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HPV vaccination and ethics - an email to Dr Richard Lehman, re BMJ Blog Richard Lehman's weekly review of medical journals

Elizabeth Hart <eliz.hart25@gmail.com>

Tue, Jan 31, 2017 at 4:42 PM

To: Tom Jefferson <jefferson.tom@gmail.com>, Peter Gøtzsche <pcg@cochrane.dk>, 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, re my ongoing emails re HPV vaccination, please see below FYI.

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

----- Forwarded message -----

From: **Elizabeth Hart** <eliz.hart25@gmail.com>

Date: Tue, Jan 31, 2017 at 4:34 PM

Subject: HPV vaccination and ethics - an email to Dr Richard Lehman, re BMJ Blog Richard Lehman's weekly review of medical journals

To: edgar.lehman@btopenworld.com

Cc: Fiona Godlee <fgodlee@bmj.com>, Juliet Dobson <jdobson@bmj.com>, Sharon Davies <sdavies@bmj.com>

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 evaluation 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?

Please note I am forwarding this email to other parties, including people associated with the Cochrane Nordic complaint to the European Medicines Agency (EMA) over maladministration at the EMA in regards to the safety of

HPV vaccines. I am keeping a record of my correspondence on this matter on my webpage: **Cochrane Nordic and HPV vaccine safety**: <https://over-vaccination.net/cochrane-collaboration/>

Sincerely

Elizabeth Hart

<https://over-vaccination.net/>

Attachment: Human papillomavirus (HPV) vaccination and Cervical Cancer: Addressing the myths. Factsheet for Professionals. Public Health England.

References: (Hyperlinks to my emails listed below can be accessed on my webpage: **Cochrane Nordic and HPV vaccine safety**: <https://over-vaccination.net/cochrane-collaboration/>)

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/publications/hpv-vaccination-and-cervical-cancer-addressing-the-myths>
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 Gøtzsche (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.

 **PHE_HPV_School_Nurse_A4_factsheet_1.pdf**
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