Ethics approval / consent re HPV vaccination studies

Elizabeth Hart <eliz.hart25@gmail.com>
Thu, Feb 9, 2017 at 4:16 PM

To: Tom Jefferson <jefferson.tom@gmail.com>, Peter Gøtzsche <pcg@cochrane.dk>
Cc: Louise.Schouborg.Brinth@regionh.dk, Karsten juhl jørgensen <kj@cochrane.dk>, Margrete Auken <margrete.auken@europarl.europa.eu>, Christopher Exley <c.exley@keele.ac.uk>

Dr Jefferson and Professor Gøtzsche, further to my correspondence re HPV vaccination, FYI, please see below my email to Fiona Godlee re ethics approval and consent re HPV vaccination studies

Regards
Elizabeth Hart
https://over-vaccination.net/

-------- Forwarded message --------
From: Elizabeth Hart <eliz.hart25@gmail.com>
Date: Wed, Feb 8, 2017 at 5:33 PM
Subject: Ethics approval / consent re HPV vaccination studies
To: Fiona Godlee <fgodlee@bmj.com>
Cc: edgar.lehman@btopenworld.com, Juliet Dobson <jdobson@bmj.com>, Sharon Davies <sdavies@bmj.com>

Dr Godlee, it appears there is no evidence to support the multiple doses of HPV vaccines given to children and young women, as I have previously outlined in my emails to you and comments on Richard Lehmans BMJ Blog.

I suggest this is a very serious ethical and possibly legal issue as participants in HPV vaccine trials, and subsequently millions of children around the world, have been coaxed into having medical interventions, i.e multiple HPV vaccinations, with no evidence of benefit. It is also notable that HPV vaccination is reported to induce antibody titre responses many fold higher than natural infection, and it is not clear if any potential downsides to this very unnatural response have been considered.

I am currently trying to ascertain what type of ethics approval procedure and consent forms were used in HPV vaccine trials, and have contacted Professor Diane Harper and Dr Ole-Erik Iversen (an author on the JAMA paper referred to by Richard Lehman) in this regard.

Dr Iversen has indicated that my enquiry should be directed to the sponsor of the study, i.e. Merck in the USA, and he is following up re a relevant contact person. I await further advice on this matter.

I asked Professor Harper if the review board for her study asked for justification for the three doses of HPV vaccine, and also asked her to provide me with a copy of the protocol, consent forms and amendments for her study. While she has not responded to these specific questions, she has provided the following response:

Dear Elizabeth

Both Merck and GSK develop childhood vaccines in 3 dose schedules to maximize immunity. There was not a discussion at the beginning questioning the practice of long term immunity induction through the use of three doses. Only after the results were published did a public health official from Quebec indicate that fewer than three doses could very well be appropriate. That started the two dose trial in Quebec. Gardasil has never had any efficacy trials showing infection or disease prevention with fewer than three doses - only antibody studies.

As time went on, the NCI group showed that Cervarix was effective in ONE dose and had the antibody titers to back it up.

The question to ask is why did WHO go with a two dose schedule instead of the ONE dose Cervarix recommendation? It would have been less expensive, just as effective, easier to implement, etc.

Best wishes
dh

(See original email response from Diane Harper in thread below.)
This is interesting information and I forward it to you for your consideration of HPV vaccination and broader questions around vaccination policy.

Sincerely
Elizabeth Hart
https://over-vaccination.net/

-------- Forwarded message --------
From: <diane.harper@louisville.edu>
Date: Mon, Feb 6, 2017 at 11:25 PM
Subject: RE: Query re ethics approval for your Cervarix study
To: Elizabeth Hart <eliz.hart25@gmail.com>

Dear Elizabeth

Both Merck and GSK develop childhood vaccines in 3 dose schedules to maximize immunity. There was not a discussion at the beginning questioning the practice of long term immunity induction through the use of three doses. Only after the results were published did a public health official from Quebec indicate that fewer than three doses could very well be appropriate. That started the two dose trial in Quebec. Gardasil has never had any efficacy trials showing infection or disease prevention with fewer than three doses - only antibody studies.

As time went on, the NCI group showed that Cervarix was effective in ONE dose! and had the antibody titers to back it up. The question to ask is why did WHO go with a two dose schedule instead of the ONE dose Cervarix recommendation? It would have been less expensive, just as effective, easier to implement, etc.

Best wishes
dh

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From: Elizabeth Hart [eliz.hart25@gmail.com]
Sent: Monday, February 06, 2017 5:45 AM
To: Diane Harper
Subject: Fwd: Query re ethics approval for your Cervarix study

Diane, re my emails below, I again ask, did nobody on the review board ask for justification for the three doses of HPV vaccine? I also request the protocol, consent forms and amendments re your study (results of which published in The Lancet in 2004).

As you know vaccine trials such as yours have impacted on international vaccination policy, and it's important to have transparency in this regard.

I look forward to your response.

Elizabeth

--------- Forwarded message ---------
From: Elizabeth Hart <eliz.hart25@gmail.com>
Date: Tue, Jan 31, 2017 at 12:45 PM
Subject: Query re ethics approval for your Cervarix study
To: Diane Harper <diane.harper@louisville.edu>
Cc: dradford <deirdrelittle2@gmail.com>, Christian Fiala <christian.fiala@aon.at>, flescher <flescher@012.net.il>

Diane, re my previous email, below.

Are you able to respond to my queries, i.e. did nobody on the review board ask for justification for the three doses of HPV vaccine?
Also, are you able to provide me with a copy of the protocol, consent forms and amendments re your study?

Regards
Elizabeth

--------- Forwarded message ---------
From: Elizabeth Hart <eliz.hart25@gmail.com>
Date: Mon, Jan 23, 2017 at 3:52 PM
Subject: Further response to Fiona Godlee, BMJ re HPV vaccination - Richard Lehman's BMJ Blog item "Two is as good as three for HPV", 5 December 2016
To: Diane Harper <diane.harper@louisville.edu>
Cc: dradford <deirdrelittle2@gmail.com>, Christian Fiala <christian.fiala@aon.at>, flescher <flescher@012.net.il>

Diane, FYI, please see below my recent response to Fiona Godlee at the BMJ re HPV vaccination.

You will see that I have queried the ethical approval process for your study.

I see in your paper that "an institutional review board approved the protocol, consent forms, and amendments".

Did nobody on this institutional review board ask for justification for the three doses of HPV vaccine?

Are you able to provide me with a copy of the protocol, consent forms and amendments?

Regards
Elizabeth

--------- Forwarded message ---------
From: Elizabeth Hart <eliz.hart25@gmail.com>
Date: Mon, Jan 23, 2017 at 3:27 PM
Subject: Re: Further response to Fiona Godlee, BMJ re HPV vaccination - Richard Lehman's BMJ Blog article re HPV vaccination (Blog published 5 December 2016: http://blogs.bmj.com/bmj/2016/12/05/richard­lehman­s­journal­review­5­december­2016/ )
To: Fiona Godlee <fgodlee@bmj.com>
Cc: Juliet Dobson <jdobson@bmj.com>, edgar.lehman@btopenworld.com, Sharon Davies <sdavies@bmj.com>

Dr Godlee, further to our previous correspondence, I again request you publish my original, unedited, comment on Richard Lehman's BMJ Blog article re HPV vaccination (Blog published 5 December 2016: http://blogs.bmj.com/bmj/2016/12/05/richard­lehman­s­journal­review­5­december­2016/ )

I have subsequently posted five more comments on Richard Lehman's BMJ Blog on this matter, and none of them have been acknowledged or published, see copy of all my unpublished comments attached. (One of these comments includes reference to Professor Diane Harper's email to me of 13 December 2016 re HPV vaccination in which she wants to make clear "...that there is no evidence of cancers prevented..."

https://mail.google.com/mail/u/0?ui=2&ik=0b56c6d81d&view=pt&search=sent&msg=15a21688d5b815a6&siml=15a21688d5b815a6 3/23
In the interests of transparency and accountability, I request that all my comments be published on Richard Lehman's *BMJ Blog*.

Dr Godlee, the *BMJ* has provided endorsement of global HPV vaccination via Richard Lehman's *BMJ Blog*. It is important that citizens be allowed to respond to the *BMJ*'s public endorsement of HPV vaccination. The journal industry must be accountable for its influence on international vaccination policy. Medical interventions such as HPV vaccination are being pressed upon the community - citizens are entitled to question the legitimacy of these interventions, and to criticise the often biased literature that supports these lucrative medical interventions. Citizens such as myself, laypeople, are finding anomalies in the 'peer-reviewed' literature, and these matters must be acknowledged and addressed.

The journal industry is publishing material behind paywalls which is impacting on international vaccination policy (e.g. the paper[1] and editorial[2] in *JAMA* referred to by Richard Lehman). Much of this material is conflicted by industry-funding and academic vaccine ideologues, resulting in biased material which should not be relied upon for vaccination policy. As of yet we have no independent and objective review of HPV vaccination, and yet the implementation of novel VLP HPV vaccine products has been fast-tracked around the world.

An article published in the UK *Daily Mail* in June 2015[3] about girls suffering adverse experiences after HPV vaccination includes illuminating comments from epidemiologist Dr Tom Jefferson, who is one of the signatories on the complaint to the European Medicines Authority (EMA) over maladministration at the EMA related to safety of the HPV vaccines.

The article reports Dr Jefferson "is highly critical of the drug company funded clinical trial data that is used to justify the use of mass vaccination" and he adds "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'*. (I suggest Dr Jefferson's comments are relevant to both the Gardasil and Cervarix HPV vaccines.)

Dr Godlee, a fundamental problem with HPV vaccination is the lack of informed consent before this medical intervention, i.e. children and parents are not being informed about the many uncertainties about the novel VLP HPV vaccine products - children are being used as unknowing guinea pigs in this massive international vaccine trial.

For example children and parents are not being informed about the lack of evidence for multiple HPV vaccine doses, or that HPV 'immunisation' induces antibody titres that are many fold higher than natural infection, as outlined in my (unpublished) comments on Richard Lehman's *BMJ Blog* and in my previous correspondence to you.

It is remarkable to discover that there was no evidence to support the three doses of HPV vaccines being imposed upon children. What sort of ethics approval did Harper et al's study undergo?[4] Did nobody ask for any justification for the three doses?

Did a 'peer reviewer' of the subsequent paper not question the justification for the three doses? There are ethical concerns here re the over-use of vaccine products and informed consent.
Similarly, HPV 'immunisation' is reported to induce antibody titres that are many fold higher than natural infection, is this very unnatural response 'a good thing'?

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

And now 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"[4] and that "there is no evidence of cancers prevented"[5].

Dr Godlee, I again request the BMJ take urgent action to raise the alarm about questionable international HPV vaccination policy, and that, for the public record, you publish my comments in response to Richard Lehman's BMJ Blog, i.e. my comments which currently remain held up in moderation, see copy attached.

Sincerely
Elizabeth Hart
https://over-vaccination.net/

References:
3. 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.
6. Email response from Professor Diane Harper to Elizabeth Hart, 13 December 2016.

On Mon, Jan 9, 2017 at 6:22 PM, Juliet Dobson <jdobson@bmj.com> wrote:
Dear Elizabeth,

Many thanks for your email. As I mentioned in my previous email to you, I can publish your comment with the edits suggested by our lawyer. This is the version of the the text that I sent you on Sat, Dec 17, 2016 at 12:45 AM.

If you are agreeable to this then I can publish your comment as soon as I hear back from you.

Best wishes,
Juliet

On 9 January 2017 at 05:19, Elizabeth Hart <eliz.hart25@gmail.com> wrote:
Dr Godlee, further to our previous correspondence, it is now a month since I submitted my original comment on Richard Lehman's BMJ Blog in response to his item Two is as good as three for HPV.

My original comment included reference to my personal email correspondence with Professor Diane Harper, and exposed the lack of evidence supporting the multiple doses of HPV vaccines being urged upon children around the world, and also raised concern about the unnaturally high antibody titres being induced by novel VLP HPV vaccination, and the lack of 'informed consent' for this medical intervention. I also
followed up with further material on this matter to both you and blogs editor Juliet Dobson, including my email correspondence with Professor Harper and Cochrane Nordic.

I understand from Juliet Dobson my original comment was checked by a lawyer. At Juliet's request, I modified my comment to include further information from Professor Harper re the 'efficacy' of HPV vaccination, including Professor Harper’s statement: "...I agree that there is no evidence of cancer prevented - especially the head and neck cancers that gardasil9 is being touted to prevent in boys". (My emphasis.)

It was my intention to follow up my original comment with an additional comment re Professor Harper’s acknowledgement "that there is no evidence of cancer prevented", but I was willing to accommodate Juliet's request to incorporate this statement in my original comment.

I have heard nothing further from the BMJ since Juliet Dobson's last email to me dated 21 December 2016, and my modified comment remains unpublished on the BMJ.

It is notable that the BMJ published a response from Cochrane Nordic's Peter Gøtzsche on Richard Lehman's BMJ Blog, challenging Richard Lehman's misleading assertion that "No adverse effects have emerged when teenage populations have been vaccinated".

Why are carefully considered comments from independent citizens such as myself being withheld from publication on the BMJ?

Dr Godlee, I am maintaining a public record of issues regarding HPV vaccination on my website, including my correspondence to Cochrane Nordic relevant to their complaint to the European Medicines Authority (EMA) over maladministration at the EMA in regards to the safety of the HPV vaccines, see: https://over-vaccination.net/cochrane-collaboration/

In an effort to publicly challenge the scientific establishment about HPV vaccination, I have today posted comments about the lack of evidence for multiple doses of HPV vaccines, concern about the unnaturally high titres induced by HPV vaccination, and the fear-mongering and lack of 'informed consent' for this medical intervention, on an article published on the Science journal website on 21 December 2016, i.e. Critics assail paper claiming harm from cancer vaccine: http://www.sciencemag.org/news/2016/12/critics-assail-paper-claiming-harm-cancer-vaccine

Dr Godlee, I again request that my modified comment raising important matters about HPV vaccination be published on the public record on Richard Lehman's BMJ Blog, as a justifiable counter-balance to Dr Lehman's uncritical endorsement of HPV vaccination.

(I will forward further criticism of Richard Lehman's item on HPV vaccination in due course.)

I request your early response on this matter.

Sincerely
Elizabeth Hart

------- Forwarded message -------
From: Elizabeth Hart <eliz.hart25@gmail.com>
Date: Fri, Dec 23, 2016 at 10:05 PM
Subject: Response to Fiona Godlee, BMJ re HPV vaccination - Richard Lehman's BMJ Blog item "Two is as good as three for HPV", 5 December 2016
To: Fiona Godlee <fgodlee@bmj.com>
Cc: Juliet Dobson <jdobson@bmj.com>
Dr Godlee, further to my previous correspondence with the BMJ re the lack of evidence for multiple doses of HPV vaccines, and concern re unnaturally high antibody titres after HPV vaccination.

I originally submitted a comment in this regard on Richard Lehman's BMJ Blog item Two is as good as three for HPV over ten days ago and my comment has still not been published.

At BMJ blogs editor Juliet Dobson's request, I modified my comment to include Professor Diane Harper's additional email response to me (13 December 2016) re the 'efficacy' of HPV vaccination, including her statement: "...I agree that there is no evidence of cancers prevented - especially the head and neck cancers that gardasil9 is being touted to prevent in boys".

I request the BMJ publish my modified comment, as provided by me to Juliet Dobson (and copied to you) on Sat 17 December 2016 at 10.51 pm (CST) / 12.21 pm (GMT). (See email thread below, and copy attached)

I understand that my original comment has been checked by a lawyer. I cannot see that the extra information I have provided poses any legal difficulties, i.e. an explanatory statement about Professor Harper's later response to me re HPV vaccination in which she agrees "...that there is no evidence of cancers prevented...", and the supporting quote from a Lancet commentary (2011) stating "A demonstrable reduction of the burden of cervical cancer - the main goal of HPV vaccines - will take several decades."[1]

Dr Godlee, I suggest citizens are being misled about HPV vaccination, particularly via the often conflicted 'peer-reviewed literature', i.e. the scientific and medical journal industry. The risks of human papillomavirus are being over-blown, and the touted benefits of HPV vaccination have not been independently and objectively evaluated, as I detailed in my email to you dated 15 December 2016. (See email thread below, and copy attached.)

Around the world reports of girls and young women experiencing adverse events after HPV vaccination have emerged, e.g. in Japan[2], Denmark[3], Ireland[4], England[5], Scotland[6], the United States[7], Canada[8], Colombia[9], India[10], New Zealand[11] etc. International victim support group SaneVax provides a record of girls and young women, and boys, who have suffered after HPV vaccination, and this group campaigns to draw attention to this problem.

Cochrane Nordic has also made a complaint to the European Medicines Agency (EMA) re its handling of the assessment of the safety of HPV vaccines[12].

In light of the international reports of adverse events after HPV vaccination, Richard Lehman's statement on his BMJ Blog that "No adverse effects have emerged when teenage populations have been vaccinated..." is misleading.

When negative stories about HPV vaccination appear the medical/scientific establishment often intervenes to shut down debate on the matter, as can be seen by the backlash against the Toronto Star's report A wonder drug's dark side (February 2015), which was subsequently censored[13], and attacks on US journalist and TV host Katie Couric, who presented personal stories from mothers who claim their daughters suffered serious harm, including death, after HPV vaccination (December 2015)[14].

Concerns about the safety of the HPV vaccines are still being stifled, as most recently evidenced in the vicious pillorying of TV presenter Melinda Messenger in the UK media, including Dr Chris Steele's arrogant and patronising attitude towards Ms Messenger for
Dr Godlee, I have brought it to your attention that there is no evidence to support multiple doses of HPV vaccines. I have also raised concern about the very high antibody titres induced by these novel VLP HPV vaccines, many fold higher than natural infection, i.e. a very *unnatural* response. Professor Diane Harper admits “the mechanism of immunogenicity from a scientific perspective is poorly understood” [16].

In fact children are unknowingly being used as guinea pigs in this massive international experiment, i.e. without their 'informed consent'.

And in response to this the *BMJ*'s Juliet Dobson says: "This is an interesting issue that you have raised. We may pursue this further in future." (Email dated 21 December 2016.)

Dr Godlee, I am flabbergasted that you have not taken immediate action to address this important international issue relevant to millions of children.

Millions of children are being pressured to have multiple doses of novel VLP HPV vaccine products with a turbo-charged aluminium adjuvant. These vaccine products create antibodies many fold higher than natural infection. We have no idea of the long-term consequences of this globally fast-tracked medical intervention. And the children and parents are not being properly informed of the low risk of papillomavirus (e.g. as admitted by Professor Ian Frazer[17] and the Australian Government National Cervical Screening Program[18]), and the uncertainties of novel VLP HPV vaccines, including that "the mechanism of immunogenicity from a scientific perspective is poorly understood" [19], and "...that there is no evidence of cancers prevented..."[20].

Do you think this is ethical Dr Godlee? Should not parents and children be warned about this?

Dr Godlee, I request that the *BMJ* take urgent action to raise the alarm about questionable international HPV vaccination policy, and that you publish my modified comment on Richard Lehman's *BMJ* Blog, as submitted by me on Sat 17 December 2016 at 10.51 pm (CST) / 12.21 pm (GMT). (See email thread below, and copy attached.)

Sincerely
Elizabeth Hart
https://over-vaccination.net/

References: (Input titles below to find internet links.)


3. *Danish HPV centres flooded by ill girls*. CPHPOST, 1 September 2015 and *Danish health authorities looking into HPV vaccines*. CPHPOST, 13 July 2015. *A Danish program accessible on Youtube reports stories of girls suffering after HPV vaccination*: https://www.youtube.com/watch?v=GO2i­r39hok

4. *HPV vaccine support group concerned at side-effects*. The Irish Times, 22 May 2015, and *CASE STUDIES: Concerns over cervical cancer vaccine in Ireland*. Irish Examiner, 16 July 2015, and *Court told
of ‘horrendous adverse effects’ of HPV vaccine. Fiona Kirby claims her daughter needs permanent care after receiving Gardasil. The Irish Times, 2 November 2015, and Mother: Gardasil disabled my child. Irish Examiner, 3 November 2015.

5. Thousands of teenage girls report feeling seriously ill after routine school cancer vaccination. The Independent, 15 July 2015, and 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. UK Daily Mail, 2/3 June 2015 and Two thousand schoolgirls suffer suspected ill-effects from cervical cancer vaccine. UK Telegraph, 12 September 2009.

6. Holyrood to consider safety of HPV vaccine. The Scotsman, 27 October 2015, and Campaigners: Schoolgirls should stop being given HPV vaccine until effects are investigated. Evening Times, 28 October 2015, and Schoolgirls should stop being given HPV vaccine until investigation into side effects, campaigner says. The Herald Scotland, 28 October 2015. Also see Freda Birrell’s presentation to the Scottish Petitions Committee on the subject of HPV vaccination safety, accessible on the SaneVax website: http://sanevax.org/hpv-vaccines-freda-birrell-addresses-petitions-committee/

7. Was the HPV Vaccine Responsible for One Girl’s Death? Footage from a show with Katie Couric accessible on Youtube: https://www.youtube.com/watch?v=LNoLeu0fw3Y

8. In 2015 a story titled A wonder drug’s dark side reported on adverse events after HPV vaccination in Canada. The article was taken down from the Toronto Star website after pressure from the medical establishment. (Also see ref. 13.)


11. Gardasil Awareness NZ website.

12. Cochrane Nordic provides links to correspondence on this matter on its Research webpage.

13. A story titled A wonder drug’s dark side reported on adverse events after HPV vaccination in Canada. The article was taken down from the Toronto Star website after pressure from the medical establishment, as detailed in this note from the publisher: https://www.thestar.com/news/2015/02/20/a-note-from-the-publisher.html


15. 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, and HPV Debate: Melinda Messenger sparks row on This Morning as she’s accused of scare-mongering for not giving her daughter the HPV vaccine. The Sun, 14 December 2016, and Melinda Messenger hits back at ‘hostile’ Holly, Phil and This Morning for ‘gagging her during HPV vaccine debate. Mirror, 16 December 2016.


17. Professor Ian Frazer 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.” Ian Frazer. Catch cancer? No thanks, I’d rather have a shot! The Conversation, 10 July 2012.
18. 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".


20. Email response from Professor Diane Harper to Elizabeth Hart, 13 December 2016.

On Wed, Dec 21, 2016 at 10:53 PM, Juliet Dobson <jdobson@bmj.com> wrote:

Dear Elizabeth,

Many thanks for your email. I have had a look through your suggested changes given it some thought. I would prefer that we stick to the text that I sent you on Sat, Dec 17, 2016 at 12:45 AM. This is an edited version of your original comment that has been approved by our lawyer. I would rather not get into any further editing or discussions about this as this is a comment rather than an article. This is an interesting issue that you have raised. We may pursue this further in the future.

If you are agreeable to this then I can publish your comment as soon as I hear back from you.

Thank you also for sending me your competing interests statement.

Best wishes,
Juliet

On 17 December 2016 at 12:21, Elizabeth Hart <eliz.hart25@gmail.com> wrote:

Juliet, thank you for your response.

Re your modifications to my original comment on Richard Lehman's BMJ Blog.

The additional comment from Professor Harper arrived after I forwarded her a copy of an email I sent to Tom Jefferson and Peter Gotzsche (re their EMA complaint re HPV vaccine safety) which included reference to Professor Harper's responses to me. It is important to keep this in context. In this regard, I have added an additional explanatory paragraph, see modified draft below, paragraph highlighted in blue.

As you have requested inclusion of Professor Harper's later response re the efficacy of Cervarix to my original comment on Richard Lehman's BMJ Blog, this will necessitate some rejigging of the original text, see modified draft below.

My inclusion of Professor Harper's later clarification re the efficacy of Cervarix, (as requested by you), is highlighted in orange. I've placed this paragraph in closer proximity to her previous comment about one dose of Cervarix and efficacy.

To support Professor Harper's comment "that there is no evidence of cancers prevented", I have quoted a Lancet commentary, see my additional paragraph highlighted in mauve.

I've also made some minor amendments, and moved a couple of sentences, see highlights in grey.
Re your suggestion that the sentence "Were three doses of HPV vaccines suggested to justify the cost of these vaccine products?" be deleted (highlighted in pink). I think this is a fair question and I would prefer the question remains. However, if your lawyer insists it must be removed, take it out.

I've also updated the list of references and included The Lancet commentary details.

In regard to your query if I have any competing interests to declare:

I am independent citizen investigating and challenging the over-use of vaccine products. I am not associated with or funded by any vaccine manufacturer.

This statement can be included to clarify my position.

Can you please advise if my rewording of my original comment, incorporating the later response from Diane Harper at your request, meets with your and your lawyer's approval?

I would also appreciate it if you would advise me when the comment is posted.

Also, I have added the previous email thread of correspondence about this matter to this response. The general continuity of this email exchange with you and Fiona Godlee is important for my records and I request that you maintain this.

Please see modified draft below.

Thanks
Elizabeth Hart
https://over-vaccination.net/

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." (Email from Diane Harper dated 11 December 2016.)

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.

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

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 as well and has proven efficacy", another study re Cervarix, published in 2013[2] 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[3] which also indicates there is no evidence to support the three dose Cervarix HPV vaccine regimen.

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/research-highlights)

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".[4]

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 that 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 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:

On Sat, Dec 17, 2016 at 12:45 AM, Juliet Dobson <jDOBSON@BMJ.com> wrote:
Dear Elizabeth,

Many thanks for sending me the correspondence to accompany your blog comment. I have discussed it with our lawyer and we have made two changes.

1. To add in an extra paragraph from Prof Harper's email to you as it seems significant to her. I've highlighted the extra text below in yellow.

2. Take out the sentence highlighted in red.

Before I publish the comment, I wanted to check with you whether you have any competing interests to declare?

Best wishes,
Juliet

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."

She later added "my comment Cervarix has proven efficacy in a single dose against incident HPV infection and incident CIN 3 -- 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 that gardasil9 is being touted to prevent in boys." [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:
2. Email response from Diane Harper, 11 December 2016.

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From: Juliet Dobson <jdobson@bmj.com>
Date: Thu, Dec 15, 2016 at 8:02 PM
Subject: Re: Richard Lehman's Blog and reference to "Two is as good as three for HPV"
To: Elizabeth Hart <eliz.hart25@gmail.com>
Cc: Fiona Godlee <fgodlee@bmj.com>
Dear Elizabeth Hart,

I am in the process of looking through your comment to Richard Lehman's blog. Please could you send on a copy of the email correspondence from Prof Harper that you refer to in your comment.

Best wishes,
Juliet

On 15 December 2016 at 06:39, Elizabeth Hart <eliz.hart25@gmail.com> wrote:

Dr Godlee, further to my submitted comment on Richard Lehman's BMJ Blog, in particular the section titled Two is as good as three for HPV, in which Richard Lehman appears to endorse this "human experiment on a large scale": http://blogs.bmj.com/bmj/2016/12/05/richard-lehmans-journal-review-5-december-2016/

As mentioned in my previous email, 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, including in Richard Lehman's BMJ Blog. 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.” (My emphasis.)

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.

Sincerely
Elizabeth Hart
https://over-vaccination.net/

References:
1. Ian Frazer. Catch cancer? No thanks, I’d rather have a shot! The Conversation, 10 July 2012.
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: http://www.frp.edu.au/module4/activity1.html

On Thu, Dec 15, 2016 at 12:28 AM, Fiona Godlee <fgodlee@bmj.com> wrote:

Dear Elizabeth Hart.

All comments are moderated and some take longer to post than others. Nor do we post all comments. Juliet Dobson is in the process of
checking your post. I expect she may need to come back to you with some queries. Further emails from you in the meantime will not help matters. Best wishes, Fiona Godlee

Dr Fiona Godlee FRCP
Editor in Chief, The BMJ

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On 14 December 2016 at 11:47, Elizabeth Hart <eliz.hart25@gmail.com> wrote:
Dr Godlee, my comment still does not appear to have been posted on Richard Lehman's blog.

A comment has been published recently on behalf of Peter Götzsche, but mine still isn't up there.

I can see my comment sitting in my Disqus account, so why is there a problem in publishing it?

Regards
Elizabeth Hart

On Wed, Dec 14, 2016 at 8:01 PM, Fiona Godlee <fgodlee@bmj.com> wrote:
Juliet Dobson is working on this and is copied in. Best wishes. Fiona

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On 14 Dec 2016, at 9:12 am, Elizabeth Hart <eliz.hart25@gmail.com> wrote:

Dr Godlee, I did post a comment on the blog, content largely as in my email to you, but it has not yet been published.
Regards
Elizabeth Hart
On Wed, Dec 14, 2016 at 6:50 PM, Fiona Godlee <fgodlee@bmj.com> wrote:

Dear Dr Hart. Many thanks for your message. If you haven't already done so, please do send a rapid response to the blog. Our letters editor Sharon Davies will be able to provide any guidance if needed. We can then see how best to pick this up elsewhere in the journal. All best wishes. Fiona Godlee

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On 14 Dec 2016, at 5:28 am, Elizabeth Hart <eliz.hart25@gmail.com> wrote:

Dr Godlee,

In his Blog (5 Dec 2016), Richard Lehman comments on a HPV vaccine study which indicates a 2 dose regimen of the 9-Valent HPV vaccine may be non-inferior to a 3 dose regimen. See blog section titled "Two is as good as three for HPV".

For years now, 3 doses of the various HPV vaccines have been pushed in the community. Richard Lehman appears to endorse this "human experiment on a large scale".

I find it remarkable that a novel medical intervention can be fast-tracked globally, without evidence to support the intervention, i.e. three doses of HPV vaccine.

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 that 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?

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

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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.

Elizabeth Hart

https://over-vaccination.net/

References:


2. Email response from Diane Harper, 11 December 2016.


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