NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard titles

- Cardiovascular risk assessment
- Lipid modification
- Secondary prevention following a myocardial infarction

Date of Quality Standards Advisory Committee post-consultation meeting:
12 May 2015

2 Introduction

The draft quality standards for cardiovascular (CV) risk assessment, lipid modification and secondary prevention following a myocardial infarction (MI) were made available on the NICE website for a 4-week public consultation period between 9 March and 8 April 2015. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standards. General feedback on the quality standards and comments on individual quality statements were accepted.

Comments were received from 16 organisations for CV risk assessment, 13 organisations for lipid modification and 11 organisations for secondary prevention following an MI. Organisations included service providers, national organisations, professional bodies, pharmaceutical companies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate, the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standards have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1–4.

3 Questions for consultation

For each draft quality standard, stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. For each quality statement what do you think could be done to support improvement and help overcome barriers?

Stakeholders were also invited to respond to the following statement-specific questions:

1. For CV risk assessment, draft quality statement 1: To aid feasibility of measurement, which specific contacts with healthcare professionals should be prioritised for performing a full formal risk assessment?

2. For secondary prevention following an MI, draft quality statement 1: Is assessment of left ventricular function happening routinely in practice?

3. For secondary prevention following an MI, draft quality statement 3: Would the definition of a cardiac rehabilitation programme be universally understood?

4. For secondary prevention following an MI, draft quality statement 5: Would the definition of an orientation session be universally understood?

4 CV risk assessment: General comments

The following is a summary of general (non-statement-specific) comments on the CV risk assessment quality standard.

- 2 stakeholders were supportive and considered the statements to be appropriate
- Other stakeholders felt the QS did not reflect the key areas for quality improvement, because it was not useful that risk assessment alone was included, without specifying what should be done in response to high risk
- Stakeholders thought the focus of the QS should be CV disease prevention, rather than a standalone QS for measuring CV risk
- A stakeholder suggested merging the CV risk assessment QS with the lipid modification QS, as both were derived from the same NICE guideline (CG181)
- Stakeholders felt that this QS over-emphasised preventative treatment with statins – other important interventions following risk assessment include lifestyle advice and blood pressure-lowering therapies, which should be referred to in this QS
- Concerns were raised that the emphasis on medication with statins may lead to a low commitment to the QS in primary care.

Consultation comments on data collection

- Stakeholders felt the proposed measures would be achievable by extracting practice-specific patient-anonymised data
- However, some stakeholders felt these measures would not be useful and data collection for risk estimations by GPs is a low priority and a burden on resources.

5 CV risk assessment: Summary of consultation feedback by draft statement

5.1 Draft statement 1

Adults under 85 years with an estimated 10-year risk of cardiovascular disease (CVD) of 10% or more are offered a full formal risk assessment using the QRISK2 assessment tool.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Clarification was requested on the area for quality improvement:
  - are people not estimating CV risk using a systematic strategy?
  - are people not following up with a full formal risk assessment?
  - is QRISK2 not being used as the formal risk assessment tool?
- Stakeholders queried how the initial CV risk estimation would be performed
- A 2-stage risk assessment process is not necessary – a simpler statement could be 'all people under X years are offered formal risk assessment'
- Concerns raised for the 10% threshold, due to lack of resources in primary care and its inappropriateness for some groups (older people or with comorbidities)
- Queries over appropriate age – should all adults under 85 years be included?
  - QRISK2 only validated in 25–84 years
  - formal assessment over 70 years (64 in men) is redundant as all are >10% risk
  - assessment in 18–25 years will be inherently extremely low risk
  - 1 stakeholder queried the 85-year cut-off: significant numbers will live for 10 years beyond age 85 and CV risk should be mitigated regardless of age
- Request for addition of a frequency for risk assessment: annually or every 5 years
- Questions over QRISK2/10-year risk estimation tools by key stakeholders:
  - too age-dependent: people under 50 with obesity, smoking or hypertension have a high lifetime risk, but fall below the 10-year 10% threshold due to age

- JBS3 risk calculator[1] recommended instead, or to use 'QRISK2 or a tool derived from QRISK2'
- inconsistency of this QS with JBS3 may cause confusion and reduce adherence.

Consultation question 4

Stakeholders made the following comments in relation to consultation question 4: *To aid feasibility of measurement, which specific contacts with healthcare professionals should be prioritised for performing a full formal risk assessment?*

- NHS Health Check should be specifically referenced, although the age range selected for these checks (40–74 years) does not match with the QS – would be a good way to increase use of QS and incentivise NHS Health Checks
- A GP register of patients of 10% CVD risk could be created, with an automatic invitation for formal assessment
- A simple method is needed to identify people at risk in the population using age alone, rather than complex methods using multi-risk factor identification
- Consultations with individuals with long-term conditions at a higher risk of CVD: COPD, asthma >40 years, hypertension, non-diabetic hyperglycaemia follow-up, obesity, rheumatology, drug and alcohol misuse, smoking cessation >40 years, weight management, dementia
- Working with alcohol care teams
- CV risk assessment could be performed in community settings other than GP practices to help manage workloads and to reduce potential barriers for those who may prefer not to visit their GP.

[1] Joint British Societies for the prevention of cardiovascular disease: risk calculator 3

5.2 Draft statement 2

Healthcare professionals do not use a tool to assess the risk of cardiovascular disease (CVD) in adults with type 1 diabetes, chronic kidney disease or familial hypercholesterolaemia.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Suggestion to focus the statement on the patient, while making reasons clear for not performing the assessment: ‘Adults with T1D, CKD or FH are considered at high risk of CVD without using a risk assessment tool.’
- A stakeholder supported the statement, but had concerns that the rationale focused on lipid-lowering, rather than blood pressure therapy or stopping smoking
- Another stakeholder thought it implied that all people with T1D, CKD or FH should receive treatment in the same way as all those at high risk, which is not correct
- Some stakeholders thought this statement was not necessary: statement 1 should just state that it does not include this group of patients
- Other groups should be included where 10-year risk tools may underestimate CV risk, such as younger patients with obesity, smoking or high blood pressure
- An organisation highlighted that the focus should not be inappropriate risk assessment in these patients, but inappropriate action following the assessment
- A stakeholder thought risk assessment may be useful for these populations in some instances, to show reduction of risk on stopping smoking or weight loss
- Concerns were raised that collecting data on not performing an assessment was a waste of resources.

6 CV risk assessment: Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Suggestion to combine the risk assessment QS with the lipid modification QS to align with NICE clinical guideline CG181
- A statement on how to identify people with an estimated CV risk >10%
- A statement on appropriate interventions in response to high risk identification:
  - ‘People with a 10-year CVD risk exceeding 10% should be offered lifestyle advice and appropriate management of high blood pressure, chronic kidney disease, diabetes and pre-diabetes, and an informed discussion about the role of statins in reducing cardiovascular risk’
- A statement on patient follow-up following high risk identification
- A statement on screening and treatment for alcohol misuse and dependence, as it is a risk factor for CVD.

7 Lipid modification: General comments

The following is a summary of general (non-statement-specific) comments on the lipid modification quality standard.

- This QS was partially supported by stakeholders, with positive responses to some statements, except for those involving statin therapy
- Concerns were raised regarding statements based on 10-year CVD risk, which was considered to be too complex and disadvantages younger people and women
  - key stakeholders suggested using a lifetime risk tool instead, such as JBS3
- Disagreement among stakeholders regarding when to use statin therapy
- Strong criticism from some stakeholders of the 10% intervention threshold recommended in NICE guideline CG181, which was also not supported
  - significant resource implications for primary care
  - over-medicalisation of people who are not considered ill: the focus should be on simple preventative measures with as little medical intervention as possible
  - may lead to confrontation between doctors and patients
  - unclear benefit to risk of statins, especially for people at lower risk levels
- Suggestion to limit to adults under 85 years for primary prevention
- Request to reference NHS Health Checks throughout this QS

Consultation comments on data collection

- Stakeholders believed data for the measures could be collected, although it may not be desirable and systems and structures were not universally available
- Potential problems due to differing IT systems across primary and secondary care
- Data collection from the National Pathology Database and GP practice data
- A stakeholder thought 100% aspiration is not justified for some statements, as the measures do not contain adequate exception reporting.

8 Lipid modification: Summary of consultation feedback by draft statement

8.1 Draft statement 1

Adults with a 10-year risk of cardiovascular disease (CVD) of 10% or more are assessed for secondary causes of dyslipidaemia before any offer of statin therapy.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Suggestion to focus on adults under 85 newly identified with a 10-year CVD risk
- This statement was not thought appropriate for the chosen population, as many people with a low risker of CVD (such as 10%) will have normal lipid profiles
- Request to specifically refer to NHS Health Check programme
- Suggestion to link to familial cholesterolaemia QS and replace with ‘Adults with total cholesterol above 7.5 mmol/l are assessed for familial hypercholesterolaemia’
- Suggestion to supplement with an additional statement on liver function testing to detect liver disease, which can also increase lipid levels.

8.2 Draft statement 2

Adults with a 10-year risk of cardiovascular disease (CVD) of 10% or more have the benefits of lifestyle changes for primary prevention discussed with them before any offer of statin therapy.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Suggestion to focus on adults under 85 newly identified with a 10-year CVD risk and to remove ‘for primary prevention’, as this is implied by the 10-year risk
- Suggestion to simplified to ‘Adults receive advice on lifestyle changes before any offer of statin therapy’
- This statement was partially supported by some stakeholders, however it was highlighted that many lifestyle changes will not affect the QRISK2 score
- Other stakeholders felt it was not appropriate and statin therapy should be given in conjunction with lifestyle advice, without delaying treatment
- Concerns were raised over the primary care burden given the large numbers of people involved, which may have a detrimental impact on other conditions
- Requests to add a timeframe before the offer of statins to not delay treatment
- Requests to reference NHS Choices for dietary advice and NHS Health Checks.

8.3 Draft statement 3

Adults with a 10-year risk of cardiovascular disease (CVD) of 10% or more for whom lifestyle changes have been ineffective or are inappropriate are offered atorvastatin 20 mg for primary prevention.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Suggestion to focus on adults under 85 newly identified with a 10-year CVD risk and to remove 'for primary prevention' as this is implied by the 10-year risk
- Request for timeframe for how long to wait before lifestyle changes were considered ineffective: 3 months?
- Some stakeholders felt that statins for primary prevention should be offered at the same time as lifestyle advice to not delay treatment, as some lifestyle changes alone will not reduce CV risk
- A stakeholder was strongly opposed to the 10% CV risk threshold for statins
- Concerns were raised that it would encourage high levels of prescribing without discussions with patients, leading to poor quality care
- Request that patients with comorbidities or drug interactions are taken into account, where statins are contraindicated or inappropriate
- Request to reference NHS Health Checks.

8.4 Draft statement 4

Adults with cardiovascular disease (CVD) are offered atorvastatin 80 mg for secondary prevention.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Suggestion to focus on adults newly diagnosed with CVD and to remove 'for secondary prevention', as this is implied by adults with CVD
- A stakeholder was strongly opposed to using atorvastatin 80 mg in this population:
  - too many would have contraindications due to age or other cautions
  - concerns over high dose statins and disorders of glucose metabolism
- Another stakeholder highlighted that not all individuals require 80 mg to achieve a 40% reduction in non-HDL cholesterol and higher doses of statins were more likely to cause side-effects: suggested rewording to 'up to 80 mg of atorvastatin'
- It was noted that atorvastatin 80 mg is not licensed for this indication, which needs to be referenced appropriately, as done so the NICE guideline CG181.

8.5 Draft statement 5

Adults who develop adverse effects on high-intensity statins are offered alternative doses of statins or an alternative statin.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- This statement was supported by some stakeholders
- Suggested rewording to ‘Adults who develop side effects on high-intensity statins are offered a lower dose of statin or an alternative statin’
- Queried whether this statement applies to all statins, or just high-intensity statins
- A clearer definition of high-intensity statins was requested, with specific examples.

8.6 Draft statement 6

Adults on high-intensity statins have a 3-month review after the start of treatment.

Consultation comments

Stakeholders made the following comments in relation to draft statement 6:

- This statement was supported by some stakeholders
- Queried whether this statement applies to all statins, or just high-intensity statins
- A stakeholder requested that the assessment time window was more flexible
- A clearer definition of high-intensity statins was requested, with specific examples
- A stakeholder suggested reviews every 3 months until non-HDL target achieved
- Stakeholders highlighted potential problems with data collection for this statement, as non-HDL cholesterol is not measured by all laboratories.

9 Lipid modification: Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- A statement to support referral to specialist assessment for people who cannot be effectively controlled in primary care on existing treatment.

10 Secondary prevention following an MI: General comments

The following is a summary of general (non-statement-specific) comments on the secondary prevention following an MI quality standard.

- The QS was well received by many stakeholders, who felt it reflected the key areas for quality improvement
- Many statements received a positive response, with stakeholders highlighting that there was current variation in practice and the QS could lead to better quality care
- Concerns were raised regarding the extra resources and finance needed to meet the standard in primary and secondary care, in terms of training, staff, facilities and equipment.

Consultation comments on data collection

- Stakeholders who responded to this consultation question were confident that data could be collected for the proposed structure measures, if systems and structures were available.

11 Secondary prevention following an MI: Summary of consultation feedback by draft statement

11.1 Draft statement 1

Adults admitted to hospital following an MI have an assessment of left ventricular (LV) function.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- This statement was supported by most stakeholders
- Suggestion to reword to ‘adults admitted to hospital with an MI…’
- Stakeholders requested clarification on the type of the assessment needed: bedside echocardiogram, echocardiogram in outpatient department, 2-D echocardiogram, Doppler echocardiogram, LV angiography, cardiac magnetic resonance imaging (MRI), nuclear imaging?
  - suggestion to add ‘using an echocardiogram’.

Consultation question 4

Stakeholders made the following comments in relation to consultation question 4: *Is assessment of left ventricular function happening routinely in practice?*

- Most stakeholders thought LV assessment was happening in the majority of hospitals before hospital discharge and would be easy to measure
- It was highlighted that although LV assessment may be routine, sharing and disseminating of results with relevant services was not
- If hospitals aren’t performing the assessment in a timely manner, this is due to lack of adequately trained staff and/or equipment.

Draft statement 2

Adults leaving hospital following an MI have details of drug titration and blood pressure and renal function monitoring shared with their GP.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Stakeholders agreed that communication with primary care was a key area, but the statement was too broad, which would be difficult to measure
- The 3 areas chosen for this statement are important to be communicated, but are more important for MI treatment rather than secondary prevention. Instead, there were suggestions to include:
  - results of investigations
  - future management plans and advice on secondary prevention
  - monitoring of anti-platelet prescription
- Queries were raised regarding ‘drug titration’: does this mean titration performed in secondary care, titration to be performed by GP, or both?
- A timeframe was requested for how quickly details should be shared
- Queries regarding whether the outcome measure of ‘30-day readmission rates’ is a good measure of quality of communication with primary care.

11.2 Draft statement 3

Adults admitted to hospital following an MI are referred for cardiac rehabilitation while they are in hospital.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Stakeholders supported this statement and thought it would be measurable
- Suggestion to reword to ‘adults admitted to hospital with an MI…’
- Queries regarding whether the outcome measure of ‘incidence of CV events’ is a useful measure of successful cardiac rehabilitation
  - requested a clearer definition of CV events, if included as a measure.

Consultation question 5

Stakeholders made the following comments in relation to consultation question 5: *Would the definition of a cardiac rehabilitation programme be universally understood?*

- Most stakeholders agreed that cardiac rehabilitation would be understood, however, the definition should be simplified without the use of clinical phrases, such as ‘psychosocial health’ and ‘cardioprotective therapies’
- A stakeholder felt that cardiac rehabilitation was perceived to only involve exercise.

11.3 Draft statement 4

Cardiac rehabilitation services provide both daytime and evening programmes in both community and home based settings.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Stakeholders expressed support for this statement and felt this area is under provided, with most programmes taking place in hospitals and during office hours
- A stakeholder highlighted that delivery of home-based, self-managed cardiac rehabilitation with the support of a facilitator is not practiced widely
- Concerns were raised regarding whether this statement would be achievable: stakeholders highlighted that increased financial support would be required, with extra nurses, physiotherapists and psychologists needed to enable coverage out of hours and in the community, as well as the number of facilities
- There was confusion as to whether ‘community settings’ included hospital programmes.

11.4 Draft statement 5

Adults who enrol on a cardiac rehabilitation programme following an MI have an orientation session within 10 days of their discharge from hospital.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- This statement was well received, as early follow-up and post-discharge support was considered important and in need of quality improvement
- Concerns were raised that the 10-day window was too short from a patient's perspective if they have to attend an outpatient clinic. Suggestions to make this more achievable for patients and clinicians included specifying 'an outpatient appointment, home visit or telephone interview'
- Stakeholders highlighted that patients may not be able to drive or be ready for physical assessment at 10 days post-discharge
- Queries were raised regarding the definition of 'assessment of cardiac function'
- Suggestion to include 'Readmission with cardiac illness within 30 days of discharge' as an outcome measure.

Consultation question 6

Stakeholders made the following comments in relation to consultation question 6: *Would the definition of an orientation session be universally understood?*

- Some stakeholders felt 'orientation session' would be understood if the definition was clear as what would be involved and where/how the session was delivered
- 2 stakeholders thought it would not be understood universally
- Suggested replacing with 'first session', 'introductory session' or 'rehabilitation needs assessment' to help patient understand the intention of the session.

12 Secondary prevention following an MI: Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- A statement on timely and complete coronary revascularisation
- A statement covering drug treatment post-MI
  - ‘People who have had an acute MI are offered drug treatment for secondary prevention in accordance with NICE guidance’
- A statement on anti-platelet treatment
  - Prescription of antiplatelet treatment
  - Assessing risk and monitoring of patients for bleeding complications
- A statement on follow-up of patients: ‘People who have been admitted to hospital with an MI are reviewed every 6 months’
- A statement on specialist referral of patients: ‘Patients who have been admitted to hospital with an MI are referred to multidisciplinary heart failure service led by a specialist, if needed’.

Appendix 1: CV Risk Assessment: Quality standard consultation comments table – registered stakeholders

Stakeholder	Statement No	Comments[2]
Department of Health	General	Thank you for the opportunity to comment on the draft for the above quality standard. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation
HEART UK	General	We have considered the draft cardiovascular risk assessment quality standard but do not have any changes to suggest.
HQT Diagnostics	General	Previous NICE reviews in Cardiology have minimised the use of Fatty Acids such as Omega-3 Fish Oil, for lack of evidence Results of recent large intervention trials with eicosapentaenoic acid (EPA) plus docosahexaenoic acid (DHA) supplements were neutral. In contrast, in epidemiologic studies, there were less clinical events after increased intake of EPA+DHA. This was found to be at an increased rate for higher levels of EPA+DHA. A standardized way of determining levels is the Omega-3 Index, which is the percentage of EPA+DHA of a total of 26 fatty acids measured in erythrocytes. According to current criteria, a low Omega-3 Index is a cardiovascular risk factor. NICE is invited to review the use of the Omega-3 Index as a diagnostic tool and an indicator of cardiovascular risk factor. Sources:

[2]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

Stakeholder	Statement No	Comments[2]
		http://www.plefa.com/article/S0952-3278(14)00079-9/abstract http://www.expertomega3.com/omega-3-study.asp?id=13 www.hqt-diagnostics.com
HQT Diagnostics	General	Major improvements in Cardiovascular health have been seen within 1-3 months of adjusting levels of Fatty Acids to achieve: • Omega-3 Index >8% • Omega-6/3 Ratio <3:1 The Omega-3 Index is designed to provide a more reliable indicator of the levels of specific Fatty Acids than any other test. Omega-3 levels can be increased by eating more oily fish or taking Fish Oil supplements. The Omega-6/3 Ratio shows the level of Omega-6 compared to Omega-3. High levels of specific Omega-6 Fatty Acids contribute to high Inflammation. This can be reduced by eating less Sunflower oil (Omega-6=64%), less Corn oil (52%) and less Soybean oil (51%). Typical Omega-6/3 Ratio in UK people before advice & supplementation range between 15:1 and 35:1. Inflammation is reduced when the ratio is <3:1 The HQT Diagnostics Fatty Acid Test shows an average of all Fatty Acids eaten over the previous 60-90 days Sources: http://omega3care.com/wp-content/uploads/2013/11/Omega-3LiteratureListJuly2013.pdf (100+ references about Cardiovascular Disease) www.omegaquant.com www.omegametrix.eu/?lang=EN www.hqt-diagnostics.com

Stakeholder	Statement No	Comments[2]
Lundbeck	General	Lundbeck is an ethical research-based pharmaceutical company specialising in central nervous system (CNS) disorders, such as depression and anxiety, bipolar disorder, schizophrenia, Alzheimer's, Parkinson's disease and alcohol dependence. Lundbeck welcomes and supports this engagement exercise for the development of a NICE quality standard on Cardiovascular risk assessment and recommends that screening and treatment for alcohol misuse including alcohol dependence is included as a risk factor within this quality standard.
Lundbeck	General	Excess alcohol consumption sits within the top five preventable health harms for western society. More than 28% of men and 20% of women in England drink in excess of Government guidelines. A single bout of drinking can cause an acute rise in blood pressure. Alcohol use is one of eight risk factors that jointly account for 61% of loss of healthy life years from cardiovascular deaths.[1] It has been found that drinking even slightly above the recommended limits that moderate alcohol consumption can result in an increased risk of cardiovascular disease. The acute effects of alcohol also include a temporary increase in the heart rate. Alcohol use also contributes to a number of cardiovascular diseases including hypertension, haemorrhagic stroke and atrial fibrillation. When alcohol consumption is reduced it is shown to have beneficial effects on blood pressure. A meta-analysis (Xin et al) demonstrates that reducing alcohol consumption was associated with a statistically significant reduction in blood pressure. The results from overviews of observational studies and randomized trials suggested that the 2-mmHg reduction seen in diastolic BP would be expected to result in a: • 17% decrease in the prevalence of hypertension • 15% reduction in the risk of stroke • 6% reduction in the risk of coronary heart disease[2] Addressing alcohol consumption is already raised in NICE guidelines [CG127] where it is cited that: 1.4.4 Ascertain people's alcohol consumption and encourage a reduced intake if they drink excessively, because this can reduce blood pressure and has broader health benefits. In the section on *'why this quality standard is needed'* Lundbeck recommends that alcohol dependence is included as a specific risk factor for the development of CVD. 1 Ruidavets JB, Ducimetière P, Evans A, et al Patterns of alcohol consumption and ischaemic heart disease in culturally divergent countries: the Prospective Epidemiological Study of Myocardial Infarction (PRIME). *British Medical Journal* 2010;341:c6077.

Stakeholder	Statement No	Comments[2]
		2 Xin X, J He, M.G. Frontini, L.G. Ogden, O.I. Motsamai, P.L. Whelton, Effects of Alcohol Reduction on Blood Pressure: A meta-analysis of randomised controlled trials. *Hypertension* 2001;38:1112-1117
Lundbeck	General	In the table on Public Health Outcomes on page 3, Lundbeck recommends that the following Indicator 'Alcohol related admissions to hospital' which is part of the Public Health Outcomes Framework for England 2013-2016, is included as part of the objective 'People are helped to live healthy lifestyles, make healthy choices and reduce health inequalities'. This would support the domain on health improvement since there were 1.4 million hospital admissions related to cardiovascular disease in 2010/11.[3] In more than 90% of cases, the risk of a first heart attack is related to nine modifiable risk factors. These are: • high blood cholesterol (lipids) • smoking and tobacco use • overweight and obesity • high blood pressure (hypertension) • poor diet • insufficient physical activity • psychosocial stress • diabetes • excess alcohol consumption 3 Services for the prevention of cardiovascular disease, NICE commissioning guides [CMG45], May 2012
Lundbeck	General	Alcohol dependence should be included as a risk factor of developing CVD.
NHS England	General	Dr Huon Gray - I have only one point to feed back to NICE, but I feel it is a very important one. The use of a 10-year CVD risk assessment tool (such as QRISK) is heavily influenced by age, and so younger people (particularly those under 50 and females even more so than males) may have a high lifetime risk of a CVD event (mainly strokes and heart attacks) but fall below the 10% 10-year risk threshold for intervention. I realise that Quality Statement 2 removes some of these potential 'at risk' people (diabetics, those with renal disease, those with FH) but it still leaves others who may be obese, with high blood pressure and are smokers, where a

Stakeholder	Statement No	Comments[2]
		lifetime CVD risk assessment tool would suggest the need for intervention but where the 10-year CVD risk is still below 10%. NICE is very aware of this concern regarding CVD risk assessment and will probably say that the Quality Standard simply refers to existing guidance (which is based on 10 year CVD risk) but I do think that this issue warrants a mention in the QS and I would be particularly keen to see NICE undertake work comparing the various CVD risk assessment tools that are now available, so that future guidance could, if appropriate, be modified.
Royal College of Nursing	General	This is to inform you that the Royal College of Nursing have submitted no comments to inform on the above quality standard consultation.
University of Nottingham	General	The last section on Page 10 “Commissioners (clinical commissioning groups) doesn’t appear to be a complete sentence
University of Nottingham	General	We were expecting some comments around risk assessment in people with serious mental illness based on tables 1 and 2 but this wasn’t mentioned later in the document.
Wolfson Institute of Preventative Medicine	General	NICE should recognize that focussing on cardiovascular disease risk estimation is not enough. The proposed methods of doing this are needlessly complicated and expensive. The argument that the information needed for these risk calculations is being collected “anyway” by GPs, and so costs the NHS nothing extra, is misguided. Much of this information is collected on the assumption that it needs to be used for risk assessment, which is, given the evidence available, of low priority. “Tools” and the “Quality Standard” will have the effect of adding to this low priority activity. The document implies that preventive treatment is limited to lipid control. This is incorrect. It is now recognized that lipid reduction needs to be accompanied by blood pressure reduction. For example, the JBS3 report embraces this and also focuses on using life years gained in place of ten year risk. NICE should revisit the area of identifying people at risk of cardiovascular disease, and specify the appropriate preventive intervention together with quantification of the health benefits arising from the intervention. References: 1. Wald NJ, Morris JK. Quantifying the benefits of chronic disease prevention: a fresh approach using cardiovascular disease as an example. *Eur J Epidemiol* 2014;29:605-612. doi: 10.1007/s10654-014-9932-1. 2. Wald NJ, Simmonds M, Morris JK. Screening for Future Cardiovascular Disease Using Age Alone Compared with Multiple Risk Factors and Age. *PLoS ONE* 2011;6(5):e18742. doi: 10.1371/journal.pone.0018742. 3. Simmonds M, Wald NJ. Risk estimation versus screening performance: a comparison of six risk algorithms for cardiovascular disease. *J Med Screen* 2012;19(4):201-205. doi: 10.1258/jms.2012.012076.

Stakeholder	Statement No	Comments[2]
British Cardiovascular Society	Q1; Statement 1	Answer: No Use of risk assessment tools over age 70 (over age 64 in men) is redundant and a waste of resources because almost everyone is screen positive (10 year risk of CVD 10% or more) on the basis of age alone. If risk assessment tools under this age are to be used, then the standard should be worded so that it does not require a two stage risk assessment process- Once would be enough. For example, people below 70 years of age should be offered formal 10-year risk assessment for cardiovascular events by QRISK2/JBS3. Is risk assessment really being promoted for 20 year-olds (Quality standard says from age 18) virtually all of whom will be at extremely low risk (particularly if assessing their 10-year risk through QRISK2)? The Quality standard is advocating a risk assessment without specifying the outcome of this assessment ie the preventive intervention that would be offered. This ought to be stated and the health gain made clear. We recommend NICE use the JBS 3 guidance as a framework since this specifies the intervention which would follow risk assessment and considers life time risk and specifically the health gain from use of specified interventions. http://heart.bmj.com/content/100/Suppl_2/ii1.full
British Cardiovascular Society	Q1; statement 2	Answer; no Doctors should not be encouraged or discouraged from using a risk assessment tool (let alone be expected to collect data and train staff to prove that the risk assessment tool is NOT being used) in a particular subgroup of patients (Type 1 Diabetes, CKD or Fh) when there is no evidence to use or not use it. The Quality standard should be silent of this and simply indicate that the Quality Standard does not cover these groups of patients.
Dietitians in Obesity Management UK	Q1	We agree with both the Quality Standards, and consider them appropriate and measurable.
Lundbeck	Q1	There are many risk factors associated with cardiovascular disease that cannot be changed such as family history, ethnicity and age. Other risk factors however that can be managed include tobacco exposure, high blood pressure (hypertension), high cholesterol, obesity, physical inactivity, diabetes, unhealthy diets, and harmful use of alcohol. 5.1% of the global disease burden is due to excessive alcohol consumption and the highest proportion of these deaths are in the form of cardiovascular diseases and diabetes.[3] This quality statement however does not include reference to harmful alcohol use as having an effect on the risk of cardiovascular disease and Lundbeck would like to see reference made. For example it could be reworded to state,

Stakeholder	Statement No	Comments[2]
		'Adults under 85 years with an estimated 10-year risk of cardiovascular disease (CVD) of 10% or more offered a full formal risk assessment using QRISK2 assessment tool. Adults with hypertension and alcohol dependence are offered a full formal risk assessment.[4] 4 Global status report on alcohol and health 2014. WHO. http://www.who.int/substance_abuse/publications/global_alcohol_report/en/
NHS England	Q1	No. The key quality issues in relation to cardiovascular risk management are firstly risk assessment using an appropriate tool and secondly follow up clinical action and intervention in response to high risk. It is a major gap that the quality standard only addresses risk assessment. Currently there is inconsistent follow up provided even for people with a 20% 10 year risk. For example 40% of people with hypertension are sub optimally managed and only 20-30% of people with a ten year CVD risk above 20% currently receive statins. We suggest that the quality standard also articulates the need for follow up that is essential for improving outcomes for people with high CVD risk. In addition there is a risk of low commitment to this quality standard in primary care because some health professionals worry that the emphasis is on medication with statins rather than behaviour support for lifestyle risk factors and clinical management of physiological risk factors. The reduction in treatment threshold to 10% will exacerbate this worry for many, and risks further disengagement from the quality standard. In contrast to this draft quality standard, the NICE clinical guidance is clear about the relative role of behaviour change and pharmacology and we believe that this should be reflected in the quality standard. We therefore suggest that a third statement is added which articulates that people with a 10 year risk that exceeds 10% should be offered: • Behaviour change support to make lifestyle changes • Appropriate management of high blood pressure, chronic kidney disease, diabetes and pre-diabetes, and An informed discussion about the role of statins in reducing cardiovascular risk.
Primary Care CVD Leadership Forum and Royal College of General Practitioners	Q1	No. The key quality issues in relation to cardiovascular risk management are firstly risk assessment using an appropriate tool and secondly follow up clinical action and intervention in response to high risk.

Stakeholder	Statement No	Comments[2]
		It is a major gap that the quality standard only addresses risk assessment. Currently there is inconsistent follow up provided even for people with a 20% 10 year risk. For example 40% of people with hypertension are sub optimally managed and only 20-30% of people with a ten year CVD risk above 20% currently receive statins. We suggest that the quality standard also articulates the need for follow up that is essential for improving outcomes for people with high CVD risk. In addition there is a risk of low commitment to this quality standard in primary care because some health professionals worry that the emphasis is on medication with statins rather than behaviour support for lifestyle risk factors and clinical management of physiological risk factors. The reduction in treatment threshold to 10% will exacerbate this worry for many, and risks further disengagement from the quality standard. In contrast to this draft quality standard, the NICE clinical guidance is clear about the relative role of behaviour change and pharmacology and we believe that this should be reflected in the quality standard. We therefore suggest that a third statement is added which articulates that people with a 10 year risk that exceeds 10% should be offered: • Behaviour change support to make lifestyle changes • Appropriate management of high blood pressure, chronic kidney disease, diabetes and pre-diabetes, and An informed discussion about the role of statins in reducing cardiovascular risk.
Public Health England	Q1	No. The key quality issues in relation to cardiovascular risk management are firstly risk assessment using an appropriate tool and secondly follow up clinical action and intervention in response to high risk. It is a major gap that the quality standard only addresses risk assessment. Currently there is inconsistent follow up provided even for people with a 20% 10 year risk. For example 40% of people with hypertension are sub optimally managed[1] and only around 20% of people with a ten year CVD risk above 20% currently receive statins[2]. We suggest that the quality standard also articulates the need for follow up that is essential for improving outcomes for people with high CVD risk. In addition there is a risk of low commitment to this quality standard in primary care because some health professionals worry that the emphasis is on medication with statins rather than behaviour support for lifestyle risk factors and clinical management of physiological risk factors. The reduction in treatment threshold to 10% will exacerbate this worry for many, and risks further disengagement from the quality standard.

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		In contrast to this draft quality standard, the NICE clinical guidance is clear about the relative role of behaviour change and pharmacology and we believe that this should be reflected in the quality standard. We therefore suggest that a third statement is added which articulates that people with a 10 year risk that exceeds 10% should be offered: • Behaviour change support to make lifestyle changes • Appropriate management of high blood pressure, chronic kidney disease, diabetes and pre-diabetes, and An informed discussion about the role of statins in reducing cardiovascular risk. 1. Joffres M, Falaschetti E, Gillespie C, et al. Hypertension prevalence, awareness, treatment and control in national surveys from England, the USA and Canada, and correlation with stroke and ischaemic heart disease mortality: a cross-sectional study. BMJ Open 2013;3:e003423. DOI: http://dx.doi.org/10.1136/bmjopen-2013-003423 2. Forster A, Dodhia H, Booth H, Dregan A, Fuller F, Miller J, Burgess C, McDermott L, Gulliford M. Estimating the yield of NHS Health Checks in England: a population-based cohort study. J Public Health. 10.1093/pubmed/fdu079. 2014
The Royal College of Anaesthetists	Q1	"Does this draft quality standard accurately reflect the key areas for quality improvement?" Our respondents broadly agree that this is a key area for QI but would question why the cut off of 85 years has been chosen. The Office for National Statistics quotes an average life expectancy at age 85 of 5.8 years for men and 6.8 years for women for the UK. Although the standard is focussing on those with an estimated 10 year risk of CVD, there will be a significant number of patients who will survive beyond 10 years at age 85 and their needs should not be forgotten. The burden for the individual, their family and health and social services of non-fatal cardiovascular events is considerable and should be mitigated for the whole population, regardless of age. In addition the guidance should be more explicit of the age at which screening should commence. The guidance says 'adult patients under 85 years', but the QRISK2 tool proforma starts at age 25 years.
The Royal College of Anaesthetists	Q1	Our respondents felt that Statement 2, as written in isolation, is unclear. Clearly all patients with type 1 diabetes, chronic renal disease and familial hypercholesterolemia are at increased risk of CVD by definition, however the statement would be much clearer if the reasons why the risk assessment tool should not be used for this group were given (i.e., risk assessment unnecessary; it would cause delay to treatment etc.).
University of Nottingham	Q1	Question 1. We think there needs to be some mention of frequency of the assessments. Should they be annual, every 5 years, every X yeas in patients with a value over XX.

Stakeholder	Statement No	Comments[2]
Wolfson Institute of Preventative Medicine	Q1	Answer: No. Statement 1 states that "adults under 85 years with an estimated 10 year risk of cardiovascular disease (CVD) of 10% or more are offered a full formal risk assessment using the QRISK2 assessment tool. " 1. Being 85 or over alone is sufficient to offer preventive treatment. Why not a younger age? 2. Almost all people aged 70 and over have a ten year risk of CVD of 10% or more on the basis of their age alone. If the ten year risk is to be used, age 70 is the logical cut-off and QRISK2 is redundant and a waste of resources above age 70. 3. Is it really intended that all adults under 85 years have a ten year risk estimation (eg. age 20)? Surely not. 4. The statement implies two assessments, one (unspecified) that identifies people with a 10% ten year risk of CVD and that leads to a QRISK assessment to identify people (again) with a 10% ten year risk of CVD. What is the first assessment? Why is there a need for two? 5. The focus of any quality standard should be on prevention, not simply measuring risk. Risk estimation, by whatever means, is not enough. Health professionals and the public need to know what intervention should be adopted, what proportion of people taking the intervention will benefit, and among these, the years of life gained without a cardiovascular disease event. This is missing from the Quality Standard. 6. The presumption that a risk estimation alone, whether it is calculated using QRISK2, or by any other similar "tool", is desirable is misplaced. It is like recommending a screening test without mention of what should be undertaken in people who are screen-positive, and an indication of the health benefit arising from this. In short, this statement is advocating a method of screening without specifying what should be done in those who are positive and the expected health benefit arising from this. We urge NICE to revisit this entirely and focus on a simple means of identifying people at risk of cardiovascular disease, specifying a simple and safe intervention, and quantifying the health benefit of this. To this end, we attach a paper that two of us wrote, entitled: "Quantifying the health benefits of chronic disease prevention: a fresh approach using cardiovascular disease as an example". [1] A similar approach has also been adopted by JSBS3. As far as statement 2 is concerned, there is the implication that patients with type1 diabetes, chronic kidney disease,

Stakeholder	Statement No	Comments[2]
		or familial hypercholesterolaemia should automatically receive preventive treatment in the same way as people identified as being at high risk through whatever screening "tool" is adopted. The difficulty here is that there is not a well-argued defence of such an approach. For example, should all 18 year old individuals with type 1 diabetes received lipid-lowering medication? This may be sensible but it needs a scientific defence. If the risk of cardiovascular disease is judged to be sufficiently high, then the argument in favour of lowering blood pressure applies in the same way as it does to lowering lipid levels. Unfortunately this document is silent on what the preventive treatment is. Reference is made only to the Lipid Modification Guidance, which may imply that blood pressure lowering is not indicated, even though it is as important as lipid lowering in the prevention of cardiovascular disease. It is a mistake to focus on one and not the other.
Dietitians in Obesity Management UK	Q2	In our view the proposed measurements are achievable if structures and systems are available.
NHS England	Q2	Yes if CSUs or SCNs considered that part of their core offer to CCGs/practices then they should be able to extract practice specific patient anonymised data.
Primary Care CVD Leadership Forum and Royal College of General Practitioners	Q2	Yes if CSUs or SCNs considered that part of their core offer to CCGs/practices then they should be able to extract practice specific patient anonymised data.
Public Health England	Q2	Yes if CSUs or SCNs considered that part of their core offer to CCGs/practices then they should be able to extract practice specific patient anonymised data.
The Royal College of Anaesthetists	Q2	"If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?" Yes, our respondents believe it could be possible, however resources (IT and manpower) would need to be made available to meet the targets.
Wolfson Institute of Preventative Medicine	Q2	Answer: It may be possible, but not useful. Collecting information on whether QRISK2 is used, given our comments above, is a misguided and inappropriate use of scarce resources.
Dietitians in Obesity Management UK	Q3	In order to reduce barriers we suggest that carrying out the assessments in community settings other than GP surgeries may overcome barriers in some groups of the community,

Stakeholder	Statement No	Comments[2]
NHS England	Q3	1. Addition of third quality statement as above 2. Robust local pathways for behaviour change support 3. Sharing performance data with CCGs and practices to facilitate learning and support 4. Best practice online resources for general practice teams 5. Local incentive schemes for general practice teams to provide the NHS Health Check and smoking cessation as CVD risk management services 6. Local incentive schemes for community pharmacy support for adherence to medical management of high CVD risk - eg statins and treatment for hypertension and CKD.
Primary Care CVD Leadership Forum and Royal College of General Practitioners	Q3	1. Addition of third quality statement as above 2. Robust local pathways for behaviour change support 3. Sharing performance data with CCGs and practices to facilitate learning and support 4. Best practice online resources for general practice teams 5. Local incentive schemes for general practice teams to provide the NHS Health Check and smoking cessation as CVD risk management services 6. Local incentive schemes for community pharmacy support for adherence to medical management of high CVD risk - eg statins and treatment for hypertension and CKD.
Public Health England	Q3	1. Addition of third quality statement as above 2. Support for uptake of NHS Health Check as key driver for systematic CVD risk assessment in people aged 40-74 3. Robust local pathways for behaviour change support 4. Sharing performance data with CCGs and practices to facilitate learning and support 5. Best practice online resources for general practice teams
The Royal College of Anaesthetists	Q3	“For each quality statement what do you think could be done to support improvement and help overcome barriers?” Please see some suggestions below:

Stakeholder	Statement No	Comments[2]
		1. Publicity campaign with the general public; information must be easily accessible and presented in a range of languages (Statement 1) 2. Self-assessment tool developed for lay use (Statement 1) 3. Extra resources (and incentives) for primary care to meet the targets (Statement 1 & 2) Ensure that the high risk groups included in statement 2 are universally receiving the correct disease modifying treatments - do we have the data to be confident that this is currently the case?
Wolfson Institute of Preventative Medicine	Q3	Answer: Nothing. This question assumes agreement with and acceptance of the two quality statements and the policies underpinning them. Given that this is not the case with the first statement, and not specified for the second, our view is that nothing should be done to support the activity.
Dietitians in Obesity Management UK	Q4	With regard to who specifically should carry out the full risk assessment in those identified as having a 10 year risk of 10% or more, in our view a formal invitation for assessment should be automatically generated when the 10% risk is identified, and this is most likely to occur within GP practice. However the assessments themselves should not be limited to GPs in our view, both to manage workload effectively and to reduce potential barriers in those who may prefer not to visit the GP. Other appropriately trained healthcare professionals could carry them out in addition to GPs.
Lundbeck	Q4	It is important that healthcare professionals work with the alcohol care team (alcohol specialist nurse, addictions psychiatrist, hepatologist, specialist liver nurse) so that patients experiencing high levels of alcohol harm will be assessed for cardiovascular disease.
NHS England	Q4	Individuals with higher risk of CVD undergoing other long term condition consultations - eg COPD, asthma >40, hypertension, non-diabetic hyperglycaemia follow up, obesity, rheumatology, drug and alcohol misuse, smoking cessation >40, weight management, dementia.
Primary Care CVD Leadership Forum and Royal College of General Practitioners	Q4	Individuals with higher risk of CVD undergoing other long term condition consultations - eg COPD, asthma >40, hypertension, non-diabetic hyperglycaemia follow up, obesity, rheumatology, drug and alcohol misuse, smoking cessation >40, weight management, dementia
Public Health England	Q4	Individuals with higher risk of CVD undergoing other long term condition consultations - eg COPD, asthma >40, hypertension, non-diabetic hyperglycaemia follow up, obesity, rheumatology, drug and alcohol misuse, smoking cessation >40, weight management, dementia.
University of Nottingham	Q4	Question 4 – we were unclear what this meant.
Wolfson Institute of	Q4	Answer: Probably none.

Stakeholder	Statement No	Comments[2]
Preventative Medicine		This question cannot be answered without specification of the assessment recommended prior to the full formal assessment (ie. the QRISK2 assessment). Moreover, the document assumes that any such multi-risk factor assessment is needed. It has been shown that risk factors such as blood pressure and cholesterol level add little discrimination between those who will and will not suffer a cardiovascular event in a given time over a person's age. Therefore resources should be focussed more on a simpler method of identifying people at risk in the population, using age alone, rather than more complex methods such as those implied and proposed in this document. The focus should be on prevention rather than measurement. We refer to two papers[2,3] on this subject, which provide the evidence underpinning this approach.
British Medical Association	Statement 1	This statement cannot be supported. The 10% intervention threshold is set too low, and there are not sufficient resources available within primary care to deliver this intervention without causing harm to other areas of health care provision. Attention should be focused on those with most to gain, either because they have higher overall risk or have a high relative risk for their age and gender; and preventing premature death and illness should be the priority area for investment. The majority of patients accept increasing risks of CVD with advancing age and relate more easily to, and are more motivated to change by, relative risk. This group will contain many people whose risk is lower than expected, and many others who by definition cannot die prematurely by virtue of their current age. The group will also contain many people with significant co-morbidities for whom intervention is inappropriate.
Kidney Research UK	Statement 1	I am a bit unclear how one identifies adults with CV risk >10% per year. There is no statement suggesting how these are indentified other than in those with pre-existing conditions. The statement is a bit illogical, in the sense that by knowing that they have a CV risk of >10% one has already performed some kind of risk assessment. It would be useful if the document gave some clues as to how to identify these subjects without including those with known diabetes and chronic kidney disease. I guess these subjects might have hypertension, rheumatoid arthritis, obesity or live in deprived areas but this should be more explicit
NHS England	Statement 1	Presumably the decision to mandate QRISK2 reflects current NICE guidance. We urge more flexibility as JBS3 has now been published and will be used by many GPs and patients. There is a high risk that mandating QRisk2 will cause confusion and reduce GP adherence to the Quality Standard. We suggest that the statement recommends QRISK2 or a tool derived from QRISK2 – as this would include JBS3 and would be consistent with the NICE Lipid guidance. There is a strong consensus that people with type 2 diabetes should be excluded from risk calculation and that they should be automatically managed as high risk. This is clearly articulated in the new JBS3 guidance. Such a major inconsistency between the NICE Quality Standard and JBS3 will cause confusion and reduce adherence to the

Stakeholder	Statement No	Comments[2]
		Quality Standard.
Primary Care CVD Leadership Forum and Royal College of General Practitioners	Statement 1	Presumably the decision to mandate QRISK2 reflects current NICE guidance. We urge more flexibility as JBS3 has now been published and will be used by many GPs and patients. There is a high risk that mandating QRisk2 will cause confusion and reduce GP adherence to the Quality Standard. We suggest that the statement recommends QRISK2 or a tool derived from QRISK2 – as this would include JBS3 and would be consistent with the NICE Lipid guidance. There is a strong consensus that people with type 2 diabetes should be excluded from risk calculation and that they should be automatically managed as high risk. This is clearly articulated in the new JBS3 guidance. Such a major inconsistency between the NICE Quality Standard and JBS3 will cause confusion and reduce adherence to the Quality Standard.
Public Health England	Statement 1	Presumably the decision to mandate QRISK2 reflects current NICE guidance. We urge more flexibility as JBS3 has now been published and will be used by many GPs and patients. There is a high risk that mandating QRisk2 will cause confusion and reduce GP adherence to the Quality Standard. We suggest that the statement recommends QRISK2 or a tool derived from QRISK2 – as this would include JBS3 and would be consistent with the NICE Lipid guidance. There is a strong consensus that people with type 2 diabetes should be excluded from risk calculation and that they should be automatically managed as high risk. This is clearly articulated in the new JBS3 guidance. Such a major inconsistency between the NICE Quality Standard and JBS3 will cause confusion and reduce adherence to the Quality Standard.
Public Health Nottinghamshire County, Public Health Nottingham City and on behalf of Nottingham and Nottinghamshire CCG	Statement 1	Comment on about quality statement 1 seems out of step with NHS Heath Checks as they make no reference to the programme and the age range is different. The quality statement should specifically refer to NHS Health Check programme as an important delivery mechanism, through liaison between CCGs and local authorities. Otherwise there is a missed opportunity to be explicit incentivising GP practices to do health checks.
Public Health Nottinghamshire County, Public Health Nottingham City and on behalf of Nottingham and	Statement 1	The desirability of having a register of patients with CVD risk of 10% or more is being considered locally as part of the estimated cost implications for the implementation of the NICE CG181. There may be concerns for having a 10 % CVD risk register will shift the focus away from management of patients with 20% or more CVD risk; where there continues to be variations amongst GP practices contributing to health inequalities locally.

Stakeholder	Statement No	Comments[2]
Nottinghamshire CCG		
Public Health Nottinghamshire County, Public Health Nottingham City and on behalf of Nottingham and Nottinghamshire CCG	Statement 1	Please note that there is a reference in the draft standards to high risk of CVD as being a risk of 10% or more. On p7 of the CVD standards it refers to: "Adults under 85 years who have been identified as being at high risk of developing CVD (those who have a greater than 1 in 10 chance of developing CVD in the next 10 years)". To my knowledge, the threshold for high risk continues to be defined as 20%, or a 1 in 20 chance of developing CVD. This continues to underpin the process of risk reduction and risk management in the NHS Health Check programme, which is the single biggest systematic programme of CVD risk assessment in England. The consideration of statins for lipid modification in people with a risk of 10-19% has not changed the definition of high risk. People in this category therefore remain eligible within NHS Health Check programme if they decline statins, whereas they would be excluded if they were deemed high risk. If the reference to 1 in 10 chance as being “high risk” could be removed from the standards it would be helpful.
University of Nottingham	Statement 1	QRISK2 works over an age range of 25-84 years so this should be reflected in the quality standard
British Medical Association	Statement 2	We do not agree with the second statement, as it appears to be aiming to have a zero number for people with DM CKD having a QRISK2 assessment after diagnosis. The true quality issue does not concern doing the assessment itself but in acting on the results, and should a marker be identified for inappropriate action then that could be supported. It must be remembered that as more health care professionals get write-access to the GP record such data could be entered outside the GP's control, so its use as a quality marker at practice level is invalidated.
Kidney Research UK	Statement 2	On behalf of Kidney Research UK, I commend the document on emphasising that patients with chronic kidney disease are at increased cardiovascular risk, and that further assessment is not necessary and lipid modification should be considered without further assessment. This is logical although my preference would be to see mention of hypertension, blood pressure and smoking cessation in addition to lipid lowering. The impression I took from this section is that the only intervention cardiovascular risk assessment leads to is lipid-lowering therapy. I’m sure this is not the intention and it may be that this document sits within a wider series of work which makes this clearer
NHS England	Statement 2	No. The key quality issues in relation to cardiovascular risk management are firstly risk assessment using an appropriate tool and secondly follow up clinical action and intervention in response to high risk. It is a major gap that the quality standard only addresses risk assessment. Currently there is inconsistent follow up provided even for people with a 20% 10 year risk. For example 40% of people with hypertension are sub optimally managed and only 20-30% of people with a ten year CVD risk above 20% currently receive statins. We suggest that

Stakeholder	Statement No	Comments[2]
		the quality standard also articulates the need for follow up that is essential for improving outcomes for people with high CVD risk.
Primary Care CVD Leadership Forum and Royal College of General Practitioners	Statement 2	No. The key quality issues in relation to cardiovascular risk management are firstly risk assessment using an appropriate tool and secondly follow up clinical action and intervention in response to high risk. It is a major gap that the quality standard only addresses risk assessment. Currently there is inconsistent follow up provided even for people with a 20% 10 year risk. For example 40% of people with hypertension are sub optimally managed and only 20-30% of people with a ten year CVD risk above 20% currently receive statins. We suggest that the quality standard also articulates the need for follow up that is essential for improving outcomes for people with high CVD risk.
Public Health England	Statement 2	No. The key quality issues in relation to cardiovascular risk management are firstly risk assessment using an appropriate tool and secondly follow up clinical action and intervention in response to high risk. It is a major gap that the quality standard only addresses risk assessment. Currently there is inconsistent follow up provided even for people with a 20% 10 year risk. For example 40% of people with hypertension are sub optimally managed [1] and only around 20% of people with a ten year CVD risk above 20% currently receive statins [2]. We suggest that the quality standard also articulates the need for follow up that is essential for improving outcomes for people with high CVD risk. 1. Joffres M, Falaschetti E, Gillespie C, et al. Hypertension prevalence, awareness, treatment and control in national surveys from England, the USA and Canada, and correlation with stroke and ischaemic heart disease mortality: a cross-sectional study. BMJ Open 2013;3:e003423. DOI: http://dx.doi.org/10.1136/bmjopen-2013-003423 2. Forster A, Dodhia H, Booth H, Dregan A, Fuller F, Miller J, Burgess C, McDermott L, Gulliford M. Estimating the yield of NHS Health Checks in England: a population-based cohort study. J Public Health. 10.1093/pubmed/fdu079. 2014
University of Nottingham	Statement 2	We don't think this statement is necessary – whilst NICE guidance doesn't recommend risk assessment in patients with CKD, type1 diabetes, the QRISK2 will calculate a score and it may benefit some patients to have this information and be able to visualise how their risk might change with stopping smoking, weight loss etc. Also a patient may need a risk assessment because of another condition (eg rheumatoid arthritis) which has been in

Stakeholder	Statement No	Comments[2]
		QOF. We think it would be pointless to collect this data and check on practices that they weren't undertaking this assessment as that would be a waste of resources. There is no point in highlighting or punishing practices for being a bit too thorough and it could be argued that some patients might request an assessment or benefit from it.

Registered stakeholders who submitted comments at consultation

- British Cardiovascular Society
- British Medical Association
- Department of Health
- Dietitians in Obesity Management UK
- HEART UK
- HQT Diagnostics
- Kidney Research UK
- Lundbeck
- NHS England
- Primary Care CVD Leadership Forum and Royal College of General Practitioners
- Public Health England
- Public Health Nottinghamshire County, Public Health Nottingham City and on behalf of Nottingham and Nottinghamshire CCG
- Royal College of Nursing
- Royal College of Anaesthetists

- University of Nottingham
- Wolfson Institute of Preventative Medicine

Appendix 2: Lipid modification: Quality standard consultation comments table – registered stakeholders

Stakeholder	Statement No	Comments[3]
British Medical Association	General	We cannot support the overall direction of this document as it is based on the intervention threshold from the NICE lipid modification guideline to which we have already expressed our lack of confidence. In addition, since the guidance was published there has been further doubt cast on the adverse effects of high intensity statins which raise questions about their suitability for primary prevention, particularly at lower risk levels. Until these doubts are resolved development of a quality standard is inappropriate. An alternative course of action in order to increase the level of support would be to target these standards at those at higher levels of 10 year risk, or at those who have a risk level significantly above that of the normal for their age and gender. The aspiration to 100% cannot be justified as there are inadequate exception-reporting measures in the proposed denominator and numerator populations to allow for those patients in whom the intervention would be harmful.
Department of Health	General	Thank you for the opportunity to comment on the draft for the above quality standard. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
HQT Diagnostics	General	Previous NICE reviews in Cardiology have minimised the use of Fatty Acids such as Omega-3 Fish Oil, for lack of evidence Results of recent large intervention trials with eicosapentaenoic acid (EPA) plus docosahexaenoic acid (DHA) supplements were neutral. In contrast, in epidemiologic studies, there were less clinical events after increased intake of EPA+DHA. This was

[3]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

Stakeholder	Statement No	Comments[3]
		found to be at an increased rate for higher levels of EPA+DHA. A standardized way of determining levels is the Omega-3 Index, which is the percentage of EPA+DHA of a total of 26 fatty acids measured in erythrocytes. According to current criteria, a low Omega-3 Index is a cardiovascular risk factor. NICE is invited to review the use of the Omega-3 Index as a diagnostic tool and an indicator of cardiovascular risk factor. Sources: http://www.plefa.com/article/S0952-3278(14)00079-9/abstract http://www.expertomega3.com/omega-3-study.asp?id=13 www.hqt-diagnostics.com
HQT Diagnostics	General	Major improvements in Cardiovascular health have been seen within 1-3 months of adjusting levels of Fatty Acids to achieve: • Omega-3 Index >8% • Omega-6/3 Ratio <3:1 The Omega-3 Index is designed to provide a more reliable indicator of the levels of specific Fatty Acids than any other test. Omega-3 levels can be increased by eating more oily fish or taking Fish Oil supplements. The Omega-6/3 Ratio shows the level of Omega-6 compared to Omega-3. High levels of specific Omega-6 Fatty Acids contribute to high Inflammation. This can be reduced by eating less Sunflower oil (Omega-6=64%), less Corn oil (52%) and less Soybean oil (51%). Typical Omega-6/3 Ratio in UK people before advice & supplementation range between 15:1 and 35:1. Inflammation is reduced when the ratio is <3:1 The HQT Diagnostics Fatty Acid Test shows an average of all Fatty Acids eaten over the previous 60-90 days

Stakeholder	Statement No	Comments[3]
		Sources: http://omega3care.com/wp-content/uploads/2013/11/Omega-3LiteratureListJuly2013.pdf (100+ references about Cardiovascular Disease) www.omegaquant.com www.omegametrix.eu/?lang=EN www.hqt-diagnostics.com
Royal College of Pathologists	General	The draft quality standard does reflect the key areas subject to the point above and the points pursued by others. I believe the data are collectable but the systems and structures are not universally available.
Sanofi	General	The link between this quality standard and the familial hypercholesterolaemia quality standard (QS41) should be made clear. This is particularly important as diagnosis of FH in England remains low - only 15-20% have been diagnosed. The quality standard should therefore include the statement that: *"Adults with a baseline total cholesterol above 7.5 mmol/l are assessed for a clinical diagnosis of familial hypercholesterolaemia"*
Wolfson Institute of Preventative Medicine	General	These comments should be read in conjunction with our comments in relation to Cardiovascular Risk Assessment Quality Standards Consultation. In general the underlying guidelines and the quality standards that relate to them are unnecessarily fussy, complicated, and intrusive. The focus should be on preventing heart attacks or strokes in the simplest and most effective way that involves as little medical intervention as possible. This is of particular importance in relation to preventive medicine in general and the current state of the NHS which is increasingly burdened by the kind of interactions and quality assessments imposed in this consultation document and the corresponding one on the cardiovascular risk standards.
British Cardiovascular Society	Statements 1-3	We would advocate the use of the JBS3 lifetime risk approach in determining selection of patients to be offered primary prevention
HEART UK	General	The draft quality standard does reflect the key areas subject to the point above and the points pursued by others. I believe the data are collectable but the systems and structures are not universally available.
NHS England	Q1	I agree that lipid modification is an important element of our attempts to reduce longer term risk of cardiovascular disease (CVD). However, and has been debated with NICE before, reliance on 10-year CVD risk tools (such as

Stakeholder	Statement No	Comments[3]
		QRISK) disadvantages younger people and women, because 10 year risk is so dependent on age. For instance, it is possible to have familial hypercholesterolaemia at the age of 30, where it is known that their life expectancy may be reduced by as much as 10 years, but not have a 10-year CVD risk >10% and thus not, by these standards, warrant lipid lowering therapy. I would strongly argue for greater use of a lifetime risk assessment tool (such as JBS3) but I expect that NICE will not accept this as it wasn't in the clinical guideline. Nevertheless, it is an important point to make because it is disadvantaging women and the young and is therefore not equitable, in my opinion. I would argue for a specific piece of work to be undertaken by NICE to re-evaluate the merits or otherwise of different CVD risk assessment tools.
Royal College of General Practitioners	Q1	The lowering of the target cardiovascular risk to 10% has a significant resource implication for primary care and potential to medicalise all of the people who do not consider themselves ill. It is unclear if the benefits of statin intervention at this level (10%) of cardiovascular risk outweighs the potential harms caused. This standard is likely to be difficult to implement in primary care and with patients, who have become increasingly wary of statins. It has the potential to cause confrontation between doctors and patients.
Wolfson Institute of Preventative Medicine	Q1	No. Statement 1 is incorrect. There is no need to carry out investigations for secondary causes of dyslipidaemia before offering statin therapy. To do so implies, for example, that everyone should be screened for hypothyroidism or nephrotic syndrome before someone is put on a statin. This is completely inappropriate. Statement 2 is incorrect because lifestyle changes and statin therapy are complementary, not alternatives. It is unreasonable to perform repeated risk estimates to see if someone falls below the ten-year risk cut-off of 10% after recommending lifestyle modifications, and then withholding statin therapy if the risk is, say, 9%, but offering it if it is 11%. All such people stand to benefit from prophylactic statin therapy. A 10% cut off is not sacrosanct. It is a means to an end. In any event lifestyle changes in practice have been found to have little material impact in altering a person's risk status, which is largely driven by a person's age and existing clinical cardiovascular disease. Regarding statement 3, we agree that people judged to be at high risk of cardiovascular disease should be offered atorvastatin 20mg for primary prevention and also advised to modify lifestyle factors appropriately. Both should be done, not one or the other. Statement 4 and statement 5 are both reasonable. Statement 6 is questionable. A formal three month review is not necessary. Assessment can depend upon symptoms rather than a formal review, and this could be done remotely. The individuals concerned should be invited to report clinical events.

Stakeholder	Statement No	Comments[3]
NHS England	Q2	This would need to be explored but a combination of data from the National Pathology Database (Jo Martin may wish to comment) and GP Practice Data may allow data to be collected for at least some of the quality measures.
Royal College of General Practitioners	Q2	It may be possible but this may divert limited primary care resources from other areas.
Wirral University Teaching Hospital	Q2	I would also comment that data collection will be difficult due to the disparate IT systems used across primary and secondary care.
Wolfson Institute of Preventative Medicine	Q2	It may be possible but not necessary or desirable.
NHS England	Q3	I think that GP incentives, such as QOF, and NHS Health Checks could do a lot to help support improvement. However, the trend in use of QOF indicators is towards their reduction, so some priority would have to be given to their alignment to the Quality Standards for this to be feasible.
Royal College of General Practitioners	Q3	Piloting the quality standard in several areas with independent monitoring of the impact on patients, carers and primary care will help support and overcome barriers.
Wolfson Institute of Preventative Medicine	Q3	For people taking cardiovascular disease preventive medication it would be useful to use mobile phone messaging to encourage adherence to therapy and enquire about possible adverse effects.
British Medical Association	Statement 1	This statement is illogical. Many, indeed most, of these people who have risks at the lower end of the suggested range will have normal lipid profiles, that is, they will not have a dyslipidaemia. It would be inappropriate to investigate this population for a condition which they do not have.
HEART UK	Statement 1	Smoking status and blood pressure are not secondary causes and should be excluded from the list. Total cholesterol is already being assessed and should be excluded from the list. Transaminase levels on their own are not a recognised cause of increased lipid concentrations. Liver disease may be responsible for increased lipids and this is already stated. A more specific statement about liver disease suggesting the use of, but not exclusively, liver function testing to unmask potential liver disease.
Public Health Nottinghamshire County, Public Health Nottingham City and on behalf of Nottingham and Nottinghamshire CCG	Statement 1	Comment on about quality statement 1. The quality statement should specifically refer to NHS Health Check programme as an important delivery mechanism, through liaison between CCGs and local authorities. Otherwise there is a missed opportunity to be explicit incentivising GP practices to do health checks.

Stakeholder	Statement No	Comments[3]
Royal College of Pathologists	Statement 1	Smoking status and blood pressure are not secondary causes and should be excluded from the list. Total cholesterol is already being assessed and should be excluded from the list.
Royal College of Pathologists	Statement 1	Transaminase levels on their own are not a recognised cause of increased lipid concentrations. Liver disease may be responsible for increased lipids and this is already stated. A more specific statement about liver disease suggesting the use of, but not exclusively, liver function testing to unmask potential liver disease.
Wirral University Teaching Hospital	Statement 1	Last sentence in the paragraph headed Rationale "Excluding secondary causes…". This would read better and make more sense if read: "Identifying secondary causes…"
British Medical Association	Statement 2	This statement can be partially supported, however it should be noted that many of the lifestyle changes advocated will have no effect on the Qrisk2 score. We are concerned that this standard will involve so many people that there will be considerable lost opportunity costs for other conditions, and that the overall health of the community may as a result reduce rather than increase. These objections could be met with a simplification of the statement to 'Adults have the benefits of lifestyle changes for primary prevention discussed with them before the offer of statin therapy'. There would need to be changes to the numerator and denominator definitions.
HEART UK	Statement 2	Stopping smoking will not reduce cholesterol levels. Because smoking may reduce HDL cholesterol, stopping smoking may if anything increase HDL and hence total cholesterol levels. It is obviously a healthy thing to do and will prevent CVD events. Source guidance is the NICE Guideline CG181 but this should explicitly guide patients to NHS Choices for dietary advice for source guidance.
Public Health Nottinghamshire County, Public Health Nottingham City and on behalf of Nottingham and Nottinghamshire CCG	Statement 2	Comment on about quality statement 2. The quality statement should specifically refer to NHS Health Check programme as an important delivery mechanism, through liaison between CCGs and local authorities. Otherwise there is a missed opportunity to be explicit incentivising GP practices to do health checks.
Royal College of Pathologists	Statement 2	Stopping smoking will not reduce cholesterol levels. Smoking may reduce HDL-cholesterol, and stopping smoking may increase HDL-cholesterol. Smoking cessation will alter the risk produced by the use of the QRisk2 equation
Royal College of Pathologists	Statement 2	Source guidance is the NICE Guideline CG181 but this should explicitly guide patients to NHS Choices for dietary advice for source guidance.
Sanofi	Statement 2	We agree that the benefits of lifestyle changes for primary prevention of a CVD event are discussed with patients who have a 10-year risk of CVD of 10% or more. However for some patients lifestyle changes alone will not be sufficient to manage their CVD risk. We believe a discussion about the benefits of lifestyle changes should be given in conjunction with an assessment of their need for initiation of a statin therapy.

Stakeholder	Statement No	Comments[3]
Wirral University Teaching Hospital	Statements 2/3	There is no mention of how long individuals should be expected to attempt lifestyle changes before an offer of statin therapy whereas quality statement 6 specifies a 3 month review after commencing a high intensity statin. A reasonable period of lifestyle intervention and review of changes before offering a statin should help improve the outcomes sought.
British Medical Association	Statement 3	This statement cannot be supported. At low levels of risk the benefits to individuals are marginal and open to dispute. The correct course of action for doctors is to discuss these issues with patients and allow them to come to a decision about their own treatment. The proposed standard will measure the degree to which doctors prescribe without these discussions, and doctors with a mechanistic high-prescribing low-discussion consultation style will achieve higher 'quality' figures than those who enter into discussions with their patients and have a collaborative approach to medical decision making. Doctors who take into account patient co-morbidities and drug interactions will likewise be wrongly labelled as having poor quality, and a high figure may well be a marker of poor quality and not high quality care.
HEART UK	Statement 3	As per QS1, smoking cessation does not explicitly decrease cholesterol but may increase HDL-cholesterol. (Ineffective lifestyle changes). However it does decrease CVD risk.
Public Health Nottinghamshire County, Public Health Nottingham City and on behalf of Nottingham and Nottinghamshire CCG	Statement 3	Comment on about quality statement 3. The quality statement should specifically refer to NHS Health Check programme as an important delivery mechanism, through liaison between CCGs and local authorities. Otherwise there is a missed opportunity to be explicit incentivising GP practices to do health checks.
Royal College of Pathologists	Statement 3	As per QS1 and noted by others smoking cessation does not explicitly decrease cholesterol but may increase HDL-cholesterol. (Ineffective lifestyle changes). However it does decrease CVD risk.
Sanofi	Statement 3	We believe that the quality statement should be more specific about how long lifestyle changes should be implemented before a patient is offered atorvastatin 20mg. We propose that the effect of lifestyle changes is evaluated after three months to ensure patients who have not seen improvement are offered atorvastatin 20mg without delay.
British Medical Association	Statement 4	This quality standard cannot be supported. There are too many people in this group who have cautions regarding this dose of atorvastatin (age, drug interactions etc) for the crude percentage of patients treated to be a marker for quality. The correct level of prescribing is likely to be at a figure below 100%, and high levels of prescribing may well indicate a doctor who is unaware or disregarding of cautions and contraindications. The recent studies linking high dose statins with disorders of glucose metabolism also need assessing.

Stakeholder	Statement No	Comments[3]
HEART UK	Statement 4	"*What the quality statement means for patients…"* This states: *This will help reduce cholesterol levels and prevent adults* etc. Atorvastatin reduces cholesterol and there is a reduction in the event rate but since clinical trials show that the risk is decreased by 30% this does not infer *prevention* from heart attack or stroke.
MSD	Statement 4	In CG181 atorvastatin 80 mg is recommended for secondary prevention of CVD, which is reflected in the quality standard. This dose does not however have a UK marketing authorisation. Recommending atorvastatin 80 mg would lead to off-label prescribing, and it should be appropriately referenced as such. MSD recommend that the wording from CG181 is incorporated into the quality standard. "At the time of publication (September 2015), atorvastatin did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing and managing medicines and devices for further information."
Public Health Nottinghamshire County, Public Health Nottingham City and on behalf of Nottingham and Nottinghamshire CCG	Statement 4	Comment on about quality statement 4. The quality statement should specifically refer to NHS Health Check programme as an important delivery mechanism, through liaison between CCGs and local authorities. Otherwise there is a missed opportunity to be explicit incentivising GP practices to do health checks.
Royal College of Pathologists	Statement 4	"*What the quality statement means for patients…"* This states: *This will help reduce cholesterol levels and prevent adults* etc. Atorvastatin reduces cholesterol and there is a reduction in the event rate but since clinical trials show that the risk is decreased by 30% this does not infer *prevention* from heart attack or stroke.
Wirral University Teaching Hospital	Statement 4	"Adults with cardiovascular disease (CVD) are offered atorvastatin 80mg for secondary prevention". Not all individuals require 80 mg of atorvastain to achieve a 40% reduction in non-HDL cholesterol. Higher doses of statins are more likely to cause side effects. Would it be better to state that individuals should be offered up to 80 mg of atorvastatin?
British Medical Association	Statement 5	This can be supported
HEART UK	Statement 5	Second sentence…..can consult recommendations 1.3.42 & 43.. to ensure that specialist advice is sought about options for treating people at high risk of CVD such as those with CKD, type 1 diabetes, type 2 diabetes or genetic dyslipidaemias, and those with CVD, who are intolerant to 3 different statins.
MSD	Statement 5	Adverse effects with statins. Whilst it is important that adults with adverse effects on high-intensity statins are offered alternative doses of statins or an alternative statin, NICE also recommends ezetimibe in TA132 and CG181 (in-line

Stakeholder	Statement No	Comments[3]
		with TA132). The aim of the quality standard is to contribute to improvements in two Department of Health outcomes frameworks and the use of all lipid-modifying therapy is critical for achieving the NHS Outcomes Framework domains: • preventing people from dying prematurely, and • enhancing quality of life for people with long-term conditions as well as the Public Health Outcomes Framework for England domains: • improving the wider determinants of health and healthcare public health, and • preventing premature mortality The draft quality standard is a lipid modification quality standard, not just a statin quality standard, so appropriate use of all NICE recommended medications for lipid modification (statins and ezetimibe) are crucial to achieve the Department of Health's outcomes framework. MSD believe that quality statement 5 should be amended to: "Adults who develop adverse effects on high-intensity statins are offered alternative doses of statins, an alternative statin, or ezetimibe with or without a statin"
Public Health Nottinghamshire County, Public Health Nottingham City and on behalf of Nottingham and Nottinghamshire CCG	Statement 5	Comment on about quality statement 5. The quality statement should specifically refer to NHS Health Check programme as an important delivery mechanism, through liaison between CCGs and local authorities. Otherwise there is a missed opportunity to be explicit incentivising GP practices to do health checks.
Sanofi	Statement 5	We support the intent of quality statement 5 to ensure patients who develop adverse effects on high-intensity statins are considered for other therapies. However, we do not believe that this should be limited to other statins. We propose that the language is changed to read: *"Adults who develop adverse effects on high-intensity statins are offered alternative statins, lower doses or regimens of high intensity statins or alternative lipid lowering therapy options."* We believe that guidance is needed to support healthcare professionals in managing patients who develop adverse effects on high-intensity statins. Where a patient's lipid levels cannot be effectively managed in primary care there should be a clear process of referral. A quality statement should be added to reflect this in line with the clinical guideline, to support specialist assessment of people who are not controlled on existing treatment.
Wirral University Teaching Hospital	Statement 5	Paragraph headed Rationale, the last sentence, "Alternative strategies should be tried …..". Two strategies are specified, dose reduction or a lower intensity statin. There is also a second high intensity statin so should there be a

Stakeholder	Statement No	Comments[3]
		further option of "changing to an alternate high intensity statin"?
British Medical Association	Statement 6	This can be supported, providing the time window for the assessment is sufficiently wide to allow for flexibility.
HEART UK	Statement 6	Local data collection may be poor unless there is a general consensus to provide non HDL-cholesterol calculations and by inference automatic total cholesterol and HDL-cholesterol measurements on all samples sent for lipid analysis. This requires all laboratories in England and Wales to offer these measurements and the required calculation on any request for lipids.
HEART UK	Statement 6	Non HDL-cholesterol as a result is not in common use in the England (and the rest of the UK) and requires local data review and education to ensure that its use is promulgated.
Public Health Nottinghamshire County, Public Health Nottingham City and on behalf of Nottingham and Nottinghamshire CCG	Statement 6.	Comment on about quality statement 6. The quality statement should specifically refer to NHS Health Check programme as an important delivery mechanism, through liaison between CCGs and local authorities. Otherwise there is a missed opportunity to be explicit incentivising GP practices to do health checks.
Royal College of Pathologists	Statement 6	Local data collection may be poor unless there is a general consensus to provide non HDL-cholesterol calculations and by inference automatic total cholesterol and HDL-cholesterol measurements on all samples sent for lipid analysis. This requires all laboratories in England and Wales to offer these measurements and the required calculation on any request for lipids.
Royal College of Pathologists	Statement 6	Non HDL-cholesterol as a result is not in common use in the England (and the rest of the UK) and requires local data review and education to ensure that its use is promulgated.
Sanofi	Statement 6	We support a regular review for patients on high-intensity statins or at risk of CVD. To improve outcomes for patients we believe the review should not be limited to 3 months after the start of treatment, but be provided on a rolling 3-month basis until patients are well controlled and achieving their targets. The rationale for statement 6 sets out several options for when the expected 40% reduction in non-HDL cholesterol has not been achieved. These options include discussing adherence and timing of dose, optimising adherence to lifestyle changes and consideration of a higher dose. In addition to these options we believe that alternative lipid lowering therapy options should also be considered, when appropriate. As set out above in reference to quality statement 5, we believe that the quality standard should highlight the need for specialist assessment in people who are not controlled on existing treatment.

Registered stakeholders who submitted comments at consultation

- British Medical Association
- British Cardiovascular Society
- Department of Health
- HEART UK
- HQT Diagnostics
- Merck Sharp and Dohme (MSD)
- NHS England
- Public Health Nottinghamshire County, Public Health Nottingham City and on behalf of Nottingham and Nottinghamshire CCG
- Royal College of General Practitioners
- Royal College of Pathologists
- Sanofi
- Wirral University Teaching Hospital
- Wolfson Institute of Preventative Medicine

Appendix 3: Secondary prevention following an MI: Quality standard consultation comments table – registered stakeholders

Stakeholder	Statement No	Comments[4]
Association of Chartered Physiotherapists in Cardiac Rehabilitation (ACPICR)	General - introduction	The paragraph states that secondary prevention for people who have had an MI includes……. Changes in lifestyle eg healthy eating, regular exercise, stop smoking and then cites cardiac rehabilitation as a separate point. This may mislead as to what cardiac rehab is as lifestyle changes for secondary prevention are a core component of cardiac rehab.
Bayer HealthCare	General	We suggest that the quality standard should also cover the uptake of drug therapy in accordance with NICE guidance. CG172 recognises that primary PCI has replaced thrombolysis in most cases of STEMI and that this improvement in acute treatment may have an impact on secondary prevention. Similarly new drug treatments including rivaroxaban have recently been licensed and recommended for the secondary prevention of ACS and therefore may also impact on secondary prevention. NICE clinical guideline 172, MI secondary prevention,[1] includes the following recommendation which is a key priority for implementation: Offer all people who have had an acute MI treatment with the following drugs: • ACE (angiotensin-converting enzyme) inhibitor • dual antiplatelet therapy (aspirin plus a second antiplatelet agent) • beta-blocker • statin Rivaroxaban (Xarelto®) has also been recently recommended in NICE technology appraisal guidance [TA335].[2] It is recommended as an option within its marketing authorisation, in combination with aspirin plus clopidogrel or aspirin alone, for preventing atherothrombotic events in people who have had an acute coronary syndrome with elevated cardiac biomarkers.

[4]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

Stakeholder	Statement No	Comments[4]
		Proposed quality statement People who have had an acute myocardial infarction are offered drug treatment for secondary prevention in accordance with NICE guidance (both clinical guidelines and technology appraisals). (1) National Institute for Health and Care Excellence. MI - secondary prevention: Secondary prevention in primary and secondary care for patients following a myocardial infarction. Nov 2013. Available from: http://www.nice.org.uk/guidance/CG172. (Last accessed: 01/04/2014). (2) National Institute for Health and Care Excellence. Rivaroxaban for preventing adverse outcomes after acute management of acute coronary syndrome. NICE technology appraisal guidance [TA335]. March 2015. Available from: http://www.nice.org.uk/guidance/ta335. (Last accessed: 01/04/2014).
British Cardiovascular Society	General	Secondary prevention for people who have had an MI includes the following: No mention of coronary revascularisation as a method of reducing morbidity and mortality associated with coronary disease following a MI.
Department of Health	General	Thank you for the opportunity to comment on the draft for the above quality standard. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
HQT Diagnostics	General	Previous NICE reviews in Cardiology have minimised the use of Fatty Acids such as Omega-3 Fish Oil, for lack of evidence Results of recent large intervention trials with eicosapentaenoic acid (EPA) plus docosahexaenoic acid (DHA) supplements were neutral. In contrast, in epidemiologic studies, there were less clinical events after increased intake of EPA+DHA. This was found to be at an increased rate for higher levels of EPA+DHA. A standardized way of determining levels is the Omega-3 Index, which is the percentage of EPA+DHA of a total of 26 fatty acids measured in erythrocytes. According to current criteria, a low Omega-3 Index is a cardiovascular risk factor. NICE is invited to review the use of the Omega-3 Index as a diagnostic tool and an indicator of cardiovascular risk factor. Sources: http://www.plefa.com/article/S0952-3278(14)00079-9/abstract

Stakeholder	Statement No	Comments[4]
		http://www.expertomega3.com/omega-3-study.asp?id=13 www.hqt-diagnostics.com
HQT Diagnostics	General	Major improvements in Cardiovascular health have been seen within 1-3 months of adjusting levels of Fatty Acids to achieve: • Omega-3 Index >8% • Omega-6/3 Ratio <3:1 The Omega-3 Index is designed to provide a more reliable indicator of the levels of specific Fatty Acids than any other test. Omega-3 levels can be increased by eating more oily fish or taking Fish Oil supplements. The Omega-6/3 Ratio shows the level of Omega-6 compared to Omega-3. High levels of specific Omega-6 Fatty Acids contribute to high Inflammation. This can be reduced by eating less Sunflower oil (Omega-6=64%), less Corn oil (52%) and less Soybean oil (51%). Typical Omega-6/3 Ratio in UK people before advice & supplementation range between 15:1 and 35:1. Inflammation is reduced when the ratio is <3:1 The HQT Diagnostics Fatty Acid Test shows an average of all Fatty Acids eaten over the previous 60-90 days **Sources:** http://omega3care.com/wp-content/uploads/2013/11/Omega-3LiteratureListJuly2013.pdf (100+ references about Cardiovascular Disease) www.omegaquant.com www.omegametrix.eu/?lang=EN www.hqt-diagnostics.com
Royal College of Nursing	General	This is to inform you that the Royal College of Nursing has no comments to submit to inform on the above draft quality standard.

Stakeholder	Statement No	Comments[4]
Action Heart	Q1	Agreed, the draft quality standard appears to reflect the key areas for quality improvement.
Association of Chartered Physiotherapists in Cardiac Rehabilitation (ACPICR)	Q1	Yes
British Cardiovascular Society	Q1	Question 1: Does this draft quality standard accurately reflect the key areas for quality improvement? I believe a key area for quality improvement is timely and complete coronary revascularisation. There is under utilisation of coronary revascularisation procedures in certain patient groups e.g. the elderly. In addition, the delay in the provision of revascularisation is often unacceptable. Finally, revascularisation is often incomplete despite evidence that complete revascularisation is more effective at preventing repeat MI and cardiovascular death. I realise that coronary revascularisation is a part of treatment offered for MI, but it also has a considerable influence on secondary prevention of further MI I am also surprised that prescription of antiplatelet treatment is not a standard, both the number of anti-platelets, the different drugs now available and the duration of treatment. At the same time, assessing risk of and monitoring patients for bleeding complications has now become a very important part of secondary prevention.
NHS England	Q1	Does this draft quality standard accurately reflect the key areas for quality improvement? yes, but with additional comment above
Action Heart	Q2	Agreed, it should be possible to collect the data for the proposed quality measures.
Association of Chartered Physiotherapists in Cardiac Rehabilitation (ACPICR)	Q2	Yes
NHS England	Q2	If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Yes
Action Heart	Q3	Statement 1 Provide patients with record books which suggests they should have their investigation date/results recorded in the book. Statement 2 Copy of details forwarded to rehabilitation teams to act as ‘backstop’. Statement 3 Suggest a rehabilitation leaflet is available to patients prior to being discharged from hospital with rehabilitation contact details. Statement 4

Stakeholder	Statement No	Comments[4]
		Statement 5 See below for suggestions.
Association of Chartered Physiotherapists in Cardiac Rehabilitation (ACPICR)	Q3	Quality statement 1 – Adequate staffing to perform LV assessment in a timely manner (pre-discharge) 2 – Need for medics on the wards to complete accurate discharge summaries to be sent (fax or internet) to the GP on discharge & copy given to the patient on discharge 3 –Inpatient teams dedicated and ring fenced to be responsible for cardiac rehab referral. Better use of IT and improved IT infrastructure for referral on to outpt cardiac rehab programmes 4- Increased resources (staffing and facilities) for outpatient cardiac rehab programmes to be able to deliver daytime and evening sessions in home and community settings 5 – Increased resources for outpatient cardiac rehab services to be able to make contact with patient 10 days post discharge. Better use of IT systems and improved IT infrastructures to ensure referral is received quickly post discharge.
NHS England	Q3	For each quality statement what do you think could be done to support improvement and help overcome barriers? Principally, much better provision of rehabilitation services. this could become part of a best practice tariff perhaps.
Action Heart	Q4	This should be happening as part of routine practice and it should be straightforward to collect this information.
Association of Chartered Physiotherapists in Cardiac Rehabilitation (ACPICR)	Q4	Yes but sharing and dissemination of results with relevant services eg cardiac rehab services does not happen routinely
British Cardiovascular Society	Q4	In the majority of hospitals, yes
NHS England	Q4	For draft quality statement 1: Is assessment of left ventricular function happening routinely in practice? Yes. almost all patients will have an echocardiogram as part of their care before hospital discharge
Action Heart	Q5	Re: Definition of cardiac rehabilitation. In agreement with the first paragraph but feel the terminology in the second paragraph could be less ‘clinical’ and more plain speaking; in particular, psychosocial health and cardioprotective therapies could be reworded or explained more completely.
Association of Chartered Physiotherapists in Cardiac Rehabilitation (ACPICR)	Q5	No, there is a perception that cardiac rehab is only about exercise
British Cardiovascular Society	Q5	Yes
NHS England	Q5	For draft quality statement 3: Would the definition of a cardiac rehabilitation programme be universally understood?

Stakeholder	Statement No	Comments[4]
		Yes
University of Exeter	Q5	Would the definition of a cardiac rehabilitation programme be universally understood? No. Although the contents of a comprehensive CR programme are well described in the BACPR 2012 Standards the delivery of home based CR with the support of a facilitator as part of a self-management is not practiced widely despite the evidence used to formulate the NICE 2013 Clinical Guidance 172.
Action Heart	Q6	Re: Definition of orientation session Yes, in agreement with the definition of an 'orientation session', as long as there is flexibility as to how and where the session can be delivered. For example, the session could be delivered in a patient's home or even via the telephone, as not all patients will be driving or fully mobile within the 10 days timeline. Could it be worth reconsidering the actual name to help patients more easily understand the intention of the session. For example, 'Rehabilitation Needs Assessment' or something similar?
Association of Chartered Physiotherapists in Cardiac Rehabilitation (ACPICR)	Q6	No the definition of an orientation session is not universally understood, needs clarification as to what it should entail, eg face to face contact or telephone contact etc, plus what does assessment of the person's cardiac function refer to? A psychological assessment may be possible (eg HAD questionnaire) by 10 days but some patients may not be ready to have a physical assessment in cardiac rehab at 10 days post discharge (eg if they have had an MI plus bypass surgery or have other significant co-morbidities)
NHS England	Q6	For draft quality statement 5: Would the definition of an orientation session be universally understood? Yes
Association of Chartered Physiotherapists in Cardiac Rehabilitation (ACPICR)	Statement 1	Clarification needed on the quality of the assessment of left ventricular function (eg bedside echo or echo in outpatient radiology dept, 2 dimensional, doppler etc)
British Cardiovascular Society	Statement 1	Quality statement: Adults admitted to hospital following an MI have an assessment of left ventricular function. Quality measures are all measurable. Mentions echo as a method for assessing LV function, but some hospitals may choose other methods eg. LV angiography, cardiac MRI, nuclear imaging. I don't think much support would be necessary to support the delivery of this quality standard as most routinely measure LV function in patients presenting with MI. In hospitals that don't, it is likely to be a question of resource, both qualified personnel and lack of suitable equipment
Medtronic	Statement 1	Quality Statement 1 appropriately recognises the need for assessment of left ventricular function however the

Stakeholder	Statement No	Comments[4]
		'Rationale' section solely explains that this helps with decisions about the titration and duration of drug treatment. This overlooks the established practice and the important role of cardiac device therapy in improving morbidity and reducing mortality in this post MI population for patients, as recommended in NICE TA 314. We therefore request that the following is added to the 'Rationale' section: *"The outcome of this assessment will also inform decisions on whether to offer and treat patients with Implantable cardioverter defibrillators and/or cardiac resynchronisation therapy"* We request the following is added to the 'What the quality statement means for patients, service users and carers' section: "Adults who are admitted to hospital after a heart attack have a type of ultrasound scan (called an echocardiogram) to see how well the blood is being pumped through their heart. This helps with decisions about the type and dose of drug treatment *and whether to offer an implantable cardiac device*." Finally, we request the following reference is added to the Source Guidance Section: *Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (2014) NICE Technology Appraisal TA314*
Novartis Pharmaceuticals Ltd	Statement 1	We support quality statement 1 which recommends that adults admitted to hospital following an MI have an assessment of left ventricular function. We would, in addition, suggest that patients that have been admitted to hospital due to an MI are also regularly reviewed, at least every 6 months, in line with the NICE Quality Standard for Chronic Heart Failure. As the NICE guideline on Chronic Heart Failure points out "Heart failure is a progressive disease characterised by high re-hospitalisation rates and complications that can lead to a decline in renal, hepatic and neurological function" (p169), for this reason regular monitoring of patients is important.
Bayer HealthCare	Statement 2	Statement 2. Adults leaving hospital following an MI have details of drug titration and blood pressure and renal function monitoring shared with their GP. We suggest that *"future management plans"* and "*advice on secondary prevention"* should also be included in this quality statement to make it more consistent with the recommendation from NICE clinical guideline 172, MI secondary prevention,[1] which is a key priority for implementation:

Stakeholder	Statement No	Comments[4]
		After an acute MI, ensure that the following are part of every discharge summary: • confirmation of the diagnosis of acute MI • results of investigations • incomplete drug titrations • future management plans • advice on secondary prevention. Secondary prevention of MI may involve taking multiple medications over long periods of time, and since it has been suggested that between a half and third of all medicines prescribed for long term conditions are not taken as recommended,[2, 3] the communication of future management plans and advice on secondary prevention is crucial in aiding adherence to treatment. Better assessment and care planning and meeting identified needs has also been identified as an area for action in the Cardiovascular Disease Outcomes Strategy,[4] where it is suggested that *"providing patient-owned care plans in either GP or community settings or on discharge from hospital gives healthcare professionals the opportunity to engage patients in self-management. Professionals may wish to consider facilitating access to more comprehensive education and training programmes such as the Expert Patient Programme or arranging follow-up contacts for education and self-management support."* (1) National Institute for Health and Care Excellence. MI - secondary prevention: Secondary prevention in primary and secondary care for patients following a myocardial infarction. Nov 2013. Available from: http://www.nice.org.uk/guidance/CG172. (Last accessed: 01/04/2014). (2) Haynes RB, McDonald H, Garg AX, Montague P. Interventions for helping patients to follow prescriptions for medications. Cochrane Database Syst Rev 2002;(2):CD000011 (3) Nunes V, Neilson J. Clinical Guidelines and Evidence Review for Medicines Adherence: involving patients in decisions about prescribed medicines and supporting adherence. London: National Collaborating Centre for Primary Care and Royal College of General Practitioners. 2009. Available from: http://www.nice.org.uk/nicemedia/live/11766/42971/42971.pdf (4) Department of Health Cardiovascular Disease Team. Cardiovascular Disease Outcomes Strategy - Improving outcomes for people with or at risk of cardiovascular disease. 5 Mar. 2013. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/217118/9387-2900853-CVD-Outcomes_web1.pdf. (Last accessed: 01/04/2014).
British Cardiovascular	Statement 2	Quality statement:

Stakeholder	Statement No	Comments[4]
Society		Adults leaving hospital following an MI have details of drug titration, blood pressure and renal function shared with their GP. Communication with primary care is an important and very broad subject. There are many different areas of a patient's hospital admission that need to be communicated to primary care and monitoring after discharge, three of which have been picked in this statement, titration of medications, monitoring of BP and monitoring of renal function. These 3 areas relate more to the treatment of patients with heart failure than secondary prevention of MI. I would favour monitoring of antiplatelet prescription in relation to secondary prevention of MI eg. Whether the duration of different anti-thrombotic medications are clearly stated and what the patients bleeding risk is, and perhaps even whether the patients Hb has been measured and communicated to the GP what it is on discharge. I am not sure the statement as it stands is going to be easy to measure, given that there are multiple medications given on discharge. For each one, would there need to be a detailed plan of how to titrate, by how much, how quickly etc. Page 11 mentions outcome measure of 30-day readmission. This is not a specific measure of the quality of communication with primary care, drug titration, monitoring of BP and renal function. Therefore measuring this would not be helpful to assess quality of communication with primary care To deliver this standard, would need more support in primary care with education provided as to why and how to titrate medications, and how to monitor. Considerable resource would need to be put in place both for primary care and community heart failure teams as well as secondary care outpatient clinic provision to help with titrating medications, monitoring BP and renal function. This will require, as always, money!
Medtronic	Statement 2	The need for clear communication of drug titration, blood pressure and renal function to support the smooth transition between hospital and primary care are key, however we believe that other key physiological measurements should also be reported. Details of the patients' left ventricular function, including echocardiogram ejection fraction and ECG QRS width calculation, should also be reported and communicated, in doing so making the secondary care physician and GP aware of the need to monitor or refer the patient for consideration of Implantable cardioverter defibrillators and/or cardiac resynchronisation therapy in line with NICE TA314: We therefore respectfully suggest that the following is added to Quality Statement 2: "Adults leaving hospital following an MI have details of drug titration, blood pressure, *left ventricular function including echocardiogram ejection fraction and ECG QRS width calculation* and renal function monitoring shared with their GP."

Stakeholder	Statement No	Comments[4]
		Ref NICE TA314 pg 4
NHS England	Statement 2	Whilst the second (of the 5) Quality Statements refers to communicating 'drug titration, blood pressure and renal function' to the GP it doesn't make any statement about what constitutes drug therapy. It may be that this is assumed but I think it would be helpful to reinforce their own guidance regarding the actual drugs that should be prescribed (unless contraindicated), such as anti-platelets, beta-blockers, ACE inhibitors/ARBs, statins)
British Cardiovascular Society	Statement 3	Quality statement: Adults admitted to hospital following an MI are referred for cardiac rehabilitation while they are in hospital. This quality statement is well thought out. It is measurable and would not need much / any additional support improvement p.14 – outcome measure – incidence of cardiovascular events – this would not be a specific measure of successful cardiac rehabilitation given that many other factors that do not relate to cardiac rehab can also lead to cardiovascular events. Incidence of cardiovascular events would also need a tighter definition e.g. over what time period, MIs, strokes, emboli etc
Novartis Pharmaceuticals Ltd	Statement 3	We support quality statement 3 which recommends that adults admitted to hospital following an MI are referred for cardiac rehabilitation while they are in hospital. Novartis proposes that patients are also referred to a multidisciplinary heart failure service led by a specialist, if needed.
Action Heart	Statement 4	It is assumed that 'community settings' includes hospital programmes, but it may be worth stating this in the statement?
British Cardiovascular Society	Statement 4	Quality statement: Cardiac rehabilitation services provide both daytime and evening programmes in both community and home based settings. This quality statement is certainly relevant and picks up on areas of under-provision in the cardiac rehab arena, namely, out of hours provision and provision in the community. Most cardiac rehab teams that I am aware of, work solely in hours and in hospitals. The quality measures are measurable and address the standard proposed. This standard would require a large amount of support in order to be achieved, mainly in the form of financial

Stakeholder	Statement No	Comments[4]
		resource to fund extra rehab nurses, physios, psychologists etc, to enable coverage out of hours and in the community and at home, and to fund more facilities in the community
Action Heart	Statement 5	The ten day window to provide an 'orientation session' is potentially quite short from the patients' point of view, particularly if they are being expected to attend an outpatient type appointment. Could the wording be changed to "should be offered" within 10 days? As stated above, the target may be easier to achieve, for patients and clinicians, if the session can be conducted as either an outpatient appointment, a home visit or a telephone interview?
British Cardiovascular Society	Statement 5	Quality statement: Adults who enrol on a cardiac rehabilitation programme following an MI have an orientation session within 10 days of their discharge from hospital. I agree it is important for patients to have early follow up following an unplanned admission to hospital. Broadly speaking this is an area where the NHS performs poorly, primarily due to poor communication between primary and secondary care and lack of outpatient and GP resource. However, cardiac rehabilitation can be used effectively to provide patients with that early post discharge support that they often require, as long as the cardiac rehab teams have the skills to distinguish important, life threatening problems from more trivial ones and then communicate these to primary care and secondary care cardiology teams. All the measures stated are measurable. However, in this instance as an outcome measure I would use re-admission with cardiac illness within 30 days of discharge, rather than uptake rates of cardiac rehabilitation programmes, which is simply more a less repeating the one of the measures that assesses the process. I would guess that support would be necessary to achieve this quality statement, as a number of hospitals and patients may well struggle to make the 10-day target. This would require extra finances to pay for large rehab teams, hospital transport etc. Page 20: Question for consultation Would the definition of an orientation session be universally understood? Yes

Registered stakeholders who submitted comments at consultation

- Action Heart
- Association of Chartered Physiotherapists in Cardiac Rehabilitation (ACPICR)
- Bayer HealthCare
- British Cardiovascular Society
- Department of Health
- HQT Diagnostics
- Medtronic
- NHS England
- Novartis Pharmaceuticals Ltd
- Royal College of Nursing
- University of Exeter

Appendix 4: Quality standard internal checks table

Internal NICE team	QS	Statement No	Comments
QS team	CV risk & Lipid mod	General	Suggested combining 'Risk Assessment' and 'Lipid Modification' into 1 QS as they are underpinned by the same guidance (CG181), but to leave 'Secondary prevention' as a separate QS, as it's derived from CG172.
QS team	CV risk	1	Queried how the estimation was performed and what was the area for quality improvement – is it that people are not estimating the risk using a systematic strategy (screening?), or not following up with a formal assessment, or not using QRISK2?
QS team	CV risk	1	Is there a match to the annual health check?
QS team	CV risk	2	Suggested changing around to focus on the patient: Adults with T1D, CKD or FH are considered at high risk of CVD without using a risk assessment tool.
QS team	Lipid mod	1,2 & 3	Limit to adults under 85 years newly identified with a 10-year risk of CVD
QS team	Lipid mod	2 & 3	Remove 'for primary prevention' as it is already implied
QS team	Lipid mod	2	Change 'have the benefits of lifestyle discussed with them' to 'receive advice on lifestyle changes'
QS team	Lipid mod	3	Requested a timeframe for how long to wait before lifestyle changes are considered effective
QS team	Lipid mod	4	Add 'newly diagnosed CVD' and remove 'for secondary prevention'
QS team	Lipid mod	4	A clearer definition of CVD is needed
QS team	Lipid mod	5	Change to 'Adults who develop ~~adverse~~ side effects on high-intensity statins are offered ~~alternative doses~~ a lower dose of statin or an alternative statin'.
QS team	Lipid mod	5 & 6	Is limiting it to high intensity necessary? Side effects can occur with any statin – and should you have a 3 month review with any statin
QS team	Lipid mod	5 & 6	Requested a clearer definition of high-intensity statins with specific examples eg. atorvastatin 80 mg
QS team	2° prevention	1 & 2	Change to 'adults with an MI'
QS team	2° prevention	1	Add 'using an echocardiogram'
QS team	2° prevention	2 & 3	Reorder statements so that 3 comes before 2
QS team	2° prevention	2	Queried whether drug titration meant titration performed in secondary care, or any titration to be performed going forwards in primary care, or both?
QS team	2° prevention	2	Requested a timeframe for how quickly the information should be shared with the GP
QS team	2° prevention	4	Queried how realistic this statement was and to check if the guideline specified all these requirements.
QS team	2° prevention	5	Replace 'orientation session' with 'first' or 'introductory' session
NICE stakeholder	CV risk	1 & 2	I think the CG181 Lipid modification clinical audit tool, clinical audit standards 1 and 2 could be referenced as a data source for the process measure for quality statement.