Kathy Cooper 3147

From: James Lyons-Weiler <jameslyonsweiler@gmail.com>
Sent: Tuesday, May 03, 2016 11:46 AM
To: IRRC; ra-stateboardofed@pa.gov; henglish@pahousegop.com; rvulakovich@pasen.gov
Cc: Kristi Wees; Holland, Mary; Brian Hooker; EDWARD FOGARTY; DEL BIGTREE; Gretchen LeFever Watson
Subject: Pending PA Vaccine policy changes and non-active Bills
Attachments: william-thompson-statement-27-august-2014-3.pdf; 160426-chernobyl.pdf; HPV study - 1 in 10 girls seriously injured by vaccine (1).pdf

To my representatives in the Government in the Commonwealth of Pennsylvania,

I submit these to you for your consideration and as Public Commentary.

I am writing with deep concerns over the current proposed changes in the Department of Health (DOH) regulation concerning vaccines. Federal and international law and standards since the Nuremberg trials have made it clear that all patient must be afforded informed consent for any medical procedure. The proposed move to reduce the time for vaccine compliance is very disturbing, as it reduces the amount of time that a parent can take to conduct sufficient checking for accuracy and thoroughness of the information provided by their doctors. Clearly this change is designed to reduce the amount of time available for doctors to discuss vaccine safety with patients, follow up on calls, schedule consultations, and perform their own inquiries, and will thereby restrict some patients to access to information they need to make informed choices about medical procedures.

Many doctors and other health care workers already fail to provide all of the information necessary to parents to make informed decision about the risk of specific vaccines to their children. I am told by pediatricians that they are under an enormous amount of pressure to reduce each office visit to seven minutes – hardly enough time to answer questions from patients seeking full information. For example, I recently called my child's doctor's office re: the HPV vaccine to inquire on safety, given the reports of large numbers of deaths and injury due to adverse reactions to the vaccine. The safety profile on HPV vaccine has been drawn into question – so much so that the nation of Japan has refused to allow its use in practice there.

I was told by the nurse that she was "required by law" to tell me that HPV vaccine was very safe, but she gave no detail on the adverse reaction. When I quoted her statement "required by law", she denied saying it. However, when I spoke with the doctor, he also said that the risk of any adverse event was very small, but could not go into any detail on the types of adverse events. I requested the vaccine insert, which he said he would send. It came to me an in a hand-written, unmarked envelope with no return address, and the insert listed a few minor possible side effects. The insert also contained the following: "For information on additional potential

adverse events, consult with your doctor". When patients are put into a Catch-22 situation, how can we be expected to trust our healthcare providers?

Patients must have the right to make *fully* informed decisions about the medical procedures to which they decide to subject their children and themselves. The efficacy of HPV vaccine is also very much in question, given that the vaccine only protects against some of type of HPV. Studies have shown that rarer, potentially more dangerous types of HPV can replace those removed due to partial vaccination. This could result in a higher rate of HPV-related cancers. The studies include one by Guo et al, (2015), which found type replacement, as well as a study conducted by CDC (Markowitz et al., 2016), which found no change in overall HPV infection rates before and after HPV vaccination. The CDC study authors incorrectly concluded that no type replacement had occurred, and I have pointed out this error in interpretation to the authors. These studies have led to other states dropping proposed mandatory HPV vaccination, including Maryland.

HPV vaccine is now known to cause early ovarian failure – i.e., to induce menopause – in young females. It is clearly not a safe vaccine, and yet UPMC's nurses and doctors continue to push it on Pennsylvanians. What else do we not know about adverse events from vaccines? I have attached a study on HOV adverse events that concludes that 1 in 10 girls are harmed.

The proposed changes would also force parents to provide evidence of chickenpox immunity from a medical professional. This is not in keeping with the principle of freedom of choice, and informed consent. If a parent has decided, after due consideration of the risks of vaccination, to forego chickenpox vaccination, to avoid unwanted adverse events and side effects, it is the right of the parent to make the decision to forego chicken vaccination. The problem with singling out a single vaccine is that no science has been done on individual vaccines that support the conclusion offered by the CDC that "Vaccines Do Not Cause Autism". In fact, of the six vaccines for which studies do exist, there is in fact preliminary scientific evidence in support of association. For 6/12 vaccines given before the age of 7, no studies have been conducted on possible association with autism, and thus the overarching conclusion that "Vaccines Do Not Cause Autism" is actually not based on any scientific evidence.

CDC called for an end to studies of possible association of vaccines and autism after a handful of studies were conducted in the mid-to-late 2000's. One of those studies, Destefano et al. (2004), is now subject to investigation by CDC for possible fraud due to the fact that the authors of the study arbitrarily and intentionally omitted two sets of results showing positive association between the MMR vaccine, and autism.

Evidence of this alleged fraud has been entered in the US Congressional Record by Rep. William Posey (FL), and is the subject of the documentary "Vaxxed", currently being screened around the country, which I urge you to screen with your colleagues.

Another proposed change would be the addition of a meningococcal vaccine requirement for students entering the 12th grade. One problem with mandatory vaccination is that if some people have a predisposed genetic risk of adverse events due to any specific vaccine, mandatory vaccination compels them with certainty to suffer that fate. While few medical procedures are 100% risk-free, the biological nature of the match between a given family's protein sequences and the sequences in adjuvanted vaccines guarantees autoimmune disorders of all types. Severe allergic reactions (anaphylaxis) can occur.

Taken from a population view, the adverse event looks rare (cited as 1 in million at CDC website). However, if one has a sibling or parent who has already suffered an allergic reaction to a vaccine, should they not have the right to refuse subjecting themselves to the same fate? A spate of instances of life-long debilitating narcolepsy cause in some families GSK's swine flu vaccine in Europe has led to GlaxoSmithKline settling with families for millions of Euros. No cases were found due to the swine flu vaccine offered by Novartis. While public health policies, laws and mandates effect everyone, personal risk is personal, and we should not want any vaccine mandate that could condemn an unwitting minority in the population to life-threatening and disabling adverse events.

People should have the chance to decline vaccination based on first principles of ethics (sanctity of self), unless there is an immediate and pressing public health emergency. Vaccine manufacturer cannot be held liable for adverse events in the US, even when Federal compensation is refused.

Another proposed set of changes is to require pertussis vaccine for kindergarten admission, remove separate listing for vaccines and only show combinations (MMR, TDaP). Some, and perhaps most, people will do fine with combined vaccines. However, individual vaccines spaced out over time may reduce the severity of individual adverse reactions. Measles is not a deadly disease. In fact, over the last ten years, there have been zero deaths due to measles, and over 100 deaths due to measles vaccination in the US. Because Pharma is not help responsible, there is no incentive for them to find out why. For other drugs, FDA requires randomized, prospective clinical trials after animal safety studies. The types of studies that CDC relies on are retrospective, or "ecological" studies, and CDC has a history of re-analyzing the data in their studies if a positive association is found, and re-analyzing the data until an association goes away.

This is not a solid basis for health care policies that are to be applied to millions of Pennsylvanians. We need to move in the other direction, and demand safer vaccines, Pharma accountability, and we need to have real science conducted on adverse events associated with vaccines before any law is passed than condemns millions of our children to the neurotoxins and unsafe epitopes in vaccines. Listing only combination vaccines would preclude parents from making informed choice on individual vaccines, whereas listing individual vaccine options would help guarantee the right to informed consent by allowing parents to opt for single vaccines at a time, and refuse others, considering whatever science is available on the safety and efficacy of each individual vaccine, which is their right.

Here is some extremely relevant text of a message recently delivered to the United Nations by Mary Holland, J.D., Research Scholar, NYU School of Law, who presented at the 25th International Health and Environment

Conference (April 26, 2016). The presentation, of which I had the pleasure of witnessing first hand (program attached), was entitled "Vaccination Policies and Human Rights", and it was received by standing ovation:

"One of the core purposes of the United Nations, set forth in Article 1 of its Charter, is to achieve international cooperation "in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion." So how must countries and the international community respect and encourage human rights for vaccination policies? This is an important question that deserves genuine scrutiny, as it profoundly affects both individual and public health.

Since World War II, the international community has recognized the grave dangers in involuntary scientific and medical experimentation on human subjects. In the aftermath of Nazi medical atrocities, the world affirmed the Nuremberg Code which stated that the "voluntary consent of the human subject is absolutely essential." The International Covenant on Civil and Political Rights further enshrined this prohibition against involuntary experimentation in its 1966 text, stating 'no one shall be subjected without his free consent to medical or scientific experimentation.' Such a prohibition is now so universally recognized that some courts and scholars have pronounced the right to informed consent in experiments as a matter of customary international law. In other words, it applies everywhere, whether or not a country has specific laws on its books to this effect, as customary norms now prohibit slavery, torture and piracy.

What about informed consent in the area of medical treatment, including preventive medical treatment? What about informed consent to vaccination? This is a controversial issue today in many countries, including the United States.

In 2005, the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted the Universal Declaration on Bioethics and Human Rights on the consensus of 193 countries. The participating countries hoped this Declaration, like the Universal Declaration of Human Rights, would become a set of guiding principles in the challenging field of human rights and medicine. On the issue of consent, the Declaration states that

'any preventive...medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information.'

It further notes that the 'sole interest of science or society' does not prevail. Thus, the international community has clearly stated that the default position for vaccination must be recommendations, not compulsion, allowing individuals, for themselves and their minor children, to accept or refuse these preventive medical interventions based on adequate information and without coercion, such as the threat of loss of economic or educational benefits. Informed consent must be the default position because compulsion, on its face, limits the rights to consent, privacy and physical integrity.

To be sure, the Declaration in Article 27 suggests that there may be limitations on these fundamental rights, but these limits must be imposed by law and must be 'for the protection of public health or for the protection of the rights and freedoms of others.' Furthermore, 'any such law needs to be consistent with international human rights law.' So how can we reach such a balance in the area of vaccination?

International human rights courts have developed a test to see if restrictions of fundamental rights are legitimate and lawful. The test studies whether the measure is lawful, strictly necessary and proportionate to the risk. The State enacting such restrictions bears the burden of proof that the compulsory medical intervention is lawful, strictly necessary and proportionate. Generally, the "strict necessity" element must be the least restrictive alternative to achieve the public health objective, and non-coercive approaches should always be considered first. Thus, the State must show that a less restrictive alternative is not feasible before adopting a highly restrictive one.

In addition to these criteria related to compulsion for vaccines, if a State mandates vaccination, then it has an affirmative obligation to provide an effective remedy for those individuals who may be injured as a result of vaccination."

The video of Mary Holland's presentation is available in two part on YouTube:

https://www.youtube.com/watch?v=gyRR-srQeVE

https://www.youtube.com/watch?v=LyhAvey_W10

While in the US, patients may seek compensation in the National Vaccine Compensation Program, no compensation is guaranteed, and they must go through a battle to prove the vaccine caused the injury suffered by their child. Surely in Pennsylvania we not want to condemn even a minority of people to lose a loved one, to suffer lifelong disabilities, with the only recourse to fight a fight in a Federal court to see compensation when they could have opted out, which is not guaranteed.

There are a number of pending bills that I would like you to work to see die in committee - they also restrict patients' right to informed consent, and the scientific basis of the claims of their universal safety are unwarranted. These include

SB 968/ HB 1785, which would mandate advertisement of flu vaccine to residents of personal care homes. This is the state doing the marketing in a place of business and in the homes of PA residents, on behalf of Pharma, which is highly questionable.

HB 883 would remove philosophical exemption and restrict religious exemptions. This bill would restrict Pennsylvanians' options of informed consent, and would represent an assault on our liberties and freedom from harm due to direct action from the state.

SB 696 would remove philosophical exemption. This isolates the assault specific to a person's individual right to informed consent. Informed consent does not mean that patients must consent after being informed. It means that patients have the right to refuse a medical procedure if they - individually, not the state - has decided given the full information required to make their choice - that the risk to them is not worth the benefit to them. The State should not intercede with laws that compel individuals to undergo medical procedures at all, especially for those for which proper studies have been conducted that show that the procedure is both safe, and effective.

I also understand that there is some interest in requiring "proof of immunization" for certain vaccines - e..g., chickenpox. I want to let you know that proof of vaccination is not the same as proof of immunization - as we know now due to outbreaks of measles, and now mumps in vaccinated populations. "Proof of immunization" would requires that doctors provide evidence of detected titres of antibodies, which they should, but do not, provide.

With doctors minimizing risks to patients, and medical professionals and lawmakers dependent on CDC information, which has conducted woefully corrupt science on vaccine safety, we must remain diligent and informed on the reality of the risks of vaccines. We can fall into the trap that CDC uses, in which they confuse an absence of evidence (no studies) as evidence of absence (of harm). We must rely on other sources for reliable information, i.e., studies published by independent researchers, and in this way, Pennsylvanians may remain vigilant and careful with the laws and mandates we place on ourselves and the human rights we continue to secure for ourselves and our children.

I urge you therefore to reserve our liberties, our freedoms, and our rights, and to NOT support the proposed changes in the DOH regulations regarding vaccines, and to work to kill the pending bills listed above, in the name of the majority caring for the at-risk minority, and in the name of preserving human rights.

I then urge you to join the growing number of Pennsylvanians and Americans who are demanding answers from CDC. I urge the PA legislators to issue a statement to the Federal Government demanding answers to the questions raised on the state of vaccine safety science revealed by Dr. William Thompson, a whistleblower at the CDC, who reveal in recorded conversations with Dr. Brian Hooker, that CDC has routinely omitted results showing association of vaccines with autism, specifically the MMR vaccine, and that they routinely manipulated the data analysis via repeated rounds of analysis to make discovered associations "go away". Dr Thompson has affirmed his position in a statement from his lawyers (attached).

Here are few quotes from Dr. Thompson's revelations to Dr. Hooker (cc'd):

Thompson: "They don't really want people to know that this data exists."

Thompson: "…among the blacks, the ones that were getting vaccinated earlier, were more likely to have autism."

Thompson: "It appears in the final publication is that race in general is downplayed. Of course it is."

Thompson: "I actually think the most interesting results are the isolated, ones that don't have their co morbid conditions. The effect is where you would think it would happen."

Thompson: "I was just looking at—I was like, oh my God, I cannot believe we did what we did. But we did."

Thompson: "The higher ups wanted to do certain things and I went along with it. In terms of chain of command, I was number four out of five. "

Thompson: "…Literally, everyone else got rid of all their documents, and so the only documents that exist right now from that study are mine."

Thompson: "There are things that I haven't even shared with you because I can't prove it, and that's what I struggle with. I don't want to share things with you that I can't prove, that there aren't hard records. I am worried that the other four people will collude and say no, that's not true."

Thompson: "That's what I keep seeing again, and again, and again where these senior people just do completely unethical, vile things and no one holds them accountable. "

Thompson: "The reason you don't see anything else circulating on the study, it was five of us behind closed doors for two years."

Thompson: "It's the lowest point in my career that I went along with that paper."

Everything we think we know about the link between vaccines and autism is based on what CDC scientists in the Immunization Safety Office have told us, and these are the same scientist that Dr. Thompson has alleged routinely conducted scientific fraud to hide association with vaccines and autism.

I therefore urge you to not support any impingement or restriction of patient's human rights, and to enact legislation demanding cleaner vaccines shown to be both safe and effective.

I urge you to please acquire a copy of the book "Vaccine Whistleblower: Exposing Autism Research Fraud at the CDC" to read for yourself the extent of corruption and malfeasance in vaccine safety research at the CDC<that Dr. Thompson revealed to Dr. Hooker. The book is available via or through your local bookseller or public library.

I will be happy to meet with you in person at your earliest convenience to answer any questions about anything I have raised in these comments.

Please contact Del Bigtree, Producer, to schedule a screening of the movie "Vaxxed". I will be happy to attend such a screening with you and answer any questions you may have.

Sincerely,

Dr. James Lyons-Weiler, PhD

References

Guo, Fangjian et al., 2015. Comparison of HPV prevalence between HPV-vaccinated and non-vaccinated young adult women (20–26 years) Human Vaccines & Immunotherapeutics 11: Issue 10, 2015. 11(10):2337-44. doi: 10.1080/21645515.2015.1066948.

Markowitz LE et al., 2016 Prevalence of HPV After Introduction of the Vaccination Program in the United States. Pediatrics. 2016 Feb 22. pii: peds.2015-1968.

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FOR IMMEDIATE RELEASE—AUGUST 27, 2014

STATEMENT OF WILLIAM W. THOMPSON, Ph.D., REGARDING THE 2004 ARTICLE EXAMINING THE POSSIBILITY OF A RELATIONSHIP BETWEEN MMR VACCINE AND AUTISM

My name is William Thompson. I am a Senior Scientist with the Centers for Disease Control and Prevention, where I have worked since 1998.

I regret that my coauthors and I omitted statistically significant information in our 2004 article published in the journal *Pediatrics*. The omitted data suggested that African American males who received the MMR vaccine before age 36 months were at increased risk for autism. Decisions were made regarding which findings to report after the data were collected, and I believe that the final study protocol was not followed.

I want to be absolutely clear that I believe vaccines have saved and continue to save countless lives. I would never suggest that any parent avoid vaccinating children of any race. Vaccines prevent serious diseases, and the risks associated with their administration are vastly outweighed by their individual and societal benefits.

My concern has been the decision to omit relevant findings in a particular study for a particular sub-group for a particular vaccine. There have always been recognized risks for vaccination and I believe it is the responsibility of the CDC to properly convey the risks associated with receipt of those vaccines.

I have had many discussions with Dr. Brian Hooker over the last 10 months regarding studies the CDC has carried out regarding vaccines and neurodevelopmental outcomes including autism spectrum disorders. I share his belief that CDC decision-making and analyses should be transparent. I was not, however, aware that he was recording any of our conversations, nor was I given any choice regarding whether my name would be made public or my voice would be put on the Internet.

I am grateful for the many supportive e-mails that I have received over the last several days. I will not be answering further questions at this time. I am providing information to Congressman William Posey, and of course will continue to cooperate with Congress. I have also offered to assist with reanalysis of the study data or development of further studies. For the time being, however, I am focused on my job and my family.

Reasonable scientists can and do differ in their interpretation of information. I will do everything I can to assist any unbiased and objective scientists inside or outside the CDC to analyze data collected by the CDC or other public organizations for the purpose of understanding whether vaccines are associated with an increased risk of autism. There are still more questions than answers, and I appreciate that so many families are looking for answers from the scientific community.

My colleagues and supervisors at the CDC have been entirely professional since this matter became public. In fact, I received a performance-based award after this story came out. I have experienced no pressure or retaliation and certainly was not escorted from the building, as some have stated.

Dr. Thompson is represented by Frederick M. Morgan, Jr., Morgan Verkamp, LLC, Cincinnati, Ohio, www.morganverkamp.com.

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25th International Conference on Health and Environment:
Global Partners for Global Solutions

30 Years of Chornobyl Legacy for the Nuclear Safety of the World

April 26, 2016

United Nations Headquarters, Tuesday, 10:00-13:00 – 14:00-18:00, Trusteeship Council

Morning Session:	30 Years of Chornobyl Legacy for the Nuclear Safety of the World (Trusteeship Council)
Introduction:	Dr. Christine K. Durbak, Conference Chair and Founder, **WIT**
Keynote Speaker	Dr. James Hansen, former NASA Director, Climatologist and Adjunct Professor at Columbia University Topic: "Energy and Climate Change: How Can Justice Be Achieved for Young People?"
Speakers	Dr. Lydia Zablotska - NCI Chernobyl Study Project "Increased risks of leukemia and thyroid disorders after Chernobyl" Dr. William Rom, Prof. NYU's College of Global Public Health Topic: "Nuclear Energy and Public Health" Dr. Todd Allen, Senior Fellow, THIRD WAY; former Deputy Director for Science and Technology, Idaho National Laboratory "A 21st Vision of Nuclear Energy"
12:00 – 13:00	Ambassadorial panel starts after the UN General Assembly session on Chernobyl (10:00 – 12:00) H.E. Mr. Volodymyr Yelchenko, Ambassador, Permanent Representative of **Ukraine** to the UN H.E. Mr. Motohide Yoshikawa, Ambassador, Permanent Representative of **Japan** to the UN H.E. Ms. Raimonda Murmokaitė, Ambassador, Permanent Representative of **Lithuania** to the UN H.E. Mr. Heiko Thoms, Ambassador, DPR of **Germany** to the United Nations H.E. Minister Counselor Jiri Ellinger, Charge d'Affaires of **Czech Republic** to the United Nations
Afternoon Session:	Toxic Contamination of Children (CR 1)
Introduction:	Dr. Christine K. Durbak, Conference Chair and Founder, **WIT** H.E. Mr. Volodymyr Yelchenko, Permanent Representative of **Ukraine** to the UN Mr. Juwang Zhu, Director for Sustainable Development, UNDESA (Invited)
Keynote Speaker	Robert F. Kennedy, Jr. "Mercury in the environment - its effect on children's health" Dr. Martha Herbert, Pediatric Neurologist, Harvard "How environmental toxins can hinder the developing brain" Dr. Leonardo Trasande, Prof. of Pediatrics, Environ. Med. and Population Health, NYU School of Med. "Unraveling the environmental causes of developmental disabilities" Mary Holland, Esq. Research Scholar, NYU School of Law "Vaccination policies and human rights" Dr. Berbard D. Goldstein, former Dean Pittsburgh Univ., School of Public Health "Little Things Matter: The Impact of Toxins on the Developing Brain"

web-Reference: www.worldinfo.org
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Vaccine xxx (2016) xxx–xxx

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Adverse events following HPV vaccination, Alberta 2006–2014

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ARTICLE INFO

Article history:
Received 21 December 2015
Received in revised form 11 February 2016
Accepted 12 February 2016
Available online xxx

Keywords:
*Papillomavirus vaccines/ae [adverse effects]
*Vaccination/ae [adverse effects]
Population surveillance
Humans
Alberta
HPV vaccination
Canada
*Product surveillance
Postmarketing

ABSTRACT

Background: In Canada, private purchase of human papilloma virus (HPV) vaccines has been possible since 2006. In Alberta, Canada, a publicly funded quadrivalent HPV vaccine program began in the 2008/2009 school year. There have been concerns about adverse events, including venous thromboembolism (VTE) associated with HPV vaccines. We describe the frequencies of adverse events following HPV vaccination among Alberta females aged 9 years or older and look at VTE following HPV vaccination.

Methods: We used the Alberta Immunization and Adverse Reaction to Immunization (Imm/ARI) repository (publicly funded vaccine), the population-based Pharmaceutical Information Network (PIN) information system (dispensing of a vaccine), and the Alberta Morbidity and Ambulatory Care Abstract reporting system (MACAR) for June 1, 2006–November 19, 2014. Deterministic data linkage used unique personal identifiers. We identified all reported adverse events following immunization (AEFI) and all emergency department (ED) utilization or hospitalizations within 42 days of immunization. We calculated the frequency of AEFI by type, rates per 100,000 doses of HPV vaccine administered and the frequencies of ICD-10-CA codes for hospitalizations and emergency department visits.

Results: Over the period 195,270 females received 528,913 doses of HPV vaccine. Of those receiving at least one dose, 192 reported one or more AEFI events (198 AEFI events), i.e., 37.4/100,000 doses administered (95% CI 32.5–43.0). None were consistent with VTE. Of the women who received HPV vaccine 958 were hospitalized and 19,351 had an ED visit within 42 days of immunization. Four women who had an ED visit and hospitalization event were diagnosed with VTE. Three of these had other diagnoses known to be associated with VTE; the fourth woman had VTE among ED diagnoses but not among those for the hospitalization.

Conclusions: Rates of AEFI after HPV immunization in Alberta are low and consistent with types of events seen elsewhere.

1. Introduction

The World Health Organization (WHO) recommends the human papillomavirus (HPV) vaccine for prevention of cervical cancer and other HPV-related diseases [1]. Quadrivalent HPV (qHPV) vaccine was authorized and became available for private purchase in Canada in 2006 for females aged 9–26 years. This authorization was expanded to include females aged 9–45 years in 2011. Bivalent HPV (bHPV) vaccine was also authorized for use among females aged 10–25 years in 2010. Canada's National Advisory Committee on Immunization (NACI) has recommended both vaccines in females aged 9–26 years of age [2]. Both vaccines were initially administered in a three-dose series; however NACI now recommends a two-dose series for immunocompetent persons aged 9–14 years [2].

Abbreviations: WHO, World Health Organization; HPV, human papillomavirus; qHPV, quadrivalent human papillomavirus; bHPV, bivalent human papillomavirus; NACI, National Advisory Committee on Immunization; AEFI, Adverse Events Following Immunization; VTE, venous thromboembolic events; ULI, unique personal identifier; Imm/ARI, immunization and adverse reaction to immunization; PIN, Pharmaceutical Information Network; ED, Emergency Department; MACAR, (Alberta) Morbidity and Ambulatory Care Abstract Reporting; ICD-10-CA, International Classification of Diseases, 10th Revision-Canadian Adaptation.

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http://dx.doi.org/10.1016/j.vaccine.2016.02.040
0264-410X/

In Alberta, the publicly funded routine childhood and adolescent vaccines are administered exclusively by public health nurses. Alberta began to deliver a publicly funded three-dose qHPV vaccine series in the 2008/09 school year for females in grade 5, most of whom were aged 10–11 years [3]. A catch-up program was implemented from 2009/10 to 2011/12 for females in grade 9 (most of whom were aged 14–15 years). Both qHPV and bHPV vaccines are also available for private purchase through pharmacies.

The monitoring of adverse events following immunization (AEFI) contributes to vaccine safety surveillance and is an important component of all vaccination programs. Vaccine safety is monitored by passive surveillance in Alberta. There have been community concerns that HPV vaccines may be associated with adverse events. Venous thromboembolic events (VTE) are a particular concern, as some were reported to occur following HPV immunization in the United States [4]. The objective of this study is to describe the frequencies of adverse events among females aged 9 years or older that occurred following HPV vaccination including looking specifically at VTE following HPV vaccination.

2. Methods

2.1. Ethics and role of funding source

The study was approved by the University of Calgary Conjoint Health Research Ethics Board (Ethics ID: REB 14-0598). The funding source had no role in study design, collection, analysis or interpretation of data, report writing or publication decision.

2.2. Data source and data extraction

Alberta has a publicly funded universal healthcare system in which >99% of residents are registered [5]. The registration file for this program includes a Person Health Number that serves as a unique personal identifier (ULI) [6] that permits data linkage at the level of the individual across other administrative databases. We used ULI to deterministically link data on vaccination, AEFI, and healthcare utilization.

Alberta's Immunization and Adverse Reaction to Immunization repository (Imm/ARI) contains complete vaccination records, including AEFI, for all publicly funded vaccines that were administered by public health since 2006. Vaccination records prior to 2006 comprise historical data and are entered electronically into Imm/ARI by public health nurses after review of paper vaccination records. The Pharmaceutical Information Network (PIN) contains records of all prescriptions dispensed by pharmacies, whether privately or publicly funded. In the case of HPV vaccine, this would only include privately funded vaccines. It is estimated that PIN captures over 95% of dispensed pharmacologic products [7]. We have assumed that all vaccine dispensed according to PIN was actually administered to the purchaser as the cost to purchaser of HPV vaccine is about $150/dose [8]. Both Imm/ARI and PIN contain information on the patient, vaccine, dose, and date that vaccine was administered/dispensed [9].

In Alberta, AEFI surveillance is a passive reporting system. Individuals who experience an AEFI report to their vaccine provider, who completes a provincial AEFI reporting form; the data are entered into Imm/ARI [10]; Alberta Health then reports AEFI to the Public Health Agency of Canada. The provincial AEFI reporting form consists of a close ended checklist of types of adverse events, accompanied by an open ended text field into which a description of event is to be entered as well as an open ended comment section. The reporting form also collects time of onset following immunization, outcome, hospitalization dates, patient identifiers, vaccine antigens, vaccination date, and dose number. Alberta policy is that providers should "Report events that do not meet specific case definitions but are felt to be significant (i.e., serious or unusual) under [checkbox] Other Severe or Unusual Events... When an AEFI is:

- Serious (death, hospitalization, congenital abnormality, residual abnormality, life threatening), unexpected (in terms of type or frequency),
- Of concern (to the vaccine, his/her caregiver(s) or AEFI reporter)."

AEFI's that meet any of these criteria should be reported regardless of consistency with time period of occurrence for the event of the case definition of any such event. VTE cases are captured by the checkbox 'other unusual events' on the AEFI reporting form. Event codes and text descriptions on all AEFI reports are reviewed by trained nurses and coded into Imm/ARI. Information related to hospitalizations and emergency department (ED) visits are captured in the Alberta Morbidity and Ambulatory Care Abstract Reporting (MACAR) system, including dates of admission and discharge, and ICD-10-CA (International Classification of Diseases, 10th Revision-Canadian Adaptation) codes for diagnoses.

We extracted data on vaccinations, AEFI reports, hospitalizations and ED visits (within 42 days of vaccination) [4,11] for all females for whom an HPV dispense or vaccination event was recorded over June 1, 2006–November 19, 2014, using ULI to link records for unique individuals.

2.3. Data analysis

We counted the number of females who received one or more doses of HPV vaccine by number of doses received and age at first dose. We described the frequencies of occurrence of AEFIs by type of AEFI, and dose number associated with the AEFI. We calculated rates of AEFI per 100,000 doses of HPV vaccine dispensed/administered by dividing counts of AEFIs by the number of vaccine doses received among the population of interest over the period. We described hospitalizations within 42 days of HPV vaccinations by ICD-10-CA diagnostic codes for the most responsible diagnoses for all hospitalizations within 42 days of immunization. "Most responsible diagnosis" is recorded by the health care provider at discharge, using general coding standards that define the most responsible diagnostic ICD code as that responsible for the greatest portion of the length of stay or greatest use of resources [12]. A hospitalization event is defined as a hospital visit where a person was admitted and discharged from a hospital. Some hospitalization events were recorded twice because the person had one hospital visit that was temporally associated with receipt of two different vaccine doses (e.g., was hospitalized within 42 days of receiving both dose 1 and dose 2). For these, we removed the duplicate event and counted it as a single hospitalization event. For each person, we assumed that a transfer from one hospital to another had occurred if the date of discharge from the first hospital was the same as the date of admission to a second hospital. We counted each hospital transfer as a separate event. However, for the purpose of describing the frequency of the most responsible diagnoses (the diagnosis that contributed the greatest to length of stay) for such persons, we counted each most responsible diagnosis if they differed between hospitalization events. We operationally defined 'serious' AEFI as those that resulted in hospitalization and counted the number of 'serious' AEFI. We linked hospitalizations and ED visits to identify those who reported both events within 42 days of vaccination. Data analyses were conducted using SAS 9.3 (SAS Institute Inc., Cary, NC 2011).

Please cite this article in press as: Liu XC, et al. Adverse events following HPV vaccination, Alberta 2006–2014. Vaccine (2016), http://dx.doi.org/10.1016/j.vaccine.2016.02.040

2.4. AEFI review to identify VTE

One investigator (MLR), a physician, reviewed all text descriptions for AEFIs coded as 'other unusual events' for evidence that the AEFI might have been VTE.

2.5. Identification of VTE not captured by AEFI reports

In order to maximize the chances of finding a VTE that was not captured by an AEFI report within Imm/ARI, we identified within MACAR all females who were hospitalized or visited the ED within 42 days of vaccination by deterministically linking Imm/ARI, PIN and MACAR using the ULI. Our definition of VTE for this study was the occurrence of an ICD-10-CA diagnostic code of I80.x or I82.x in any of the potential diagnostic code fields (25) for a hospitalization or ED (10) visit. For any woman who had such an ICD-10-CA code for a hospitalization or ED visit, one investigator (MLR) reviewed all ICD codes for that event to assess if they were consistent with any other condition for which VTE is known to occur as per Spencer and colleagues [13].

3. Results

3.1. Source population

As can be seen from Table 1, from June 1, 2006 to November 19, 2014, 195,270 females received one or more doses of HPV vaccine. They received a total of 528,913 publicly and privately funded doses of vaccine over the study period. Nearly all of the vaccine was qHPV (99.2% of doses). The majority of women received three doses of HPV vaccine (82.4%), while a smaller proportion received only two doses (9.9%) or only one dose (6.4%). Most were aged 9–14 years (79.5%) when their first dose of HPV vaccine was received, followed by age groups 15–19 years (10.0%), 20–24 years (5.9%), or 25–29 years (2.7%).

Table 1
Distribution of HPV vaccine by numbers of women aged 9+ years immunized, by attributes of recipients and vaccine.

Characteristic	Number of women (%)	
N women immunized		195,270 (100)
Number of doses received per individual		
	1	12,473 (6.4)
	2	19,280 (9.9)
	3	160,950 (82.4)
	4+	2567 (0.1)
Age (years) at which first dose of vaccine received		
	9–14	155,300 (79.5)
	15–19	19,483 (10.0)
	20–24	11,551 (5.9)
	25–29	5351 (2.7)
	30–34	1725 (0.9)
	35–39	874 (0.4)
	40–44	583 (0.3)
	45+	403 (0.2)
Type of vaccine funding		
	Public	164,743 (84.4)
	Private	29,025 (14.9)
	Mixed[a]	1502 (0.8)
Total number of doses dispensed/administered		528,913 (100)
Type of vaccine dispensed/administered		
	qHPV	524,645 (99.2)
	bHPV	4193 (0.8)
	Unknown	75 (<0.1)

[a] Mixed funding: some doses were publicly funded, some were privately purchased.

3.2. Frequency of occurrence of AEFI & serious AEFI events

Of the 195,270 women who received HPV vaccine, 192 (<0.1%) reported one or more AEFI events (198 AEFI events). Of the 192, 186 reported one AEFI event, while six reported two different AEFI events. All AEFI events occurred after receipt of the qHPV vaccine. Six persons who experienced an AEFI had received one or more vaccines in addition to HPV on the same day as they received HPV vaccine. Table 2 displays the frequency of occurrence of types of AEFI by dose of HPV vaccine in series received that corresponded to the AEFI event. Among the 198 events, the most commonly reported events were allergic reaction ($n = 90$), other unusual events ($n = 34$), other rash ($n = 32$), and pain and/or swelling ($n = 23$) (Table 2). Most AEFI events occurred after receipt of the first dose of vaccine ($n = 117$), followed by second ($n = 55$) and third ($n = 25$) doses. Review of the text fields for 'other unusual events' found none of these events to be consistent with VTE.

Of the 192 persons reporting AEFI events, five had a serious AEFI, (all classified as 'serious' because of hospitalization); however only 4 of them were hospitalized within 42 days of immunization. The fifth person was hospitalized on day 110, well outside of the 42 day window.

3.3. Rate of occurrence & outcome of AEFI events

Over the study period, the rate of AEFI events was 37.4 per 100,000 doses of HPV vaccine administered (95% CI: 32.5–43.0). The rate varied over time: no events were reported for 2006 or 2007, however only about 5000 doses of vaccine were dispensed in those years (data not shown). For the period January 1, 2008–November 19, 2014, the rate was 37.7 per 100,000 doses (95% CI: 32.8–43.3). AEFI rates varied over time, peaking in 2011 (Fig. 1).

Of the 198 AEFI events, the outcomes were known for 171, all of which were full recovery.

3.4. Hospitalization within 42 days of vaccination

Among the 195,270 females who received HPV vaccine, 958 were hospitalized (1053 hospitalization events) within 42 days of immunization; however only 4 of those hospitalized had a reported AEFI (see above). Of the 958 who were hospitalized, most (861, 89.8%) had only one hospitalization event within 42 days of immunization. The large majority of those hospitalized were aged 9–14 years (66.0%) or 15–19 years (22.0%). The proportion of hospitalizations that occurred on the same day as vaccination was 0.7%, 34.6% within 1–14 days, 32.8% within 15–28 days, and 31.9% within 29–42 days (data not shown).

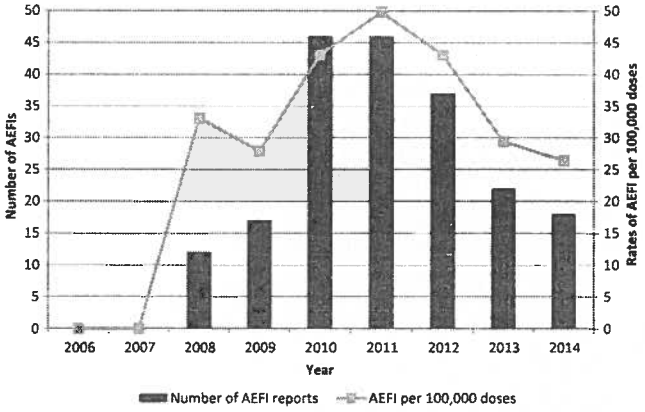

Fig. 1. Numbers of AEFI and AEFI rates/100,000 doses dispensed 2006–2014.

Table 2
Distribution of types of AEFI by dose of vaccine for which AEFI event reported.[a]

	Number of doses of HPV vaccine received at time of occurrence of AEFI				N persons
	1	2	3	5	
Allergic reaction	54	32	4	0	90
Other unusual events	20	10	4	0	34
Other rash	23	3	6	0	32
Pain and/or swelling	12	5	5	1	23
Fever	1	2	1	0	4
Severe diarrhea	1	2	1	0	4
Anaphylaxis	2	0	1	0	3
Adenopathy	1	1	0	0	2
Convulsion/seizure	1	0	1	0	2
Anesthesia/paraesthesia	1	0	0	0	1
Arthralgia/arthritis	0	0	1	0	1
Erythema multiforme	0	0	1	0	1
Sterile abscess	1	0	0	0	1
Total	117	55	25	1	198

[a] Six of the 192 persons who experienced an AEFI had an AEFI on two occasions.

Thirty-two women had hospital transfers. Thirty-one women had one hospital transfer and one woman had two transfers, resulting in 69 hospitalization events. Of these, six transfers (12 events) had the same most responsible diagnosis. Fourteen women had multiple hospitalization records because they received two doses of HPV vaccine within 42 days, and thus both doses were temporally associated with the hospitalization. Fifty-two persons had more than one hospitalization event because they were hospitalized on separate occasions (i.e., these were not hospital transfers). From the 1053 hospitalization events, after accounting for transfers, we counted 1047 most responsible diagnoses.

The frequencies of the 1047 most responsible diagnoses are shown in Table 3. Mental, behavioral and neurodevelopmental disorders (19.4%) were the most frequently coded most responsible diagnoses, followed by diseases of the digestive system (15.8%), and injury, poisoning and certain other consequences of external causes (13.8%).

3.5. Identification of VTE among those hospitalized

In addition to assessing frequencies of the most responsible diagnoses we examined all ICD-10-CA diagnostic codes (in any of the fields possible for hospitalizations) for codes corresponding to our case definition of VTE. There were three women who had such codes. The first had a most responsible diagnosis of Z50.1 (other physical therapy), and an I80.2 other diagnosis. She was 26 years of age and received the first dose of HPV vaccine 23 days prior to hospitalization. The other ICD-10-CA codes were consistent with having incurred an injury.

The second, aged 11 years, had a most responsible diagnosis of R07.4 (chest pain unspecified), and an I80.1 other diagnosis. She had received the third dose of HPV vaccine 14 days prior to hospitalization. The other ICD-10-CA codes for this hospitalization indicated the presence of a congenital heart defect known to be associated with VTE.

The third was hospitalized for most responsible diagnosis of I80.2 (phlebitis and thrombophlebitis of other deep vessels of lower extremities). She was 14 years of age and received the third dose of HPV vaccine 11 days prior to hospitalization. Review of the other ICD 10 codes for this hospitalization indicated that the VTE was classified as a complication of other diagnoses (sepsis) that caused the hospitalization.

Two of these three persons had received one or more vaccines in addition to HPV on the same days as they received HPV vaccine. None of those hospitalized with a VTE diagnosis died.

Table 3
Frequency of most responsible diagnoses among women hospitalized within 42 days of immunization.

ICD 10 Chapter codes	Count (%)
Certain infectious and parasitic diseases (A00-B99)	29(2.8)
Neoplasms (C00-D49)	22(2.1)
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism (D50-D89)	12(1.1)
Endocrine, nutritional and metabolic diseases (E00-E89)	35(3.3)
Mental, Behavioral and Neurodevelopmental disorders (F01-F99)	204(19.4)
Diseases of the nervous system (G00-G99)	35(3.3)
Diseases of the eye and adnexa (H00-H59)	4(0.4)
Diseases of the ear and mastoid process (H60-H95)	8(0.8)
Diseases of the circulatory system (I00-I99)	15(1.4)
Diseases of the respiratory system (J00-J99)	104(9.9)
Diseases of the digestive system (K00-K95)	165(15.8)
Diseases of the skin and subcutaneous tissue (L00-L99)	8(0.8)
Diseases of the musculoskeletal system and connective tissue (M00-M99)	73(7.0)
Diseases of the genitourinary system (N00-N99)	54(5.2)
Pregnancy, childbirth and the puerperium (O00-O9A)	8(0.8)
Certain conditions originating in the perinatal period (P00-P96)	1(0.1)
Congenital malformations, deformations and chromosomal abnormalities (Q00-Q99)	19(1.8)
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified (R00-R99)	66(6.3)
Injury, poisoning and certain other consequences of external causes (S00-T88)	144(13.8)
External causes of morbidity (V00-Y99)	0(0)
Factors influencing health status and contact with health services (Z00-Z99)	41(3.9)
Total	1047(100)

3.6. ED visits within 42 days of immunization

Among those who received HPV vaccine, 19,351 had an ED visit within 42 days of immunization (26,849 events). Of these, 713 also had a hospitalization within 42 days. Among those with an ED visit and hospitalization event, 4 were diagnosed with VTE (including the 3 hospitalized with a VTE diagnosis described above). One person visited the ED and was diagnosed with VTE, but did not have any ICD-10-CA codes consistent with VTE among the discharge diagnoses for the hospitalization.

Please cite this article in press as: Liu XC, et al. Adverse events following HPV vaccination, Alberta 2006–2014. Vaccine (2016), http://dx.doi.org/10.1016/j.vaccine.2016.02.040

4. Discussion

In this study, we linked vaccination data with AEFI reports, hospitalization records, and ED visit records, at a population-level, to describe AEFI type as well as to identify VTEs that may be related to HPV vaccination among women aged 9 years or older. We found an AEFI rate (37.4/100,000 doses) that was substantially less than that from reports from the American Vaccine Adverse Event Reporting System (VAERS) (53.9/100,000 doses) [14]. The most common types of adverse events that we observed (e.g., allergic reactions, 'other unusual events', rash) were similar to those found from analysis of the VAERS data [14] and similar to those seen in the province of Ontario [15]. Our results are consistent with other large post-licensure safety and surveillance studies that found that HPV vaccines are safe [11,16].

While we observed three cases of VTE among those hospitalized within 42 days of immunization, all three had other health conditions known to be associated with VTE. While one additional person had an ED visit with a VTE code, this code was not among the discharge diagnoses for the immediately following hospitalization. We think it likely that the VTE diagnosis from the ED visit was a tentative diagnosis that was not substantiated by further investigations during hospitalization. While Gee and colleagues [4] noted an association with VTE after HPV immunization, this association was not statistically significant, only five confirmed cases were observed and all of those cases had other known risk factors for VTE. Other investigators have found no association between HPV vaccination and the occurrence of VTE [11,16–18].

In Alberta, AEFI events are reportable if they meet case definitions outlined by Alberta Health [10]. AEFI reports are reviewed by public health nurses who ensure AEFIs meet case definitions and enter the data into Imm/ARI. We found a higher rate of AEFI events (37.4/100,000) than that reported for the Ontario schoolgirl HPV immunization program over 2007–2011 (19.2/100,000 doses dispensed) [15]. These differences are almost certainly due to the use of stricter guidelines for the classification of AEFI in Ontario. Harris and colleagues identified 213 qHPV AEFI reports for Ontario, of whom only the 133 classified as 'confirmed' were used in their analyses. If all 213 reports had been used, the Ontario rate of AEFI would have been 30.7/100,000; a rate much closer to that which we observed. However, as was also seen in Ontario, AEFI rates varied by year. Passive surveillance data may be affected by numerous factors, including "biased reporting, underreporting and the inability to determine whether a vaccine caused the adverse event in any individual report" [19]. Changes in reporting may result from changes in the reporting practices of healthcare personnel, or by community concerns (resulting in increased reporting to healthcare personnel) [20,21]. It is possible that the 2011 publication of the report of Gee and colleagues [4] might have affected reporting rates elsewhere, including in Ontario and in Alberta. However it is also possible that a longer follow-up time for HPV immunizations administered in the earlier years of the study period may also have contributed to the observed pattern of reporting.

The strengths of this study included capturing women who had received either publicly funded or privately purchased HPV vaccines. Similarly, in addition to the passively reported AEFI data, our design overcame the limitations of passive reporting in our search for VTE by accessing the records of all hospitalizations for the entire population of women immunized regardless of types of vaccine received or modes of vaccine funding. However, our study also has limitations. Residents of Alberta who were hospitalized within Alberta but immunized out of province would not have been captured. Similarly, those who were immunized within Alberta but hospitalized out of province would not have been captured. We do not know how many women this would be, but posit that the numbers are small. We did not validate the ICD codes for hospitalizations or emergency department visits by chart review. As the predictive value of ICD codes for VTE is variable [17] this may have led to misclassification of outcome. Even in the absence of misclassification, it is possible that VTE identified during hospitalization might have had symptom onset prior to hospitalization. Finally, the women in our study received 528,913 doses of vaccine: thus AEFI that occur very rarely but which are truly associated with immunization with HPV vaccine would not be detected.

5. Conclusion

Adverse events following HPV immunization in Alberta are low, consistent with those seen elsewhere, and consistent in the types of event seen elsewhere.

Authors' contribution

XCL participated in data analysis, data interpretation and drafted the manuscript. CAB participated in study conceptualization, study design, acquired the data and participated in data analysis, data interpretation and drafting the manuscript. KAS participated in study conceptualization, study design, data interpretation and drafting the manuscript. MLR participated in study conceptualization, study design, data interpretation and drafting the manuscript. LWS participated in study conceptualization, study design, data interpretation and drafting the manuscript. All authors critically reviewed the manuscript.

Acknowledgement

The study was funded by a research agreement with the Alberta Ministry of Health (RSO 1026380).

Conflicts of interest: None of the authors have any competing interests.

References

[1] World Health Organization. Human papillomavirus vaccines: WHO position paper, October 2014. Wkly Epidemiol Rec 2014;43(89):465–92.
[2] National Advisory Committee on Immunization. Update on the recommended Human Papillomavirus (HPV) vaccine immunization schedule. Public Health Agency of Canada; 2015. Available from: http://www.phac-aspc.gc.ca/naci-ccni/acs-dcc/2015/hpv-vph_0215-eng.php [cited October 19, 2015].
[3] Government of Alberta. Government approves vaccine program to protect girls from cancer; 2008. Available from: http://alberta.ca/release.cfm?xID=237617ED835A4-93CA-9697-D24EF32FB5CC5196 [cited October 19, 2015].
[4] Gee J, Naleway A, Shui I, Baggs J, Yin R, Li R, et al. Monitoring the safety of quadrivalent human papillomavirus vaccine: findings from the Vaccine Safety Datalink. Vaccine 2011;29(46):8279–84.
[5] Government of Alberta. Alberta Health Care Insurance Plan Statistical Supplement 2013/2014; 2015. Available from: http://www.health.alberta.ca/documents/AHCIP-Stats-Supplement-14.pdf [December 17, 2015].
[6] Liu X, Simmonds K, Russell M, Svenson L. Herpes zoster vaccine (HZV): utilization and coverage 2009–2013, Alberta, Canada. BMC Public Health 2014;14(1):1098.
[7] Alberta Health. Overview of administrative health datasets; 2015. Available from: http://www.health.alberta.ca/documents/Research-Health-Datasets.pdf [December 17, 2015].
[8] Alberta Health Services. Cervical cancer: about HPV and the HPV vaccine; 2012. Available from: http://www.screeningforlife.ca/cervicalscreening/about-hpv-a-hpv-vaccine [cited June 3, 2015].
[9] Alberta Health. An overview of Alberta's Electronic Health Record Information System; 2015. Available from: http://www.albertanetcare.ca/documents/An_Overview_of_Albertas_EHRIS.pdf [October 19, 2015].
[10] Government of Alberta. Adverse events following immunization (AEFI) policy for Alberta Immunization Providers; 2015. Available from: http://www.health.alberta.ca/documents/AIP-AEFI-Policy-2015.pdf [October 19, 2015].
[11] Scheller N, Pasternak B, Svanström H, Hviid A. Quadrivalent human papillomavirus vaccine and the risk of venous thromboembolism. JAMA 2014;312(2):187–8.

[12] Canadian Institute for Health Information. Canadian coding standards for version 2012 ICD-10-CA and CCI. Ottawa, ON: CIHI; 2012. Revised September 2012.
[13] Spencer FA, Emery C, Lessard D, Anderson F, Emani S, Aragam J, et al. The Worcester Venous Thromboembolism Study. J Gen Intern Med 2006;21(7):722–7.
[14] Slade BA, Leidel L, Vellozzi C, et al. Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine. JAMA 2009;302(7):750–7.
[15] Harris T, Williams DM, Fediurek J, Scott T, Deeks SL. Adverse events following immunization in Ontario's female school-based HPV program. Vaccine 2014;32(9):1061–6.
[16] Arnheim-Dahlström L, Pasternak B, Svanström H, Sparén P, Hviid A. 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;347.
[17] Naleway AL, Crane B, Smith N, Daley MF, Donahue J, Gee J, et al. Absence of venous thromboembolism risk following quadrivalent human papillomavirus vaccination, Vaccine Safety Datalink, 2008–2011. Vaccine 2016;34(1):167–71.
[18] Yih WK, Greene SK, Zichittella L, Kulldorff M, Baker MA, de Jong JLO, et al. Evaluation of the risk of venous thromboembolism after quadrivalent human papillomavirus vaccination among US females. Vaccine 2016;34(1):172–8.
[19] Varricchio F, Iskander J, Destefano F, Ball R, Pless R, Braun MM, et al. Understanding vaccine safety information from the Vaccine Adverse Event Reporting System. Pediatr Infect Dis J 2004;23(4):287–94.
[20] Eberth JM, Kline KN, Moskowitz DA, Montealegre JR, Scheurer ME. The role of media and the Internet on vaccine adverse event reporting: a case study of human papillomavirus vaccination. J Adolesc Health 2014;54(3):289–95.
[21] Goodman MJ, Nordin J. Vaccine adverse event reporting system reporting source: a possible source of bias in longitudinal studies. Pediatrics 2006;117(2):387–90.

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