Rt Honourable Sarah Wollaston, MP

21/10/2014

NICE should be independently investigated in relation to its systems designed to deal with conflicts of interest of its Guideline Development Group Panels

Dear Sarah,

We write to you as the Chair of the Health Select Committee to seek the Committee's views on what we believe are serious shortcomings in the National Institute of Health and Care Excellence's evaluation processes, which has resulted in the recommendation to offer statin medications to those at low risk of cardiovascular disease. We have particular concerns in relation to the management of conflicts of interest of the Guideline Development Group panels, and apparent systemic weaknesses which the Institute appears to have no appetite to address. We are concerned that the system of recruitment, appointment and the monitoring of conflicts of interest of Panels is not fit for purpose.

We feel that Professor David Haslam has failed to adequately address crucial points from a letter previously written by a number of us on the subject of the medicalisation of 5 million healthy individuals, potential conflicts of interest, industry bias, hidden data and loss of professional confidence. Professor Haslam's letter is attached.

The medicalisation of 5 million healthy individuals

Professor Haslam mentions that "the [NICE] independent guideline group has carefully considered benefits and harms (of statins) in a systematic way with modelling to explore areas of uncertainty" and that the group was able to reach the conclusion that the "benefits outweigh the harms and that statins are clinically and cost effective for people with a CV risk of 10% or over".

He says that the "potential sizeable increase in the number of people who might take statins as a result of this guidance [that] the potential costs to the NHS may be lower than in 2012 due to a reduction in their price".

However, a paper published in the BMJ which underwent further analysis – both groups being independent of industry conflicts, concludes that statins do not reduce overall mortality or serious illness in those with a 10% risk of CVD.[1] We therefore find it unhelpful that NICE's director of clinical practice, Professor Mark Baker uses such emotive language when describing the benefits of statins, conflating the effects of heart disease as a condition which "kills, maims and destroys lives" in the same context as prescribing statins to those at low risk. In our view, this could be perceived as scaremongering and persuading people to take statins when the evidence does not clearly support this statement. The public might expect better from NICE.

Potential conflicts of interests

He states that he is "very concerned that (NICE) guidance should carry the support of the professions" but appears to have not acknowledged the views of representative organisations of UK Doctors –namely the British Medical Association and the Conference of Local Medical Committees, both in terms of grave concerns in regards to access to the raw data and perhaps more importantly conflicts of interest within NICE's guideline development groups.

We continue to be concerned about the 'independence' of this guideline group in particular where 8 of 12 members had direct financial ties to the companies that manufacture statins. Indeed paradoxically disclosure of a conflict can increase the bias in advice, because it may expose advisors to "moral hazard", feeling licenced and strategically encouraged to emphasise their advice even further. As a result, disclosure may fail to solve the problems created by conflicts of interest and may sometimes even make matters worse.[2]

Transparency is important but accuracy and objectivity should be the gold standard expected of an independent panel. It has recently come to light that one member withdrew or resigned (it is not clear) from the panel during the period of evaluation due to an issue of conflict of interest. It is not possible to understand from published information or reports in the Press what systems failures may have occurred in this particular case from which lessons might be learned. Indeed there does not appear to be any acknowledgment by NICE that any failure occurred.

The BMA takes the issue of potential conflicts of interest very seriously. At the recent ARM (June 23rd 2014) the following motion was passed with overwhelming support. "*That this meeting believes in any advisory committee of NICE ,when guidance on any drug is issued,..it must be made clear that* ***none*** *of the members must have a financial interest in pharmaceutical companies which manufacture the drug"*

NICE asserts that its panels adhere to the Nolan Standards of Public Life. We believe the system of appointment to panels and the processes employed to manage conflicts of interest are not fit for purpose. Members of the Panel in this case had relationships with organisations which could derive financial benefit from the conclusions that were drawn. We wish to be absolutely clear that we are not accusing any individuals of knowingly acting in a way which fell short of these standards. However we believe that there are insufficient governance arrangements and procedures undertaken by NICE to be confident that conflicts of interest can be managed in a way which is consistent with the Nolan Principles.

Hidden Data, industry Bias and Loss of professional confidence

Professor Haslam rightly agrees that "results of all clinical studies should be made publicly available and that he would "prefer not to use data that is subject to access restrictions for commercial reasons" and that "researchers should be able to access anonymised raw trials data" and that NICE is a signatory to the All Trials initiative but then this information appears to be ignored when drawing up the report. This appears entirely contradictory. Furthermore prior to the publication of the final guidance NICE has disappointingly seemed to have ignored the views of the organisation that represents General Practitioners.

The LMC Conference (May 23rd 2014) representing the UK's 40,000 GPs unanimously passed the following motion;

"*in light of the Cochrane review of the effectiveness of antiviral influenza treatments published in April 2014, conference calls upon NICE to refrain from recommending a reduction to the current treatment threshold for primary prevention of cardiovascular disease with statin therapy until this is supported by evidence deriving from complete public disclosure of all clinical trials data"*

This reflected the views of the LMC conference that a number of medications had similarly been recommended in the past by NICE, and subsequently been removed from guidance or even withdrawn altogether over safety concerns when further research data had become available. This is particularly pertinent to mass prescription of statins where enormous uncertainty exists about the nature and extent of statins side effects because of a systemic lack of transparency.

We respectfully feel that NICE has failed in its very purpose to act in accordance with independence both in terms of the data in regards to statins and also to be freed from conflicts of interest.

We believe that NICE has an important role to play but that it is vital that it carries the confidence of the public and profession. We believe that there are a number of ways in which systems could be strengthened to increase transparency and to minimise the possibility of conflicts of interest. This might include the selection of an independent clinical guidelines panel who could call upon witnesses to promote a greater understanding of the difference in views and the evidence behind this. We also believe that a broader approach must be taken, for matters which have societal implications to include assessing public opinion when recommending treating healthy individuals who do not have diseases. We feel it is important that NICE no longer recruits and appoints panels from specific interested nominated parties and that the decisions of these more independent panels can be challenged and subsequently modified by a system of independent arbitration where appropriate.

We thus think it would be helpful if NICE were to be investigated by an independent parliamentary body. We therefore recommend that the **Health Select Committee** consider addressing this matter as a matter of urgency.

Yours Sincerely

Professor Klim McPherson, Chair UK Health Forum,

Dr Kailash Chand OBE, Deputy Chair BMA Council

Lord Ian Mccoll of Dulwich, CBE

Dr Clare Gerada, GP, Past Chair , RCGP

Professor David Haslam, Chair, National Obesity Forum

Dr JS Bamrah, Consultant Psychiatrist, BMA Council member

Professor Simon Capewell, Professor of Clinical Epidemiology, University of Liverpool

Dr Simon Poole, GP

Dr Malcolm Kendrick, GP

Dr Aseem Malhotra, London Cardiologist

Professor David Newman, Associate Professor of Emergency Medicine and director of clinical research Icahn School of medicine, Mt Sinai, New York, USA

1. Abramson John D, Rosenberg Harriet G, Jewell Nicholas, Wright James M. Should people at low risk of cardiovascular disease take a statin? BMJ 2013; 347:f6123

2. http://www.cbdr.cmu.edu/mpapers/CainLoewensteinMoore2005.pdf