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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INDICATOR DEVELOPMENT PROGRAMME

Consultation report on indicator(s)

Indicator area: Primary prevention of cardiovascular disease

Consultation period: 26 January 2015 – 23 February 2015

Potential output: Recommendations for the NICE Menu for the Quality and Outcomes Framework (QOF)

Contents

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Indicators included in the consultation

ID	Indicator	Evidence base
IND-8	The percentage of patients aged between 25 and 84 years, with a new diagnosis of hypertension recorded between the preceding 1 April and 31 March who have had a face-to-face cardiovascular risk assessment using the QRISK2 risk assessment tool within 3 months of the date of the hypertension diagnosis.	Recommendation 1.1.8 from the NICE guideline on lipid modification.
IND-9	The percentage of patients aged between 25 and 84 years, with a new diagnosis of hypertension or diabetes recorded between the preceding 1 April and 31 March who have had a face-to-face cardiovascular risk assessment using the QRISK2 risk assessment tool within 3 months of the date of the diagnosis.	Recommendations 1.1.8 and 1.1.10 from the NICE guideline on lipid modification.
IND-10	The percentage of patients aged between 25 and 84 years, with a new diagnosis of hypertension recorded between the preceding 1 April and 31 March who have a recorded cardiovascular risk assessment score of 10% or greater who are currently treated with statins.	Recommendation 1.1.8 from the NICE guideline on lipid modification.
IND-11	The percentage of patients aged between 25 and 84 years, with a new diagnosis of hypertension or diabetes recorded between the preceding 1 April and 31 March who have a recorded cardiovascular risk assessment score of 10% or greater who are currently treated with statins.	Recommendations 1.1.8 and 1.1.10 from the NICE guideline on lipid modification
IND-12	The contractor establishes and maintains a register of patients with a 10-year risk of CVD of 10% or more.	Recommendations 1.1.1, 1.1.4 and 1.1.6 from the NICE guideline on lipid modification

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Summary of consultation responses

A number of stakeholders welcomed potential additional cardiovascular disease (CVD) primary prevention indicators commenting that these would be a valuable addition and help rebalance following the removal of CVD indicators in previous years.

IND-8 and IND-9

- stakeholders were generally keen to extend the CVD risk assessment to include people with newly diagnosed hypertension and diabetes
- the requirement for the risk assessment to be undertaken 'face to face' was queried by stakeholders, with a number suggesting this was unnecessary
- stakeholders queried the requirement to solely use QRISK2, it was suggested this was too prescriptive
- the potential misalignment between the proposed indicators and the NHS Health Check Programme was noted
- there was also a request for clarity as whether this indicator would exclude people with existing CHD, diabetes, stroke and/or TIA as per the current CVD primary prevention indicator.

IND-10 and IND-11

- stakeholders suggested there is potential for statin therapy to be incentivised at the expense of lifestyle modification – which appears inconsistent with the intent of the NICE guideline on lipid modification (CG181)
- stakeholders were strongly in favour of indicators to promote informed patient choice and lifestyle advice in addition to statin therapy to encourage implementation of best practice to prevent CVD
- whilst noting that the 10% risk threshold is consistent with the latest NICE guidance it was highlighted that this is still divisive amongst clinicians
- despite reluctance for incentivised prescribing at the 10% threshold, stakeholders acknowledged the benefit of offering statin treatment after or alongside lifestyle modification

- the potential for an increase in exception reporting should the threshold be adjusted to 10% was suggested

- stakeholders queried why the indicators are limited to people with hypertension and diabetes rather than all people with high CVD risk. There were suggestions to include all people at high risk of CVD including people with chronic kidney disease (CKD).

IND-12

- stakeholders were generally supportive of a register of people with a 10-year risk of CVD of 10% or more. It was suggested this may be possible using information on GP systems or using information from NHS Health Checks

- the purpose of the register was queried, with a stakeholder suggesting this had the potential to 'over-medicalise risk'.

Other comments

A number of stakeholders including PH England and the Primary Care CVD Leadership Forum suggested the development of an indicator that incentivises a register for people with a high risk of developing type 2 diabetes.

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Comments by indicator (IND-8 and IND-9)

The percentage of patients aged between 25 and 84 years, with a new diagnosis of hypertension recorded between the preceding 1 April and 31 March who have had a face-to-face cardiovascular risk assessment using the QRISK2 risk assessment tool within 3 months of the date of the hypertension diagnosis.

The percentage of patients aged between 25 and 84 years, with a new diagnosis of hypertension or diabetes recorded between the preceding 1 April and 31 March who have had a face-to-face cardiovascular risk assessment using the QRISK2 risk assessment tool within 3 months of the date of the diagnosis.

Stakeholders noted that CVD risk assessment in people with newly diagnosed hypertension was previously a QOF indicator which worked well and there was general support for this to be expanded to include people with diabetes.

Generally stakeholders were supportive of extending the population covered by the indicators to include people with newly diagnosed diabetes i.e. preference of IND-9 over IND-8, commenting that there are unlikely to be many people with diabetes (particularly those with type 2 diabetes in the age range specified) who would not meet the 10% threshold.

Diabetes UK highlighted that primary prevention of cardiovascular disease relies on managing modifiable risk factors, such as diabetes. The Royal College of General Practitioners (RCGP) welcomed the idea of hypertension being considered a risk factor for several diseases and highlighted that IND 9 includes IND-8 since this covers both people with hypertension and diabetes.

The British Medical Association (BMA) also supported IND-9 on the proviso that the requirement for the assessment to be face-to-face is removed. The BMA considered that the important feature is to ensure the assessment is undertaken (rather than the requirement for this to be at a face to face consultation) with any subsequent treatment agreed through shared decision making. A number of comments were received from other stakeholders over the need for a face-to-face assessment with queries over the rationale for this, given QRISK2 is available online and can be completed using information in the patient record.

One stakeholder suggested that many people would be diagnosed elsewhere with GPs simply coding for CVD and undertaking any ongoing monitoring. Another stakeholder felt this detracted from checking blood pressure away

from GP surgeries and using IT and telephone consultations. A significant number of stakeholders did not consider the specification of this element necessary.

A number of comments were received over the applicability of QRISK2 to the whole primary care population, noting in particular the use in younger people. Stakeholders suggested QRISK2 is age dominated and thus younger populations with similar lifestyle risk factors have significantly lower scores. It was also noted that alternative tools may be being used in some practices and these are embedded into the primary care software. It was suggested that alternative tools e.g. lifetime CVD risk tools or Joint British Society 3 (JBS3) may be more suitable for people under 40 years. However, the indicators are in line with the NICE guidance on its use for CVD risk assessment, including all adults up to the age of 84.

The NHS Health Checks programme highlighted concerns of potential overlap between these indicators and the NHS Health Checks Programme. They commented that this may be confusing and represents inefficient use of resources, noting the potential for duplication of payments. They also expressed concerns that GPs may negate their responsibility to complete NHS Health Checks to fulfil their QOF requirements. One stakeholder noted that many people aged 45-74 years may have already had a QRISK2 risk assessment at their NHS Health Check but that for those that have not, these indicators would be beneficial. Another stakeholder commented that assessing people with raised blood pressure or diabetes typically includes undertaking QRISK2 and as such, a CVD risk assessment may have already been done in these populations.

There was a request for clarity as whether this indicator would exclude people with existing CHD, diabetes, stroke and/or TIA as per the current CVD primary prevention indicator. Stakeholders also queried if the CVD risk assessment could be undertaken 3 months before or 3 months after diagnosis in line with current QOF indicators for primary prevention of CVD. Other stakeholders considered it preferable to have longer than 3 months to assess CVD risk and suggested up to 1 year may be more suitable.

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Specific issue for consideration during consultation:

Stakeholders were asked during consultation to suggest an alternative way to identify people 'at high risk' of CVD in line with NICE guidance which recommends a systematic strategy for undertaking QRISK2.

- a number of stakeholders highlighted that automatic stratification searches can be run on GP clinical systems to identify people with risk factors.
- the NHS Health Check programme implements its current programme using a standard template embedded into computer software to run batch analysis using information already held by GP practices. Data sharing between local authorities and clinical commissioning groups would therefore allow people to be identified through the NHS Health Checks Programme.
- other suggestions for defining people at high risk of CVD included obesity according to BMI and waist circumference, waist height ratio, brachial and ankle blood pressures, smoking status in relation to age, HbA1c level, and simple age cut offs.

Comments by indicator (IND-10 and IND-11)

> *The percentage of patients aged between 25 and 84 years, with a new diagnosis of hypertension recorded between the preceding 1 April and 31 March who have a recorded cardiovascular risk assessment score of 10% or greater who are currently treated with statins.*
>
> *The percentage of patients aged between 25 and 84 years, with a new diagnosis of hypertension or diabetes recorded between the preceding 1 April and 31 March who have a recorded cardiovascular risk assessment score of 10% or greater who are currently treated with statins.*

A number of stakeholders, including the RCGP, noted that lifestyle modification is not currently covered and queried how a GP would demonstrate that a patient is making lifestyle modifications before deciding to consider or take statins. Some stakeholders considered that lifestyle modification should be included as this has the potential to offer similar benefits as statins.

A number of stakeholders considered that an offer of statins would more accurately reflect the NICE guidance and suggested that the focus should be

around the discussion with the patient and offer of treatment. Stakeholders commented that effective primary prevention of CVD is a complex clinical area with a number of factors to take into account, the most important of which are the views of the patient. It was felt that to evaluate this in a measure of prescribing disempowers patients and undermines informed patient choice. There was general consensus that the focus of this indicator should therefore be the discussion on the potential risks and benefits of lifestyle modification and, where appropriate, an offer of pharmacological therapy.

A number of stakeholders noted the controversy surrounding the 10% intervention threshold for CVD risk. It was acknowledged that this reflects the most recent evidence but was felt by some that, due to the considerable debate surrounding the updated guidance, there may be lack of professional support for incentivising a 10% threshold in QOF at present. Stakeholders considered the workload generated from these indicators potentially significant for primary care and questioned the benefit of statin therapy in people with a CVD risk of 10%. There was also acknowledgment of the potential for an increase in exception reporting should the threshold be adjusted to 10%.

The BMA considered it vital for the credibility of QOF to remain focussed on indicators that are supported by the profession as a whole and this is an area which does not have wholesale support. It was suggested that keeping the treatment threshold at 20% may be more likely to influence clinical behaviour due to the wider consensus on this target. One stakeholder considered the 10 year 10% threshold as assessed by QRISK2 may disadvantage some groups e.g. young people with significantly elevated lifetime risk and females as their risk is lower in QRISK2 than when assessed in other ways. A stakeholder considered the upper age range too high commenting that many older people would have 10 year risks greater than 10% by virtue of age alone. It was felt that the likely high levels of exception reporting in this group due to contraindications would negate the statistical validity of indicators.

Stakeholders queried why the indicators are limited to people with hypertension and diabetes rather than all people with high CVD risk. There were suggestions to include all people at high risk of CVD including people with CKD.

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Specific issue for consideration during consultation:

Stakeholders were asked during consultation whether lifestyle modification and statin therapy should be jointly incentivised and whether an indicator to specifically target lifestyle modification before statin therapy would be beneficial.

- the majority of stakeholders noted the value in lifestyle modification and considered this a crucial element of care for people at risk of CVD. Stakeholders noted NICE guidance recommends lifestyle modification as well as statin therapy.

- however stakeholders considered that incentivising lifestyle advice alone may lead to an avoidable cardiovascular risk burden.

- the relationship between indicators for lifestyle modification and statin therapy in terms of achievement and timeframes were considered important. Most stakeholders considered lifestyle modification before statin therapy appropriate.

- it was agreed there needs to be a definition of what constitutes 'lifestyle advice' to ensure consistency in delivery.

- onward referrals to lifestyle modification services e.g. stop smoking service, weight management service, alcohol services etc. could be considered in addition to lifestyle advice.

Comments by indicator (IND-12)

> *The contractor establishes and maintains a register of patients with a 10-year risk of CVD of 10% or more.*

Mixed comments were received from stakeholders in relation to establishing a register of all people at risk of CVD. A number of stakeholders welcomed the idea of a register for people at high risk of CVD commenting that this enables targeting of preventative work such as lifestyle modification and statin therapy.

It was felt that this indicator would be of value in improving clinical follow up and ongoing support for people identified via the NHS Health Check pathway and could be possible using information from NHS Health Checks or GP clinical systems. Other stakeholders considered it unreasonable to expect practices to establish a CVD risk register and considered this over-medicalising risk.

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Specific issue for consideration during consultation:

Stakeholders were asked during consultation whether it would be feasible and desirable to have a register of all patients identified as having 10 year risk of CVD of 10% or more.

- some stakeholder considered a register of people with a QRISK2 score of >10% a sensitive measure of local health for communities.
- it was noted that currently GPs are required to recall patients with a QRISK2 score >20% for annual follow up under the NHS Health Check Programme but currently there is no register in place to do this.
- stakeholders suggested populating the register using the NHS Health Check data as this is systematic and the data is sent to practices.
- it was queried if the register would be implemented retrospectively in order to identify people already with QRISK2 score of >10% and exclude people already identified as having CVD.
- there were queries around removing people from the register where their QRISK2 score falls below 10%, highlighting that this is not a static measure and can change with clinical and lifestyle modification.
- stakeholders recommended further strengthening this indicator with the inclusion of lifestyle modification and statin therapy with consideration for separate registers for people with a 10% - 19% CVD risk and a >20% CVD risk.
- her stakeholders highlighted the potential for this to become a tick box exercise open to gaming i.e. whereby a single patient with a QRISK2 score can create the register and trigger payment.
- concerns were also expressed that a 10% target may shift the focus away from managing people with a >20% risk increasing health inequalities.
- it was suggested that targeting people most likely to benefit by establishing an upper age limit and/or higher CVD risk threshold may be better.
- it was suggested that in order to have an overall strategy to target people at risk this should include people with CKD and diabetes.

- there was strong support for a separate register for people at high risk of diabetes using data from the NHS Health Check programme noting that this would be in line with the national Diabetes Prevention Programme currently being established by NHS England.

Considerations for the Advisory Committee

The specific issues that the Advisory Committee is asked to consider when making recommendations on which indicators should be published on the NICE menu for the QOF are stated below.

These issues are also addressed in the indicator development reports which will include suggestions for possible amendments to how the indicators should be specified following piloting and public consultation.

The Advisory Committee is asked to consider:

- whether CVD risk assessment should include both people with newly diagnosed hypertension and type 2 diabetes?
- whether CVD risk assessment should take place at a face-to-face consultation?
- if age and populations covered by different tools requires discussion or whether CVD risk assessment should be limited to the use of QRISK2.
- potential overlap with the NHS Health Checks programme
- the timeframe by which a CVD risk assessment should take place in relation to the date of the diagnosis e.g. 3 months before or 3 months after.
- if there are appropriate exclusions for these indicators e.g. 'established CVD' and what this should constitute, and people who have already had a CVD risk assessment e.g. at their NHS Health Check.
- whether additional indicators (or previous QOF indicator CVD-PP002[1]) around lifestyle modification should be considered to reflect the NICE guidance on lipid modification.

[1] CVD-PP002: The percentage of patients diagnosed with hypertension (diagnosed on or after 1 April 2009) who are given lifestyle advice in the preceding 15 months for: increasing physical activity, smoking cessation, safe alcohol consumption and healthy diet

  - the timing of potential indicators for lifestyle modification in relation to statin therapy
  - See NICE guideline CG181

- what constitutes 'lifestyle advice'.
- issues relating to the reduction to the current threshold for statin therapy (20%) to a 10% 10 year CVD risk including exception reporting.
- whether limiting these indicators to people with hypertension and diabetes rather than all people with high CVD risk (including those with CKD) is appropriate?
- whether a CVD risk register should be established using agreed criteria e.g. standard clinical searches using information already on the GP clinical system or information from NHS Health Checks
- whether additional indicators should be developed to complement a register and what these should be e.g. statin therapy and lifestyle modification.
- the development of an indicator that incentivises a register for people with a high risk of developing type 2 diabetes

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Appendix A: Consultation comments

Indicator ID	Stakeholder organisation	Comment
IND 8	Action on Smoking and Health (ASH)	Identifying people at high risk: People aged over 40 who smoke.
IND 8	British Heart Foundation	We agree. We note specific reference to a particular risk assessment tool. This could be a barrier for some practices that currently use a different risk assessment tool. These algorithms are often embedded in the primary care software and so not it is not trivial task to switch to a difference CVD risk assessment
IND 8	British Kidney Patient Association	As many of the QoF indicators for CKD have been removed, (despite there having been an increase in CKD detection and management since it was first introduced) we suggest that people with CKD, also identified as at high risk of CVD (see NICE CG182 on CKD) are included here.
IND 8	British Medical Association	This indicator can be supported if the requirement for the assessment to be face-to-face is removed. The important feature is that the assessment should be done, and the patient involved in the decision making that results, these two events need not be simultaneous. Many GPs deal with administrative tasks such as reviewing test results in the early morning or late at night when the presence of the patient is impractical. Prioritisation of those with hypertension or diabetes can be supported.
IND 8	County Durham and Darlington Local Medical Committee	There's no need to have a face-to-face cardiovascular risk assessment for this group of patients. Typically as part of the assessment of someone with raised blood pressure or diabetes a QRISK2 will be calculated on the basis of information gathered and might indeed already have been used to guide the need for intervention (in line with NICE guidance!). It would be more relevant simply to say a QRISK2 will be calculated.
IND 8	Dietitians in Obesity Management UK (domUK), a specialist group of the British Dietetic Association.	In order to identify people 'at high risk' of CVD for the purposes of the QOF, we suggest using obesity measured by BMI and WC, since obesity is a major risk for CVD, and CVD is a complication of poorly controlled Type 2 diabetes, which is highly prevalent in those with obesity, particularly visceral obesity.

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IND 8	East and North Hertfordshire CCG	Preferable to have longer than 3 months to allow treatments to work and take effect e.g. up to 1 year
IND 8	Heart UK	• NICE guidance recommends a systematic strategy to identify people likely to be at highrisk before a full formal risk assessment is carried out. For the purposes of the QOF, people with newly diagnosed diabetes and hypertension have been pragmatically selected for a formal assessment of CVD risk. Can stakeholders suggest a method to identify people 'at high risk' of CVD for the purposes of the QOF? HEART UK is of the view that the NHS Health Checks Programme is an important way to engage the public in health prevention by identifying risk factors for CVD, providing individuals with information to reduce their risk of CVD through lifestyle changes, and reducing their risk of CVD through treatment where necessary. HEART UK would like to see better data sharing between Local Authorities and Clinical Commissioning Groups so that patients identified through the NHS Health Checks Programme are managed as well as possible. We feel the national CVD register would fulfil this requirement.
IND 8	Primary Care CVD Leadership Forum	We agree. It is clinically and cost effective to identify those at high CVD risk and intensify treatment as well as offering lifestyle interventions and statin treatment as appropriate. Presumably the specification of QRISK2 reflects current NICE guidance. We question whether it makes sense to be prescriptive as JBS3 has now been developed and will be used by many.
IND 8	Public Health Nottinghamshire County	QOF IND 8 seems out of step with NHS Heath Checks as they make no reference to the programme and the age range is different. The indicator should specifically refer to NHS Health Check programme. Otherwise there is a missed opportunity to be explicit incentivising GP practices (through QOF) to do health checks. The focus appears to be on newly diagnosis hypertensive patients whereas it will be more useful if the QOF indicators were based around the NHS Health Check programme inclusion criteria. In essence, it will be useful to add the QOF indicator rationale for the focus on hypertension and how this related to the NHS Health Check programme.
IND 8	South Cheshire and Vale Royal CCG's	Searches could be run to pick out those with a positive family history, obesity, age over 60, and a smoker. This would likely pick up other at risk patients.
IND 8	Telford and Wrekin council	Systematic identification of likely high Risk using stratification searches run on clinical systems to identify those with any previous BP over 140/90 , those with a total cholesterol above 5 or an HDL below 1,or Family history of CVD<age 60 or known high risk ethnicities. Could or will the clinical

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		system providers agree to design common high risk searches?
IND 8	University of Leeds	More than 40% of subjects with diabetes are undiagnosed. Generalised obesity is used as a measure of high risk of diabetes and cardiovascular disease; however, the BMI thresholds vary for different populations. Waist height ratio threshold of more than 0.5 is considered abnormal across the populations. US preventative task force uses a BP threshold for testing of glycaemic status but that also misses a more than half of subjects with diabetes. Moreover, the prevalence of hypertension and its association with cardiovascular disease can be different in diverse populations. Increased systolic ankle blood pressure is associated with diabetes and higher hazard ratios for fatal and nonfatal cardiovascular events in Europeans. In certain populations, the value of increased systolic ankle blood pressure (as one of the earliest signs of subclinical atherosclerosis) might be greater than that of increased systolic brachial blood pressure at a relatively younger age with short lifetime exposure to risk factors. Therefore a simple and easy combination of waist, height, brachial and ankle blood pressures can be used as non-invasive, in expensive tools for identifying people 'at high risk' of diabetes and CVD for the purposes of the QOF across all populations.
IND 8/9	British Geriatrics Society	Checking their blood pressure, blood sugar, Body mass index and ECG (for atrial fibrillation) periodically e.g. ? yearly.
IND 8/9	NHS Health Checks	Can stakeholders suggest a method to identify people 'at high risk' of CVD for the purposes of QOF? The NHS Health Check programme is in place nationally to identify those aged 40-74 at high-risk of CVD and includes face-to-face QRISK2 assessment. Locally, we have employed incentives within our Locally Commissioned Service for the programme, to target patients on Mental Health and/or Learning Disability registers and those with a high QRISK2 score. These methods have been proven to be successful in increasing our identification of high risk individuals. To implement this, we have designed and embedded a template into EMIS software to run batch analysis to identify those with

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		high estimated QRISK 2 scores, enabling practices to invite those patients for a health check first. This batch analysis is based on information already held by GP practices with no additional resources required to run the searches and identify these patients.
IND 8/9	NHS Health Checks	Do you think there are potential unintended consequences to implementing any of these indicators? Our primary concern is that there may be a degree of overlap of cardiovascular risk assessment between these potential new QOF indicators and the existing NHS Health Checks Programme. This not only represents a potential source of confusion and inefficient use of resources but also raises the question about the possibility of duplication of payments. GP practices may also in the process of fulfilling QOF requirements; negate their responsibility to fully compete NHS health checks on patients who are eligible.
IND 8/9	NHS Health Checks	Do you think there is potential for differential impact? We acknowledge that QRISK2 is validated as a means of calculating risk of cardiovascular disease in adults aged 25-84. However, age is one of the most influential components in the QRISK2 calculation, and our local data has shown that patients age 35 – 39 have a significantly lower QRISK2 score than patients over 40, despite having a similar rate of lifestyle risk factors. This influence is likely to be even higher among those under 35 because of the weighting of age on QRisk2 score. Based on Islington Public Health GP dataset extraction (September 2012), 97.8% (CI 97.9% to 99.2%) of patients aged 35 – 40 had a low Qrisk2 score (<10% risk). For those aged 40 – 44 this was 93.3% (CI 92.0% to 94.4%). The full breakdown is provided below. 5-yr age group QRisk2 <10% QRisk2 10% - 19% QRisk2 >20% 35-39 98.7% 1.3%* 40-44 93.3% 6.0% 0.7% 45-49 83.8% 13.8% 2.4% 50-54 63.5% 30.4% 6.1% 55-59 35.2% 52.4% 12.4% 60-64 14.5% 65.0% 20.5% 65-69 4.2% 62.1% 33.7% 70-74 0.5% 43.7% 55.9%

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		*these two figures have been combined as the numerator values are too small to be disclosed Can you suggest how the indicator might be delivered differently to different groups to reduce health inequalities? We feel that there is a potential disadvantage in communicating a low QRISK2 score to patients who have several lifestyle risk factors for CVD. Other approaches to communicating risk such as a lifetime CVD risk score, JBS3, may be more suitable for patients under 40
IND 8/9	PHE Learning Disabilities Observatory	QOF IND 8 and QOF IND 9: Is the QRISK2 tool suitable for use with people with learning disabilities in terms of any reasonable adjustments needed to its presentation/use? Doesn't QOF IND 9 include QOF IND 8? Will it be possible to identify whether people with learning disabilities have similar treatment to others? Is Disaggregation possible?
IND 8/9	RCGP	The College is encouraged that there is now support for the idea that hypertension is properly considered to be one risk factor of several diseases. Note that indicator 9 includes indicator 8. RCGP Overdiagnosis Group Agreement on the QRISK action level needs to be decided i.e. is it 10% or 20% 10 year risk? Also QRISK is not accurate for people in their 80s and would potentially discriminate against these – we see many chronological 80 year olds who are biologically 70 years old and likely to have another 10 years of quality life ahead of them. (GR)
IND 8/9	South East Coast Cardiovascular Strategic Clinical Network (SEC CVD SCN)	It seems suprising that there is no mention of prediabetes (or Impaired glucose regulation) in the cardiovascular risk reduction particularly if there is to be a BMI indicator. Prediabetes carries similar risks to Type 2 diabetes in terms of cardiovascular disease and surely Hba1c needs to be one of the indicators in allowing identification of high risk individuals.
IND 8/9	South East Staffordshire & Seisdon Peninsular CCG	This has the potential to be quite complex, but as a starting point all patients with Type II diabetes should be considered high risk within the age group specified.
IND 8/9	Whalebridge Practice, Swindon and QOF Database Website	The use of the QRISK2 formula for patients with newly diagnosed hypertension was previously a QOF indicator until a couple of years ago when it was withdrawn. It worked well and there is no particular reason why it should not return. Similarly there is no reason not to extend this to patients newly diagnosed with diabetes. There will be few patients with diabetes who will not meet the 10%

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		threshold. The NICE guideline is unhelpful in its suggestion that high risk groups are determined before a full assessment without specifying this in more detail. Playing around with the formula suggests that it couple be worth screening all smokers over 50 years of age but a full assessment of whether this met the criteria for screening would be required and is likely outside the scope of this committee or consultation.
IND 8/9	Whitehall Surgery	Considering many patients will be diagnosed elsewhere, and GPs will simply code the condition and monitor them, considering many of them will be working age and we are aiming to get people checking their BP away from doctors and to use IT and telephone consultations, “face to face” in unnecessary, mainly with that short time limit. And why two indicators rather than just one?
IND 8/9	Yorkshire and Humber Commissioning Support Unit	Does the indicator allow for the assessment to be undertaken within the period three months before and three months after diagnosis? The wording does not make this clear
IND 8/9	Yorkshire and Humber Commissioning Support Unit	Would these indicators exclude patients who already have a diagnosis of CVD?
IND 9	Action on Smoking and Health (ASH)	Identifying people at high risk: People aged over 40 who smoke.
IND 9	British Heart Foundation	We agree. As with QOF IND 8, we note the specific reference to a particular risk assessment tool. This could be a barrier for some practices that currently use a different risk assessment tool. These algorithms are often embedded in the primary care software and so not it is not trivial task to switch to a difference CVD risk assessment
IND 9	British Medical Association	This indicator can be supported if the requirement for the assessment to be face-to-face is removed. The important feature is that the assessment should be done, and the patient involved in the decision making that results, these two events need not be simultaneous. Many GPs deal with administrative tasks such as these in the early morning, or late at night when the presence of the patient is impractical. Prioritisation of those with hypertension or diabetes can be supported.

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IND 9	County Durham and Darlington Local Medical Committee	There's no need to have a face-to-face cardiovascular risk assessment for this group of patients. Typically as part of the assessment of someone with raised blood pressure or diabetes a QRISK2 will be calculated on the basis of information gathered and might indeed already have been used to guide the need for intervention (in line with NICE guidance!). It would be more relevant simply to say a QRISK2 will be calculated.
IND 9	Diabetes UK	Primary prevention of cardiovascular disease relies on managing modifiable risk factors, such as diabetes. Our recommendation to IND 2. is equally applicable to this indicator. Establishing a register of people at high risk of diabetes (using the steps recommended in PH38) would identify people – in addition to those already included on the diabetes register – where interventions would be appropriate to reduce the risk of identifying primary prevention.
IND 9	Dietitians in Obesity Management UK (domUK), a specialist group of the British Dietetic Association.	In order to identify people 'at high risk' of CVD for the purposes of the QOF, we suggest using obesity measured by BMI and WC, since obesity is a major risk for CVD, and CVD is a complication of poorly controlled Type 2 diabetes, which is highly prevalent in those with obesity, particularly visceral obesity.
IND 9	East and North Hertfordshire CCG	Required clearer definition
IND 9	London Borough of Bexley – Public Health	IND-9 would be the preferred Primary Prevention of cardiovascular disease (risk assessment) As a pragmatic approach this would seem sensible. However, people between the ages of 45-74 years who have been newly diagnosed as having hypertension or diabetes through the NHS Health Check programme would have had a QRISK2 risk assessment at the time of the NHS Health Check so having a subsequent check within 3 months would be pointless given their initial NHS Health Check score. However, those newly diagnosed outwith the NHS Health Check programme would benefit from a formal assessment.
IND 9	NHS England and NHS Employers	See comments for indicator 8.
IND 9	Public Health Nottinghamshire County	See comments to QOF IND 8, it is unclear as to reason why hypertension is included in this indicator in addition to diabetes.
IND 9	Yorkshire and Humber Commissioning Support Unit	Patients with diabetes and/or hypertension feels like a sensible group of patients to target

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IND 8/10/11	NHS England and NHS Employers	There are effective tools currently in place for primary prevention of CVD (statin therapy). However, there is merit in incentivising lifestyle change over statins for this group at 10-20% risk-positive benefits for their hypertension and drug load too. Why describe treatment with atorva 20 as high intensity? Does this indicator include patients with existing CHD, diabetes, stroke and/or TIA as the current CVD primary prevention indicator excludes these existing conditions? What is the rationale for specifying that this is delivered face-to-face? This tool is an online tool informed by questions which can be answered via the patient record, so why does this need to be face-to-face?
IND 8/9/10/11	British Cardiovascular Society	We note the use of the QRISK2 score system and the 10% 10 year CVD threshold for offering treatment. 1. The use of this threshold disadvantages young people with significantly elevated lifetime risk and females. We advocate the use of lifetime risk as use in the JBS 3 guidelines http://heart.bmj.com/content/100/Suppl_2/ii1.full 2. QRISK2 is age dominated, therefore most men over 60 and women over 70 will fulfil the 10% threshold it would simplify the work of primary care practitioners to include all such patients as eligible
IND 8/9/10/11/ 12	Merck Sharp & Dohme Ltd	MSD appreciates the opportunity to comment on the consultation for potential new indicators for inclusion in the NICE QOF indicator menu. MSD believe that the five proposed primary prevention of cardiovascular disease indicators are a valuable addition to the QOF. During the consultation on the draft of CG181 MSD had concerns around how the recommendations of using QRISK2 for formal risk assessment of CVD, moving to a 10% or greater 10-year risk of developing CVD and initiation of statin treatment in this primary prevention group would be implemented. By introducing these QOF indicators and incentivising their implementation this would be valuable for patients. It is important that these indicators are included in the NICE menu for publication in August 2015.
IND 8/9/10/11/	Spire Southampton Hospital/ NHS	I've looked at the proposals and obviously welcome the additional CVD prevention QOF indicators, which will go some way towards rebalancing things after so many CVD indicators were 'lost' last time

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12		around.
IND 10	County Durham and Darlington Local Medical Committee	This is always problematic because not every patient chooses to have treatment with a statin initially and many prefer to try lifestyle modifications in line with NICE guidance. Furthermore to avoid burdening patients newly diagnosed with chronic disease and so as not to introduce too many new drugs at once it is not always appropriate to start lipid-lowering treatment soon after diagnosis.
IND 10	Action on Smoking and Health (ASH)	Yes, ASH believes that an indicator to specifically target lifestyle modification before statin therapy would be beneficial. We have concerns about the term "lifestyle advice" used here in the context of smoking cessation. “Lifestyle advice” might continue to perpetuate the idea that health care professionals should be advising smokers simply to stop rather than advising them how to stop and offering them treatment and support and treatment. An indicator specifically to target smoking before statin therapy would be beneficial but the wording should therefore be explicit containing the elements of requiring a statement "that the best/most effective way to stop smoking is with support and treatment” and “offering where the support and treatment can be obtained” There are both health and economic benefits of helping people to stop smoking and for those who succeed, many will no longer need to be prescribed statins. A study by Muir and colleagues examined the eligibility of patients in general practice for statin therapy using recommended screening guidelines (the Sheffield Tables) in which statins would be prescribed to those with a risk of heart attack in excess of 3% per year. They showed that if smokers who were assigned to statins at screening stopped smoking, over 80% would fall below the threshold needing statin therapy. (Muir J, Fuller A, Lancaster T (1999) Applying the Sheffield tables to data from general practice. British Journal of General Practice, 49, 218-9)
IND 10	British Heart Foundation	We do not agree. While this indicator is supported by recommendation from the NICE guideline on lipid modification, we do not agree that practitioners should be incentivised to treat with statins at a 10% threshold. While the NICE guidance states:

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		"1.3.18 Offer atorvastatin 20 mg for the primary prevention of CVD to people who have a 10% or greater 10 year risk of developing CVD. Estimate the level of risk using the QRISK2 assessment tool. [new 2014]" this is preceded by recommendations 1.3.14 and 1.3.16: "1.3.14 Before offering statin treatment for primary prevention, discuss the benefits of lifestyle modification and optimise the management of all other modifiable CVD risk factors if possible. [new 2014]" and "1.3.16 Offer people the opportunity to have their risk of CVD assessed again after they have tried to change their lifestyle. [new 2014]" Therefore, this indicator, and QOF IND 11, do not adequately reflect the NICE guidance as we understand it.
IND 10	British Medical Association	It is vital for the credibility of QOF that it remains focussed on indicators that make a significant difference to individual patients, where the evidence base for benefit is strong, and the profession as a whole backs their inclusion; the proposal to include a measure of statin use at the 10% risk threshold fails on all these counts. A QOF indicator for this will not measure the quality of care offered by practices to their patients, merely their willingness to resort to pharmacological rather than behavioural intervention, which is hardly a measure of good care. A practice which involves patients in a discussion about the relative risks and benefits of statin therapy and informs patients with the use of decision aids to show 'numbers needed to treat' and 'numbers needed to harm' will have lower prescribing figures for statins than one which simply prescribes, but will be providing higher quality care, so this proposed indicator is incompetent. Effective primary prevention of cardiovascular disease is a difficult and complex clinical situation, with a plethora of factors to take into account, the most important of which are the views of the patient. Attempts to evaluate this nuanced discussion by measuring crude prescription numbers is not only medically unjustifiable but incentivises an interventionist doctor-knows-best model of care which disempowers patients and undermines informed patient choice. The age range is too great to be used as a quality measure, as all patients in the upper age range will have 10 year risks greater than 10% by virtue of age alone, but many of these will be unsuitable

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		for statin therapy due to comorbidities, intolerance, or limited life expectancy. The large number of patients requiring completely appropriate exemption reporting will negate the statistical validity of the collected figures. With regard to the two specific questions, lifestyle modification will not have a significant impact on risk as measured by the QRISK2 calculator on early review. Annual formulaic intervention on smoking, alcohol, and diet for all patients is an unproductive activity and negates the sensible modification of hypertension indictors introduced in 2014-15. If it is desired to put forward an indicator regarding statins into the negotiation process for inclusion into QOF we would recommend an indicator measuring the patients who have had at diagnosis a discussion about statin therapy using a recognised decision making aid.
IND 10	Coastal West Sussex CCG	I feel that lifestyle measures should be included as an alternative to an offer of statins.
IND 10	Dietitians in Obesity Management UK (domUK), a specialist group of the British Dietetic Association.	In our view an indicator to specifically target lifestyle modification before statin therapy would be beneficial but should include 'healthy diet and effective weight management where appropriate'.
IND 10	EQUIP	The benefit to individual patients with a CVD risk of 10% from treatment with a statin is very small and the workload generated potentially enormous for a primary care system under enormous pressure It would be more beneficial to offer lifestyle advice including exercise but difficult to establish whether this would be more than a tick box exercise.
IND 10	EQUIP	I believe that roughly 7 million patients in the UK are taking a statin which delays 7000 deaths per year (we all go in the end and perhaps just increase our chances of dying from cancer or dementia). Many of these will have a much higher risk than 10% so the benefits for most individuals with a risk of 10% are reducing a less than 1 in 1000 risk of dying each year – alternatively 990 patients are taking a pill for 10 years to prevent the deaths of 10. This would not seem to be the best use of scarce health professional resource and if presented to patients in this way might reduce pill taking particularly if they did not have a family history of CVD. Important to quantify if possible the benefits of lifestyle interventions before the implementing treatment with pills. The recent initiative from medical Royal Colleges re the benefits of exercise are important. The GPPAQ tool was not fit for

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		purpose.
IND 10	Heart UK	• NICE guidance recommends treatment with statin therapy for anyone who has a CVD risk assessment score of 10% or greater where lifestyle modification is ineffective or inappropriate. Do stakeholders think lifestyle modification and statin therapy should be jointly incentivised? Yes, both are important. • Do stakeholders think an indicator to specifically target lifestyle modification before statin therapy would be beneficial? For example: The percentage of patients diagnosed with hypertension (diagnosed on or after 1 April) who are given lifestyle advice in the preceding 12 months for: smoking cessation, safe alcohol consumption and healthy diet? Yes
IND 10	Institute of Primary Care & Health Sciences/ Arthritis Research UK Primary Care Centre, Keele University	There is still sufficient uncertainty/controversy about 10% cut-off to re-look at this indicator. Easy to tick a box to say lifestyle advice given – much less easy to do this effectively.
IND 10	Kingstone Surgery	The indicator should relate to a discussion about statins including their risks and benefits and an offer to prescribe. It is the shared decision making process that should be incentivised not what the patient decides since they are not accountable for the indicator result. The lifestyle indicator is not relevant because patients will still potentially benefit from a statin even if they have improved their lifestyle. I would also bring the age limit down to 74 if the indicator is introduced.
IND 10	Medical Directorate - NHS England	Why is the incentive for statin treatment in people with high CVD risk limited to those with hypertension and diabetes, and not all people with high CVD risk? Presumably people who elect not to take statins would be 'excepted'.
IND 10	N/A - individual comment	There should be more emphasis on lifestyle change for those with hypertension and diabetes. If GPs are incentivised for prescribing statins it may reduce their motivation to refer patients to smoking cessation, weight loss etc etc
IND 10	NHS England and NHS Employers	See comments for indicator 8. This indicator is likely to be unpopular.

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		The 10% target is controversial and it is not felt that this indicator would change current practise.
IND 10	Primary Care CVD Leadership Forum	We acknowledge that the suggestion of a 10% threshold reflects the most recent NICE guidance. We accept there is value in a register of individuals whose 10 year CVD risk is greater than 10% (see IND 12 below) so that these individuals can be advised of the evidence around lifestyle and statins at this risk level. However because there is considerable debate on this at present, it would have limited real world value to incentivise 10% as the treatment threshold. We suggest setting the treatment threshold at 20% as a first aspiration because there is wider consensus on this threshold, and at this time it is likely to have a much greater influence on clinical behaviour than a 10% treatment threshold. Secondly it is important that the indicator does not require prescription of statins. Rather it should refer to 'provision of lifestyle advice and offer of statins' - this would reflect more accurately what the 2014 NICE guidance actually says.
IND 10	Public Health Nottinghamshire County	It is unclear why QOF IND 10 and 11 focus on hypertension or not all patients with 10% or greater CVD risk. In addition there are significant estimated cost implications for implementing statin therapy for 10% or greater CVD risk. Therefore the implementation of this aspect of the NICE CG 181 is being considered locally.
IND 10	RCGP	This indicator does not encourage pursuit of lifestyle modification and in fact promotes over-medicalisation of risk rather than disease. How would a GP demonstrate that a patient is following lifestyle modification before making a decision on statin prescribing? The decision should be made by the patient after a discussion about the pros and cons (and perhaps the controversies around the industry-weighted evidence promoting statin prescribing) and not be swayed by a payment to a GP. This is lifelong prescribing and should not be influenced by a GP's income. Physical fitness is not mentioned – probably counts for at least as much benefit as statin prescribing. (RP) Issue of lifestyle modification being ineffective is interesting. It has been already stated how difficult GPs are finding supporting patients to lose weight; the same applies to our efforts to reduce blood cholesterol with dietary modification, and our effectiveness at getting patients to take exercise. If incentivised via QOF, as it is already in an indicator for those with high blood pressure, there is a risk that this becomes a box-ticking exercise with no serious content, as in other areas. RCGP

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		Overdiagnosis Group
IND 10	Royal National Institute of Blind People	Specific issue for consideration during consultation: NICE guidance recommends treatment with statin therapy for anyone who has a CVD risk assessment score of 10% or greater where lifestyle modification is ineffective or inappropriate. Do stakeholders think lifestyle modification and statin therapy should be jointly incentivised? Yes, lifestyle modification and Statin therapy should be jointly supported as this will aid prevention of cardiovascular disease.
IND 10	Royal National Institute of Blind People	Do stakeholders think an indicator to specifically target lifestyle modification before statin therapy would be beneficial? For example: The percentage of patients diagnosed with hypertension (diagnosed on or after 1 April) who are given lifestyle advice in the preceding 12 months for: smoking cessation, safe alcohol consumption and healthy diet? Studies indicate that smoking is associated with the sight threatening eye condition, Age-Related Macular Degeneration (Woodell et al., 2014; Ni Dhubhghaill et al., 2010). In light of this we welcome an indicator to specifically target lifestyle modification prior to Statin therapy.
IND 10	South Cheshire and Vale Royal CCG's	I think Lifestyle Changes should be given parity with Statin therapy initially. We do not want to encourage people to just be put on medication; changes to Lifestyle will be beneficial to the patient as a whole.
IND 10	Telford and Wrekin council	the indicator needs to induce the offer of lifestyle intervention first followed by a review to check whether it has been effective in reducing risk to below 10%. If not then statin offer is next step, so may be best achieved with 2 indicators. If the consultation reveals clinical reluctance to statin prescribing at 10% risk, the indicator needs to be structured in a way that strongly promotes lifestyle advice. Recent evidence also suggests better outcomes in addressing population risk factors rather than statin prescribing which may be adding to inequalities. BMJ Open2015;5:e006070 doi:10.1136/bmjopen-2014-006070
IND 10	Yorkshire and Humber Commissioning Support Unit	There is the potential for statin therapy to be incentivised at the expense of lifestyle modification. Indicators focusing on lifestyle modification would be preferable
IND 10/11	East Sussex Public health	QOF IND 11 is preferable over QOF IND 10, as it also includes diabetes, a condition also high risk for CVD.

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		The indicators as they are currently proposed could perversely incentivise statin therapy as the first line treatment for primary prevention of CVD in those with greater than 10% CVD risk, and dis-incentivise clinicians to provide lifestyle modification advice and support as the first line treatment, as recommended by NICE. Both statin therapy and lifestyle modification should be jointly incentivised to encourage implementation of best practice aimed at prevention of CVD. This should include an additional indicator to specifically target lifestyle modification before statin therapy. For example, the percentage of patients diagnosed with hypertension or diabetes given lifestyle advice in the preceding 12 months for: healthy diet, increasing physical activity, smoking cessation and safe alcohol consumption.
IND 10/11	PHE	Even though safe alcohol consumption is mentioned in the example for a proposed lifestyle modification indicator, there is no action being requested of primary care concerning alcohol and suggest this be included in the wording.
IND 10/11	British Kidney Patient Association	Targeting lifestyle modification first is always beneficial and there is good evidence that statins are very useful for people at all stages of kidney disease, so this use should be included.
IND 10/11	Binscombe Medical Centre	The indicators relate to the new NICE guidance concerning the use of statins in patients with a 10 year CVD risk > 10%. The guidance states that in this case a statin should be offered, but the draft indicators are for those who are actively treated. The lipid modification guidelines by NICE have proved to be one of the most controversial NICE guidelines as they imply that most men over 60 and most women over 65 should be offered a statin. Many patients will not want to take a statin at this level of risk, since the numbers needed to treat are high. For this reason the guidelines rightly state that statins should be offered, and that the decision to treat should be based on an informed choice by the patient. If these QOF indicators proceed in their current form then the emphasis will shift from the choice of an informed patient to the active use of a statin. Doctors will be penalised for encouraging informed choice, and patients may be pressured into taking treatment in order to help attain a target.

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		The indicators would be far better if they measured not the proportion of these patients taking a statin, but the proportion that have had an informed, face-to-face discussion with their GP about the use of statins, with the use of an approved patient decision aid (which would need to be supplied to GPs in order to facilitate this). It will be imperative that there is no requirement to have this discussion on an annual basis in future years, since this will prove irritating to patients who have made an informed decision, and have significant resource implications for GPs in this indicator runs for several years. On a separate note it is slightly baffling to have one indicator for a new diagnosis of hypertension and a second for a new diagnosis of hypertension or diabetes, since this seems to duplicate matters.
IND 10/11	Jiggins Lane Medical Centre (Note - 2 proformas submitted)	Many of the concerns that I have about the use of statins in patients with a Qrisk of less than 20% have been well articulated already by Professor David Haslam and colleagues, when the NICE draft guidelines were first proposed [1]. The main points of concerns that have already been made by him and ignored by yourselves are as follows: • Lowering the threshold for intervention with statins will lead to the medicalisation of 5 million healthy adults • The wide variation in the reports of adverse effects in statin trials leads one to believe that some trials had “run in” periods when patients not tolerating them were excluded before any analysis took place. In other words the statistical analyses may not truly be “intention to treat”. • Concerns that pharmaceutical companies have not released all the data they have on statin trials. • The effect of publication bias on statin trials, all but one of these was sponsored by pharmaceutical companies. • The fact that most GPs would not ask to be prescribed a statin for themselves, leading to a loss of professional confidence in the healthcare targets they are being asked to meet • Concerns over conflicts of interest of panel members of the NICE guideline panel, who have financial links with pharmaceutical companies (Please see original letter for references) In addition to these I would add that the opportunity cost of offering statins to patients with a Qrisk of over 10% is massive. The following process would use up time and practice resources that are

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		simply not currently available: Ø Patient attends for blood test/BP check etc Ø Explanation of results and risks to patients leading to shared-decision making Ø Lifestyle advice offered Ø Statin offered Ø Measurement of LFTs 1 month after initiation Ø Explanation of results Ø Re-measurement of cholersterol:HDL ratio in perhaps 3 months to check efficacy Ø Explanation of results All of these things take time and resources. Furthermore, it is difficult to quantify the effect on the psychology of the patient. I would imagine they are more likely to adopt the sick role, more likely to attend with minor aches and pains, more likely to go to A+E, because they think they are "at risk". It will make the "worried well", more worried. Furthermore, there is no apparent scope available for patients to have a period of time to put lifestyle measurements into place, dietary and weight loss, to see the effect that this might have on their Qrisk. A wider discussion needs to be had to decide if an absolute risk reduction of 3-4% is worth the investment of so much time, energy and resources (figures from the Qintervention site). Do patients realise that when they are at a lower risk that statins will prolong their life by 3-4 months over 20 to 25+ years?[2] 1. http://www.nice.org.uk/Media/Default/News/NICE-statin-letter.pdf [accessed 12 Feb 2014] 2. http://cpr.sagepub.com/content/20/5/827?ijkey=553e60b1aa2b64d2707935ae3908c25568e4b012&keytype2=tf_ipsecsha [accessed 12 Feb 2014]
IND 10/11	NHS Health Checks	Do stakeholders think lifestyle modification and statin therapy should be jointly incentivised? We feel that lifestyle intervention is equally important for the reduction of CVD risk and these should be jointly incentivised.
IND 10/11	NHS Health Checks	Do stakeholders think an indicator to specifically target lifestyle modification before statin therapy would be beneficial? Yes, we feel that an indicator to specifically target lifestyle modification before statin therapy would be beneficial. This should include lifestyle advice in the preceding 12 months for physical activity, in

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		addition to the three outlined in the example provided (smoking cessation, safe alcohol consumption, and healthy diet).
IND 10/11	NHS Health Checks	Do you think there are any barriers to implementing the care described by any of these indicators? Locally we have commissioned a number of lifestyle services and it would be preferable for primary care staff to offer referrals into appropriate services, in addition to providing lifestyle advice. However, in some areas there may be concerns regarding the availability and capacity of lifestyle services. Some local GPs have expressed a concern regarding overprescribing of statins. The availability of lifestyle services could not only increase patient choice and autonomy over the management of their risk of CVD but also provide GPs with a possible alternative or precursor to medical therapy.
IND 10/11	Pennine Surgery	We are completing NHS health checks and are finding hypertension during these assessments. Some of these patients have not been seen for years so they will not have had previous life style advice. This would not be possible this would only work on new hypertensions having advice the first year and if no improve the next year then start on a statin.
IND 10/11	Public Health England	The proposal is to limit the incentive for statin treatment in people with high CVD risk to those with hypertension and diabetes - why not all people with high CVD risk. Presumably people who elect not to take statins would be excepted.
IND 10/11	RCGP	Many of the concerns that we have about the use of statins in patients with a QRISK of less than 20% have been well articulated already by Professor David Haslam and colleagues, when the NICE draft guidelines were first proposed [1]. The main points of concerns that have already been made are as follows: • Lowering the threshold for intervention with statins will lead to the medicalisation of 5 million healthy adults • The wide variation in the reports of adverse effects in statin trials leads one to believe that some trials had “run in” periods when patients not tolerating them were excluded before any analysis took place. In other words the statistical analyses may not truly be “intention to treat”. • Concerns that pharmaceutical companies have not released all the data they have on statin trials. • The effect of publication bias on statin trials, all but one of these was sponsored by pharmaceutical companies. • The fact that most GPs would not ask to be prescribed a statin for themselves, leading to a loss of

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		professional confidence in the healthcare targets they are being asked to meet • Concerns over conflicts of interest of panel members of the NICE guideline panel, who have financial links with pharmaceutical companies In addition to these we would add that the opportunity cost of offering statins to patients with a QRISK of over 10% is massive. The following process would use up time and practice resources that are simply not currently available: Ø Patient attends for blood test/BP check etc. Ø Explanation of results and risks to patients leading to shared-decision making Ø Lifestyle advice offered Ø Statin offered Ø Measurement of LFTs 1 month after initiation Ø Explanation of results Ø Re-measurement of cholersterol: HDL ratio in perhaps 3 months to check efficacy Ø Explanation of results All of these things take time and resources. Furthermore, it is difficult to quantify the effect on the psychology of the patient. Furthermore, there is no apparent scope available for patients to have a period of time to put lifestyle measurements into place, dietary and weight loss, to see the effect that this might have on their QRISK. A wider discussion needs to be had to decide if an absolute risk reduction of 3-4% is worth the investment of so much time, energy and resources (figures from the Qintervention site). Do patients realise that when they are at a lower risk that statins will prolong their life by 3-4 months over 20 to 25+ years? [2] The group would be happier if this indicator was not used at all, because of all the reasons outlined above. A compromise may be that instead of measuring the percentage of patients with a QRISK of 10% on a statin, that the wording be altered to: “percentage of patients with a QRISK over 10% that have been offered the opportunity to discuss the potential benefits of statins using an approved shared decision making patient decision tool.” Although this wouldn’t necessarily mitigate the risks of over medicalisation and massive opportunity costs outlined above.

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		1. http://www.nice.org.uk/Media/Default/News/NICE-statin-letter.pdf [accessed 12 Feb 2014] 2. http://cpr.sagepub.com/content/20/5/827?ijkey=553e60b1aa2b64d2707935ae3908c25568e4b012&keytype2=tf_ipsecsha [accessed 12 Feb 2014] RCGP Overdiagnosis Group
IND 10/11	South East Coast Cardiovascular Strategic Clinical Network (SEC CVD SCN)	I think that they should be jointly incentivised ie that within a 12 month period in those patients who have a CVD risk of > 10 % which remains above 10 % within the same 12 month period, despite lifestyle advice, the contractor should be paid only if the patient commences a statin. If the patient refuses a statin then they should be excluded from this indicator. There needs to be a mention of activity and sleep within the lifestyle advice. The problem with incentivising lifestyle advice is that many patients do not follow the advice or follow it transiently. Incentivising for lifestyle advise alone will likely lead to an avoidable cardiovascular risk burden.
IND 10/11	South East Staffordshire & Seisdon Peninsular CCG	This indicator does not feel entirely appropriate as it is linked to the prescribing of statins. The rationale clearly sets out where NICE recommends the use of statins but fails to recognise para 1.3.12 of the guidance which puts the patient at the centre of the decision making process. This therefore potentially sends out the wrong message and potentially will lead to larger patient numbers being prescribed statins inappropriately. I'd prefer to see an incentive that documents that the risks and benefits of lifestyle modification have been discussed and that statins have also been discussed and where appropriate offered. The risks and benefits of statins also need to be explained- ie for a 1000 patients like you with a 10-year CV risk of 10%, a 100 will have an event. If all 1000 take statins 25 fewer will have an event, but 975 won't have any benefit, but may get adverse effects. Faced with this many patients are likely to decline, and therefore GPs should not be incentivised by prescribing rates in isolation.
IND 10/11	Whalebridge Practice, Swindon and QOF Database Website	The problems with these indicators is well highlighted in the consultation document. These indicators specifically refer to patients in whom a new diagnosis is made in the previous year (in reality exception reporting requirements are likely to extend this to around fifteen months). If lifestyle intervention is to be first line (and this is appropriate in patients with a relatively low risk and hence low benefit) then this is most likely to be in the first six to nine months after diagnosis. Lifestyle changes take some time to show their benefit. Some patients will be little more than three

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		months after diagnosis when lifestyle interventions should still be working their way through to blood tests or BP readings. The indicators could be reworded to specify any intervention - whether lifestyle or pharmaceutical. Alternatively it could be changed to look at any year other than the one of diagnosis. It should also be noted that, although the NICE guidance is currently 10% risk threshold, this remains controversial amongst practicing clinicians
IND 10/11	Whitehall Surgery	There is controversy about statin use at 10% risk, more considering latest research suggesting some of the benefits implied in the initial statin studies have been secondary to diet/exercise/lifestyle rather than tablets themselves. What is needed is not to overmedicate, but to promote healthy lifestyle. That should be the code to add, not simply a statin.
IND 10/11/12	Hambleton, Richmondshire and Whitby CCG	Concerns regarding a 10% risk level. At present it is 20% over 10 years, at 10 % we risk medicalising almost all of the population. If someone smokes they will have a greater than 10% risk. We should encourage smoking cessation rather than prescribing a statin.
IND 11	British Heart Foundation	We do not agree. See our comments above for QOF IND 10. Lifestyle modification should be offered and incentivised independently of statin treatment.
IND 11	British Medical Association	It is vital for the credibility of QOF that it remains focussed on indicators that make a significant difference to individual patients, where the evidence base for benefit is strong, and the profession as a whole backs their inclusion; the proposal to include a measure of statin use at the 10% risk threshold fails on all these counts. A QOF indicator for this will not measure the quality of care offered by practices to their patients, merely their willingness to resort to pharmacological rather than behavioural intervention, which is hardly a measure of good care. A practice which involves patients in a discussion about the relative risks and benefits of statin therapy and informs patients with the use of decision aids to show 'numbers needed to treat' and 'numbers needed to harm' will have lower prescribing figures for statins than one which simply prescribes, but will be providing higher quality care, so this proposed indicator is incompetent. Effective primary prevention of cardiovascular disease is a difficult and complex clinical situation, with a plethora of factors to take into account, the most important of which are the views of the patient. Attempts to evaluate this nuanced discussion by measuring crude prescription numbers is not only

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		medically unjustifiable but incentivises an interventionist doctor-knows-best model of care which disempowers patients and undermines informed patient choice. The age range is too great to be used as a quality measure, as all patients in the upper age range will have 10 year risks greater than 10% by virtue of age alone, but many of these will be unsuitable for statin therapy due to comorbidities, intolerance, or limited life expectancy. The large number of patients requiring completely appropriate exemption reporting will negate the statistical validity of the collected figures. With regard to the two specific questions, lifestyle modification will not have a significant impact on risk as measured by the QRISK2 calculator on early review. Annual formulaic intervention on smoking, alcohol, and diet for all patients is an unproductive activity and negates the sensible modification of hypertension indictors introduced in 2014-15. If it is desired to put forward an indicator regarding statins into the negotiation process for inclusion into QOF we would recommend an indicator measuring the patients who have had at diagnosis a discussion about statin therapy using a recognised decision making aid.
IND 11	Coastal West Sussex CCG	I feel that lifestyle measures should be included as an alternative to an offer of statins.
IND 11	County Durham and Darlington Local Medical Committee	For these reasons it might be better to have an indicator that looks at lifestyle advice as an initial intervention and then a further indicator that looks at current treatment of statins not in patients diagnosed in the year leading up to March 31 but in the year prior to this.
IND 11	County Durham and Darlington Local Medical Committee	This is always problematic because not every patient chooses to have treatment with a statin initially and many prefer to try lifestyle modifications in line with NICE guidance. Furthermore to avoid burdening patients newly diagnosed with chronic disease and so as not to introduce too many new drugs at once it is not always appropriate to start lipid-lowering treatment soon after diagnosis.
IND 11	Diabetes UK	We are concerned that the blanket approach of statin therapy would not be appropriate as an indicator, particularly for such a wide age range. There is potential to include people for whom statin therapy would not be appropriate. We would recommend the other proposed indicators are considered further.
IND 11	Dietitians in Obesity Management UK (domUK), a specialist group of the British	In our view an indicator to specifically target lifestyle modification before statin therapy would be beneficial but should include ‘healthy diet and effective weight management where appropriate’.

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	Dietetic Association.	
IND 11	East and North Hertfordshire CCG	As with QOF IND 9, requires clearer definition
IND 11	EQUIP	See comments for IND 10
IND 11	Heart UK	• NICE guidance recommends treatment with statin therapy for anyone who has a CVD risk assessment score of 10% or greater where lifestyle modification is ineffective or inappropriate. Do stakeholders think lifestyle modification and statin therapy should be jointly incentivised? Yes • Do stakeholders think an indicator to specifically target lifestyle modification before statin therapy would be beneficial? For example: The percentage of patients diagnosed with hypertension or diabetes (diagnosed on or after 1 April) who are given lifestyle advice in the preceding 12 months for: smoking cessation, safe alcohol consumption and healthy diet? Yes
IND 11	Kingstone Surgery	The same comments apply as to 10. Most diabetics will have a risk of over 10% anyway and I would keep the current cholesterol target indicator for diabetics.
IND 11	London Borough of Bexley – Public Health	IND-11 is the preferred indication for Primary Prevention of cardiovascular disease (statin therapy). Yes, lifestyle modification and statin therapy should be jointly incentivised. Yes, there should be an indicator to specifically target lifestyle modification before statin therapy, however, it should not simply record lifestyle advice but referral offered into lifestyle modification e.g. stop smoking service, weight management service, Health Trainer, alcohol services etc.
IND 11	Medical Directorate - NHS England	Why is the incentive for statin treatment in people with high CVD risk limited to those with hypertension and diabetes, and not all people with high CVD risk? Presumably people who elect not to take statins would be 'excepted'.
IND 11	NHS England and NHS Employers	See comments for indicator 8. This indicator is likely to be unpopular. The 10% target is controversial and it is not felt that this indicator would change current practise.
IND 11	Primary Care CVD Leadership Forum	We acknowledge that the suggestion of a 10% threshold reflects the most recent NICE guidance. We accept there is value in a register of individuals whose 10 year CVD risk is greater than 10% (see IND 12 below) so that these individuals can be advised of the evidence around lifestyle and statins at this risk level.

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		However because there is considerable debate on this at present, it would have limited real world value to incentivise 10% as the treatment threshold. We suggest setting the treatment threshold at 20% as a first aspiration because there is wider consensus on this threshold, and at this time it is likely to have a much greater influence on clinical behaviour than a 10% treatment threshold. Secondly it is important that the indicator does not require prescription of statins. Rather it should refer to 'provision of lifestyle advice and offer of statins' - this would reflect more accurately what the 2014 NICE guidance actually says.
IND 11	Public Health Nottinghamshire County	It is unclear why QOF IND 10 and 11 focus on hypertension or not all patients with 10% or greater CVD risk. In addition there are significant estimated cost implications for implementing statin therapy for 10% or greater CVD risk. Therefore implementation of this aspect of the NICE guidance 181 is being considered locally.
IND 11	RCGP	Same concerns as above – we are concerned about this indicator. It may be better to incentivise the giving of lifestyle advice (RP) As above this one includes indicator 10. What is the rational for this? RCGP Overdiagnosis Group
IND 11	South East Coast Cardiovascular Strategic Clinical Network (SEC CVD SCN)	I think it would be desirable to allow people in this risk category to understand that they might need to consider a change in lifestyle, treatment etc. The counter argument is that whilst 10 % of this population may develop CVD over 10 years 90% won't so we may be "medicalising" a large group of people. My counter would be we can't tell who will get the disease so we have to treat all and the lifestyle modifications to reduce CVD risk are the same or similar as those used to reduce cancer risk and dementia risk so we are adding value elsewhere.
IND 11	Unknown	I have large concerns over the 10% CVD risk threshold to commence statins. I am not convinced the evidence at this level is robust. I suspect the net effect is over treatment and drug side effects and poor patient compliance. Please can this be revised.
IND 12	Boehringer Ingelheim	BI would welcome a register of all patients identified as having a 10-year risk of CVD of 10% or more.
IND 12	British Geriatrics Society	Yes it would be feasible and desirable however there is a risk that using the 10% risk cut off – that statins are used in too high an age group. The indicator much make clear when statins are inappropriate (acc to evidence based guidance such as Stopp and Start)

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IND 12	British Heart Foundation	We agree with this indicator. However, there is little point in holding a register unless you do something to modify CVD risk. We would suggest offering life style advice and statin treatment.
IND 12	British Kidney Patient Association	We agree that it would be beneficial to maintain a register of people with a 10 year risk of CVD of 10% or more. We ask that a formula that includes kidney function and proteinuria is used so that the register includes these patients. This should be part of the overall strategy to target people at risk, which includes the CKD population (est 7-10% whole population depending on level of CKD)
IND 12	British Medical Association	This register will include far more patients than is practical to prioritise, particularly with no limit on age range, and will identify people who have a lower than average cardiovascular risk for their age. If a register is to be produced it should more adequately target those with most to gain by intervention, and this could be done by substantially reducing the upper limit and/or increasing the risk threshold for intervention.
IND 12	Diabetes UK	Diabetes UK support the establishment of this register and would suggest that those found to be at high risk of diabetes, through the NHS Health Checks programme for example, be included on this register.
IND 12	East and North Hertfordshire CCG	The CCG would suggest that a register is unhelpful as it is the actions taken that are of greater benefit
IND 12	East Sussex Public health	This indicator would be of significant value to improving clinical follow up and ongoing support for primary prevention of CVD for those identified with a 10% or greater CVD risk in the NHS Health Check pathway. The NHS Health Check programme is a key tool for identifying those at risk of CVD, and a QOF indicator to encourage a register would help improve local pathways and monitoring. Clinician knowledge and attitudes regarding this lower 10% threshold, may present a barrier to implementation. For example, we are aware some clinicians believe there is not sufficient evidence to support this new guideline. While it may be considered feasible to implement the risk register, further clinical leadership and support may be required to overcome this potential barrier, for example by increasing awareness of the evidence to support implementation with the clinical community, including the recommended treatment of lifestyle modification and statin therapy where lifestyle modification has been unsuccessful. This indicator could therefore be further strengthened by inclusion of lifestyle modification and statin

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		therapy, as recommended by NICE and proposed for the previous primary prevention CVD risk indicators.
IND 12	Heart UK	• NICE guidance (CG 181) recommends that a systematic strategy should be used to identify people who are likely to be at high risk of CVD. The guideline suggests that people with an estimated 10 year risk of CVD of 10% or more should be prioritised for further investigation and preventative treatment and interventions. Do stakeholders think it would be feasible and desirable to have a register of all patients identified as having a 10-year risk of CVD of 10% or more? YES, HEART UK fully endorses this idea.
IND 12	Institute of Primary Care & Health Sciences/ Arthritis Research UK Primary Care Centre, Keele University	Not reasonable to expect practices to do this.
IND 12	London Borough of Bexley – Public Health	Yes, providing lifestyle interventions is a crucial element of reducing the risk of CVD for people who have a 10 year CVD risk of 10% or more. There should be a register of all patients who are identified in order to target prevention work.
IND 12	N/A - individual comment	No harm in this, but the QOF must make it clear that these patients should be under surveillance and identified and treated/counselled as their risk increases....not just sitting on a register waiting for CAD!!
IND 12	NHS England and NHS Employers	We would not support this indicator as it would be just another register. Registers can be built in to the indicators to avoid requiring a separate incentive.
IND 12	NHS Health Checks	Do stakeholders think it would be feasible and desirable to have a register of all patients identified as having a 10-year risk of CVD of 10% or more? We feel that it would be of value for practices to establish and maintain a CVD risk register. The NHS Health Check Programme sets out a requirement for GP practices to recall patients for an annual follow up if they have a QRISK2 score >20%, however, there is currently no register in place. Whilst it would be feasible and desirable to have a risk register of patients with a 10-year risk of CVD of 10% or more, we would also recommend that there is a separate risk register or a distinction within the register itself to identify those with a 10 year risk of CVD of 20% or more. This would assist practices in implementing the annual follow up

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		review as per the NHS Health Check Best Practice Guidance. Whilst we would be strongly in favour of maintaining a CVD risk register, we would prefer to see some form stratification within the register itself that allows patients to be investigated and followed up more easily as well directing them to the most appropriate services. We would have a preference for the implementation of two risk registers, one for CVD risk of 10% - 19% and one for CVD risk >20%.
IND 12	NHS Health Checks	Do you think there are any barriers to implementing the care described by any of the indicators? It is not clear whether the indicator would require practices to implement the register retrospectively, i.e. to identify those who have already been identified as having a QRISK2 score of >10%. We feel that this would be required to ensure that the risk register is accurate. Additionally, the QRISK2 score is not a static measure but one that can change with clinical and lifestyle modification. Therefore, the process of removing somebody from the register if their score falls below 10% should be clarified. Furthermore, the QOF indicator proposed does not stratify CVD risk score by level of CVD risk, therefore making it challenging for GP practices to identify those at high risk (>20%) who may need further intervention, including an annual follow-up as per the NHS Health Check programme best practice guidance, if they are age 40 – 74.
IND 12	Primary Care CVD Leadership Forum	We agree it is reasonable to establish a CVD risk register as the NHS Health Check will systematically identify people with a 10 year risk that exceeds 10%. This information is sent to practices and it will be very easy to populate the register. We also strongly recommend an indicator that incentivises a register for people with high risk of type 2 diabetes. People at high risk of diabetes will be systematically identified in the NHS Health Check as well as in routine primary care. There is a very strong evidence base that intensive interventions in people at risk of diabetes substantially reduce the risk of diabetes developing. NHS England is currently establishing a national Diabetes Prevention Programme as part of the 'radical upgrade in prevention'. This will require the identification of people at high risk (ie abnormal but non diabetic level HbA1c) so that they can be offered intensive interventions.

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IND 12	Public Health England	The PHE proposal for a cvd risk register is included as we recommended informally. The proposal we made for a diabetes risk register is not included. Given the commitment to a diabetes prevention programme it would seem appropriate to align and add the latter considering the national plans for a diabetes prevention programme now underway.
IND 12	Public Health Nottinghamshire County	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.
IND 12	RCGP	A register of people with QRISK >10 would offer a sensitive measure of the background health of the local community – the only concern is for those who fall outside of the age criteria for QRISK and who would benefit from intervention being denied access to this. (GR)
IND 12	RCGP	There is a concern here that this indicator will over-medicalise risk rather than disease, particularly as evidence continues to be hotly debated and is divisive. (RP) Those patients who have asked for or accepted treatment will be recalled anyway. Those who know they are at risk can ask for review whenever they want, and those who don't want to be treated will do their best to avoid recall and would probably not want to be on a register. RCGP Overdiagnosis Group
IND 12	South Cheshire and Vale Royal CCG's	I would support a register of people with a 10yr CVD risk above 10%.
IND 12	South East Staffordshire & Seisdon Peninsular CCG	Agreed- in all reality patients with a 10% risk are likely to have an increased risk over time (unless lifestyle measures are adopted and successful) A register will therefore help to identify patients for further review.
IND 12	Telford and Wrekin council	If 10% is the threshold at which intervention should commence then these patients should be identifiable, but it is unclear what further requirement there is: ie. Do these patients then have Annual review Do people on this register that have no other coded disease stay in the NHS Health Check

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		programme on 5 year review?
IND 12	West Sussex County Council	think this would raise questions of how you maintain such a register. How would such people be systematically identified?
IND 12	Whalebridge Practice, Swindon and QOF Database Website	A register of patients with 10% risk would be interesting but it is not clear what purpose this would be expected to serve. QOF registers are simply a list on a screen of the result of a search. This data would already be on the computer. There would be an incentive to increase this number to add to prevalence (if this had its own area) but the number of points allocated would have to be relatively high to incentivise this.
IND 12	Whitehall Surgery	This is a simple and useless tick box exercise. Only one patient with CVD score done and you are done.
IND 12	Yorkshire and Humber Commissioning Support Unit	Patients with a raised CVD risk score, but who do not have established CVD, are liable to become a forgotten group of patients. Those with a risk score >20% (and those taking a statin) are not eligible for an NHS Health Check. Patients not on a formal disease management programme can slip through the net
IND 12	Yorkshire and Humber Commissioning Support Unit	Would this indicator exclude patients who already have a diagnosis of CVD?

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Appendix B: Equality impact assessment for IND-8, IND-9, IND-10, IND-11 and IND-12 (primary prevention of cardiovascular disease)

Table 1

Protected characteristics
Age
Disability
Gender reassignment
Pregnancy and maternity
Race
Religion or belief
Sex
a) Sexual orientation
b) Other characteristics
Socio-economic status c) Depending on policy or other context, this may cover factors such as social exclusion and deprivation associated with geographical areas or inequalities or variations associated with other geographical distinctions (e.g. the North/South divide, urban versus rural).
Marital status (including civil partnership)
Other categories Other groups in the population experience poor health because of circumstances often affected by, but going beyond, sharing a protected characteristic or socioeconomic status. Whether such groups are identifiable depends on the guidance topic and the evidence. The following are examples of groups covered in NICE guidance: • Refugees and asylum seekers • Migrant workers • Looked after children • Homeless people.

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Indicator Equality Impact Assessment form
Development stage: Consultation
Topic: Primary prevention of cardiovascular disease

1. Have relevant equality issues been identified during this stage of development? • Please state briefly any relevant issues identified and the plans to tackle them during development
The NHS Health Checks Programme noted that whilst QRISK2 has been validated for use the importance given to age in the underlying formula means younger populations (e.g. 35 – 39 years) with similar lifestyle risk factors have significantly lower QRISK2 score than those for example aged over 40 years. They commented that this may disadvantage people with several lifestyle risk factors for CVD and suggested that alternative tools e.g. lifetime CVD risk tools or Joint British Society 3 (JBS3) may be more suitable for people under 40 years. The RCGP commented that QRISK2 is not accurate for people aged over 80 years and could also potentially disadvantage this group. One stakeholder considered the 10% threshold may disadvantage some groups e.g. young people with significantly elevated lifetime risk and females. PHE Observatory queried the suitability of QRISK2 for people with learning disabilities in terms of needing any reasonable adjustments in presentation/use.
2. Have relevant bodies and stakeholders with an interest in equality been consulted • Have comments highlighting potential for discrimination or advancing equality been considered?
Yes – stakeholders from all 4 UK countries were encouraged to comment on the potential new indicators as part of the NICE consultation and a wide group of relevant groups and organisations were contacted. Please refer to appendix A of the 'process report for indicators in development' for a full list of stakeholders consulted directly via email.
3. Have any population groups, treatments or settings been excluded at this stage in the process? Are these exclusions legal and justified? • Are the reasons for justifying any exclusion legitimate?
The proposed indicators cover people with hypertension in line with current primary prevention of cardiovascular disease QOF indicators for lipid modifications and people with diabetes following Committee discussions to expand the current CVD-PP indicators. This selection was considered pragmatic for the purposes of measurement. Stakeholder comments suggested this list could be expanded to include additional groups including those asses to be 'at risk' of CVD. The British Kidney Patient

Association considered people with CKD should also be included in line with NICE guidance. It was thought that currently these groups would also benefit from interventions and therefore should be included. QRISK2 has been validated for use in people aged 25-84 years and as such there is an age restriction on this indicator to reflect the age range specified in the tool. One stakeholder noted concerns that a 10% CVD risk register may shift the focus away from managing people with a >20% risk and that this may contribute to health inequalities.
4. Do any of the indicators make it impossible or unreasonably difficult in practice for a specific group to access a test or intervention? • Does access to the intervention depend on membership of a specific group? • Does a test discriminate unlawfully against a group? • Do people with disabilities find it impossible or unreasonably difficult to receive an intervention?
No – comments from the consultation exercise do not suggest that the indicators will make it impossible or unreasonably difficult in practice for a specific group to access a test or intervention.
5. Do the indicators advance equality? • Please state if the indicator as described will advance equalities of opportunity, for example by making access more likely for certain groups, by tailoring the service to certain groups, or by making reasonable adjustments for people with disabilities?
There were no consultation comments to suggest that the indicators would necessarily advance equalities in terms of people with protected characteristics or other relevant characteristics.