, there is insufficient evidence to indicate that the vaccine is a cause. This will remain under review.”

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Science shows HPV vaccine has no dark side

To attribute rare devastating occurrences to a vaccine requires evidence of causation, which the Star didn't have in its article on Gardasil.

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Given the power of HPV vaccine to prevent disease and death, a long Toronto Star article that appears to suggest that the HPV vaccine causes harm is troubling and disappointing, write Juliet Guichon and Dr. Rupert Kaul.

By: Juliet Guichon Dr. Rupert Kaul Published on Wed Feb 11 2015

The HPV vaccine was created to prevent an infection that causes cancer. That is pretty exciting. After all, Terry Fox’s arduous marathon a day was to raise money for a cancer cure. Did he even imagine that we would have a vaccine to prevent cancer?

Given the power of HPV vaccine to prevent disease and death, a long [Toronto Star article](#) that appears to suggest that the HPV vaccine causes harm is troubling and disappointing. Although the article states in the fifth paragraph that “there is no conclusive evidence showing the vaccine caused a death or illness,” its litany of horror stories and its innuendo give the incorrect impression that the vaccine caused the harm.

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Very unfortunately, this article may well lead readers to doubt both the scientific evidence and the recommendations of the Public Health Agency of Canada, the Society of Obstetricians and Gynecologists of Canada, the National Advisory Committee on Immunization, and the Canadian Cancer Society about vaccination.

The Star story states that some people became sick and even died after being vaccinated against HPV infection. Yet, after HPV vaccination, some people might have won a major scholarship or the lottery. Does this mean the vaccine caused the award or the win? Hardly.

The fact that one event follows another does not mean that the first event caused the second — in scientific terms, correlation is not causation.

For example, the number of shark attacks and ice cream sales rise when the weather is hot. The confusion of correlation and causation here is funny because, of course, the shark attacks don’t cause the ice cream sales increase. But in the case of the HPV vaccine, such confusion is not funny because HPV infection can have very serious consequences that the vaccine helps prevent.

HPV infection causes nearly all cervical cancers and cancers of the vulva, vagina, penis, anus and throat. Two strains (“types”) of HPV, called HPV16 and HPV18, are responsible for about 70 per cent of cervical cancers and an even higher proportion of the other HPV-associated cancers. Two other HPV types, HPV6 and HPV11, cause about 90 per cent of genital warts. The vaccine smeared by the Star’s article, Gardasil, prevents infection by these four strains of HPV.

In 2008, approximately 610,000 cases of cancer worldwide were attributable to HPV.

HPV infections in Canada annually result in 85,000 physician consultations for genital wart infections, 1,450 newly diagnosed cases of cervical cancer and 106,000 patients with cervical lesions that require expensive, painful treatment that can cause infertility and premature birth. In Canada, 380 women die from cervical cancer every year, many of them in the prime of life. HPV infections are a very real threat to the health of Canadians.

All of us must take very seriously the potential complications of any drug or vaccine. Gardasil was licensed only after its safety was studied in clinical trials with more than 29,000 people. After licensing, reported side effects are collected in a vaccine safety database. Researchers studied that database after more than half a million doses of Gardasil had been administered. The only — and very rare — serious side effect of HPV vaccines that they identified was allergic reactions. Public health officials who continue to study these databases have not found evidence of any other serious side effects.

The Star presented the stories of women who have suffered greatly. The article was engaging, dramatic and might have created fear. But study after study has shown that there is no causal link between the events the Star reported and the vaccine. About 169 million doses of the HPV vaccine have been administered worldwide. In any given large population, there will be illness and death. This is a statistical fact. To attribute rare

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devastating occurrences to a vaccine requires evidence of causation, of which the international scientific community and the Star article have none.

When such articles appear, we all lose. Those of us in a position to influence others have a responsibility to provide the best evidence about health-related issues. In this case, the evidence is very clear that the risks associated with HPV infection are much greater than the risks associated with vaccination.

We hope Star readers will continue to rely on evidence-based public health recommendations to protect all our children from cancer. Those recommendations save lives.

Juliet Guichon, of the University of Calgary, is the recipient of the Canadian Medical Association Medal of Honour for HPV vaccine related work. Dr. **Rupert Kaul** is a Professor in the Departments of Medicine and Immunology, and the Head of the Division of Infectious Diseases at the University of Toronto.

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Opinion / Public Editor


Public editor criticizes the Star's Gardasil story

Scientific evidence has concluded the HPV vaccine is safe and effective so why did Star publish a story that raised alarms about its safety?

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By: [Kathy English](#) Public Editor, Published on Fri Feb 13 2015

The Toronto Star has come under intense fire from Canada’s public health community for its investigation last week into Gardasil, the HPV vaccine given to teenaged girls across Canada to prevent cancer.

The investigation, published on the Star’s front page with a large banner headline — “A wonder drug’s dark side” — told you that “Hundreds of thousands of teen girls have safely taken Gardasil ... But a Star investigation has found that since 2008 at least 60 Canadians experienced debilitating illness after inoculation. Patients and parents say the incidents point to the full disclosure of risks.”

That alarmist information is not the full story.

What you need to know and understand fully is the fact that there is no scientific medical evidence of any “dark side” of this vaccine. The Gardasil vaccine has been tested by highly credible national and global public health agencies and the scientific evidence overwhelmingly concludes that it is safe and effective.

That was made quite clear in an [Opinion page article](#) published in the Star this week. That article was written and endorsed by 65 Canadian specialists in infectious diseases, public health or related sciences.


The only — and very rare — serious side effects of HPV vaccines that scientific studies point to are allergic reactions. Continuing studies of databases of adverse effects “have not found any evidence of any other serious side effects,” the experts said in their article.

That opinion article was submitted to rebut the Star’s Gardasil investigation and provide important and necessary perspective to our readers. The Star did the right thing in publishing the health specialists’ article. I believe it presents the established scientific facts on Gardasil, making clear the vaccine’s value in preventing cervical and other cancers.

The experts who endorsed the article and the public health community throughout North America have weighed in vigorously, expressing strong concern that the Star’s

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East Gardiner’s fate in council is up in the air, despite Tory

investigation was alarmist in the face of the established science. I agree.

These critics rightly charge that in giving disproportionate and dramatic play to the heartbreaking stories of young women who suspect their illnesses are linked to having received the vaccine — and, indeed, either they or their doctors have reported those illnesses to a public database that collects individuals’ reports of adverse vaccine reactions — the proven scientific evidence of the vaccine’s safety was not made clear enough to readers.

In matters of public health, the science of vaccine safety is significant. Penny Park, executive director of the Science Media Centre of Canada , a non-profit organization set up to encourage excellence in media coverage of science issues, told me that this is of great importance in medical stories that have an impact on personal and public health.

“Especially in medical stories, journalists must be held to the highest standards,” she said. “The impact of misinformation is far too grave, not only for our own personal health, but for decisions on public policy.”

While journalists certainly have every right to investigate the medical, pharmaceutical and public health establishments – and indeed, should – the standards of excellence and responsibility expected in any journalism that pertains to health and medicine demands that the evidence-based science be given proper weight over the emotional stories of individuals that science labels “anecdotal evidence.”

The widespread criticism of the Star’s story expressed by those within the medical, scientific and public health communities is fair and valid. The many experts who have come forward to explain fully the science of this vaccine’s safety are highly credible. I believe they have spoken up out of genuine concern that the Star has fallen short of evidence-based standards of reporting on public health. They fear the Star investigation could cause harm if young women and their parents don’t fully understand the robust evidence of the vaccine’s safety and thus, avoid the vaccine.

The Star now understands and takes seriously the concerns and criticism. As publisher John Cruickshank said in responding publicly on CBC Radio’s *As it Happens* this week, “We failed in this case. We let down. And it was in the management in the story at the top. I take responsibility and we will focus on doing better in the future.”

It’s too bad there isn’t a vaccination to prevent journalistic misstep. I suspect we’d all line up for that shot about now. The fallout here has been devastating for the newsroom. As editor Michael Cooke rightly points out, “the Star has a long history of important investigative reporting on possible safety issues of the drugs we use and the pharmaceutical industry that produces them. The piece on the HPV vaccine Gardasil was done as part of that stream of coverage.”

To be fair, in the Gardasil investigation, reporters David Bruser and Jesse McLean absolutely do not conclude or state that the vaccine caused any of the suspected side effects the young women talk about. The article was written carefully to try to impart to readers the message that there was no conclusive evidence.

And, if you read the article carefully, you will see that it states explicitly the fact that “there is no conclusive evidence showing the vaccine caused a death or illness.” It explains that in all of the cases discussed in the article, it is the *opinion* of a patient or

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The Star's Public Editor

her doctor that a drug has caused a side-effect. As well, the story tells you that comprehensive clinical trials and other data “show the vaccine’s well-studied safety and efficacy.”

It includes the voice of Dr. Jennifer Blake, president of the Society of Obstetricians and Gynaecologists of Canada, who said, “I’m extremely comfortable that this is a safe vaccine.” It reports that hundreds of thousands of girls in Canada have safely taken Gardasil.

But the proven and stated fact of the vaccine’s safety was seemingly lost to too many. I think that’s largely due to the dramatic front-page presentation with its large headline heralding the vaccine’s “dark side” and subheadline telling you that 60 Canadians experienced debilitating illness after inoculation.

That subhead doesn’t inform you that there is no science-based evidence whatsoever that the vaccine caused those debilitating illnesses. The captions accompanying the photos of four girls contained none of the above context the story took care to include.

The main photo caption accompanying a large photo of a mother sitting in her deceased daughter’s bedroom and stating, “Linda Morin found her 14-year-old daughter Annabelle dead in the bathtub shortly after she received her second injection of the HPV vaccine Gardasil” is alarmist in the face of the fact that there is no scientific evidence to prove the vaccine caused her daughter’s death.

The reports of these young women’s illnesses come from a public database of adverse vaccine effects. The Star’s investigations editor, Kevin Donovan, has said publicly he believes this is valid information and the investigation gave voice to women who believe their debilitating illnesses were caused by the vaccine.

But, as public health experts have made clear to me in dozens of emails this week, by the standards of evidence-based science and science reporting, such stories are considered “anecdotal evidence” only. These reports in no way prove the vaccine caused harm. To allay fear, that important context needed to be proclaimed much more boldly in the article and its presentation.

The reporters told me from the outset that “the story is neither anti-vaccine nor pro-vaccine.”

“As with many of our other articles published as part of our ongoing investigation into drug safety, this one is mainly about transparency. In this case, transparency for girls and their parents so that they get all of the available risk and benefit information,” the reporters stated last week.

That’s a valid intent but unfortunately I don’t think that’s what came through to a great many readers — hence the intense public outcry. On first reading the story and particularly on viewing the dramatic video that includes a mother who believes her daughter’s death may be linked to the vaccine, even I felt an immediate pang of alarm over having allowed my own daughter to receive the vaccine — and relief that she experienced no ill effects.

In its overall presentation, the Star provided mixed messages. It needed to make crystal clear in big bold type the fact that the scientific evidence has concluded the vaccine is safe and that there is no evidence at all to indicate that the ill effects the young women reported to the vaccine effects database were caused by the vaccine.

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Ongoing scientific studies of databases of adverse effects done by credible organizations have all concluded the HPV vaccine is safe and effective. The World Health Organization says so. So do the Centers for Disease Control and Prevention, the Public Health Agency of Canada and Canada’s National Advisory Committee on Immunization. The Canadian Cancer Society also agrees.

The public outcry over this investigation is not surprising given that the Star chose to publish it in the same week that a measles outbreak made news across North America and public health officials have expressed concerns about parents who refuse to get their children vaccinated against the highly contagious disease because of fears that the vaccine causes autism.

Evidence-based medicine has discredited any factual basis for that fear. Still, it persists, driven by “anti-vaxxers” who focus on emotional, non-scientific, anecdotal evidence from parents who believe their child’s autism was caused by the measles vaccine. Public health officials have battled for many years to create public understanding of the childhood vaccine’s safety by stressing the importance of scientific evidence over individual and anecdotal suspicions of harm that cannot be proven by science.

The Star’s editor, Michael Cooke, now understands these concerns and takes full responsibility for the newsroom’s missteps here.

“I apologize to our readers and to the people in the medical community, and especially to those who believe our story could be used to fuel the anti-vaccine movement,” he said. “There was a bad story-management combination approved by me: a foreboding headline, undue emphasis on the front page and terrible timing.

“There is a current and intense debate over immunization that has raged since the latest measles outbreak and I did not put the proper framework around the story. More should have been done to acknowledge the fraught framework in which the story was published.”

I agree with that and would go further. In looking at all of this, I have to wonder why the Star published this at all — especially at this sensitive time in public health. If there is no proof that any of the young women’s illnesses, or the 60 adverse reactions in the database, were caused by the vaccine, then what is the story?

In coming days, I expect there will be much discussion in the newsroom about what has been learned here. One thing made clear to me this week is the fact that if anyone in the newsroom had consulted with any one of the Star’s excellent health and medical reporters, they could have explained the inherent land mines in not giving greater weight to scientific evidence in a story of such importance to public health.

The Star fell short in not giving its readers public health information in a manner that meets the standards of responsibility expected in evidence-based science journalism.

In matters of life, death and public health, the science matters.

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News

A note from the publisher

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Published on Fri Feb 20 2015

On Feb. 5, the Toronto Star published a Page 1 article with the headline “A wonder drug’s dark side” beneath a “Star investigation” label.

The article focused on several young women who had grown sick sometime after taking the anti-papillomavirus vaccine Gardasil.

The story included the caveat that none of these instances had been conclusively linked to the vaccine.

However, the weight of the photographs, video, headlines and anecdotes led many readers to conclude the Star believed its investigation had uncovered a direct connection between a large variety of ailments and the vaccine.

Some doctors and public health officials were troubled by the story treatment and by the lack of reference to the many studies which conclude the risks of Gardasil are low.

All major studies conducted after widespread inoculations began in 2006 have concluded the risks posed by Gardasil are no greater than those identified in the trial period before the vaccine was licensed and accepted for widespread use.

These include a study by researchers from the U.S. Centers for Disease Control and the U.S. Food and Drug Administration and an analysis of Gardasil safety issues in 37 countries by the World Health Organization’s Collaborating Centre for International Drug Monitoring, published in 2011. As well, an abstract from a Canadian study of the results of several million inoculations between 2006 and 2010 was presented to American Public Health Association meetings in 2013.

The Star story also drew responses from health researchers who praised the Star’s attempts to sift through data in which the red flag of an undiscovered side-effect might be found.

No drug is absolutely safe for all people in all conditions of health. Now that tens of millions of young women have taken the vaccine, it is conceivable that very rare reactions may emerge that weren’t identified earlier.

All vaccines, including Gardasil, have side-effects. The better known they are, the more

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safely the vaccine can be deployed.

This is what the article sought to achieve as well as to note that acknowledged risks are not always properly communicated.

We remain committed to this line of reporting. However, we have concluded that in this case our story treatment led to confusion between anecdotes and evidence.

For that reason, the Gardasil story package of Feb. 5 will be removed from our website.

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The number of Adverse Drug Reaction (ADR) reports associated with the HPV vaccine broken down by reaction PT

(Reaction) PT	Number of reports
Dizziness	1988
Headache	1494
Nausea	1455
Pain in extremity	949
Syncope	699
Malaise	681
Vomiting	621
Fatigue	543
Pyrexia	428
Rash	336
Pallor	304
Hypoaesthesia	301
Peripheral swelling	291
Paraesthesia	205
Erythema	197
Urticaria	194
Feeling hot	192
Pain	176
Injection site swelling	172
Lethargy	169
Limb discomfort	166
Abdominal pain	161
Tremor	156
Abdominal pain upper	146
Pruritus	140
Injection site pain	136
Arthralgia	133
Dyspnoea	131
Asthenia	125
Injection site erythema	125
Vision blurred	125
Somnolence	124
Myalgia	113
Skin discolouration	112
Flushing	107
Influenza like illness	107
Diarrhoea	102
Seizure	100
Oropharyngeal pain	98
Body temperature increased	94
Peripheral coldness	93
Cold sweat	87
Musculoskeletal stiffness	81
Hyperhidrosis	76
Swelling face	76
Chills	75
Loss of consciousness	73
Anaphylactic reaction	66
Rash generalised	66
Rash macular	66
Feeling cold	63

Injection site mass	63
Muscular weakness	61
Hypersensitivity	58
Rash pruritic	56
Decreased appetite	55
Chest pain	54
Injection site rash	52
Lip swelling	52
Chest discomfort	51
Migraine	51
Back pain	50
Presyncope	47
Hyperventilation	46
Visual impairment	45
Contusion	43
Abdominal discomfort	42
Dyskinesia	42
Neck pain	40
Feeling abnormal	37
Cough	36
Injection site reaction	36
Local swelling	36
Lymphadenopathy	36
Throat tightness	34
Unresponsive to stimuli	34
Eye swelling	33
Nasopharyngitis	33
Chronic fatigue syndrome	32
Paraesthesia oral	32
Swelling	32
Local reaction	31
Rash erythematous	31
Tachycardia	31
Post viral fatigue syndrome	30
Alopecia	29
Cyanosis	28
Heart rate increased	28
Injection site bruising	28
Muscle twitching	28
Photophobia	28
Anxiety	27
Injection site inflammation	27
Injection site warmth	27
Disturbance in attention	25
Injection site pruritus	25
Swollen tongue	25
Eye movement disorder	24
Gait disturbance	24
Hypotension	24
Muscle rigidity	24
Skin warm	24
Confusional state	23
Sensory loss	23
Tearfulness	23
Discomfort	22
Disorientation	22

Exposure during pregnancy	22
Insomnia	22
Muscle spasms	21
Panic attack	21
Weight decreased	21
Dizziness postural	20
Joint swelling	20
Musculoskeletal pain	20
Dermatitis allergic	19
Inflammation	19
Throat irritation	19
Wheezing	19
Abasia	18
Amenorrhoea	18
Feeling of body temperature change	18
Menstruation irregular	18
Mydriasis	18
Asthma	17
Blister	17
Menorrhagia	17
Nervousness	17
Tenderness	17
Balance disorder	16
Dysstasia	16
Epistaxis	16
Palpitations	16
Pruritus generalised	16
Sensory disturbance	16
Abortion spontaneous	15
Eyelid oedema	15
Generalised tonic-clonic seizure	15
Injection site hypoaesthesia	15
Dysphagia	14
Ear pain	14
Epilepsy	14
Hypersomnia	14
Memory impairment	14
Viral infection	14
Angioedema	13
Deafness	13
Eczema	13
Hot flush	13
Pharyngeal oedema	13
Skin reaction	13
Urinary incontinence	13
VIIIth nerve paralysis	13
Dysarthria	12
Eye pain	12
Fall	12
Lower respiratory tract infection	12
Vertigo	12
Blindness transient	11
Depression	11
Dysgeusia	11
Hallucination	11
Hypokinesia	11

Injection site induration	11
Maternal exposure timing unspecified	11
Tinnitus	11
Abnormal behaviour	10
Blindness	10
Condition aggravated	10
Diplopia	10
Head discomfort	10
Hypopnoea	10
Mobility decreased	10
Oedema peripheral	10
Abdominal pain lower	9
Amnesia	9
Complex regional pain syndrome	9
Crying	9
Hypoaesthesia oral	9
Infectious mononucleosis	9
Irritable bowel syndrome	9
Vaginal haemorrhage	9
Anaemia	8
Depressed mood	8
Dry skin	8
Emotional disorder	8
Emotional distress	8
Erythema multiforme	8
Foetal exposure during pregnancy	8
Gastroesophageal reflux disease	8
Hearing impaired	8
Heart rate decreased	8
Herpes zoster	8
Injection site nodule	8
Menstrual disorder	8
Mouth swelling	8
Petechiae	8
Photosensitivity reaction	8
Skin irritation	8
Activities of daily living impaired	7
Aggression	7
Agitation	7
Aphonia	7
Blood pressure decreased	7
Blood pressure increased	7
Heart rate irregular	7
Hypotonia	7
Joint stiffness	7
Menstruation delayed	7
Panic reaction	7
Postural orthostatic tachycardia syndrome	7
Pulse abnormal	7
Respiratory rate increased	7
Sleep disorder	7
Speech disorder	7
Visual field defect	7
Abdominal distension	6
Alopecia areata	6
Autoimmune disorder	6

Blood glucose increased	6
Dry throat	6
Dysmenorrhoea	6
Dyspepsia	6
Gastrointestinal disorder	6
Hemiparesis	6
Hypertension	6
Hypoacusis	6
Injection site discolouration	6
Injection site irritation	6
Muscle fatigue	6
Narcolepsy	6
Nasal congestion	6
Pain of skin	6
Premature baby	6
Retching	6
Type 1 diabetes mellitus	6
Abortion induced	5
Acne	5
Anaphylactic shock	5
Aphasia	5
Bradycardia	5
Burning sensation	5
Circulatory collapse	5
Dehydration	5
Dry mouth	5
Encephalitis	5
Encephalitis autoimmune	5
Face oedema	5
Gastritis	5
Guillain-Barre syndrome	5
Haematemesis	5
Hyperacusis	5
Hyperaesthesia	5
Immune system disorder	5
Infection	5
Injection site infection	5
Injection site urticaria	5
Injection site vesicles	5
Laryngeal oedema	5
Limb immobilisation	5
Listless	5
Live birth	5
Mouth ulceration	5
Movement disorder	5
Muscle tightness	5
Musculoskeletal discomfort	5
Ocular hyperaemia	5
Personality change	5
Pharyngitis	5
Pollakiuria	5
Purpura	5
Rash maculo-papular	5
Seizure anoxic	5
Slow response to stimuli	5
Visual acuity reduced	5

Weight bearing difficulty	5
Altered state of consciousness	4
Areflexia	4
Arthritis reactive	4
Arthropathy	4
Body temperature decreased	4
Colitis ulcerative	4
Consciousness fluctuating	4
Constipation	4
Coordination abnormal	4
Dermatitis contact	4
Erythema nodosum	4
Eye disorder	4
Eye pruritus	4
Feeling drunk	4
Generalised erythema	4
Groin pain	4
Hallucination, auditory	4
Henoch-Schonlein purpura	4
Hordeolum	4
Inappropriate schedule of drug administration	4
Injected limb mobility decreased	4
Injection site coldness	4
Injection site haemorrhage	4
Mass	4
Miliaria	4
Monoplegia	4
Paralysis	4
Paranoia	4
Poor peripheral circulation	4
Psychomotor hyperactivity	4
Rhinorrhoea	4
Seizure like phenomena	4
Skin exfoliation	4
Suicidal ideation	4
Tachypnoea	4
Thirst	4
Vitreous floaters	4
Weight increased	4
Abnormal loss of weight	3
Anaphylactoid reaction	3
Arthritis	3
Asthenopia	3
Autonomic nervous system imbalance	3
Body temperature fluctuation	3
Bronchospasm	3
Capillary disorder	3
Cataplexy	3
Cluster headache	3
Cognitive disorder	3
Deafness transitory	3
Decreased interest	3
Depressed level of consciousness	3
Diffuse alopecia	3
Dissociation	3
Fear	3

Feeding disorder	3
Feeling jittery	3
Food allergy	3
Food intolerance	3
Furuncle	3
Grip strength decreased	3
Hyperglycaemia	3
Hypothyroidism	3
Immune thrombocytopenic purpura	3
Influenza	3
Injection site discharge	3
Injection site movement impairment	3
Iron deficiency	3
Juvenile idiopathic arthritis	3
Mood altered	3
Mood swings	3
Myoclonus	3
Nervous system disorder	3
Optic neuritis	3
Oral pain	3
Pain in jaw	3
Partial seizures	3
Petit mal epilepsy	3
Photopsia	3
Platelet count decreased	3
Psoriasis	3
Psychotic disorder	3
Pupil fixed	3
Quality of life decreased	3
Rash papular	3
Restlessness	3
Rheumatoid arthritis	3
Salivary hypersecretion	3
Sinus tachycardia	3
Skin disorder	3
Skin lesion	3
Skin mass	3
Skin papilloma	3
Sudden onset of sleep	3
Systemic lupus erythematosus	3
Tonsillitis	3
Type III immune complex mediated reaction	3
Upper respiratory tract infection	3
Urinary tract infection	3
Urticaria chronic	3
Vitamin D deficiency	3
Adrenocortical insufficiency acute	2
Allergy to animal	2
Alopecia totalis	2
Ankyloglossia congenital	2
Anogenital warts	2
Appendicitis	2
Appetite disorder	2
Ataxia	2
Atrioventricular septal defect	2
Autoimmune thyroiditis	2

Back disorder	2
Bedridden	2
Beta haemolytic streptococcal infection	2
Blood glucose decreased	2
Blood iron decreased	2
Bradyphrenia	2
Breast tenderness	2
Bronchitis	2
Candida infection	2
Cellulitis	2
Choking sensation	2
Colour blindness acquired	2
Congenital cystic kidney disease	2
Congenital skin dimples	2
Conjunctival hyperaemia	2
Dark circles under eyes	2
Delirium	2
Delusion	2
Depressive symptom	2
Diabetes mellitus inadequate control	2
Diabetic ketoacidosis	2
Diplegia	2
Disinhibition	2
Double outlet right ventricle	2
Dysphemia	2
Dysphonia	2
Ear discomfort	2
Eating disorder	2
Educational problem	2
Excessive eye blinking	2
Extensive swelling of vaccinated limb	2
Eye irritation	2
Fibromyalgia	2
Flank pain	2
Foaming at mouth	2
Foetal growth restriction	2
Frequent bowel movements	2
Gaze palsy	2
Growth retardation	2
Haemoptysis	2
Haemorrhage	2
Hallucination, visual	2
Head banging	2
Hormone level abnormal	2
Ill-defined disorder	2
Immobile	2
Immunisation reaction	2
Incoherent	2
Increased tendency to bruise	2
Induration	2
Infection susceptibility increased	2
Injection site cellulitis	2
Injection site discomfort	2
Injection site scab	2
Intentional self-injury	2
Irritability	2

Jaundice	2
Labyrinthitis	2
Limb hypoplasia congenital	2
Limb reduction defect	2
Lip blister	2
Liver disorder	2
Maternal exposure before pregnancy	2
Meningism	2
Mental impairment	2
Muscle contractions involuntary	2
Musculoskeletal chest pain	2
Nail discolouration	2
Nerve injury	2
Neuralgia	2
Night sweats	2
Odynophagia	2
Oligomenorrhoea	2
Oral discomfort	2
Oral pruritus	2
Otitis media	2
Ovarian cyst	2
Papule	2
Pelvic pain	2
Periorbital oedema	2
Polycystic ovaries	2
Premature labour	2
Preternatural anus	2
Procedural dizziness	2
Productive cough	2
Pulmonary aplasia	2
Pulmonary arteriopathy	2
Pulmonary hypoplasia	2
Pulmonary valve stenosis	2
Raynaud's phenomenon	2
Respiratory disorder	2
Respiratory tract infection	2
Rubber sensitivity	2
Screaming	2
Seborrhoeic dermatitis	2
Self esteem decreased	2
Sensation of foreign body	2
Serum ferritin decreased	2
Shock	2
Skin hypertrophy	2
Skin tightness	2
Sneezing	2
Social avoidant behaviour	2
Somatisation disorder	2
Spinal pain	2
Spine malformation	2
Status epilepticus	2
Tension headache	2
Tetany	2
Thinking abnormal	2
Thought blocking	2
Thrombocytopenia	2

Thrombosis	2
Tonic clonic movements	2
Type I hypersensitivity	2
Type IV hypersensitivity reaction	2
Ulcer	2
Urinary retention	2
VACTERL syndrome	2
Vitamin B12 deficiency	2
Vulval oedema	2
Vulval ulceration	2
Vulvovaginal swelling	2
Abdominal migraine	1
Abdominal tenderness	1
Abnormal faeces	1
Abnormal sleep-related event	1
Abortion threatened	1
Acarodermatitis	1
Accommodation disorder	1
Acute lymphocytic leukaemia	1
Acute myeloid leukaemia	1
Acute psychosis	1
Acute respiratory failure	1
Ageusia	1
Agnosia	1
Alanine aminotransferase increased	1
Allergic oedema	1
Altered visual depth perception	1
Amniotic cavity infection	1
Anaemia vitamin B12 deficiency	1
Anal fissure	1
Antinuclear antibody increased	1
Apathy	1
Aplastic anaemia	1
Application site pustules	1
Arrhythmia	1
Arteriovenous malformation	1
Atrioventricular block	1
Atrophy	1
Autoimmune hepatitis	1
Autophobia	1
Axillary mass	1
Axillary nerve injury	1
Axillary pain	1
Basal ganglia stroke	1
Basilar migraine	1
Behcet's syndrome	1
Benign hydatidiform mole	1
Bipolar disorder	1
Birth mark	1
Bladder fibrosis	1
Bladder pain	1
Bladder spasm	1
Blindness unilateral	1
Blood albumin abnormal	1
Blood cortisol decreased	1
Blood count abnormal	1

Blood disorder	1
Blood pH increased	1
Blood pressure abnormal	1
Blood pressure immeasurable	1
Blood pressure systolic decreased	1
Bone cancer	1
Bone pain	1
Breast enlargement	1
Breast pain	1
Breast swelling	1
Breath sounds abnormal	1
Bruxism	1
Burnout syndrome	1
CSF cell count increased	1
Cardiac arrest	1
Cardiac murmur	1
Cell marker increased	1
Cerebellar ataxia	1
Cerebral palsy	1
Cerebral thrombosis	1
Cerebrovascular disorder	1
Cervical dysplasia	1
Cervical incompetence	1
Cervix inflammation	1
Cheilitis	1
Chorea	1
Choroiditis	1
Chronic myeloid leukaemia	1
Circumoral oedema	1
Cleft palate	1
Clonic convulsion	1
Clonus	1
Clumsiness	1
Coagulopathy	1
Colitis	1
Congenital anomaly	1
Conjunctivitis	1
Contracted bladder	1
Corneal reflex decreased	1
Costochondritis	1
Cystitis noninfective	1
Deafness bilateral	1
Decreased activity	1
Deep vein thrombosis	1
Delayed puberty	1
Demyelination	1
Dermatitis	1
Dermatitis artefacta	1
Diabetes insipidus	1
Diarrhoea haemorrhagic	1
Disability	1
Disturbance in social behaviour	1
Droping	1
Drug administered at inappropriate site	1
Drug hypersensitivity	1
Drug ineffective	1

Dry eye	1
Duodenitis	1
Dyshidrotic eczema	1
Dyslexia	1
Dyspraxia	1
Dystonia	1
Dysuria	1
Eczema vesicular	1
Electrocardiogram QT prolonged	1
Electrocardiogram T wave inversion	1
Electrocardiogram abnormal	1
Emotional poverty	1
Encephalitis lethargica	1
Eosinophilia	1
Epiglottitis	1
Eructation	1
Euphoric mood	1
Excoriation	1
Exercise tolerance decreased	1
Extra dose administered	1
Eye discharge	1
Eye inflammation	1
Eyelid disorder	1
Eyelid ptosis	1
Eyelids pruritus	1
Face injury	1
Facial pain	1
Facial paresis	1
Facial spasm	1
Fear of crowded places	1
Fear of death	1
Feeling guilty	1
Feeling of despair	1
Flatulence	1
Focal segmental glomerulosclerosis	1
Foetal death	1
Foetal distress syndrome	1
Foetal heart rate abnormal	1
Folliculitis	1
Foot deformity	1
Functional gastrointestinal disorder	1
Gastric dilatation	1
Gastric disorder	1
Gastritis erosive	1
Gastroenteritis viral	1
Gastrointestinal haemorrhage	1
Gastrointestinal hypomotility	1
Gastrointestinal infection	1
Gastrointestinal inflammation	1
Gastrointestinal motility disorder	1
Gastrointestinal pain	1
Gastrointestinal ulcer	1
General physical health deterioration	1
Genital pain	1
Gingival disorder	1
Gingival swelling	1

Gingivitis	1
Glaucoma	1
Glossodynia	1
Growing pains	1
Grunting	1
Guttate psoriasis	1
Haemolytic uraemic syndrome	1
Haemorrhoids	1
Halo vision	1
Hashimoto's encephalopathy	1
Head injury	1
Hepatic cyst	1
Hepatic function abnormal	1
Hepatitis viral	1
Herpes virus infection	1
High arched palate	1
Hypermobility syndrome	1
Hyperpyrexia	1
Hypertonia	1
Hypertonic bladder	1
Hypoglycaemia	1
Hypomania	1
Hyporesponsive to stimuli	1
Hypospadias	1
IVth nerve paralysis	1
Ichthyosis	1
Immediate post-injection reaction	1
Impaired gastric emptying	1
Impaired work ability	1
Impetigo	1
Impulse-control disorder	1
Inappropriate affect	1
Incontinence	1
Increased appetite	1
Increased bronchial secretion	1
Infusion site hypoaesthesia	1
Inguinal hernia	1
Inguinal hernia repair	1
Injection site abscess	1
Injection site granuloma	1
Injection site injury	1
Injection site joint movement impairment	1
Injection site joint pain	1
Injection site nerve damage	1
Injection site oedema	1
Injection site papule	1
Injection site paraesthesia	1
Injection site scar	1
Inner ear disorder	1
Intentional overdose	1
Iris adhesions	1
Iritis	1
Joint contracture	1
Joint effusion	1
Kidney infection	1
Labour complication	1

Lacrimation increased	1
Lactose intolerance	1
Laryngeal papilloma	1
Laryngitis	1
Lid sulcus deepened	1
Lip pain	1
Lip ulceration	1
Liver function test abnormal	1
Localised oedema	1
Lumbosacral plexus lesion	1
Lupus-like syndrome	1
Lymphoedema	1
Masked facies	1
Mastication disorder	1
Mastitis	1
Mastocytosis	1
Medulloblastoma	1
Metabolic disorder	1
Metamorphopsia	1
Metastases to liver	1
Metrorrhagia	1
Micturition urgency	1
Middle insomnia	1
Migraine with aura	1
Mixed connective tissue disease	1
Molluscum contagiosum	1
Monoparesis	1
Motion sickness	1
Motor dysfunction	1
Mouth injury	1
Multiple allergies	1
Muscle contracture	1
Muscle injury	1
Muscle swelling	1
Myalgia intercostal	1
Myasthenia gravis	1
Myelitis transverse	1
Myoclonic epilepsy	1
Myositis	1
Nasal obstruction	1
Neck mass	1
Negative thoughts	1
Neoplasm malignant	1
Nephrotic syndrome	1
Neuritis	1
Neurogenic bladder	1
Neurological symptom	1
Neutropenia	1
Neutrophil count decreased	1
Nodule	1
Obsessive thoughts	1
Obsessive-compulsive disorder	1
Ocular discomfort	1
Ocular myasthenia	1
Oesophageal discomfort	1
Oesophageal mucosal hyperplasia	1

Oestradiol decreased	1
Optic disc disorder	1
Oral herpes	1
Oral mucosal blistering	1
Oral mucosal eruption	1
Oropharyngeal discomfort	1
Orthostatic hypotension	1
Osteitis	1
Osteoporosis	1
Ovarian disorder	1
Ovarian failure	1
Overlap syndrome	1
Oxygen saturation decreased	1
Painful respiration	1
Palindromic rheumatism	1
Palmar erythema	1
Pancreatic disorder	1
Pancreatic neuroendocrine tumour metastatic	1
Pancreatitis	1
Pancytopenia	1
Panniculitis	1
Papilloma viral infection	1
Paralysis flaccid	1
Parosmia	1
Peak expiratory flow rate decreased	1
Pelvic inflammatory disease	1
Pericardial effusion	1
Peripheral circulatory failure	1
Peripheral sensory neuropathy	1
Peripheral vascular disorder	1
Peritonitis	1
Peroneal nerve palsy	1
Pharyngeal erythema	1
Physical disability	1
Piloerection	1
Pituitary tumour	1
Pityriasis lichenoides et varioliformis acuta	1
Pleuritic pain	1
Pneumonia viral	1
Pneumothorax	1
Poisoning	1
Poor quality sleep	1
Posture abnormal	1
Pre-eclampsia	1
Pregnancy with injectable contraceptive	1
Product substitution issue	1
Protein total abnormal	1
Proteinuria	1
Psychiatric symptom	1
Puberty	1
Pulse absent	1
Pulse pressure decreased	1
Puncture site reaction	1
Pupillary disorder	1
Pupillary reflex impaired	1
Quadriparesis	1

Radiculitis brachial	1
Rash follicular	1
Rash vesicular	1
Reaction to preservatives	1
Rectal haemorrhage	1
Reflux gastritis	1
Regurgitation	1
Renal disorder	1
Renal failure	1
Respiration abnormal	1
Respiratory arrest	1
Respiratory distress	1
Respiratory rate decreased	1
Respiratory syncytial virus infection	1
Respiratory tract inflammation	1
Retinal vasculitis	1
Saliva altered	1
Salivary gland cancer stage I	1
Scab	1
Scar	1
Sebaceous naevus	1
Sedation	1
Self-injurious ideation	1
Sepsis	1
Septic rash	1
Severe acute respiratory syndrome	1
Sinus arrhythmia	1
Sinus headache	1
Sinusitis	1
Skin burning sensation	1
Skin depigmentation	1
Skin haemorrhage	1
Skin infection	1
Skin striae	1
Sleep attacks	1
Sleep terror	1
Slow speech	1
Small intestinal bacterial overgrowth	1
Smear cervix abnormal	1
Social phobia	1
Soft tissue disorder	1
Spinal cord oedema	1
Splenomegaly	1
Staphylococcal infection	1
Stevens-Johnson syndrome	1
Streptococcal sepsis	1
Stridor	1
Suicide attempt	1
Synovitis	1
Systemic inflammatory response syndrome	1
Systemic lupus erythematosus rash	1
T-cell type acute leukaemia	1
Talipes	1
Temperature intolerance	1
Temperature regulation disorder	1
Thermal burn	1

Thrombophlebitis superficial	1
Tongue coated	1
Tonsillar hypertrophy	1
Tooth erosion	1
Trichorrhexis	1
Umbilical discharge	1
Urinary tract inflammation	1
Urine output decreased	1
Urticaria pigmentosa	1
Uterine cervix atrophy	1
Uterine leiomyoma	1
Uveitis	1
Vlth nerve paralysis	1
Vaccination complication	1
Vaccination site hypersensitivity	1
Vaginal discharge	1
Vaginal lesion	1
Vaginal mucosal blistering	1
Vaginal ulceration	1
Varicella	1
Vasculitis	1
Vasculitis cerebral	1
Vasodilation procedure	1
Vasospasm	1
Ventouse extraction	1
Vestibular disorder	1
Viraemia	1
Vitamin B12 increased	1
Vitamin C deficiency	1
Vitiligo	1
Vomiting projectile	1
Vulval disorder	1
Vulvar dysplasia	1
Vulvovaginal candidiasis	1
Vulvovaginal human papilloma virus infection	1
Vulvovaginal pain	1
Vulvovaginal pruritus	1
Weight gain poor	1
White blood cell count decreased	1
Wound	1
Wrong technique in drug usage process	1
Yellow skin	1

Figure 11: Percentage of serious reactions per SOC associated with Influenza vaccine

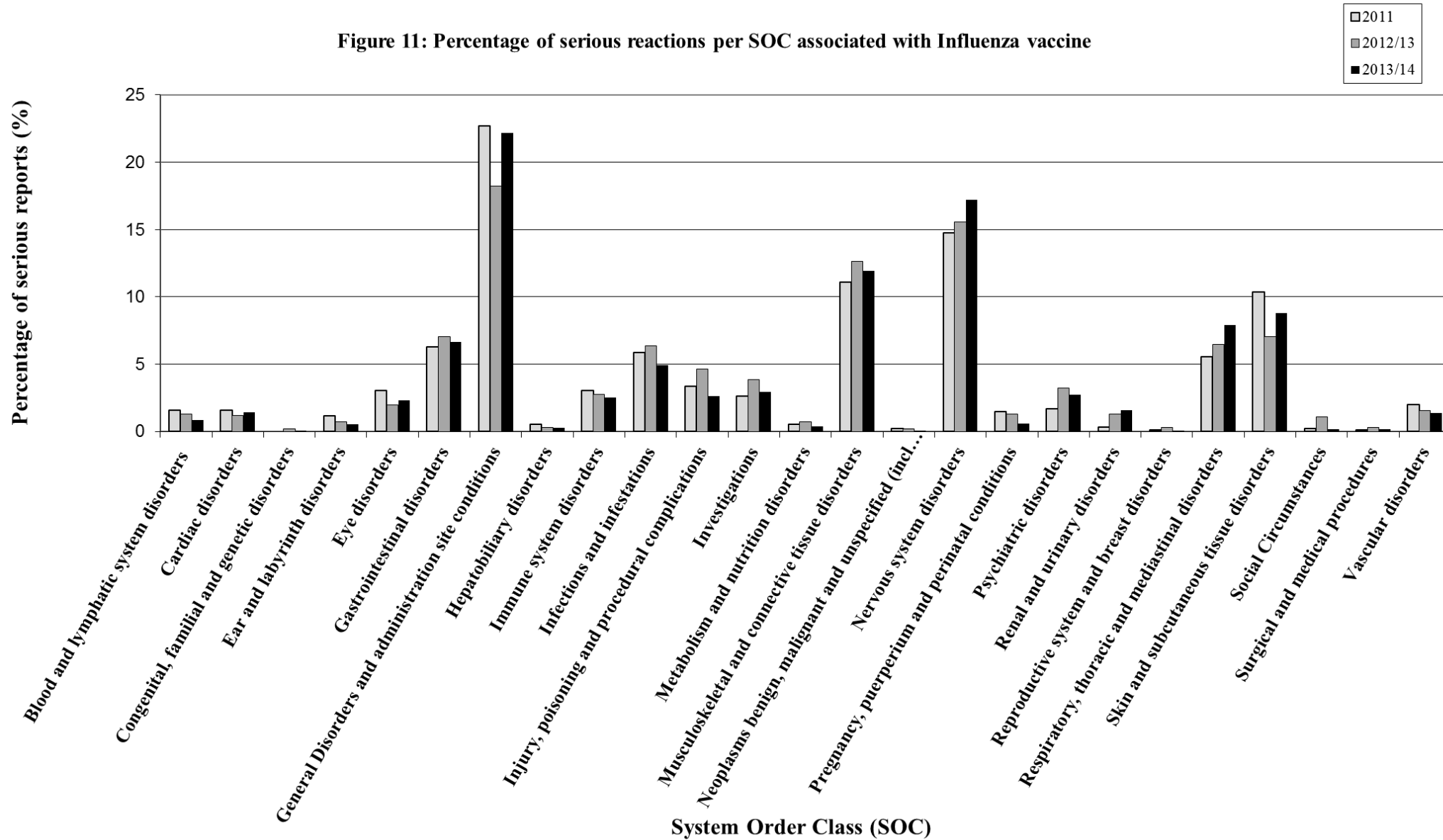


Figure 7: Percentage of serious reactions per SOC associated with Revaxis vaccine

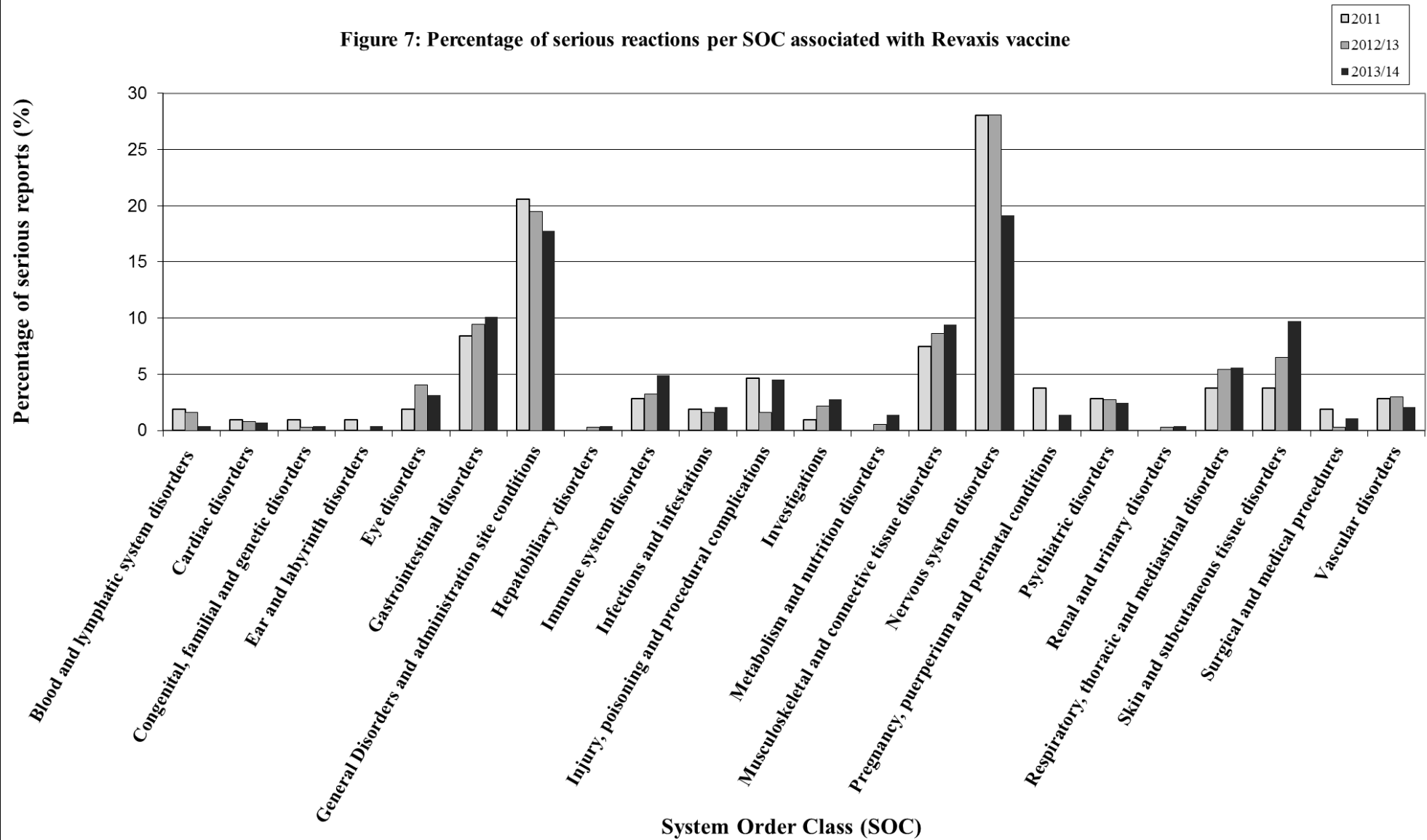


Figure 8: Percentage of serious reactions per SOC associated with Human Papillomavirus vaccine

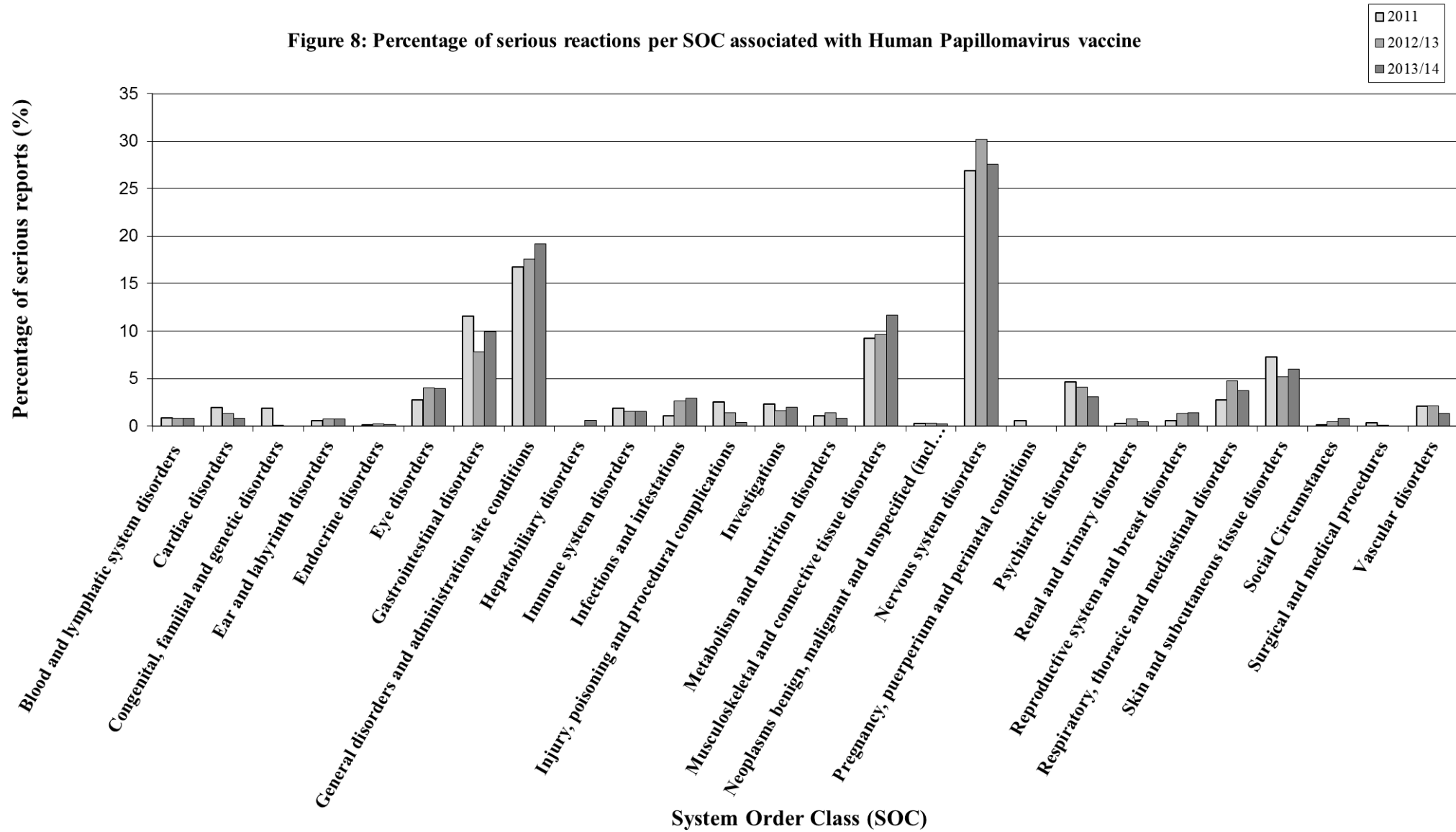
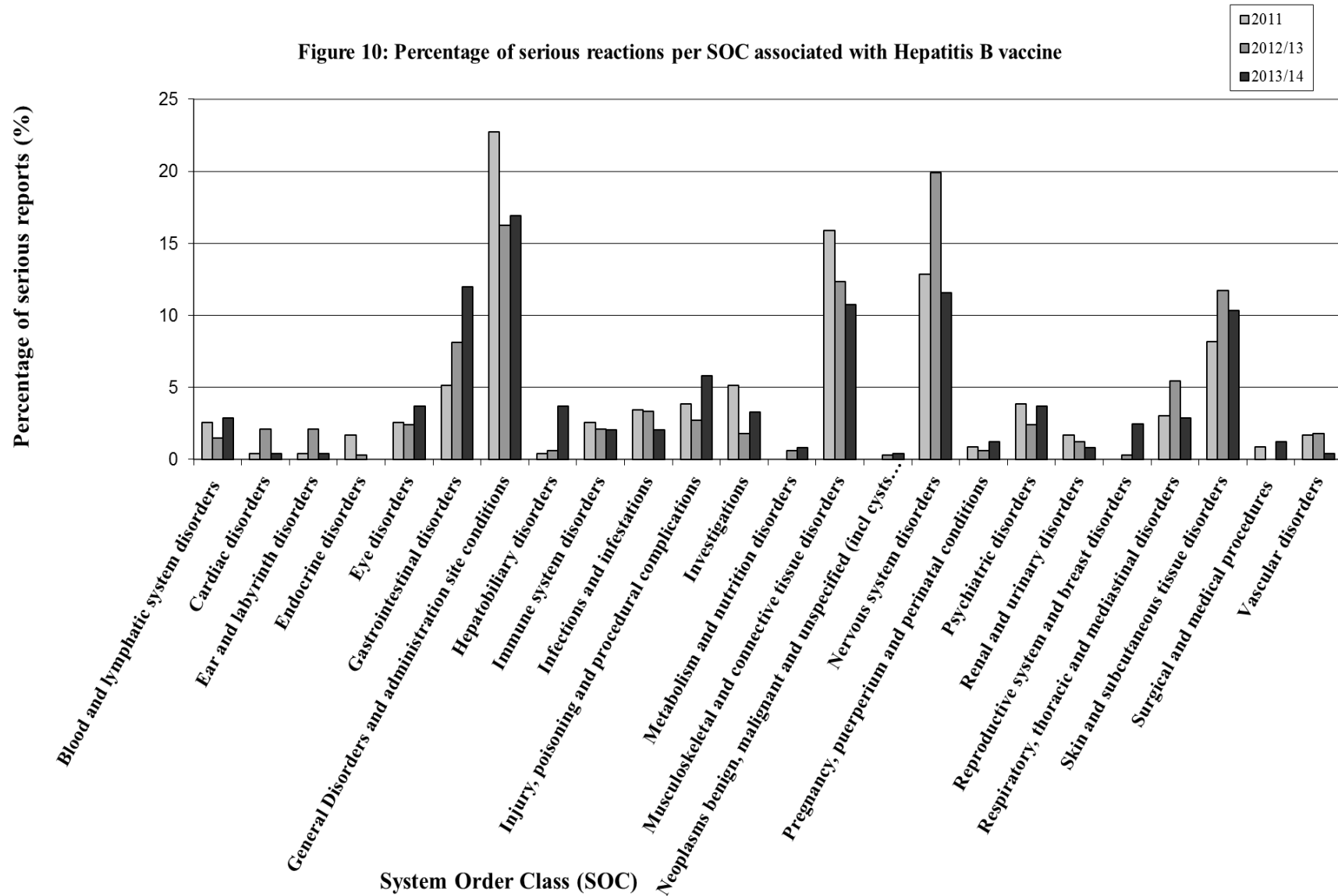


Figure 10: Percentage of serious reactions per SOC associated with Hepatitis B vaccine



**MHRA**

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Petra Ratajova

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R.E. FOI 15/184

06th May 2015

Dear Ms Ratajova,

Thank you for your FOI request on the 15th April where you requested Adverse Drug Reaction (ADR) reports in association with a vaccine from the 1st January 2005, including the total number of serious and non-serious ADR reports and the total number of ADR reports in children under the age of 10, between 11 and 18, and in adults aged 19 or over.

As you may already aware, the Yellow Card Scheme is the UK system for collecting and monitoring information on suspected ADRs in association with medicines and vaccines. The Scheme is run by the Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the Commission on Human Medicines (CHM), and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. There is also a legal obligation for pharmaceutical companies to report serious side effects for their products. Spontaneous adverse reaction reporting is the commonest source for identification of drug safety signals, and often provides an early warning of possible hazards.

Further to your request, please may I refer you to table 1 below which summarizes the total number of UK spontaneous suspected ADR reports received by the MHRA in association with a vaccine between 1st January 2005 and 22nd April 2015 including the total number of serious and non-serious reports. The data provided relates to vaccines contained within the routine immunization schedule, a copy of this can be found via the following link: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/315489/PHE-Routine-childhood-imm-July-2014-03.pdf

Table 1: Total number of UK spontaneous suspected ADR reports in association with a vaccine between 1st January 2005 and 22nd April 2015 including serious and non-serious reports

Vaccine 01/01/2005 - 22/04/2015	Total number of ADR reports	Total number of serious reports	Total number of non-serious reports
Diphtheria,tetanus, pertussis, polio and <i>Haemophilus influenza</i> type b (DTaP/IPV/Hib)	1309	683	626
Tetanus, diphtheria and polio (Td/IPV)	1076	637	439
Diphtheria,tetanus, pertussis and polio (DTaP/IPV)	1190	469	721

Rotavirus (Rotarix)	412	261	151
Pneumococcal disease (PCV)	1560	840	720
Meningococcal group C disease (Men C)	769	459	310
Hib/Men C	279	150	129
Measles, mumps and rubella (MMR)	1594	1113	481
Pneumococcal disease (PPV)	963	635	328
Fluenz Tetra	872	379	493
Shingles (Zostavax)	626	394	232
Human Papilloma Virus (HPV)	8228	2587	5641
Influenza virus	2944	2380	564

I can confirm that the MHRA has received a total of 21,822 UK spontaneous suspected ADR reports between the 1st January 2005 and 22nd April 2015 in association with the vaccines in the routine immunization schedule, 10,987 of these were serious reports and 10,835 were non-serious. Please be aware that one ADR report may contain more than one vaccine as some vaccinations within the schedule are administered within the same time period. Please also be aware that during this time period many millions of doses of these vaccines have been administered in the UK.

A suspected ADR report is considered 'serious' according to two criteria; firstly whether the original reporter considers the report to be serious. A single case may be deemed serious due to a number of reasons. The seriousness criteria for ADR reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and are defined as 6 possible categories which are documented on the Yellow Card. We ask reporters to select one of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant. In addition to this each ADR has been assigned either serious or non-serious using our medical dictionary (MedDRA), this criteria is specific to the reaction term and not influenced by the individual situation, outcome or severity of the reaction. Therefore an ADR report can be serious because the reporter considers the reaction to be serious or because the reaction term itself is considered serious in our medical dictionary. In cases where the reporter has not indicated the seriousness of the reaction, we will assess the case and select the medically significant criteria if for example the report contains one or more serious ADRs term.

Further to your enquiry, please may I refer you to table 2 which shows the breakdown of total number of ADR reports into the age groups requested in your enquiry. Please note that age is not a mandatory field on a Yellow Card and therefore may not always be reported; only reports where the age of the patient has been stated by the reporter are included in the table below.

Table 2: Total number of ADR reports in association with vaccines between 1st January 2005 and 22nd April 2015 in children under the age of 10, between 11 and 18 and in adults 19 or over

Vaccine 01/01/2005 - 22/04/2015	Total number of reports in children under the age of 10	Total number of reports in children between the age of 11 and 18	Total number of reports in adults 19+
Diphtheria, tetanus, pertussis, polio and <i>Haemophilus influenza</i> type b (DtaP/IPV/Hib)	1199	3	1
Tetanus, diphtheria and polio (Td/IPV)	22	703	267
Diphtheria, tetanus, pertussis and polio (DtaP/IPV)	1046	11	86

Rotavirus (Rotarix)	385	0	6
Pneumococcal disease (PCV)	1459	8	14
Meningococcal group C disease (Men C)	503	182	84
Hib/Men C	262	2	4
Measles, mumps and rubella (MMR)	1013	163	306
Pneumococcal disease (PPV)	87	31	794
Fluenz Tetra	665	148	7
Shingles (Zostavax)	0	0	626
Human Papilloma Virus (HPV)	18	7793	83
Influenza virus	169	61	2478

I can confirm that the MHRA has received a total of 6,828 UK spontaneous suspected ADR reports between 1st January 2005 and 22nd April 2015 for children under the age of 10, 9,105 reports for children between the age of 11 and 18, and 4,756 reports for adults 19 or over in association with vaccines in the immunization schedule.

It is important to note that a Yellow Card report is not proof of a side effect occurring, but merely a suspicion by the reporter that the vaccine may have caused the side effect. Yellow Card reports may therefore relate to true side effects of the vaccine, or they may be due to coincidental, underlying medical conditions that would have occurred anyway in the absence of vaccination.

Furthermore the number of reports received via the Yellow Card Scheme does not directly equate to the number of people who suffer adverse reactions to drugs for a number of reasons, as this scheme is associated with an unknown and variable level of under-reporting. ADR reporting rates may be influenced by the seriousness of reactions, their ease of recognition, extent of use of a particular drug and promotion and publicity about a drug.

Please be assured that as with all medicines and vaccines, the MHRA is closely monitoring the safety of all vaccines in the UK. Should any important safety issues be identified, appropriate regulatory action would be taken and communicated to healthcare professionals and patients alike.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of receipt of the response to your original letter.

Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely,
FOI Team,
Vigilance and Risk Management of Medicines Division.

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