Discussion on BMJ blogs

Richard Lehman’s journal review—5 December 2016

Unpublished comments by Elizabeth Hart listed below

Elizabeth_Hart • a minute ago Hold on, this is waiting to be approved by BMJ blogs.

Richard Lehman, parents/children and young women are being coerced into having HPV vaccination based on biased and questionable material, and health professionals are in the front line presenting this material.

Do you think this is ethical?

Dr Lehman, in your co-authored article Ten Commandments for patient-centred treatment, your fourth commandment states: "Shared decision making with patients should rest on clear knowledge of harms and benefits, derived from objective analysis and comparisons between the best existing alternatives. All industry-sponsored sources of information should be avoided."[1] (My emphasis.)

So what is your position on industry-sponsored trials that support the use of medical interventions, e.g. HPV vaccination?

In your BMJ Blog item on HPV vaccination[2], the study you refer to in JAMA[3] was sponsored and funded by Merck & Co, which manufactures HPV vaccines. All the academic co-authors have been investigators for Merck Sharp and Dohme Corp, a subsidiary of Merck & Co. Inc, and many also have other conflicts of interest.

The editorial supporting the JAMA paper[4] is co-authored by Lauri E. Markowitz of the US Centers for Disease Control and Prevention. In this JAMA editorial, Markowitz et al state: "Following national introductions of HPV vaccination, significant declines in vaccine-type HPV prevalence, genital warts, and cervical precancers have been observed in the United States and other countries."

The reference given to support this statement in the JAMA editorial is a systematic review and meta-analysis of HPV vaccination programmes, published in The Lancet Infectious Diseases in 2015[5], many of the authors of which have conflicts of interest, e.g. they have received funding from companies associated with the HPV vaccines, i.e. Merck, GlaxoSmithKline, bioCSL and Sanofi Pasteur MSD. (Lauri Markowitz is also an author on this paper, and declares no competing interests. I will return to this in future correspondence.)

Markowitz et al also note: "For all 3 HPV vaccines, licensure was based on data from large pivotal clinical trials establishing efficacy in young adult populations", citing another review authored by people associated with HPV vaccine companies Merck & Co, GlaxoSmithKline, Sanofi Pasteur and CSL.[6]

It seems to me these papers supporting HPV vaccination are "industry-sponsored sources of information".

It is also notable that the LID paper, and the JAMA paper and editorial, are all published behind these journals' paywalls. So these publications, which are influential on international HPV vaccination policy, are not open access for public scrutiny.

I'm confused by your position Dr Lehman. In Ten Commandments for patient-centred treatment you say "All industry-sponsored sources of information should be avoided", and yet in your BMJ Blog item on HPV vaccination, the primary audience for which is health professionals, you rely on industry-sponsored and journal pay-walled material to support your careless endorsement of HPV vaccination.

As I mentioned in my recent email to BMJ Editor-in-Chief, Fiona Godlee[7], your colleague Tom Jefferson is reported to be "highly critical of the drug company funded clinical trial data that is used to justify the use of mass vaccination", adding "that pharmaceutical companies may hide negative results deep in their trials data and hugely inflate the benefits".

Dr Jefferson says: "The HPV vaccine's benefits have been hyped and the harms hardly investigated...The reason for introducing vaccination against HPV was to prevent cancer...but there is no clinical evidence to prove it will do that. We have to tread a very careful line, weighing the potential benefits and harms that a vaccine may cause. With HPV, the harms have not been properly studied...It is extremely difficult to publish anything against HPV vaccination. Vaccines have become like a religion. They are not something you question. If you do, you are seen as being an anti-vaccine extremist. The authorities do not want to hear 'side-effect'".[8][9]

Dr Lehman, the community is not being properly informed about the uncertainties of novel VLP HPV vaccination.

Reports of adverse experiences after HPV vaccination are emerging around the world. The scientific/medical establishment appears to be stifling concerns about HPV vaccination.[10]

For example, a Factsheet for Health Professionals, published by Public Health England[11], purports to address the 'myths' about HPV vaccination, downplaying concerns about this questionable medical intervention, and urging parents/girls to have HPV vaccination.

This 'factsheet' appears to be a response to adverse publicity about HPV vaccination in the UK media, i.e. adverse experiences after HPV vaccination reported in newspapers such as The Independent[12] and Daily Mail[13] in mid 2015, and the recent controversy surrounding TV presenter Melinda Messenger's publicised concerns about HPV vaccination.[14]

The PHE factsheet unequivocally supports HPV vaccination and downplays any risk. The factsheet states: "The UK programme has already contributed to preventing future deaths from cervical cancer. We expect it to eventually prevent hundreds of cancer deaths every year." I suggest this is an exaggerated spin on HPV vaccination's supposed effectiveness.

An author of a HPV vaccine trial paper[15], Professor Diane Harper, admits "there is no evidence of cancers prevented"[16], and commentary published in The Lancet in 2011 also notes "A demonstrable reduction of the burden of cervical cancer - the main goal of HPV vaccines - will take several decades".[17]

If health professionals rely on the biased PHE factsheet, parents/children and young women will not be properly informed about HPV vaccination. They will remain unaware that there is no independent and objective evaulation of HPV vaccination; that there is no evidence to support multiple doses of HPV vaccines[18]; that "there is no evidence of cancers prevented"[19]; nor will they be informed that HPV vaccines have novel aluminium adjuvants, and vaccination is reported to induce antibody titres many fold higher than natural infection, with who knows what possible downsides.[20] There is also no mention in the PHE factsheet of the potential for a continuous shift in the prevalence of HPV types ('type replacement') as a result of vaccination[21] and the uncertainties this brings.

Dr Lehman, in Ten Commandments for patient-centred treatment you say "Shared decision making with patients should rest on clear knowledge of harms and benefits, derived from objective analysis and comparison between the existing alternatives".

Do you think the PHE 'factsheet' on HPV vaccination provides "clear knowledge of harms and benefits" and "objective analysis" about HPV vaccination for health professionals and their patients?

I suggest it does not.

It is alarming that health professionals are relying on this questionable PHE sponsored HPV vaccination 'advertorial' in discussions with their patients.

Dr Lehman, HPV vaccination is a massive international experiment, with fast-tracked novel VLP HPV vaccine products - children and young women are unknowing guinea pigs in this vaccine trial. Do you think it is ethical for health professionals to coerce parents/children and young women into having HPV vaccination based on biased and questionable material?

References: (Hyperlinks to my emails listed below can be accessed on my webpage: Cochrane Nordic and HPV vaccine safety: https://over-vaccination.net/c...
1. Richard Lehman et al. Ten Commandments for patient-centred treatment. Br J Gen Pract. 2015 Oct;65(639):532-533.
2. Two is as good as three for HPV. BMJ Blog - Richard Lehman's journal review - 5 December 2016.
3. Ole-Erik Iversen et al. Immunogenicity of the 9-Valent HPV Vaccine Using 2-Dose Regimens in Girls and Boys vs a 3-Dose Regimen in Women. JAMA. 2016; 316(22):2411-2421. Original Investigation December 13, 2016.
4. Lauri E. Markowitz et al. Two vs Three Doses of Human Papillomavirus Vaccine. New Policy for the Second Decade of the Vaccination Program. Editorial. JAMA. Published online November 21, 2016.
5. Melanie Drolet et al. Population-level impact and herd effects following human

papillomavirus vaccination programmes: a systematic review and meta-analysis. Lancet Infect Dis. Published online March 3, 2015.
6. John T Schiller et al. A review of Clinical Trials of Human Papillomavirus Prophylactic Vaccines. Vaccine. 2012 Nov 20; 30(0 5): F123-F138.
7. See my email further response to Fiona Godlee, Editor-in-Chief of the BMJ, as forwarded to Dr Tom Jefferson and Professor Peter Gøtzsche, 23 January 2017.
8. Just how safe is the cervical cancer jab? More and more families say their daughters suffered devastating side-effects from the HPV vaccine and experts are worried too. Daily Mail, 3 June 2015.
9. I suggest Dr Jefferson's comments are relevant to both the Gardasil and Cervarix HPV vaccines.
10. See my email response to Fiona Godless, Editor-in-Chief of the BMJ, as forwarded to Dr Tom Jefferson and Professor Peter Gøtzsche, 23 December 2016.
11. HPV vaccination and Cervical Cancer: Addressing the myths. Factsheet for Health Professionals. Public Health England. 23 December 2016: https://www.gov.uk/government/...
12. Thousands of teenage girls enduring debilitating illnesses after routine school cancer vaccination. The Independent, 31 May 2015.
13. Just how safe is the cervical cancer jab? More and more families say their daughters suffered devastating side-effects from the HPV vaccine and experts are worried too. Daily Mail, 3 June 2015.
14. See for example: Why I stopped my little girl from having the cervical cancer jab: TV presenter Melinda Messenger is one of a number of mothers worried about the possible side effects of the HPV vaccination. Daily Mail, 30 November 2016, updated 2 December 2016; and Row erupts on This Morning sofas as Melinda Messenger is accused of scare-mongering over her decision NOT to give her teenage daughter the HPV vaccine. Daily Mail, 14 December 2016, updated 15 December 2016.
15. Diane M. Harper et al. Efficacy of a bivalent L1 virus-like particle vaccine in prevention of infection with human papillomavirus types 16 and 18 in young women: a randomised controlled trial. Lancet. Vol. 364. November 13 2004.
16. Email from Diane Harper to Elizabeth Hart, 13 December 2016.
17. Mona Saraiya, Susan Hariri (Centers for Disease Control and Prevention). HPV vaccine effect: is the glass half full or half empty? The Lancet. Vol. 377. June 18, 2011.
18. See my email to Dr Tom Jefferson and Professor Peter Gotzsche (relevant to the Cochrane Nordic complaint) dated 12 December 2016.
19. Email from Diane Harper to Elizabeth Hart, 13 December 2016.
20. See my emails to Dr Tom Jefferson (relevant to the Cochrane Nordic complaint) dated 29 November 2016 and 9 December 2016.
21. See for example Sonja Fischer et al. Shift in prevalence of HPV types in cervical cytology specimens in the era of HPV vaccination. Oncology Letters 12: 601-610, 2016; and Fangjian Guo et al. Comparison of HPV prevalence between HPV-vaccinated and non-vaccinated young adult women (20-26 years). Human Vaccines & Immunotherapeutics 11:10, 2337-2344; October 2015. Drolet et al, op cit, also acknowledge the possibility of type replacement.

Elizabeth_Hart • 3 minutes ago Hold on, this is waiting to be approved by BMJ blogs.

It is pertinent to consider the history of globally fast-tracked HPV vaccination, consider this Australian perspective below.

Summary:

Australia was the first country to implement a funded national HPV vaccination program with Gardasil added to the National Immunisation Program from April 2007.

The implementation of HPV vaccination in Australia occurred in very dubious circumstances, with political interference in the approval process for this vaccine product. This provides an illuminating case study of the way politicians are manipulated into implementing taxpayer funded medical interventions of questionable value.

Subsequent to the fast-tracked implementation of HPV vaccination in Australia, in a domino effect, HPV vaccination has been rolled out around the world, with many millions of children being vaccinated with multiple doses of the still experimental VLP HPV vaccine products.

HPV vaccination is seen as an Australian 'success story', with the co-inventor of the technology enabling the HPV vaccines, Ian Frazer, being named 'Australian of the Year' in 2006. At that time many people, including politicians, were swept away by the idea of what was then misleadingly described as a 'cervical cancer vaccine'. The long-term uncertainties about the effectiveness and safety of this vaccine product were not properly considered by decision-makers.

Gardasil HPV vaccination was originally rejected for addition to the Australian National Immunisation Program Schedule by the Pharmaceutical Benefits Advisory Committee (PBAC) in 2006, a decision that was overturned with 24 hours after interference by then Coalition Prime Minister John Howard in the run-up to the 2007 federal election, when Gardasil vaccination was implemented for girls.

In July 2012 then Labor Federal Health Minister Tanya Plibersek oversaw implementation of Gardasil vaccination for boys with enthusiastic public support from Ian Frazer. In his official message of support for the funding of the national HPV vaccine program for boys, Ian Frazer failed to declare his conflict of interest, i.e. that he receives royalties from the sale of HPV vaccines in the developed world.

In an article promoting HPV vaccination at the time, Ian Frazer infers the implementation of HPV vaccination will unequivocally prevent death from cervical cancer. The public is being seduced by exaggerations of the effectiveness of HPV vaccination. For example, Ian Frazer is credited as being "The man who saved a million lives". In fact there is no evidence that Ian Frazer has saved any lives, it will take decades to know the outcome of universal fast-tracked HPV vaccination and this will require independent and objective observation, which is not evident at the current time.

The basis for mass vaccination with the HPV vaccines to prevent cancers such as cervical cancer is highly questionable. I suggest Gardasil HPV vaccination should not be on the Australian taxpayer funded vaccination schedule, and that the fast-tracked implementation of still experimental HPV vaccination in 2006/2007 should be subject to an investigation.

Further background:

Gardasil HPV vaccination for girls was fast-tracked in Australia when Coalition politician Tony Abbott was Federal Health Minister in 2006.

The Gardasil HPV vaccine was originally rejected by the Australian Pharmaceutical Benefits Advisory Committee (PBAC) "on the basis of uncertainty about duration of effect and unfavourable cost effectiveness".

A media release issued by Tony Abbott's office at the time states: "(PBAC) has not recommended the human papillomavirus vaccine (HPV), marketed by CSL as GARDASIL® for listing on the National Immunisation Program at this time...PBAC has advised that there was a lack of information in CSL's application on how long the vaccine remains effective, whether a booster would be needed and if so, how to determine the right target group for the follow up. The PBAC was also not provided with enough information on the long term effects of the vaccine on the incidence of cervical cancer. The PBAC also found that it is not cost effective for taxpayers at this time to fund GARDASIL® on the National Immunisation Program at the price proposed by CSL..." (My emphasis.)

Despite the PBAC's considerable doubts about the Gardasil vaccine product, the PBAC's decision to reject the addition of Gardasil to the national vaccination schedule was hurriedly overturned, after political interference and other lobbying by vested interests.

In their paper, The Australian funding debate on quadrivalent HPV vaccine: A case study for the national pharmaceutical policy, Elizabeth Roughead et al note: "Within the first 24h of the decision (to not recommend Gardasil) becoming public it was condemned by the leader of the opposition, the opposition health spokesperson, 22 women senators of both parties and the Queensland government. All called on the government to intervene. "Federal opposition health spokeswoman Julia Gillard said a Labor government would overturn a decision". Opposition Leader Kim Beazley urged Mr Howard to intervene so the PBAC would reverse its decision". "The Queensland deputy premier said "frankly the Health Minister Tony Abbott, in all conscience has to intervene". In what would appear to be an unprecedented move, the Queensland government published a full-page advertisement in the Sunday Mail, which was an "open letter to Mr Howard seeking a commitment to include the vaccine in the National Immunisation Scheme as soon as possible". The group of 22 female senators also wrote to Mr Abbott, asking him to "intervene" on the PBAC's decision." (My emphasis.)

Roughead et al also note "Experts, who were not necessarily independent, also disputed the PBAC decision. Dr Gerry Wain, who was usually cited as Westmead Hospital gynaecology director or NSW cervical screening program scientific director, but rarely acknowledged as the chair of CSL's Gardasil advisory board, said "They clearly don't value the lives and

health of Australian women, especially young, poor women who can't afford to buy it but need it most". (My emphasis.)

After this intense lobbying, then Coalition Prime Minister John Howard intervened, overturning the PBAC's rejection of Gardasil, and delivering "sparkling prime ministerial endorsement to Gardasil" along with a clear direction to then Health Minister Tony Abbott, "that the immunisation program should proceed. And pronto."

Commenting on the 22 female senators who interfered and helped overturn the PBAC's approval processes in regards to Gardasil HPV vaccination, Julie Rowbotham, the Sydney Morning Herald's Medical Editor at the time, said: "The senators want Gardasil hurried onto a national program on the grounds that you can't put a price on someone's life. But if they succeed in bending the cost-effectiveness rules, they will effectively be setting the lives of women who develop cervical cancer above those of people who happen to be afflicted by different fatal diseases and miserable illnesses. That is offensive."

The Gardasil initiative has indeed taken funds which might have been more usefully expended against "different fatal diseases and miserable illnesses". For example, Gardasil vaccination of boys and girls in 2013/2014 cost A$97 million, a very questionable expenditure, but a lucrative windfall for bioCSL, Professor Ian Frazer, and the University of Queensland. These parties benefit from royalties from the sale of HPV vaccines in developed countries.

In regards to future revaccinations with this product, i.e. 'boosters', Julie Rowbotham also notes: "The advisory committee's concern that booster shots may be needed in future is not a trivial quibble. Duration of protection is a critical issue when the aim is to achieve lasting human papillomavirus immunity and it is central in determining a reasonable price for the vaccine now."

The concern about the need for 'booster' shots is an important consideration. Apart from the additional cost, the current example of the apparently defective acellular pertussis (whooping cough) vaccine, which may actually be causing new strains of the disease to develop, and spreading the disease via vaccinated individuals, and the inexplicable recommendations for repeated 'boosters' throughout life with this defective vaccine, also raises the alarm about the future of still experimental VLP HPV vaccination.

Research which indicates some vaccines might support the evolution of more virulent viruses, and the reported early waning of maternal antibodies in infants born to measles-vaccinated mothers, also gives food for thought for those capable of thinking about the 'big picture' and the possibility of unintended consequences.

There is much that is unknown about the long-term effects of vaccination, hence we should exercise caution in implementing new vaccine products for diseases which pose little serious risk for the majority of the population, and which take away health funding from other more effective health strategies.

I suggest we should also be considering if an over-use of vaccine products may have long-term repercussions similar to the over-use of antibiotics and the rise of superbugs. Are there any independent and objective academics in the area of infectious diseases capable of considering this possibility, or are all the academics in this area too busy carrying out clinical trials of vaccine products for vaccine manufacturers?

Marion Haas also provides some commentary on the Australian Government's interference with the PBAC's initial rejection of Gardasil, noting Prime Minister Howard "intervened personally by announcing that the drug would be subsidised (i.e. listed) as soon as the manufacturer offered the right price. The PBAC subsequently convened a special meeting and recommended that Gardasil be listed on the PBS".

Haas notes government reaction which results in reversal of PBAC decisions has "the potential to send signals to manufacturers and lobby groups that a decision made by the PBAC may be reversed if sufficient public and/or political pressure is able to be brought to bear on the PBAC...this may undermine the processes used by the PBAC to determine its recommendations and hence the perceived independence of the PBAC."

Marion Haas et al provide further analysis in their paper Drugs, sex, money and power: An HPV vaccine case study. Their analysis of HPV vaccination implementation in seven industrialised countries, including Australia, shows that these countries "approved the vaccine and established related immunization programs exceptionally quickly even though there still exist many uncertainties as to the vaccine's long-term effectiveness, cost-effectiveness and safety" and that "some countries even bypassed established decision-making processes". Haas et al also note the voice of special interest groups was prominent in all countries, "drawing on societal values and fears of the public".

Haas et al warn "It is important that decision-makers adhere to transparent and robust guidelines in making funding decisions in the future to avoid capture by vested interests and potentially negative effects on access and equity."

After the Australian Government's interference in this matter, other countries adopted HPV vaccination, resulting in billions of dollars' worth of sales for the makers of the HPV vaccines, i.e. Merck (Gardasil) and GlaxoSmithKline (Cervarix), and royalties for entrepreneurial scientist Ian Frazer from sales of HPV vaccines in developed countries, and for CSL which receives royalties from sales of Gardasil.

I suggest former Prime Minister John Howard made a very big blunder when he submitted to the lobbying of senators, other politicians and vested interests, and overturned the PBAC's initial rejection of the Gardasil HPV vaccine in 2006.

The addition of the Gardasil HPV vaccine to the Australian taxpayer funded national vaccination schedule is highly controversial and also raises questions about what level of disease risk justifies mass vaccination.

There must be an urgent review of industry and politically motivated HPV vaccination in Australia and elsewhere.

As I have demonstrated, the fast-tracked implementation of universal HPV vaccination is highly questionable. Citizens must be informed of the controversial historical background on this matter.

Note: A fully referenced version of this information is included in my email to Dr Tom Jefferson and Professor Peter Gøtzsche, dated 25 January 2017: https://elizabethhart.files.wordpress.com/2013/02/the-history-of-questionable-fast-tracked-global-hpv-vaccination.pdf


Elizabeth_Hart 11 days ago
Pending

In my comments regarding HPV vaccination on this BMJ Blog, I have provided an example of an independent citizen, i.e. me, scrutinising so-called peer-reviewed papers.

It is remarkable that I, a mere layperson, discovered there was no evidence to support the three doses of HPV vaccines being imposed on children. Why didn't a 'peer-reviewer' query this and flag the ethical issues e.g. over-use of vaccine products and lack of informed consent?

Similarly, I took notice of the fact that HPV 'immunization' is reported to induce antibody titres that are many fold higher than natural infection, and queried if this unnatural response was 'a good thing'?

Again, it is remarkable that a 'peer-reviewer' did not query this.

And these vaccine products have been fast-tracked around the world, and even scientists such as Professor Diane Harper admit "the mechanism of immunogenicity from a scientific perspective is poorly understood"[1] and that "there is no evidence of cancers prevented"[2].

Fast-tracked HPV vaccination is a massive international scandal and there must be an inquiry into this now.

Reference:

1. Diane M Harper. Prophylactic human papillomavirus vaccines to prevent cervical cancer: review of the Phase II and III trials. Therapy (2008) 5(3), 313-324.
2. Email from Professor Diane Harper to Elizabeth Hart, 13 December 2016.


Elizabeth_Hart 11 days ago
Pending

Further to my previous comments, on 12 December 2016 I forwarded an email including Professor Harper's responses to me about HPV vaccination to Dr Tom Jefferson and Professor Peter Gøtzsche in relation to their complaint over maladministration at the European Medicines Agency (EMA) related to the safety of the HPV vaccines. (Correspondence re their complaint is currently published on the Nordic Cochrane website: http://nordic.cochrane.org/res...)

I also forwarded a copy of this email to Professor Harper, and on 13 December 2016 she responded: "Elizabeth - my comment Cervarix has proven efficacy in a single dose against incident HPV infection and incident CIN3 - not against cancer - just be clear about what my intents in my statement referred to. I agree that there is no evidence of cancers prevented - especially the head and neck cancers gardasil9 is being touted to prevent in boys."

As Professor Harper acknowledges "there is no evidence of cancers prevented". Commentary published in The Lancet in 2011 also notes "A demonstrable reduction of the burden of cervical cancer - the main goal of HPV vaccines - will take several decades".[1]

This is not the message being presented to the public, which instead receives biased propaganda promoting HPV vaccination from the likes of Public Health England which states: "The UK programme has already contributed to preventing future deaths from cervical cancer. We expect it to eventually prevent hundreds of cancer deaths every year."[2]

Reference:

1. Mona Saraiya, Susan Hariri (Centers for Disease Control and Prevention). HPV vaccine effect: is the glass half full or half empty? The Lancet. Vol. 377. June 18, 2011.
2. Factsheet for Health Professionals: Human papillomavirus (HPV) vaccination and Cervical Cancer - Addressing the myths: https://www.gov.uk/government/...

Elizabeth_Hart 11 days ago

Pending

As mentioned in my previous comment, in regards to HPV 'immunisation' inducing antibody titres that are 80- to 100- fold higher than those observed following natural infection, HPV vaccine co-inventor Ian Frazer (2010)[1] cites a paper by Diane Harper et al regarding the bivalent HPV vaccine (2004)[2], i.e. presumably Cervarix. (This study was funded and coordinated by GlaxoSmithKline Bioglogicals.)

It appears Frazer generalises about high antibody titres after HPV vaccination, i.e. Gardasil and Cervarix, from Harper et al's paper about Cervarix.[2]

In a later review paper (2008)[3], Diane Harper refers to high antibody titres after both vaccines, i.e. "the peak response to vaccination was robustly 100-200-fold higher than natural infection titers for both vaccines in neutralizing type-specific antibody titers for both HPV 16 and 18", although in a later paper (2009)[4] Harper says peak titre after Gardasil vaccination is 104-fold higher than natural infection for HPV 16, and 27-fold higher than natural infection titres for HPV 18.

In essence though, it appears HPV vaccination with both vaccines creates a much higher antibody response than natural infection, and from my layperson's perspective I wonder if there is any downside to this unnatural response?

In her 2008[3] review paper, Harper also states: "Despite both vaccines having a 100% seroconversion 1 month after three doses of vaccine, the mechanism of immunogenicity from a scientific perspective is poorly understood. The measure of antibody induction by geometric mean titers (GMTs) is dependent on the assay system used, and is not comparable between HPV types within one manufacturer or for identical HPV types between manufacturers."

It is concerning that the novel virus-like particle (VLP) vaccine products Gardasil and Cervarix have been fast-tracked globally, when "the mechanism of immunogenicity from a scientific perspective is poorly understood".

In her 2008[3] review paper, Harper states: "...both vaccines contain a proprietary adjuvant system to improve the immunologic response to the VLP antigens. The adjuvant system, AS04, in Cervarix contains both an aluminium salt and a toll-like receptor-4 agonist (monophosphoryl lipid A); the adjuvant system in Gardasil contains an aluminium salt called aluminium hydroxyphosphate sulfate. Clinical trials in humans show that the HPV 16/18 VLPs adjuvanted with AS04 induce a significantly greater initial antibody response than do the HPV16/18 VLPs adjuvanted with aluminium hydroxide alone, and this superior response continues for at least 4 years...Experiments in mice show that the Merck proprietary amorphous aluminium hydroxyphosphate sulfate used in Gardasil induces a greater initial antibody response to HPV16 VLPs than does the aluminium hydroxide adjuvant alone..."

A VacZine Analytics press release titled "GSK and Cervarix - is AS04 a double edged sword?" (2007)[5] says the novel adjuvant AS04 contained in Cervarix "is a combination of standard aluminium hydroxide and the new component, monophospholipid A (MPL). MPL is a derivative of the lipid A molecule found in gram-negative bacteria and is considered one of the most potent immune system stimulants known".

Merck's proprietary amorphous aluminium hydroxyphosphate sulfate used in Gardasil also appears to be more potent than aluminium hydroxide adjuvant alone.[3]

Harper says the purpose of the adjuvant "is to prolong the immune response for as long as possible with the smallest amount of antigen (VLP) possible".[4]

Again, I register my concern that the novel Gardasil and Cervarix VLP HPV vaccine products have been fast-tracked around the world, particularly as "the mechanism of immunogenicity from a scientific perspective is poorly understood".

If children and their parents were properly informed of the unnaturally high antibody titre induced by both the novel aluminium adjuvanted Gardasil and Cervarix vaccine products, and that scientists such as Diane Harper admit the mechanism of immunogenicity of these products is poorly understood from a scientific perspective, I wonder if they would consent to this still experimental medical intervention?

References:

1. Ian H Frazer. Measuring serum antibody to human papillomavirus following infection or vaccination. Gynecologic Oncology 118 (2010) S8-S11.
2. Diane M Harper et al. Efficacy of a bivalent L1 virus-like particle vaccine in prevention of infection with human papillomavirus types 16 and 18 in young women: a randomised controlled trial. Lancet, 2004; 364: 1757-65.
3. Diane M Harper. Prophylactic human papillomavirus vaccines to prevent cervical cancer: review of the Phase II and III trials. Therapy (2008) 5(3), 313-324.
4. Diane M Harper. Currently Approved Prophylactic HPV Vaccines. Expert Rev Vaccines. 2009; 8 (12): 1663-1679).
5. GSK and Cervarix - is AS04 a double edged sword? Press Release. VacZine Analytics. Posted online 19 Dec 2007.

Elizabeth_Hart 11 days ago

Pending

Further to my previous comments, in a review paper published in 2010, co-inventor of the HPV vaccines, Ian Frazer, states: "HPV immunization induces peak geometric mean antibody titers that are 80- to 100-fold higher than those observed following natural infection [19]. Furthermore, after 18 months, mean vaccine-induced antibody titers remain 10- to 16-fold higher than those recorded with natural infection [19], and these levels appear to be preserved over time, suggesting that immunization may provide long-term protection against infection..." (See page S9.)

HPV 'immunization' inducing antibody titres that are 80- to 100-fold higher than those observed following natural infection seems to be a very unnatural response.

Is this a good thing? Does anybody know?

Frazer's review paper is titled Measuring serum antibody to human papillomavirus following infection or vaccination, published in Gynecologic Oncology 118 (2010) S8-S11, and funded by Merck & Co. Inc. His reference for his high antibody titre comment is a paper by Diane M Harper et al - Efficacy of a bivalent L1 virus-like particle vaccine in prevention of infection with human papillomavirus types 16 and 18 in young women: a randomised controlled trial, published in The Lancet, Vol 364 November 13, 2004, and funded and co-ordinated by GlaxoSmithKline Biologicals.

In their paper Harper et al state: "Geometric mean titres for vaccine-induced antibodies to HPV antibodies were over 80 and 100 times greater than those seen in natural infections with HPV-18 and HPV-16, respectively. Vaccine-induced titres remained substantially raised at 18 months, and were still 10-16 times higher than those seen in women with natural HPV-16 or HPV-18 infections, respectively." (See page 1763.)

And on page 1764: "We have shown that the HPV-16/18 virus-like particle vaccine adjuvanted with AS04 induces a level of antibody production against HPV-16/18 that is much higher than that induced by natural infection. Previous work has shown that combinations of the adjuvants MPL and aluminium salts induce an enhanced immune response compared with antigen alone or adjuvanted with only aluminium, at both the humoral and cellular level. These findings suggest that the immune responses induced in vaccinated women may provide a longer duration of protection than the protective effects induced by natural HPV infection; however, a protective antibody level has not been established nor is there sufficient data currently available to estimate the duration of vaccine-induced protection."

Should we be concerned that HPV vaccines produce antibodies over 80 and 100 times greater than those seen in natural infections with HPV-18 and HPV-16 respectively, and which remain substantially raised months after vaccination?

Again, does anybody know?


Elizabeth_Hart 11 days ago

Pending

As mentioned in my previous comment, at this time there is no independent and objective analysis validating HPV vaccination, and apparently no scientific basis for the three dose regimen, certainly not for Cervarix. (I have contacted Professor Ian Frazer to question the evidence base for three doses of Gardasil HPV vaccines. We have had some email correspondence on this matter and I am currently considering his responses.)

I suggest the public is being misled about the promoted 'efficacy' of globally fast-tracked HPV vaccination. At this time we have no idea of the long-term effects of this very

questionable novel medical intervention, particularly if the risks will outweigh the touted benefits.

I also suggest there is much fear-mongering about HPV and cancer. Misinformation about HPV and cancer risk abounds, much of it emanating from the so-called 'scientific' community.

For example, in an article promoting HPV vaccination[1], HPV vaccine entrepreneur Professor Ian Frazer definitively states cervical cancer "kills over 250,000 women world wide every year" and describes cervical cancer as the "second most common cause of cancer death in women", but provides no evidence to support these statements.

The use of these alarming statistics is highly questionable in countries where the risk of cervical cancer is very low.

Professor Frazer's alarmist annual 250,000 death rate is not relevant to Australian girls and women. Published statistics indicate that an estimated 245 deaths were attributed to cancer of the cervix in Australia in 2014.[2]

The risk of cervical cancer has been steadily decreasing in Australia. Between 1982 and 2014 cervical cancer was one of the cancers showing the greatest percentage-point decrease in incidence, from 14.2 to 7.0 per 100,000.[3] In the same period, the age standardised mortality rate of cervical cancer decreased from 5.2 to 1.8 per 100,000.[4]

Cervical cancer is listed as 19th on a list of the estimated 20 most common causes of death from cancers for females in 2010[5] and 2014[6], which is at odds with Professor Frazer's statement that cervical cancer is the "second most common cause of cancer death in women".

Even a report on HPV vaccination in Australia acknowledges the low risk of cancer, saying "Australia has one of the lowest rates of incidence and mortality from cervical cancer in the world.[7] In 2008, there were 9 cases of cervical cancer per 100,000 women of all ages, and in 2007, the age-standardised mortality rate from cervical cancer was 2 deaths per 100,000.[8] These are the lowest rates observed to date. Cervical cancer in Australia now occurs predominantly in unscreened or under-screened women."[9]

Which raises the question - why did Australia implement mass HPV vaccination in 2007 when the disease threat was low, screening would still have to take place, and the long-term effects of HPV vaccination were unknown?

This expensive initiative also took funding away from other pressing medical problems. For example Gardasil vaccination of boys and girls in 2013/2014 cost over $97 million[10], a very questionable expenditure, but a lucrative windfall for bioCSL, Professor Ian Frazer[11], and

the University of Queensland.[12] These parties benefit from royalties from the sale of HPV vaccines in developed countries.

In regards to HPV, the Australian Government's National Cervical Screening Program webpage notes "Most HPV infections clear up by themselves without causing any problems" and "It is important to remember that most women who have HPV, clear the virus and do not go on to develop cervical abnormalities or cervical cancer".[13]

Professor Frazer even acknowledges the low risk of cancer himself in his article promoting HPV vaccination on The Conversation website. In his advertorial, "Catch cancer? No thanks, I'd rather have a shot!" he says: "Through sexual activity, most of us will get infected with the genital papillomaviruses that can cause cancer. Fortunately, most of us get rid of them between 12 months to five years later without even knowing we've had the infection. Even if the infection persists, only a few individuals accumulate enough genetic mistakes in the virus-infected cell for these to acquire the properties of cancer cells."

Professor Frazer admits only "a few individuals accumulate enough genetic mistakes in the virus-infected cell for these to acquire the properties of cancer cells".

Given the admitted low risk associated with HPV and cancer, I question whether it is justifiable to compel millions of children to be repeatedly vaccinated with novel, turbo-charged aluminium-adjuvanted VLP HPV vaccines.

Who knows what interference with the natural progression of generally benign HPV may throw up in future, with the global fast-tracking of the still experimental VLP HPV vaccines. There is much scope here for 'unintended consequences', and the current generation of children and young people are the unsuspecting guinea pigs.

Parents and children are not being properly informed about still experimental HPV vaccination, their right to 'informed consent' is being denied.

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1. Ian Frazer. Catch cancer? No thanks, I'd rather have a shot! The Conversation, 10 July 2012.
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3. See page 20, Cancer in Australia: An overview 2014.
4. See page 52, Cancer in Australia: An overview 2014.
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7. International Agency for Research on Cancer. CANCERMondial. 2012. (Accessed 11 July 2012). As quoted in NCIRS Evaluation of the National Human Papillomavirus Vaccination Program. Final Report. 28 August 2014.
8. Australian Institute of Health and Welfare (AIHW). Cervical screening in Australia 2009-2010. Cancer series no. 67. Cat. no. CAN 63. Canberra: AIHW; 2012. As quoted in NCIRS Evaluation of the National Human Papillomavirus Vaccination Program. Final Report. 28 August 2014.
9. NCIRS Evaluation of the National Human Papillomavirus Vaccination Program. Final Report. 28 August 2014.
10. The National HPV Vaccination Program is a school-based program provided under the National Immunisation Program (NIP). Vaccinations provided under the NIP are free for eligible cohorts. The current contract with bioCSL for supply of Gardasil for the National HPV Vaccination Program is for both the male and female programs for 2013 and 2014, at a total cost of $97,678,540.96 (GST Inclusive). Senate Community Affairs Committee. Answers to Estimates Questions on Notice. Health and Ageing Portfolio. Additional Estimates 13 & 15 February 2013. Question: E13-172.
11. "Ian Frazer as co-inventor of the technology enabling the HPV vaccines receives royalties from their sale in the developed world." Disclosure statement on Ian Frazer's article "Catch cancer? No thanks, I'd rather have a shot!" The Conversation, 10 July 2012.
12. "The Merck vaccine, Gardasil, was commercially released in 2006. Under the licensing arrangements, milestone and royalty payments from the sale of the Merck and GSK vaccines will be payable to UniQuest and will ultimately flow back to UQ (University of Queensland) and the researchers (Ian Frazer)." Group of Eight Australia. Module 4: Intellectual property and commercialisation. Case Study: Gardasil - an example of university licensing.
13. About the human papillomavirus (HPV) and cervical cancer. Australian Government National Cervical Cancer Screening Program. Webpage accessed 13 December 2016.


Elizabeth_Hart a month ago
Pending

Richard Lehman, re your commentary on “Two is as good as three for HPV”, and your apparent support for this “human experiment on a large scale”.

Children around the world are being given three doses of the novel VLP HPV vaccine products Cervarix and Gardasil.

In regards to the three dose HPV vaccine regimen, I recently contacted Professor Diane Harper, an author of the study re the bivalent HPV vaccine (i.e. Cervarix), published in The

Lancet in 2004[1], to ask her if titres were measured after individual doses or after all three doses in that study.

I was surprised when Professor Harper responded that "The titers were measured one month after the third dose."[2]

Professor Harper's response indicates that titres were not measured after each individual dose.

So it appears it was not proven that three doses of Cervarix HPV vaccine were required.

In her email response to me, Professor Harper said: "The need for long-term protection drove the fear that three doses would be needed. As we learned one dose of cervarix provides high titers as well and has proven efficacy. It is unfortunate that the WHO would not recommend one dose of cervarix worldwide."

In regards to Professor Harper's statement "As we learned one dose of cervarix provides high titers...", another study re Cervarix, published in 2013[3] states: "Antibody levels following one-dose remained stable from month 6 through month 48. Results raise the possibility that even a single dose of HPV VLPs will induce long-term protection." This study was followed up with further analysis in 2015[4] which also indicates there is no evidence to support the three dose Cervarix HPV vaccine regimen.

It is shocking to discover there was no evidence to support the three dose HPV vaccine regimen.

HPV vaccination has been fast-tracked around the world. Children are being given three doses of novel, turbo-charged aluminium-adjuvanted VLP HPV vaccines which produce unnaturally high titres, i.e. HPV vaccination induces antibody titres are are 80- to 100-fold higher than those observed following natural infection, which seems to be a very unnatural response.[5,6]

Scientists such as Professor Harper admit "the mechanism of immunogenicity from a scientific perspective is poorly understood".[7] Children are being used as guinea pigs in a massive international experiment - is this ethical? What are the implications here in regards to informed consent?

While the studies I have referred to are about the Cervarix HPV vaccine, this leads to questions about the Gardasil HPV vaccine - what is the evidence supporting vaccination with three doses of the Gardasil HPV vaccine product?

Were three doses of HPV vaccines suggested to justify the cost of these vaccine products?

As for Professor Harper's suggestion that Cervarix "has proven efficacy", as far as I am aware, there is as yet no independent and objective systematic review of the efficacy of HPV vaccination in preventing cervical cancer, i.e. untainted by pharma influence or bias.

I suggest the public is being misled about the promoted 'efficacy' of globally fast-tracked HPV vaccination. At this time we have no idea of the long-term effects of this very questionable medical intervention, particularly if the risks will outweigh the touted benefits.

In my opinion the benefits of HPV vaccination are being over-hyped, and children and their parents are being grossly misinformed about HPV vaccination. At this time there is no independent and objective analysis validating HPV vaccination, and no scientific basis for the three dose regimen.

This is a massive international scandal.

References:

1. Diane M Harper et al. Efficacy of a bivalent L1 virus-like particle vaccine in prevention of infection with human papillomavirus types 16 and 18 in young women: a randomised controlled trial. Lancet. Vol. 364. November 13 2004.
2. Email response from Diane Harper, 11 December 2016.
3. Mahboobeh Safaeian et al. Durable Antibody Responses Following One Dose of the Bivalent Human Papillomavirus L1 Virus-Like Particle Vaccine in the Costa Rica Vaccine Trial. Cancer Prev Res; 6(11) November 2013.
4. Aimee R Kriemer et al. Efficacy of fewer than three doses of an HPV-16/18 AS04-adjuvanted vaccine: combined analysis of data from the Costa Rica Vaccine and PATRICIA trials. The Lancet Oncology Vol 16, July 2015.
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