

14th March, 2018

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Norman Lamb, MP
Chair,
UK Government's Parliament Science and Technology Committee,
Houses of Parliament.

Re: Clarification of evidence presented to Parliamentary Science and Technology Committee meeting, Wednesday 7th March 2018, about the UK Flu vaccination programme.

Dear Chair,

We are writing to you about the evidence presented to the Parliamentary Science and Technology Committee meeting on Wednesday 7th March 2018 (Meeting started at 9.29am, ended 11.20am) about the UK Flu vaccination programme.

We independently reviewed the session on the Parliamentlive.tv and could not find evidence-based answers to a number of questions your Committee put to the panel. We think the Government, the public and health professionals require better informing.

We set out each of these questions in response to the committee's questions (see appendix) and the expert panel's responses.

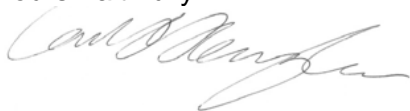
Questions:

1. How many people die each year with a clinical diagnosis of influenza-like illness and with a positive test for influenza?
2. How many people are admitted to hospital each year with a clinical diagnosis of influenza-like illness and with a positive test for influenza?
3. What is the maximum contribution influenza vaccination in >60 could make in reducing annual mortality?
4. What high quality evidence is there that adjuvanted vaccines reduce laboratory proven influenza, lower respiratory tract infection, hospitalisation and deaths in the elderly?
5. What is the evidence that mandatory vaccination for healthcare workers reduces (laboratory proven) influenza, lower respiratory tract infection, hospitalisation and deaths in at-risk patient groups?

We believe answers based on facts and not models, projections, opinions or estimates should be presented to the Committee. We expect the same standard. If the panel cannot provide data for the current season, they should provide data for the previous seasons and update the series with the current period data when it is available.

We consider the government should seek to set out the answers to these five question to reduce uncertainty and better inform the vaccination program.

Yours Faithfully

A handwritten signature in black ink, appearing to read 'Carl Heneghan'.

Carl Heneghan BM, BCh, MA, MRCGP DPhil (Oxon)
Professor of Evidence-Based Medicine

A handwritten signature in black ink, appearing to read 'Tom Jefferson'.

Tom Jefferson
Associate Tutor

Centre for Evidence-Based Medicine, University of Oxford

Conflict of interest

Professor Heneghan has received expenses and fees for his media work. He has received expenses from the WHO, FDA, and holds grant funding from the NIHR, the NIHR School of Primary Care Research, The Wellcome Trust and the WHO. He has received financial remuneration from an asbestos case. He has also received income from the publication of a series of toolkit books published by Blackwells. He receives expenses for teaching EBM and is also paid for his GP work in NHS out of hours. CEBM jointly runs the EvidenceLive Conference with the BMJ and the Overdiagnosis Conference with some international partners which are based on a non-profit making model.

Professor Heneghan and Dr Jefferson were co-recipients of a UK National Institute for Health Research grant for a Cochrane review of neuraminidase inhibitors for influenza and were holders of a Cochrane Methods Innovations Fund grant to develop guidance on the use of regulatory data in Cochrane reviews.

In addition, Dr Jefferson receives royalties from his books published by Il Pensiero Scientifico Editore, Rome and Blackwells. Dr Jefferson is occasionally interviewed by market research companies about phase I or II pharmaceutical products. In 2011-13, Dr Jefferson acted as an expert witness in litigation related to the antiviral oseltamivir, in two litigation cases on potential vaccine-related damage and in a labour case on influenza vaccines in healthcare workers in Canada. He has acted as a consultant for Roche (1997-99), GSK (2001-2), Sanofi-Synthelabo (2003), and IMS Health (2013). In 2014 he was retained as a scientific adviser to a legal team acting on oseltamivir. Dr Jefferson has a potential financial conflict of interest in the drug oseltamivir. In 2014-16, Dr Jefferson was a member of three advisory boards for Boehringer Ingelheim. Dr Jefferson was a member of an independent data monitoring committee for a Sanofi Pasteur clinical trial on an influenza vaccine. Between 1994 and 2013, Dr Jefferson was the coordinator of the Cochrane Vaccines Field. Dr Jefferson is co-holder of a John and Laura Arnold Foundation grant for development of a RIAT support centre (2017-2020) and Jean Monnet Network Grant, 2017-2020 for The Jean Monnet Health Law and Policy Network. Dr Jefferson is undertaking a technology assessment of the NeuroAD device for its manufacturer, Neuronix Ltd.

Appendix

1. How many people die each year with a clinical diagnosis of influenza-like illness and with a positive test for influenza?
2. How many people are admitted to hospital each year with a clinical diagnosis of influenza-like illness and with a positive test for influenza?
3. What is the maximum contribution influenza vaccination in >60 could make in reducing annual mortality?

Committee question and expert panel comment:

Committee: A certain number of people die each year from flu do we have any data on the death rate? This season compared to previous seasons? (Time: 9.43)

Panel: *We monitor the mortality on a week to week period and compare that to previous average estimates to calculate the excess mortality...*

4. What high quality evidence is there adjuvanted vaccines reduce laboratory proven influenza, lower respiratory tract infection, hospitalisation and deaths in the elderly?

Committee question and expert panel comment:

Panel: *Adjuvants increase the elderly immune response (9.39)*

Absolute importance of moving to the adjuvant advice of the adjuvants for the elderly in order so we do not miss an opportunity for next season.... From October we will see a much greater use of adjuvant vaccines in the elderly. (9.48)

The issue between quadrivalent and trivalent in elderly people is almost a red herring compared to the new factor of the addition of adjuvant, which is an absolute game changer in terms of how the elderly immune response works in relation to a vaccine (10.10)....

Committee: *therefore we have the potential to see significant death in flu in elderly people?*

Indeed... my understanding the modelling data suggests that we will see a very significant reduction in the elderly consulting with influenza and being hospitalized next winter as a result of using adjuvant vaccines.

Panel: *Is it proven do we need to reflect on the data?*

Committee: *There are some studies from other countries - we'd, therefore, expect to see a 20% improvement in vaccine effectiveness.... We know it works and the trial data shows it works*

Some of the data that we have used to move to the adjuvanted vaccines comes from studies and experiments performed in Italy - has there been a national program of use of adjuvants vaccines in Italy. (10.17)

Question 5. What is the evidence that mandatory vaccination for healthcare workers reduces Laboratory proven influenza, lower respiratory tract infection, hospitalisation and deaths in at risk groups?

Committee question and expert panel comment:

Committee: *Do you think there should be a mandatory vaccination for healthcare workers? (11.01)*

Panel: *this year the figure is approaching 70 % of HCWs are vaccinated, and this will be the highest year ever - a success story in terms of those rates going up - ensure that staff have the opportunity to be vaccinated -*

It is a professional duty and obligation for HCWS to be vaccinated and to be protected - it is reflected in Good Medical Practice and guidance - and present a duty on HCWs to be vaccinated

Committee: Is mandatory vaccination under consideration?

Panel: All HCW, social care workers should be vaccinated - protects them, reduces sickness cases and risk of passing onto patients when subclinical infection occurs,...

Committee: One would imagine that here is a stronger case to have the jab in nursing care homes than in a hospital?

Panel: *The case is stronger*