

## Familial Hypercholesterolaemia Committee meeting

**Date:** 05/09/2016

**Location:** Manchester

**Minutes:** Final

<b>Committee members present:</b>	
Steve Pilling (Chair) (SP)	Section 1- 5
Praveen Ali (PA)	Section 1- 4
Jim Gray (JG)	Section 1- 5
Jo Josh (JJ)	Section 1- 5
Grace Marsden (GM)	Section 1- 5
Julian Treadwell (JT)	Section 1- 5
Simon Corbett (Condition Specific) (SC)	Section 1- 5
Tarek Antonios (Condition Specific) (TA)	Section 1- 5
Nazish Khan (Condition Specific) (NK)	Section 1- 5
Jean MacLeod (Condition Specific) (JM)	Section 1- 5
Steve Forster (Topic Expert) (SF)	Section 1- 5
Lisa Gritzmacher (Topic Expert) (LG)	Section 1- 5
Steve Humphries (Topic Expert) (SH)	Section 1- 5
Nadeem Qureshi (Topic Expert) (NQ)	Section 1- 5
Robert McNabb (Topic Expert) (RM)	Section 1-5
Uma Ramaswami (Topic Expert) (UR)	Section 1- 5

<b>In attendance:</b>		
Phil Alderson (PA)	Clinical Advisor – NICE	Section 1- 5
Sara Buckner (SB)	Technical Analyst – NICE	Section 1- 3
Paul Crosland (PC)	Health Economist – NICE	Section 1- 5
Rebecca Parsons (RP)	Project Manager - NICE	Section 1- 5
Adam Storrow (AS)	Resource Impact Lead – NICE	Section 2- 5

<b>Observers:</b>		
Martin Domanski	Project Manager – NICE	Section 1 – 5
Jess Fielding	Public Involvement Advisor – NICE	Section 1-5

**Apologies:**

None

**1. Welcome and induction**

The Chair welcomed the Committee members and attendees to the second meeting on Familial Hypercholesterolaemia (FH). The Committee members and attendees introduced themselves. The committee and NICE team introduced themselves.

**1. Welcome and objectives for the meeting**

The meeting was opened to the public. The committee and NICE team introduced themselves.

The Chair welcomed the members of the public to the meeting. The members of the public had been briefed already, both verbally and in writing by the NICE team, and the Chair reminded them of the protocol for members of the public, whose role is to observe (they should not speak or ask questions). No filming or recording of the meeting is permitted. The Chair reminded all present that the Committee is independent and advisory, that its decisions and recommendations to NICE do not represent final NICE guidance, and that they may be changed as a result of public consultation.

The Chair informed the Committee that no apologies had been received.

The Chair outlined the objectives of the meeting:

- To recap the clinical evidence and cost-effectiveness for FH part 1
- Introduction to the new review protocols for FH part 2
- Economic evidence presentation

**2. Confirmation of matter under discussion, and declarations of interest**

The Chair confirmed that, for the purpose of managing conflicts of interest, the matter under discussion for FH part 1 was the clinical and cost-effectiveness of using the following strategies for identifying people with FH through:

- Primary care electronic databases to identify people with
  - a. history of early myocardial infarction (MI) (<60 years) and hypercholesterolemia
  - b. family history of ischemic heart disease and hypercholesterolemia or;
- Secondary care electronic databases
  - a. within cardiac care facilities or cardiac investigation units to identify people with history of early MI (<60 years) and hypercholesterolemia or
  - b. within pathology departments to identify people through pathology databases with history of early MI (<60 years) and hypercholesterolemia

- Direct and Indirect cascade testing (including reverse cascade testing)

The matters under discussion for FH part 2 were:

In adults and children with suspected FH, what is the clinical and cost effectiveness of the following tests to diagnose FH:

- Biochemical assays
- Clinical signs and symptoms
- DNA testing
- Combinations and/or sequences of the above

What is the clinical and cost effectiveness in improving outcome in individuals with FH of the following monotherapy:

- Statins versus placebo

Name	Job title, organisation	Declarations of Interest, date declared	Classification of interest	Decision taken
<b>Condition specific standing members</b>				
Tarek Antonios	Senior Lecturer and Consultant Physician, St George's University Hospital NHS Foundation Trust	None <b>Declared - 29/03/16</b>	Not applicable	Declare and Participate
Simon Corbett	Consultant Cardiologist, University Hospital Southampton	Network Service Adviser for the British Cardiovascular Society. This role incorporates the regional specialty adviser role for the Royal College of Physicians. No expenses are paid <b>Declared - 21/05/14</b>	Personal Non-financial Non-specific	Declare and Participate
Simon Corbett	Consultant Cardiologist, University Hospital Southampton	Director for Clinical Effectiveness for employer (University Hospital Southampton NHS Foundation Trust). Part of this role involves the dissemination and implementation of NICE guidance in the Trust. <b>Declared - 21/05/14</b>	Personal Non-financial Non-specific	Declare and Participate

Simon Corbett	Consultant Cardiologist, University Hospital Southampton	Independent cardiologist on the Trial Steering Committee of the randomised controlled AVATAR trial, a randomised trial of medical therapy vs ablation in patients with atrial fibrillation. The study is sponsored by Imperial College London and is part funded by Medtronic. Travel expenses are paid by Imperial.  <b>Declared - 02/04/14</b>	Personal Non-financial Non-specific	Declare and Participate
Simon Corbett	Consultant Cardiologist, University Hospital Southampton	Elected to the British Cardiovascular Society's Guidelines and Practice committee. The remit of this committee is to review, and where felt appropriate, endorse guidelines and to consider and respond to issues relating to the professional clinical practice of Society members.  <b>Declared - 25/05/16</b>	Personal Non-financial Non-specific	Declare and Participate
Nazish Khan	Principal Pharmacist Cardiac Services , Royal Wolverhampton Hospital	Contributed to an advisory board hosted by Astra Zeneca (unpaid).No expenses paid  <b>Declared - 25/03/16</b>	Personal Non-financial Non-specific	Declare and Participate
Jean MacLeod	Consultant Physician in Diabetes and General Medicine, University Hospital of North Tees	Honoraria received from pharmaceutical company for delivering educational sessions to GPs in Sept 15 from Johnson & Johnson  <b>Declared - 28/03/16</b>	Personal Financial Non-specific	Declare and Participate
Robert McNabb	Condition Specific Lay Member	Member of all Wales Cardiac Rehabilitation & Heart Failure Working Group  <b>Declared - 31/03/16</b>	Personal Non-financial Non-specific	Declare and Participate

Robert McNabb	Condition Specific Lay Member	Member of British Heart Foundation and Cancer Research UK Patient Data Reference Panel  <b>Declared - 31/03/16</b>	Personal Non-financial Non-specific	Declare and Participate
Robert McNabb	Condition Specific Lay Member	Member of MHRA UK Stakeholder Platform for Reclassification of Non-Prescription Drugs  <b>Declared - 31/03/16</b>	Personal Non-financial Non-specific	Declare and Participate
Robert McNabb	Condition Specific Lay Member	Member of MHRA Patient Group Consultative Forum  <b>Declared - 31/03/16</b>	Personal Non-financial Non-specific	Declare and Participate
Robert McNabb	Condition Specific Lay Member	Daughter & son-in-law are NHS doctors  <b>Declared - 27/05/16</b>	Personal Non-financial Non-specific	Declare and Participate
Robert McNabb	Condition Specific Lay Member	Member of the Advisory Group for the REGenableMED research project looking at the regenerative medicine and medical innovation. As ESRC-funded project based at the University of York  <b>Declared - 27/05/16</b>	Personal Non-financial Non-specific	Declare and Participate
<b>Topic expert members</b>				
Steve Forster	Lay member	Contributed to FH Awareness Raising Film sponsored by Amgen – Message From the Heart. Received small payment for contribution  <b>Declared – 25/01/16</b>	Personal Financial Non-specific	Declare and Participate

Steve Forster	Lay member	I received expenses and payment for attending a NICE Appraisal committee for Evolocumab (20th October 2015)  <b>Declared – 26/02/16</b>	Personal Financial Non-specific	Declare and Participate
Lisa Gritzmacher	Nurse Specialist, Bristol Royal Infirmary	Since May 15 I provide teaching sessions to primary care regarding FH and our service. Merck Sharp & Dohme Limited MSD) is providing administrative support for my meetings. However, they have no influence over the session content and I am not getting any payment from them for this  <b>Declared – 12/02/16</b>	Personal Non-financial Non-specific	Declare and Participate
Lisa Gritzmacher	Nurse Specialist, Bristol Royal Infirmary	I have attended conference as an attendee as part of my learning and development in my role as a British Heart Foundation (BHF) funded FH nurse so their content included information about and related to FH ( HEART UK 16/09/15 to 18/09/15)  <b>Declared – 26/02/16</b>	Personal Non-financial Specific	Declare and Participate
Lisa Gritzmacher	Nurse Specialist, Bristol Royal Infirmary	I have presented at a conference (BCS,09/06/15) on the BHF day which was related to setting up my FH service. Travel costs only were paid by the BHF  <b>Declared – 26/02/16</b>	Personal Financial Specific	Declare and Participate

Lisa Gritzmacher	Nurse Specialist, Bristol Royal Infirmary	I have presented a poster at HEART UK conference about VUS testing. I did win the runner up prize for the poster. VUS testing is different to cascade screening so it isn't directly to do with the review questions, but when we test people for FH sometimes we find gene alterations that we don't know enough about to classify them as either FH or not, so we call these variants of unknown significance (VUS).		
Steve Humphries	Emeritus Professor Cardiovascular Genetics, University College London School of Medicine	I have published 10 papers on FH over the last year and have an additional 3 in press and 5 that will be submitted in the next year.  <b>Declared – 21/01/16</b>	Personal Non-financial Specific	Declare and Participate in agenda items relating to presentation and discussion of the evidence, Exclude from participation in the discussion of the authored paper for recommendation development.
Steve Humphries	Emeritus Professor Cardiovascular Genetics, University College London School of Medicine	I am the Director of the Royal College of Physicians' Paediatric FH Register which started data collection in late 2012 and now has >350 registered patients. Current funding is from the BHF till August 2016. I have recently submitted a grant for continued funding to the International Atherosclerosis Society who are using funds from Pfizer to support this activity.  <b>Declared – 21/01/16</b>	Non-personal Financial Specific	Declare and Participate

Steve Humphries	Emeritus Professor Cardiovascular Genetics, University College London School of Medicine	<p>I am the co-author of the 2013, 2014 and 2015 European Atherosclerosis Society (EAS) guidelines Development Group for management and treatment of FH in adults and children These reviews was supported by unrestricted educational grants to the EAS from Amgen, Aegerion, AstraZeneca, Genzyme, Hoffman-La Roche, Kowa Europe, Novartis, and Sanofi-Aventis/Regeneron. These companies were not present at the Consensus Panel meetings, had no role in the design or content of the Consensus Statement, and had no right to approve or disapprove the final document.</p> <p>Costs for my travel to the EAS panel meetings were covered by the Society</p> <p><b>Declared – 21/01/16</b></p>	Personal Financial Specific	Declare and Participate (Personal costs were for travel / accommodation only)
Steve Humphries	Emeritus Professor Cardiovascular Genetics, University College London School of Medicine	<p>I am a committee member of the FH implementation group chaired by Prof Huon Grey to direct and monitor the &gt;20 BHF funded FH Nurses (2013-now). Travel expenses paid</p> <p><b>Declared – 21/01/16</b></p>	Personal Financial Specific	Declare and Participate
Steve Humphries	Emeritus Professor Cardiovascular Genetics, University College London School of Medicine	<p>I chair the Steering Committee of the Southampton FH cascade testing implementation group. Travel expenses are paid</p> <p><b>Declared – 21/01/16</b></p>	Personal Financial Specific	Declare and Participate



Steve Humphries	Emeritus Professor Cardiovascular Genetics, University College London School of Medicine	For the last 2 years I have been a committee member of a team convened by HEARTUK to implement electronic note searching in GP practice to identify FH patients. This activity has been sponsored by Sanofi. I received no funding or expenses for this attendance. Sanofi and HEARTUK have as of yesterday agreed to discontinue this activity.  <b>Declared – 09/03/16</b>	Non-personal Non-financial Specific	Declare and Participate
Steve Humphries	Emeritus Professor Cardiovascular Genetics, University College London School of Medicine	In September 2015 I gave a named lecture on FH at the HEARTUK annual conference, and my travel expenses were covered. HEARTUK receives sponsorship from several Pharmaceutical companies (including MSD, Pfizer, Amgen, Sanofi etc)  <b>Declared – 09/03/16</b>	Personal Financial Specific	Declare and Participate (Personal costs were for travel / accommodation only)
Steve Humphries	Emeritus Professor Cardiovascular Genetics, University College London School of Medicine	I attended (December 2015) one meeting of a Panel convened on behalf of Sanofi to discuss implementation of NICE FH guidelines. I received no funding or expenses for this attendance. Given any potential conflict of interest I resigned from this panel in February 2016  <b>Declared – 09/03/16</b>	Personal Non-financial Specific	Declare and Participate

Steve Humphries	Emeritus Professor Cardiovascular Genetics, University College London School of Medicine	I am organising and chairing a session at the HEARTUK conference in Edinburgh this June. The session is sponsored by Alexion. HEARTUK do not cover registration or travel costs of Chairs of such sessions and Alexion have agreed to cover these expenses. I will not be speaking or presenting any data and neither will any Alexion representative  <b>Declared - 08/06/16</b>	Personal Financial Non-specific	Declare and Participate
Nadeem Qureshi	Clinical Professor in Primary Care, University of Nottingham	Undertaking grant funded health service research on identification of familial hypercholesterolaemia and familial cancer in primary care. University has received grant funding for this research.  <b>Declared – 08/02/16</b>	Non-personal Financial Specific	Declare and Participate
Nadeem Qureshi	Clinical Professor in Primary Care, University of Nottingham	Invited to a PCSK9 Education and Research Forum at Amsterdam Schiphol Airport on 22 May 2015. The Forum receives sponsorship from pharmaceutical companies. I paid my own travel but the Forum paid for 1 nights accommodation  <b>Declared - 28/02/16</b>	Personal Financial Specific	Declare and Participate (Personal costs were for travel / accommodation only)
Uma Ramaswami	Consultant Metabolic Paediatrician, Royal Free Hospital	None <b>Declared – 03/02/16</b>	Not applicable	Declare and Participate

### 3. Presentations

The Chair introduced Sara Buckner, Technical Analyst, who gave a recap of the clinical evidence for FH part 1.

SB presented the draft review protocols for FH part 2 during which the new review questions were discussed.

The Committee discussed the review protocols and sought clarification on a number of queries from the NICE team. It was confirmed that the NICE team would send out an email to the Committee requesting comments on the information presented at the meeting.

The Chair then asked Paul Crosland, Health Economist, to present the draft economic plan to the Committee. A confidential paper co-authored by Steve Humphries (SH) was circulated to the Committee to review.

#### **4. Next steps and any other business**

Rebecca Parsons (RP) advised the Committee on the next phase key dates for the update. The Chair summarised the day and thanked the Committee for their contribution to the meeting.

**Date of next meeting:** 29 and 30 November 2016

**Location of next meeting:** NICE Manchester Office