

Familial Hypercholesterolaemia Committee meeting

Date: 10/06/2016

Location: London

Minutes: Agreed

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

In attendance:		
Sara Buckner (SB)	Technical Analyst – NICE	Section 1- 4
Paul Crosland (PC)	Health Economist – NICE	Section 1- 4
Hugh McGuire (HM)	Technical Advisor – NICE	Section 1- 4
Clifford Middleton (CM)	Guideline Commissioning Manager - NICE	Section 1- 4
Ian Pye (IP)	Project Manager – NICE	Section 1- 4
Lorraine Taylor (LT)	Associate Director - NICE	Section 1- 4

Observers:		
Alison Lloyd	Technical Analyst – NICE	Section 1 - 4

Apologies:

Praveen Ali

Standing committee member

1. Welcome and induction

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

The Chair introduced LT who gave a short induction presentation. The committee members asked a number of process questions for clarification.

1. Welcome and objectives for the meeting

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

Four members of the public observed the meeting. 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 apologies had been received. These are noted above.

The Chair outlined the objectives of the meeting, which included discussing the clinical and cost-effectiveness of using the following strategies for identifying people with Familial Hypercholesterolaemia 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)

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

Name	Job title, organisation	Declarations of Interest, date declared	Classification of interest	Decision taken
Condition specific standing members				
Simon Corbett	Consultant Cardiologist	Network Service Adviser for the British Cardiovascular Society. This role incorporates the regional specialty adviser role for the Royal College of Physicians. Declared – 21/05/14	Personal Non-financial Non specific	Declare and participate
Simon Corbett	Consultant Cardiologist	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. Declared – 21/05/14	Personal Non-financial Non-specific	Declare and participate
Simon Corbett	Consultant Cardiologist	Independent cardiologist on the Trial Steering Committee of the randomised controlled AVATAR trial, a	Personal Non-financial Non specific	Declare and participate

		<p>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.</p> <p>Declared – 02/04/15</p>		
Simon Corbett	Consultant Cardiologist	<p>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.</p> <p>Declared – 25/05/16</p>	<p>Personal Non-financial Non specific</p>	Declare and participate
Nazish Khan	Clinical Professor in Primary Care	<p>Contributed to an advisory board hosted by Astra Zeneca (unpaid)</p> <p>Declared – 25/03/16</p>	<p>Personal Non-financial Non specific</p>	Declare and participate
Jean MacLeod	Consultant Metabolic Paediatrician	<p>Honoraria received from pharmaceutical company for delivering educational sessions to GPs in Sept 15 from Johnson & Johnson</p> <p>Declared – 28/03/16</p>	<p>Personal Financial Non specific</p>	Declare and participate
Topic expert members				
Steve Forster	Lay member	<p>Contributed to FH Awareness Raising Film sponsored by Amgen – Message From the Heart. Received small payment for</p>	<p>Personal Financial Non specific</p>	Declare and participate

		contribution Declared – 25/01/16		
Steve Forster	Lay member	I received expenses and payment for attending a NICE Appraisal committee for Evolocumab (20 th October 2015) Declared – 26/02/16	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 Declared – 12/02/16	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) Declared – 26/02/16	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. Declared – 26/02/16	Personal Non-financial Specific	Declare and participate
Steve Humphries	Emeritus Professor	I have published 10 papers on FH over the	Personal	Declare and participate in

	Cardiovascular Genetics, University College London School of Medicine	last year and have an additional 3 in press and 5 that will be submitted in the next year. Declared – 21/01/16	Non-financial Specific	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. Declared – 21/01/16	Non-personal Financial Specific	Declare and participate
Steve Humphries	Emeritus Professor Cardiovascular Genetics, University College London School of Medicine	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	Personal Financial Specific	Declare and participation (personal costs were for travel only)

		<p>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>Declared – 21/01/16</p>		
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 >20 BHF funded FH Nurses (2013-now)</p> <p>Declared – 21/01/16</p>	Personal Non-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</p> <p>Declared – 21/01/16</p>	Personal Non-financial Specific	Declare and participate
Steve Humphries	Emeritus Professor Cardiovascular Genetics, University College London School of Medicine	<p>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</p>	Non-Personal Non- financial Specific	Declare and participate

		agreed to discontinue this activity. Declared – 09/03/16		
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) Declared – 09/03/16	Personal Financial Specific	Declare and participation (personal costs were for travel 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 Declared – 09/03/16	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	Personal Financial Non-specific	Declare and participate

		Declared 08/06/16		
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. Declared – 08/02/16	Non-personal Financial Specific	Declare and participation
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	Personal Financial Specific	Declare and participation (personal costs were for accommodation only)

As a result of the interests declared the Chair, following advice from the NICE team decided that a Topic Expert may be asked to leave the meeting during some of the formation of recommendations. This will be clarified at the appropriate point if the committee discussion is relevant to the declared interest.

3. Presentations

The Chair introduced SB, Technical Analyst, who gave a brief overview of the topic and an overview of the parameters for the evidence review. SH gave a brief description of FH. The Chair asked the Topic Specific lay member, SF, to give a brief outline of their experience and key issues from a lay perspective. SB asked the Topic Experts some questions for clarification. SB gave a description of the different classification systems used by different countries.

The Chair took questions from the group. There was some discussion about the classification of FH.

SB presented the review protocol for the review question. The Chair asked the topic specific experts to give their views on the review protocol outcomes. SB asked SH to briefly explain the genes that are looked for in genetic testing for FH.

The Committee discussed the evidence and sought clarification to a number of

queries from the NICE team. There was discussion relating to the testing for FH both genetic and clinical. The committee raised questions in relation to the quality of the datasets available. SH highlighted four papers that he felt should have been included within the evidence. SB will check these papers against the review protocol.

The Chair then asked PC, Health Economist, to present the economic plan to the Committee which included a brief induction to health economics and resource impact. PC asked the committee if they felt an economic model should be developed. The Chair invited questions from the committee. The committee discussed and agreed the criteria for the economic model.

The meeting was closed to the public by the Chair and the Committee moved on to drafting recommendations.

SB gave a short presentation on making recommendations. LT gave a short presentation of equality duties and NICE and asked the committee if there are any particular equality issues in relation to this update. The committee discussed issues relating to ethnicity and people whose first language is not English.

SB presented the current recommendations from CG71 for review by the committee. The committee discussed the current recommendations.

4. Next steps and any other business

LT presented the next steps in the process of updating of the guideline. The Chair summarised the day and thanked the Committee for their contribution to the meeting.

Meeting closed at 16:25

Date of next meeting: 5 September 2016

Location of next meeting: NICE Manchester Office