NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INDICATOR DEVELOPMENT PROGRAMME

Consultation report

Indicator area: Cardiovascular disease (CVD)

Consultation period: 22 March – 21 April 2022

Date of Indicator Advisory Committee meeting: 14 June 2022

Contents

Summary of indicators included in the consultation

ID	Indicator	Evidence source
IND2022-125	The percentage of patients with a CVD risk assessment score of ≥10% identified in the preceding 12 months who are offered advice and support for smoking cessation, safe alcohol consumption, healthy diet and exercise within 3 months of the score being recorded.	Cardiovascular disease: risk assessment and reduction, including lipid modification (2014) recommendations 1.2.1 to 1.2.16
IND2021-114	The percentage of patients with a CVD risk assessment score of ≥20% identified in the preceding 12 months who are offered advice and support for smoking cessation, safe alcohol consumption, healthy diet and exercise within 3 months of the score being recorded.	Cardiovascular disease: risk assessment and reduction, including lipid modification (2014) recommendations 1.2.1 to 1.2.16
IND2022-126	The percentage of patients with a CVD risk assessment score of ≥10% who are currently treated with a lipid modifying therapy.	Cardiovascular disease: risk assessment and reduction, including lipid modification (2014) recommendation 1.3.18 NICE TA385: Ezetimibe. NICE TA694: Bempedoic acid with ezetimibe
IND2021-115	The percentage of patients with a CVD risk assessment score of ≥20% who are currently treated with a lipid modifying therapy.	Cardiovascular disease: risk assessment and reduction, including lipid modification (2014) recommendation 1.3.18 NICE TA385: Ezetimibe NICE TA694: Bempedoic acid with ezetimibe
IND2021-116	The percentage of patients with existing CVD who are currently treated with a lipid modifying therapy.	Cardiovascular disease: risk assessment and reduction, including lipid modification (2014) recommendation 1.3.20 NICE TA385: Ezetimibe NICE TA694: Bempedoic acid with ezetimibe NICE TA393: Alirocumab. NICE TA394: Evolocumab NICE TA733: Inclisiran
IND2021-117	The percentage of patients with CKD, on the register, who are currently treated with a lipid modifying therapy.	Cardiovascular disease: risk assessment and reduction, including lipid modification (2014) recommendation 1.3.27 NICE TA385: Ezetimibe NICE TA694: Bempedoic acid with ezetimibe NICE TA393: Alirocumab NICE TA394: Evolocumab NICE TA733: Inclisiran

General comments

Stakeholders commented that familial hyperlipidaemia should be covered in these indicators, or at minimum include a link to guidance.

Stakeholders emphasised the importance of combining health checks into the same appointment as an important resource consideration.

The needs of people with a learning disability were highlighted as was the importance of ensuring they are not excluded.

Stakeholders had concerns about the coverage of patients having a QRISK score, as well as the possibility for QRISK scores to change as patients age or receive treatment.

Considerations for the advisory committee

The committee is asked to consider stakeholder concerns around the percentage of people who receive a QRISK assessment. OpenSafely data (see Paper 5e) shows that 37% of people aged 40-84 years (excluding existing CVD, CKD and type 1 DM) had a risk assessment in the last 5 years.

IND2022-125: lifestyle advice when CVD risk is ≥10%

The percentage of patients with a CVD risk assessment score of ≥10% identified in the preceding 12 months who are offered advice and support for smoking cessation, safe alcohol consumption, healthy diet and exercise within 3 months of the score being recorded.

Rationale

Cardiovascular risk assessment aims to identify people who do not already have CVD but who may be at high risk of developing it. Those people can then be offered focused interventions, including help to stop smoking, and advice on diet (including alcohol intake) and physical activity to support primary prevention of CVD through managing lifestyle risk factors.

Summary of consultation comments

Stakeholders felt that a CVD risk assessment score of ≥10% captured a high number of patients and might have a significant impact on primary care workload. They fed back on the possibility of the indicator becoming a one size fits all tick-box exercise, and risks of deterring the recording of QRISK scores.

Stakeholders also supported a CVD risk assessment score of ≥10%, highlighting that it aligned with existing NHS goals and NICE guidance, and that earlier behaviour change had more impact.

Clarification was asked for on whether the indicator aimed to capture patients with a previous CVD risk assessment, or if the aim was for assessments to be repeated annually. Additionally, clarification was sought on whether the lifestyle advice and support should be repeated.

Considerations for the advisory committee

The committee is asked to consider whether the impact on general practice workload would make this indicator unachievable.

IND2021-114: lifestyle advice when CVD risk is ≥20%

The percentage of patients with a CVD risk assessment score of ≥20% identified in the preceding 12 months who are offered advice and support for smoking cessation, safe alcohol consumption, healthy diet and exercise within 3 months of the score being recorded.

Rationale

Cardiovascular risk assessment aims to identify people who do not already have CVD but who may be at high risk of developing it. Those people can then be offered focused interventions, including help to stop smoking, and advice on diet (including alcohol intake) and physical activity to support primary prevention of CVD through managing lifestyle risk factors.

NICE guidance recommends lifestyle modification for people with a CVD risk assessment score of 10% or more. This indicator uses a score of 20% or more as a potential pragmatic approach to focus on those with the greatest need and address concerns around the workload implications of a denominator using 10% or more.

Summary of consultation comments

There was concern from stakeholders that patients would be likely to be receiving lifestyle advice already.

Specific question included at consultation

- Is an indicator that uses a score of 20% or more a potential pragmatic approach to focus on those with the greatest need for lipid management and address concerns around the workload implications of a denominator using 10% or more?

Stakeholder comments were mixed, with some feeling that a risk assessment score of ≥20% was a pragmatic way of reducing workload pressures, others still feeling there would be a significant workload increase, and most stakeholders having concerns about deviating from the guidance that uses ≥10%.

Considerations for the advisory committee

The committee is asked to consider:

- Whether a significant portion of patients have already received lifestyle advice and support relevant to CVD. A 2022 analysis of the provision of lifestyle advice found that a minority of patients with diabetes or hypertension received lifestyle advice or had this recorded in their medical records.
- The potential for this indicator to mitigate the impact on workload compared to IND2022-125.

IND2022-126: lipid modifying therapies for primary prevention when CVD risk is ≥10%

The percentage of patients with a CVD risk assessment score of ≥10% who are currently treated with a lipid modifying therapy.

Rationale

Lipid modifying therapies can help lower LDL cholesterol as part of primary prevention of CVD if lifestyle interventions are ineffective or inappropriate.

Summary of consultation comments

While there was support for this indicator, some stakeholders felt that a CVD risk assessment score of ≥10% captured a high number of patients, and might have a significant impact on primary care workload. Stakeholders fed back that lifestyle modifications may be preferable for patients with this level of risk and so patient choice needed to be reflected, otherwise there was a possibility to deter recording of QRSIK scores.

Some stakeholders felt that the indicator should focus on statins only, with current wording allowing for use of drugs with poorer evidence bases, and also noted that there was no incentive to optimise the lipid modifying therapy, or to use high intensity statins.

It was suggested that the definition of ‘currently treated’ be extended from prescription in the last 6 months to prescription in the last 12 months.

It was noted that there would be overlap between this indicator and indicators in the Primary Care Network DES and well as the Investment and Impact Fund (CVD risk score greater than 20% currently treated with statins).

Considerations for the advisory committee

The committee is asked to consider:

- Whether the impact on workload would make this indicator unachievable.
- Whether the indicator should be limited to statins only.

IND2021-115: lipid modifying therapies for primary prevention when CVD risk is ≥20%

The percentage of patients with a CVD risk assessment score of ≥20% who are currently treated with a lipid modifying therapy.

Rationale

Lipid modifying therapies can help lower LDL cholesterol as part of primary prevention of CVD. NICE guidance recommends lipid modifying therapy for people with a CVD risk score of 10% or more if lifestyle interventions are ineffective or inappropriate. This indicator uses a score of 20% as a potential pragmatic approach to focus on those with the greatest need for lipid management and address concerns around the workload implications of a denominator using 10% or more.

Summary of consultation comments

It was noted that there would be overlap between this indicator and indicators in the Primary Care Network DES as well as the Investment and Impact Fund.

Specific question/s included at consultation

- Is an indicator that uses a score of 20% or more a potential pragmatic approach to focus on those with the greatest need for lipid management and address concerns around the workload implications of a denominator using 10% or more?

A majority of stakeholders had concerns about using a target that captures a subset of the population in the guidance, that uses ≥10%, and would prefer IND2022-126. A minority of stakeholders felt that a score of ≥20% was a pragmatic way of reducing workload pressures.

Considerations for the advisory committee

The committee is asked to consider:

- The potential for this indicator to mitigate the impact on workload compared to IND2022-126.
- Would this indicator risk undertreatment in people with a risk between 10 and 20%?

IND2021-116: lipid modifying therapies for secondary prevention

The percentage of patients with existing CVD who are currently treated with a lipid modifying therapy.

Rationale

The NHS England Lipid Management pathway defines cardiovascular disease (CVD) as angina, previous myocardial infarction, revascularisation, stroke or TIA or symptomatic peripheral arterial disease (see IND2021-117 below for people with CKD). Lipid modifying therapies can help lower LDL cholesterol as part of secondary prevention of CVD.

Summary of consultation comments

There was general support from stakeholders for this indicator.

Some stakeholders suggested revisions, including being specific to statins, and limiting the indicator to patients with existing CVD with a most recent measure of non-HDL-C below 2.5mmol/l.

It was highlighted that was no incentive to progress through the lipid management pathway, or to optimise the lipid modifying therapy.

It was suggested that the definition of ‘currently treated’ be extended from prescription in the last 6 months to prescription in the last 12 months.

Considerations for the advisory committee

The committee is asked to consider:

- Whether the indicator should be limited to statins only.
- The proposal to extend the definition of ‘current treatment’ to within the last 12 months.

IND2021-117: lipid modifying therapies for people with CKD

The percentage of patients with CKD, on the register, who are currently treated with a lipid modifying therapy.

Rationale

People with chronic kidney disease (CKD) are at increased risk of cardiovascular disease (CVD). Lipid modifying therapies can help lower LDL cholesterol as part of primary and secondary prevention of CVD in people with CKD.

Summary of consultation comments

While there was agreement with the aim of this indicator, there were various suggestions for what it should also cover, including CVD (included in IND2021-116) and familial hypercholesterolaemia.

Some stakeholders felt that the indicator should focus on statins only, with current wording allowing for use of drugs with “poorer evidence bases”.

It was suggested that the definition of ‘currently treated’ be extended from prescription in the last 6 months to prescription in the last 12 months.

Stakeholders highlighted that when assessed with QRISK3, which includes CKD in the assessment, many CKD patients have a score of < 10% and therefore may not need to be on lipid modifying therapy, and this could lead to low achievement of the indicator. NICE CG181 recommendation 1.1.11 advises not to use a risk assessment tool to assess CVD risk in people GFR category G3a or above, and/or albuminuria.

Considerations for the advisory committee

The committee is asked to consider:

- Whether the indicator should be limited to statins only
- The proposal to extend the definition of ‘current treatment’ to within the last 12 months.

Appendix A: Consultation comments

General comments

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
1.	N/A	Amgen Ltd	Amgen welcome the development of the new indicators. Where we have seen a slowing of the improvements in cardiovascular mortality the inclusion of new indicators for lipid management is particularly welcome [1]. We recognise that to support the goals outlined in the NHS Long Term Plan [2] there needs to be alignment across different policy and clinical initiatives. Indicator development is a key part of the process to signpost and incentivise healthcare systems where to focus effort and resource. To improve management of patients in areas where there is unmet health need, such as in patients with raised lipids, we firmly believe that these indicators need to be developed into full QoF indicators. It has been documented how the removal of indicators can remove a focus on those related clinical areas. A 2018 report commissioned by NHS England demonstrated that when QOF indicators are removed, there were substantial increases in the proportions of patients who did not have a required measurement during the financial year when the indicator was removed and, in some cases, performance dropped to levels lower than were recorded before the indicator was introduced [3] Our comments relate to the specifics in the indicators and also the impact and alignment on wider policy drivers.	Thank you for your comment.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			[1] England Factsheet; British Heart Foundation. January 2022 [2] NHS Long Term Plan; 2019 https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/ [3] Impact of Removing Indicators from the Quality and Outcomes Framework: Retrospective Study Using Individual Patient Data in England. Anna Wilding, Evangelos Kontopantelis, Luke Munford, Matt Sutton; University of Manchester. Policy Research Unit in the commissioning and healthcare system 28th June 2018.	
2.	N/A	British Cardiovascular Society	BCS would also strongly recommend that the document has a clear link to guidance on familial hyperlipidaemia (FH), since those patients will face CVD risk which will be considerably higher than that estimated from conventional risk calculators.	Thank you for your comment. NICE will review the inclusion of people with FH, however concerns have been raised around attribution of responsibility if the care of some people with FH is managed by specialist services.
3.	N/A	HEART UK	CVD Lipid Management Familial Hypercholesterolaemia The NICE approved AAC Lipid Management Guidelines cover primary prevention, secondary prevention and Familial Hypercholesterolaemia. Indicators for lipid management should cover all three scenarios. Not covering FH risks suboptimal treatment for this high-risk group and patient harm as they can be wrongly assessed using Q-Risk.	Thank you for your comment. NICE will review the inclusion of people with FH, however concerns have been raised around attribution of responsibility if the care of some people with FH is managed by specialist services.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			NICE recommends considering drug therapy for patients with FH by the age of 10 years and lifestyle interventions from an even earlier age. We know through CVDPrevent they are being diagnosed later in life and missing years of potentially beneficial treatment	
4.	N/A	HEART UK	Primary Prevention Q Risk as a denominator Q Risk: This presumes that patients will have a Q-Risk recorded which it isn't always the case and the score changes with age and with treatment for lipids. Practices who have low levels of recording of Q-Risk will find this much easier to achieve than practices who have high levels of Q-Risk recorded. The first thing a practice will do is add a Q-risk to all patients on lipid lowering therapy. Adds no benefit to patient care makes results look good.	Thank you for your comment. The committee acknowledged potential variation in QRISK recording. A separate indicator was previously discussed focussed on regular recording of CVD risk. It was not progressed because of existing reporting in relation to the NHS Health Check.
5.	N/A	HEART UK	Primary Prevention numerator It would be much cleaner to have an outcome related metric e.g. non-HDL-C below 2.5mmol/l as per secondary prevention (see comment 9). NICE CG181 recommends HIST for such patients to achieve at least a 40% reduction of non-HDL-C. A metric that looks at prescribing and is not focused on the use of High Intensity Statins & Combination therapies, allows for suboptimal prescribing and compliance issues. Falsely reassuring the prescriber and patient that they are being optimally managed, undertreatment risks patient harm.	Thank you for your comment. The committee discussed the utility of an absolute value non-HDL target given difficulties in calculating percentage reductions in clinical IT systems. NICE has agreed to continue to explore this.
6.	N/A	NHS England and NHS Improvement	For people with a learning disability, the importance of understanding the context of their general health, how it is progressing, the importance of a holistic annual health check. In	Thank you for your comment.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			relation to all the indicators (and not just for people with a learning disability): important that the checks are done together rather than in multiple health appointments.	
7.	N/A	NHS England and NHS Improvement	It might be practically more difficult to ensure that people with a learning disability and autistic people are included and so a risk that they are left out of the denominator: which would in turn create an appearance that care of whole patient group is being given. Very important that all the denominators do not inadvertently exclude people.	Thank you for your comment. The equality impact assessment highlights the need to invite all eligible people with diabetes, including people with one or more learning disabilities.
8.	N/A	Royal College of General Practitioners	Background information • The RCGP is calling for an independent review of contractual requirements, such as the Quality Outcomes Framework (QOF). Reforming contractual requirements such as QOF will not only enable high-trust environments that encourage quality improvement processes and professional judgement, rather than top-down edicts which perversely incentivise tick-box approaches to medicine. • A focus on patients, especially those who are more disadvantage, not targets is essential. We need an independent review of how to better ensure vulnerable patients get the care they need without resorting to some of the box ticking exercises in the current Quality Outcomes Framework (QOF). The problems that were identified linked to health inequalities during the COVID19 pandemic suggest to us that a careful review of the model and its impact and value is overdue – as is the fundamental need to prioritise workload over the next	Thank you for your comment. NICE has no role in the negotiations for QOF. The committee has previously discussed the feasibility of indicators specifically focussed on review of women of child-bearing age who are prescribed valproate. Denominator numbers on average are too small to be suitable for use in the QOF. However, the committee agreed that the NICE team are to explore the value of an indicators for use outside the QOF. The suggestion to develop indicators focused on chronic fatigue syndrome has been shared with NHS England.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			couple of years with significant, varied waiting times for care and delays in review. It is important that patients get appointments when they need them or when their GP feels it is clinically appropriate to reach out to them. Unfortunately, the current QOF system incentivises check-ups based on a strict artificial calendar determined nationally, rather than on the needs of individual patients. In Scotland they have managed to maintain high standards of care and put greater faith in patients and clinicians to make judgements. Learning from models across the UK should form part of a review into the ideal model for England In view of the safety issues surrounding Valproate, we are surprised that there is not a quality indicator being considered for review of females of child bearing age who are prescribed valproate and wonder whether this should be considered (both for people with epilepsy and those given valproate for another reason). In view of the recent ME CFS guidance and the need for increased capacity of appointments in primary care, we are surprised that this is not considered as one of the indicators for QOF	
9.	N/A	Royal College of Physicians	The RCP is grateful for the opportunity to respond to the above consultation.	Thank you for your comment.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			We would like to endorse the response submitted by the British Cardiovascular Society (BCS).	

Question 1: Do you think there are any barriers to implementing the care described by these indicators?

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
10.	1	British Cardiovascular Society	No	Thank you for your comment.

Question 2: Do you think there are potential unintended consequences to implementing/ using any of these indicators?

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
11.	2	British Cardiovascular Society	Using 10 year risk scores will tend to underestimate the lifetime risks faced by younger patients with risk factors for CVD.	Thank you for your comment.

Question 3 : Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
12.	3	British Cardiovascular Society	No (Note that NICE has recently removed the suggestion that eGFR be adjusted for race, a move we support)	Thank you for your comment.

Question 4 : If you think any of these indicators may have an adverse impact in different groups in the community, can you suggest how the indicator might be delivered differently to different groups to reduce health inequalities?

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
13.	4	British Cardiovascular Society	No, although patients from economically deprived areas/backgrounds are likely to be at higher risk than appears to be the case from most risk scoring systems.	Thank you for your comment.

Comments about groups of indicators

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
14.	IND2022-125 IND2021-114 IND2022-126 IND2021-115	Amgen Ltd	The NHS Long Term Plan includes a clear goal to prevent 150,000 heart attacks, strokes, and dementia cases [1]. To achieve this target will require coordinated efforts across the healthcare system and will require a strong public health prevention approach, especially in those at risk of suffering a	Thank you for your comment. The committee agreed that using a CVD risk score of 10% or more was appropriate as it was key to positive health outcomes.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			cardiovascular (CV) event such as the groups described in these indicators. Identifying primary prevention patients whose risk is ≥10% will support management of a larger number of patients and would help reduce the risk of avoidable harm in patients whose risk is less than the 20% threshold. If there are concerns about workload implications, then a lower achievement threshold could be set. Having a single intervention threshold of ≥10% should not only make it more likely to support the NHS in hitting the 150,000 prevention target and potentially bring a renewed focus on the NHS Health Checks, but also help create the right behaviours aligned to tackling primary prevention [1] NHS Long Term Plan; 2019 https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/ [2] England Factsheet; British Heart Foundation. January 2022	
15.	Primary Prevention denominator Relates to IND2022-125 IND2022-126 IND2021-117	HEART UK	If the intention is to prevent, then identify all the conditions that would benefit as per the NICE approved lipid management pathway. No ASCVD (as covered in secondary prevention) No FH (as treatment targets differ – but there must be an indicator for FH see point 1, or these high-risk patients will get missed) FH diagnosis is a key target within the NHS Long Term Plan AND ANY OF:	Thank you for your comment. NICE will review the inclusion of people with FH, however concerns have been raised around attribution of responsibility if the care of some people with FH is managed by specialist services. Any risk assessment from the CVDASS cluster will be included. NICE guidance recommends using clinical judgement to decide on

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			Last CVD risk (any from CVDASS cluster) >=10% (includes old Framingham codes – so you don't miss people who were started on statins long ago) Or any of the below where the patient will already have a Q Risk of 10% or above (whether recorded or not, adding the code doesn't improve the outcome). Age 85+ Diabetes and age over 60 (risk is always >=10%) CKD 3-5 (and, ideally, CKD GxA3) T1DM and >40y T1DM and diagnosis >10y (over 18) T1DM and smoker T1DM and hypertension T1DM and microalbuminuria/albuminuria	appropriate management for people over 85 years. People with diabetes or CKD are included in separate published indicators.

IND2022-125 and IND2021-114

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
16.	N/A	Amgen Ltd	A key tenet of the NHS Long Term Plan directs how the NHS will take action to improve prevention of avoidable disease and exacerbations, as well as investing to narrow the gap in health inequalities between the best and worst performing areas. Cardiovascular disease is one of the conditions most strongly associated with health inequalities, with people living in England's most deprived areas being almost four times more likely to die prematurely of CVD than those in the least deprived	Thank you for your comment.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			area [1]. Wider action on prevention will help people stay healthy and moderate demand on the NHS. Mindful of a desire to support this evolution in a future landscape, underpinned by co-operation and integration, we would recommend the development of two additional indicators. The first indicator relates to patients becoming more engaged with their own healthcare. There are several directives and policies that talk to the need for patients to be more closely involved in their healthcare decisions in terms of the treatments they receive, the care setting for delivery and how technology can help patients stay involved in decisions about their care. These include: • The Elective Recovery Plan which highlights the aim to enable people to make informed decisions and be more in control of managing their own care [2] • The Royal Pharmaceutical Society's good practice guidance for Medicines Optimisation where patients are encouraged to be more engaged, understand more about their medicines and are able to make choices, including choices about prevention and healthy living [3]. • Patient Initiated Follow Up (PIFU), as part of the NHSEI Outpatient Transformation Programme, an approach which helps empower patients to manage their own condition and plays a key role in enabling shared decision making and supported self-management in line with the personalised care agenda [4]. • The Personalised care agenda highlights that as well as being morally the right thing to do, a growing body of	

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			evidence shows that better outcomes and experiences, as well as reduced health inequalities, are possible when people have the opportunity to actively shape their care and support [5]. **1. Percent of patients with a CVD risk score of ≥10% or ≥20% who have demonstrated improved self-management.** The percentage of patients with a CVD risk assessment score of ≥10% or ≥20% identified in the preceding 12 months have sought out advice and engaged with allied HCPs to support an understanding and management of their condition within 3 months of the score being recorded. The second indicator supports the goal of addressing the impact of health inequalities. In keeping with a desire to reduce the impact of health inequalities on outcomes in patients with, or at risk of, cardiovascular disease we believe an indicator to drive quality improvement in this area would be a positive step forward. We would therefore suggest a second indicator that focusses attention in this area. **2. Percentage of patients with a CVD risk assessment score of ≥10% or ≥20% who are currently treated with a lipid modifying therapy who live in the most deprived area with greatest unmet need as identified through CORE20+5.**	

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			[1] Cardiovascular disease: A major cause of health inequalities**.** Health Matters; Public Health England; March 2019 [2] Delivery Plan for Tackling the COVID-19 Backlog of Elective care; NHSE/I February 2022. *[3] Medicines Optimisation: Helping patients to make the most of medicines; Good practice guidance for healthcare professionals in England. Royal Pharmaceutical Society: May 2013* *[4] Patient Initiated Follow up; NHSEI* *https://www.england.nhs.uk/outpatient-transformation-programme/patient-initiated-follow-up-giving-patients-greater-control-over-their-hospital-follow-up-care/* [5] Universal Personalised Care; Implementing the Comprehensive Model; NHSEI 2019. [6] CORE20PLUS5: Core20PLUS5 – An approach to reducing health inequalities; https://www.england.nhs.uk/about/equality/equality-hub/core20plus5/	
17.	N/A	HEART UK	NICE recommends lifestyle advice at a QRisk of 10% or above. Delaying lifestyle advice until a 20% threshold is met increases the risk of harm to patients. Suggestion remove IND2022-114	Thank you for your comment. The committee agreed that using a CVD risk score of 10% or more was appropriate as it was key to positive health outcomes. Indicator IND2022-114 was not progressed to publication.
18.	N/A	NHS England and NHS Improvement	Advice could include a referral to Social Prescribing Facilitator. Inclusion of link to Personalised Care Model – https://www.england.nhs.uk/personalisedcare/comprehensive-model-of-personalised-care/?msclkid=9f74bea7c15311ec97e6686708f634cb	Thank you for your comment.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
19.	N/A	UKCPA Cardiovascular Committee	The denominators for the indicators are the numbers of patients with high CVD scores identified “in the preceding 12 months”. It should be clarified whether this means people without a previous CVD assessment. If not, then every patient should have their CVD risk assessed every 12 months.	Thank you for your comment. The primary prevention lifestyle indicator includes only patients with a CVD risk assessment score recorded in the previous 12 months.
20.	N/A	UKCPA Cardiovascular Committee	It should be clarified whether lifestyle advice & support for those with high CVD scores should be offered just once when they go above the 10% and 20% thresholds or at regular intervals for as long as their CVD score remains high. As this can have an impact on workload, it may be prudent to clarify that this can be provided by appropriately trained members of the MDT other than the GP	Thank you for your comment.

IND2022-125

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
21.	N/A	British Medical Association	Having a risk >10% could be seen as too low a measurement, as it might mean a decrease in the recording of CVD risk calculations. This sort of advice is often given when reviewing lipid results, but patient may not be there to give the advice to and advice is usually given at some other time, which may not be the QOF time frame. Is there evidence that this is beneficial at a population and patient level? In addition, what are the numbers of patients	Thank you for your comment. The committee agreed that using a CVD risk score of 10% or more was appropriate as it was key to positive health outcomes. The majority of stakeholders did not support the alternative indicators using a CVD risk of 20% or more.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			projected to fall into this group – it is likely to be large and thus have significant workload implications for general practice.	For details of benefit and patient numbers please see published validity assessments.
22.	N/A	NHS England and NHS Improvement	The earlier behaviour change is achieved the greater the impact on risk – We would support the 10% threshold for this indicator	Thank you for your comment. The committee agreed that using a CVD risk score of 10% or more was appropriate as it was key to positive health outcomes.
23.	N/A	NHS England and NHS Improvement	There is no requirement for practices to calculate and record the QRisk score. People will only be included in this indicator if QRisk score is recorded. Should there is an indicator requiring that a QRisk score is recorded for the eligible population at least every 5 years to ensure we do not omit a large potential cohort of at-risk patients	Thank you for your comment. The committee acknowledged potential variation in QRISK recording. A separate indicator was not progressed focussed on regular recording of CVD risk because of existing reporting in relation to the NHS Health Check.
24.	N/A	Primary Care Cardiovascular Society	The earlier behaviour change is achieved the greater the impact on risk – We would support the 10% threshold for this indicator These interventions are relatively low workload wise – signposting, highlighting risks etc. Will have a greater impact on a population level than just targeting the >20% group	Thank you for your comment. The committee agreed that using a CVD risk score of 10% or more was appropriate as it was key to positive health outcomes.
25.	N/A	Primary Care Cardiovascular Society	There is no requirement for practices to calculate and record the Q-Risk score. People will only be included in this indicator if Q-Risk score is recorded. How would you ensure that the eligible population are included? Should there be an indicator requiring that a Q-Risk score is recorded for the eligible population at least every 5 years to ensure we do not omit a large potential cohort of at-risk patients?	Thank you for your comment. The committee acknowledged potential variation in QRISK recording. A separate indicator was not progressed focussed on regular recording of CVD risk because of existing reporting in relation to the NHS Health Check.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			Is there any modelling that gives an estimate to potential numbers if the 10% threshold is used? Would the size of the workload deter the recording of the Q risk score? Is there any upper age to this as Q-risk is used up to the age of 84 but likely most (all) patients will score above 10%? This is more intensive and resource heavy from a primary care point of view and may be unrealistic? Will Q-risk 3 / further updates be incorporated into GP systems to allow these to be used routinely and more easily in primary care	There is no upper age limit to the indicator on primary prevention with lipid lowering therapies. People with a previous QRISK score of 10% or more may continue to benefit from medication after the age of 85. Personalised care adjustments should be considered when provision of medication is not suitable for the patient. Any risk assessment from the CVDASS cluster will be included.
26.	N/A	Royal College of General Practitioners	For this indicator to proceed it would need to consider a personalised care approach which is central to change management with patients and at the heart of the NHSE plans to improve patient care. In its current form it does not address this and instead assumes every person requires the same brief intervention/advice which could potentially lead to increased health inequalities. Q1. Barrier to implementation include significant workload and workforce pressures in primary care. Q2: Unintended consequences include • the risk that if this progresses it will become a simple tick box exercise and not achieve it's aims to improve population health. Patients need time and often multiple consultations to help with behaviour change relating to cardiovascular risk. Adding this as an indicator risks	Thank you for your comment. The committee agreed that patient choice should be considered. Workload implications were considered and it was agreed that the long-term workload increase would be far greater without early intervention, and could be split between different primary care roles to reduce impact.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			standard advice being distributed to all patients in the same way, rather than focusing on the needs of individuals and the point in the change management cycle that they are. Q3: None identified Q4: For this indicator to reach the groups that need help the most, a blanket CVD risk of 10% or more and a standardised approach should be reconsidered. A personalised care approach to ensure those most at need, get advice and support that is bespoke to their needs would be more beneficial. In view of the workload pressures associated with the high volume of patients this is likely to affect, we would recommend a 20% CVD Risk threshold. Giving more support to those at highest risk will aim to reduce health inequalities and will be in line with the NHSE approach to prioritising those at highest risk. E.g. the UCLH proactive care framework approach supported by NHS@home Exclusions should include those who refuse intervention, not only those with diagnosed CVD as this requires a personalised care approach. Q7. If this indicator were to progress, we strongly recommend a threshold of 20% risk and not 10% in view of the volume of work that will be required to meet its aims.	

IND2021-114

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
27.	N/A	British Medical Association	This group is likely to be getting this advice already as per NICE guidance. How many patients is this and what workload is expected as a result?	Thank you for your comment. This indicator has not progressed to publication.
28.	N/A	NHS England and NHS Improvement	The earlier behaviour change is achieved the greater the impact on risk – We would support the 10% threshold for this indicator (IND2022-125)	Thank you for your comment. This indicator has not progressed to publication.
29.	N/A	NHS England and NHS Improvement	There is no requirement for practices to calculate and record the QRisk score. People will only be included in this indicator if QRisk score is recorded. Should there be an indicator requiring that a QRisk score is recorded for all the eligible population at least every 5 years to ensure we do not omit a large potential cohort of at-risk patients (as per AF CHADSVASc score)	Thank you for your comment. This indicator has not progressed to publication.
30.	N/A	Primary Care Cardiovascular Society	The earlier behaviour change is achieved the greater the impact on risk – We would support the 10% threshold for this indicator (IND2022-125)	Thank you for your comment. This indicator has not progressed to publication.
31.	N/A	Primary Care Cardiovascular Society	There is no requirement for practices to calculate and record the Q-Risk score. People will only be included in this indicator if Q-Risk score is recorded How would you ensure that the eligible population are included? Should there be an indicator requiring that a Q-Risk score is recorded for all the eligible population (up to the age of 84?) at least every 5 years to ensure we do not omit a large potential cohort of at- risk patients (as per AF CHA2DS2VASc score)	Thank you for your comment. This indicator has not progressed to publication.

Question 7 : Is an indicator that uses a score of 20% or more a potential pragmatic approach to focus on those with the greatest need for lipid management and address concerns around the workload implications of a denominator using 10% or more?

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
32.	7	UKCPA Cardiovascular Committee	Using the 20% indicator is a pragmatic way of balancing workload while targeting patients that will benefit more from CVD prevention however that should not be limited to lipid management.	Thank you for your comment. The committee considered all comments and the indicators using a CVD risk of 20% or more have not progressed to publication

IND2022-126 and IND2021-115

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
33.	N/A	HEART UK	NICE recommends atorvastatin 20mg if lifestyle modification is ineffective or inappropriate at a QRisk of 10% or above. This indicator is solely for prescribing any oral lipid lowering therapy at any dose - which is very disappointing. NICE CG181 recommends HIST for such patients to achieve at least a 40% reduction of non-HDL-C. The fundamental problem with these prescribing indicators is that they cannot distinguish between HIST and non-HIST and there is no incentive to optimize lipid lowering therapy. This cannot contribute to meaningful quality improvement. A measurement indicator would capture prescribing, adherence and monitoring of response to therapy with optimisation of lipid lowering therapy where appropriate, and is directly associated with CVD outcomes.	Thank you for your comment. Currently the extraction of data for the QOF would not be able to differentiate between doses of statins. The accompanying guidance will state that high intensity statins should be provided as first line pharmacological therapy. The indicators using a CVD risk of 20% or more have not progressed to publication

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			There is nothing in NICE guidance to differentiate management of those at CVD risk >=10% and >=20%. Delaying treatment until a QRisk 20% threshold is met increases the duration of exposure to modifiable risk factors and increases risk of harm to patients. This indicator therefore seems unnecessary and may encourage such procrastination. If an additional indicator is desired, one relating to identification and management of FH would be more useful. Suggestion remove IND2021-115	
34.	N/A	NHS England and NHS Improvement	These proposed indicators will overlap with existing indicators in the PCN DES and IIF	Thank you for your comment. The committee noted this overlap.
35.	N/A	Primary Care Cardiovascular Society	These proposed indicators will overlap with existing indicators in the PCN DES and IIF	Thank you for your comment. The committee noted this overlap.
36.	N/A	Royal College of General Practitioners	Comment on definition: Please do not list the names of the drugs in the indicator. This information is not required and is not present in any other indicator and so stands out as an exception. Clinicians are capable of understanding what a “lipid modifying drug is. It is very unusual for this to be included and we would question why it is included in this section. Q1. Barriers to implementation include: • This indicator must take into account personalised care approaches to care and the time taken for patients to make decisions as to whether to take medication. This is a personalised choice and must remain so when patients have capacity to make a decision. We would request the time line of 6 months is extended to 12 months if this indicator progresses. Patients are called in for their annual reviews on a rotational basis. Keeping the reporting to the final 6 months of the cycle	Thank you for your comment. The committee agreed that consideration should be given to the use of personalised care adjustments to account for situations when patients decline lipid lowering therapy or it is contra-indicated. The list of medications has been removed. The committee agreed to retain the definition of current treatment in line

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			risks these patients not being called in based upon need and priority of care, but instead, leaving them to the final 6 months of the cycle to simply “tick the box” and achieve the highest proportion of prescribing. This risks patients who are at risk, receiving treatment late. Lifestyle changes and lipid modifying therapies are not an either/or situation and this would allow for a more person-centred approach to CVD management. Q2. Keeping the reporting to the final 6 months of the cycle risks these patients not being called in based upon need and priority of care, but instead, leaving them to the final 6 months of the cycle to simply “tick the box” and achieve the highest proportion of prescribing. This risks patients who are at risk, receiving treatment late. Lifestyle changes and lipid modifying therapies are not an either/or situation and this would allow for a more person-centred approach to CVD management. The key to cardiovascular disease is working with patients in a person centred way to ensure they continue to consider all options for treatment. This is the bedrock of primary care and must be maintained at all costs. Q3. Non identified Q4. None identified Q8. If this indicator were to proceed, we would strongly suggest using the 20% threshold rather than 10% due to the workload implications of including the high number of those with a 10% risk score	with existing indicators that use the same timeframe. The committee agreed that using a CVD risk score of 10% or more was appropriate as it was key to positive health outcomes.
37.	N/A	UKCPA Cardiovascular Committee	The definition of current treatment with lipid modifying therapy is prescription of any lipid modifying drug in the previous 6 month period. It must be clarified that treatment must be continuous i.e	Thank you for your comment. The committee agreed to retain the definition of current treatment in line

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			initial prescription in the past 6 months & subsequent prescriptions up to the end of the reporting period.	with existing indicators that use the same timeframe.

IND2022-126

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
38.	N/A	AstraZeneca	We are supportive of the need to ensure that first line interventions for those with a CVD risk risk>10% include therapeutics as well as lifestyle management.	Thank you for your comment.
39.	N/A	British Medical Association	Including a risk level of >10% is too low a measurement, as many patients do not have any discussion until risk gets to 10%, at which point many would like to try and make lifestyle changes and do not want statin. There would be a perverse incentive NOT to code the CVD risk in these cases. However, patient choice does need to be allowed for, so that those that decline can be coded properly. Current NICE guidance advises lipid lowering therapy amongst other modalities including lifestyle advice – therefore, what is the evidence of benefit at this low CVD risk? It medicalises a very large proportion of the population, increases prescribing costs and will have significant workload implications for general practice at onset and with ongoing review. In addition, there will be some harmed by adverse effects of medication.	Thank you for your comment. The committee agreed that consideration should be given to the use of personalised care adjustments to account for situations when patients decline lipid lowering therapy or it is contra-indicated.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
40.	N/A	NHS England and NHS Improvement	All lipid lowering therapies are not equal. In line with NICE guidance, the majority of patients should be prescribed a statin for primary prevention to ensure optimal outcomes. I would prefer to see this as the proposed indicator: The percentage of patients with a CVD risk assessment score of ≥10% who are currently treated with a statin.	Thank you for your comment. The committee considered limiting the indicator to statins only, and agreed that while statins would be first line treatment, there needs to be consideration for other treatment options, and chose to retain the focus on lipid lowering therapies.
41.	N/A	Primary Care Cardiovascular Society	All lipid lowering therapies are not equal. In line with NICE guidance most patients should be prescribed a statin for primary prevention to ensure optimal outcomes. Would this be a better indicator: the percentage of patients with a CVD risk assessment score of ≥10% who are currently treated with a statin. Is there a way to encourage prescribing of high intensity statin (as defined by NICE i.e., > 40% LDL-C reduction) in the indicator ? Very few lipid lowering drugs have an evidence base for primary prevention and are therefore not recommended – we need to ensure the QOF indicators do not give the impression that any lipid lowering drug will do. The unintended consequence would be clinicians bypassing statins and initiating ezetimibe to fulfil the requirements of the indicators which ultimately compromise clinical outcomes as it is less potent and has no primary prevention outcomes data. Agree that a ≥10% threshold for Q-risk score is appropriate for this indicator. Should patients with type 1 diabetes also be excluded	Thank you for your comment. The committee considered limiting the indicator to statins only, and agreed that while statins would be first line treatment, there needs to be consideration for other treatment options, and chose to retain the focus on lipid lowering therapies. Currently the extraction of data for the QOF would not be able to differentiate between doses of statins. The accompanying guidance will state that high intensity statins should be provided as first line pharmacological therapy The committee agreed that a CVD risk score of 10% or more was appropriate as it was key to positive health outcomes.

IND2021-115

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
42.	N/A	AstraZeneca	We have serious concerns about the precedent that NICE would be setting by adopting a “pragmatic” approach to introducing an indicator that does not reflect NICE guidance on best practice in condition management. NICE’s commitment to robust evidence-based guidance is the foundation of both its global reputation and its value to clinicians, the NHS, and ultimately patients. It is vital that NICE does not dilute its guidance to the NHS, to ensure that there is clarity on what constitutes best practice for patients and transparency in how this compares to what is delivered in practice. The challenges that can be associated at times with delivering best practice are already implicitly recognised both in relation to the non-mandatory nature of NICE guidance and the voluntary nature of the QOF. Beyond the principle, we also do not believe that NICE’s proposed approach would be a pragmatic solution that would lesson workload pressures in primary care. While there may be a limited short-term capacity saving associated with fewer initiations of treatment, over the longer-term delaying the point at which effective therapies will be offered to patients is likely to lead to poorer patient outcomes and greater pressures on workforce if individuals do go on to develop CVD. Overall, we believe that IND2021-115 would run counter to the wider prevention agenda and the focus on improving outcomes for CVD through earlier intervention.	Thank you for your comment. This indicator has not progressed to publication.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
43.	N/A	British Medical Association	Same as above. Considerable workload associated with some patient risk for an as yet unquantified primary prevention benefit	Thank you for your comment. This indicator has not progressed to publication.
44.	N/A	NHS England and NHS Improvement	The threshold should be 10%	Thank you for your comment. This indicator has not progressed to publication.
45.	N/A	Primary Care Cardiovascular Society	The threshold should be 10% Other comments as per IND2022-126	Thank you for your comment. This indicator has not progressed to publication.

Question 8 : Is an indicator that uses a score of 20% or more a potential pragmatic approach to focus on those with the greatest need for lipid management and address concerns around the workload implications of a denominator using 10% or more

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
46.	N/A	UKCPA Cardiovascular Committee	Yes it is a pragmatic approach	Thank you for your comment. The committee considered all comments and the indicators using a CVD risk of 20% or more have not progressed to publication.

IND2021-116

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
47.	N/A	Amgen Ltd	Amgen fully support the development of an indicator that focusses on lipid management in those patients with established atherosclerotic disease. This group of patients are at increased risk of suffering additional cardiovascular events and there is extensive evidence to show that intensively managing their lipids will reduce this risk [1, 2, 3]. The NICE clinical guideline CG181; Cardiovascular disease: risk assessment and reduction, including lipid modification, recommends starting treatment with the high intensity statin atorvastatin 80mg [4]. More recently the Accelerated Access Collaborative published the NICE endorsed Summary of National Guidance for Lipid Management for Primary and Secondary Prevention of CVD, which recommended prescribing a high intensity statin in adult patients with CVD [5]. It also includes a table detailing which statins can be considered high intensity. In line with this approach, the European Society of Cardiology guidelines recommend a high-intensity statin is prescribed up to the highest tolerated dose to reach the goals set for the specific level of risk [6]. Given the evidence base supporting the use of high intensity statins and a more intensive lipid lowering approach, as well as guidance to encourage increased use of high intensity statins, we would recommend that this indicator be amended to read as follows:	Thank you for your comment. The committee considered limiting the indicator to statins only, and agreed that while statins would be first line treatment, there needs to be consideration for other treatment options, and chose to retain the focus on of lipid lowering therapies. Currently the extraction of data for the QOF would not be able to differentiate between doses of statins. The accompanying guidance will state that high intensity statins should be provided as first line pharmacological therapy

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			1. The percentage of patients with existing CVD who are currently treated with a high intensity statin. [1] Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170 000 participants in 26 randomised trials; Cholesterol Treatment Trialists' (CTT) Collaboration. Lancet 2010; 376: 1670–81 [2] Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease. Sabatine, MS et al., *NEJM.* 2017; 376:1713-1722 [3] Alirocumab and Cardiovascular Outcomes after Acute Coronary Syndrome. Schwartz, GG et al., *NEJM.* 2018; 379:2097-2107 [4] NICE clinical guideline CG181; Cardiovascular disease: risk assessment and reduction, including lipid modification https://www.nice.org.uk/guidance/cg181/chapter/1-Recommendations accessed April 2022. [5] A summary of national guidance for lipid management for primary and secondary prevention of cardiovascular disease (CVD); April 2022. https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2020/04/Summary-of-national-guidance-for-lipid-management-for-primary-and-secondary-prevention-of-cardiovascular-disea.pdf accessed April 2022. [6] 2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk, The Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS). European Heart Journal (2019) 00, 1_78.	

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
48.	N/A	Amgen Ltd	CVD covers a number of atherosclerotic conditions, but by far the biggest are coronary heart disease (CHD) and stroke or TIA with 1.9million people living in England living with CHD and 1.1million people living in England having survived a stroke or TIA respectively [1]. Clinical management to ensure patients are optimally managed can be significantly different for these two conditions [2, 3]. In keeping with the clear differences in these treatment pathways delineating management, we believe that this indicator should be split out into two separate indicators. This is to reinforce that these different vascular conditions retain a focus as ones requiring different approaches to treatment. We would suggested the following two indicators: **1. The percentage of patients who have suffered a stroke who are currently treated with a lipid modifying therapy.** **2. The percentage of patients with existing CHD who are currently treated with a lipid modifying therapy.** [1] England Factsheet; British Heart Foundation. January 2022 [2] NHS Rightcare Stroke Pathway https://www.england.nhs.uk/rightcare/products/pathways/stroke-pathway/ [3] NICE clinical guideline CG185; Acute coronary syndromes https://www.nice.org.uk/guidance/ng185/resources/acute-coronary-syndromes-pdf-66142023361477 accessed April 2022.	Thank you for your comment. The committee chose to keep the existing scope for this indicator.
49.	N/A	British Medical Association	This seems appropriate as per current guidance.	Thank you for your comment.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
50.	N/A	HEART UK	This should be revised to the percentage of patients with existing CVD with latest non-HDL-C below 2.5mmol/l within the last 12 months CVDPrevent shows most patients are on lipid lowering treatment so the indicator as it stands would add little benefit, but we know the problem is suboptimal treatment. CG181 refers to a 40% reduction, but NICE acknowledge that this can't be calculated from data held in GP clinical systems with any accuracy, if at all. Hence the acceptance of a non-HDL-C threshold level as a proxy. A measurement indicator of patients with non-HDL-C <2.5 mmol/L would capture prescribing, adherence and lipid optimisation, the number of those with non-HDL-C >=2.5 corresponds to the population who should be assessed for inclisiran or other injectable therapies as per NICE TA733, 393/4. The target group for review are those who exceed the threshold, some of whom will have achieved a 40% reduction from a higher than average baseline level and not require further intervention, but this is likely to be a minority. A measurement indicator will focus attention on lipid optimisation. That will lower lipid levels in this group of high-risk patients and save lives. These patients will be being reviewed anyway so there's little additional workload for primary care.	Thank you for your comment.
51.	N/A	NHS England and NHS Improvement	As with primary prevention, it is important that for the majority of patients, statins are prescribed as the mainstay of lipid-lowering therapy. To achieve the indicator as is, a patient could be on any	Thank you for your comment. The committee considered limiting the indicator to statins only, and

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			lipid lowering therapy (i.e. ezetimibe monotherapy), which is not in line with NICE guidance or the evidence base. We would prefer to see: The percentage of patients with existing CVD who are currently treated with a statin. This is the first step in the NHS England lipid management pathway for secondary prevention. As highlighted in the NHS England lipid management pathway, initial statin treatment in secondary prevention may not sufficiently lower a patient's non-HDL-c/LDL-C levels. As such further options may then be considered by clinicians based on shared decision-making with the patient. To support a pathway approach to the indicators, NICE should consider a second indicator around escalation of therapy in those patients not achieving a target non-HDL or LDL level along the lines of: The percentage of patients with existing CVD who are not achieving a target non-HDL of < 2.5mmol/L who are offered additional lipid lowering therapy (beyond statin) The unintended consequence of the indicator as currently drafted is twofold: Firstly, to reduce uptake of statins and increase uptake of drugs with a lesser evidence base, rather than following the NHS England pathway; secondly, it does not encourage clinicians and patients to review and move through the lipid management pathway in support of optimal management and patient outcomes, risking clinical inertia via a process-based measure. Note: data may be an issue here as the PCSK9iMabs are usually prescribed in secondary care and therefore would not be picked	agreed that while statins would be first line treatment, there needs to be consideration for other treatment options, and chose to retain the focus on lipid lowering therapies.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			up via primary care system searches. Inclisiran may also be prescribed and administered outside the practice in a community hub or secondary care.	
52.	N/A	Primary Care Cardiovascular Society	As with primary prevention, it is important that for most patients statins are prescribed as the mainstay of lipid-lowering therapy. To achieve the indicator as is, a patient could be on any lipid lowering therapy (i.e., ezetimibe monotherapy), which is not in line with NICE guidance or the evidence base. Suggestion: The percentage of patients with existing CVD who are currently treated with a statin. The unintended consequence of the indicator as currently drafted is to reduce uptake of statins and increase uptake of drugs with a lesser evidence base Is a further indicator needed to ensure escalation of therapy in those patients not achieving a target non-HDL or LDL level despite maximum tolerated dose of statin. The percentage of patients with existing CVD who are not achieving a target non-HDL of < 2.5mmol/L who are offered additional lipid lowering therapy (beyond statin)? Note: data may be an issue here as the PCSK9iMabs are usually prescribed in secondary care and therefore would not be picked up via primary care system searches. Inclisiran may also be prescribed and administered outside the practice in a community hub or secondary care.	Thank you for your comment. The committee considered limiting the indicator to statins only, and agreed that while statins would be first line treatment, there needs to be consideration for other treatment options, and chose to retain the focus on lipid lowering therapies.
53.	N/A	Royal College of General Practitioners	Comment on definition: Please do not list the names of the drugs in the indicator. This information is not required and is not present in any other indicator and so stands out as an exception.	Thank you for your comment.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			Clinicians are capable of understanding what a “lipid modifying drug” is. It is very unusual for this to be included and we would question why it is included in this section. Q1. Barriers to implementation include: • This indicator must take into account personalised care approaches to care and the time taken for patients to make decisions as to whether to take medication. This is a personalised choice and must remain so when patients have capacity to make a decision. We would request the time line of 6 months is extended to 12 months if this indicator progresses. Patients are called in for their annual reviews on a rotational basis. Q2 Keeping the reporting to the final 6 months of the cycle risks these patients not being called in based upon need and priority of care, but instead, leaving them to the final 6 months of the cycle to simply “tick the box” and achieve the highest proportion of prescribing. This risks patients who are at risk, receiving treatment late. Lifestyle changes and lipid modifying therapies are not an either/or situation and this would allow for a more person-centred approach to CVD management. Q3 None identified Q4. None identified This indicator may affect shared decision making between a GP and patient as a patient may chose not to take a statin or other lipid modifying therapy. The patient should instead be offered	The list of medications has been removed. The committee agreed that consideration should be given to the use of personalised care adjustments to account for situations when patients decline lipid lowering therapy or it is contra-indicated.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			both lifestyle change and CVD prevention advice to allow them to make the best decision for them.	
54.	N/A	UKCPA Cardiovascular Committee	The definition of current treatment with lipid modifying therapy is prescription of any lipid modifying drug in the previous 6 month period. It must be clarified that treatment must be continuous i.e initial prescription in the past 6 months & subsequent prescriptions up to the end of the reporting period.	Thank you for your comment.

IND2021-117

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
55.	N/A	AstraZeneca	We agree with the overarching aim of this proposed indicator. However we propose that, in line with NG203 and TA775, sodium-glucose transport protein 2 (SGLT2) inhibitors should be included as an additional category of treatment, to capture data on the proportion of patients who are treated with a lipid modifying therapy such as an ACE inhibitor or ARB, **and** an SGLT2. This would help to assess and encourage uptake of SGLT2s, which NICE has recognised address an unmet need and represent more effective treatments for some patients with CKD – this data could also be used to identify variations in adoption and enable support to be targeted where it is most needed to address health inequalities.	Thank you for your comment. Medication has been included in the definition on this indicator in line with NICE guidance.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			Separately, we believe that NICE should also create an indicator to assess levels of uptake of SGLT2s for people with type 2 diabetes and CKD, in line with NG28 Type 2 diabetes in adults: management. In turn, and in line with NG203, the source guidance should also reference NICE's TA775 for dapagliflozin for treating CKD	
56.	N/A	British Medical Association	This would be a huge workload if it includes CKD3. Is there evidence of lipid modification benefit in CKD?	Thank you for your comment. Please see published validity assessments for details on benefit and patient numbers.
57.	N/A	HEART UK	Patients without CVD or FH and CKD should be included in the Primary Prevention denominator. Having a separate CKD lipid modification group as defined in IND 2021-117 mixes primary prevention and secondary prevention (those with CKD & CVD). The treatment targets are different	Thank you for your comment. The committee chose to keep the existing scope for this indicator.
58.	N/A	NHS England and NHS Improvement	QRisk3 includes CKD in the overall risk assessment and many CKD patients are being assessed as having QRisk3 score < 10%. Are we confident that we should still be recommending lipid lowering for all CKD patients? Also, same issue as above – the evidence base is for statins	Thank you for your comment. The indicator development process does not revisit the evidence base for guideline recommendations.
59.	N/A	Primary Care Cardiovascular Society	Q-Risk3 includes CKD (3-5) in the overall risk assessment, but some CKD patients are being assessed as having Q-Risk3 score < 10%. Are we confident that we should still be recommending lipid lowering for all CKD patients? Also, same issue as above – the evidence base is for statins.	Thank you for your comment. The indicator development process does not revisit the evidence base for guideline recommendations..

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
60.		Royal College of General Practitioners	Comment on definition: Please do not list the names of the drugs in the indicator. This information is not required and is not present in any other indicator and so stands out as an exception. Clinicians are capable of understanding what a “lipid modifying drug” is. It is very unusual for this to be included and we would question why it is included in this section. Q1. Barriers to implementation include: • This indicator must take into account personalised care approaches to care and the time taken for patients to make decisions as to whether to take medication. This is a personalised choice and must remain so when patients have capacity to make a decision. We would request the time line of 6 months is extended to 12 months if this indicator progresses. Patients are called in for their annual reviews on a rotational basis. Q2 None identified Q2 Keeping the reporting to the final 6 months of the cycle risks these patients not being called in based upon need and priority of care, but instead, leaving them to the final 6 months of the cycle to simply “tick the box” and achieve the highest proportion of prescribing. This risks patients who are at risk, receiving treatment late. Lifestyle changes and lipid modifying therapies are not an either/or situation and this would allow for a more person-centred approach to CVD management. Q3 None identified Q4. None identified This indicator may affect shared decision making between a GP and patient as a patient may chose not to take a statin or other	Thank you for your comment. The list of medications has been removed. The committee agreed that consideration should be given to the use of personalised care adjustments to account for situations when patients decline lipid lowering therapy or it is contra-indicated.

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
			lipid modifying therapy. The patient should instead be offered both lifestyle change and CVD prevention advice to allow them to make the best decision for them.	
61.	N/A	UKCPA Cardiovascular Committee	The definition of current treatment is slightly different than previous indicators (i.e the 6 month time frame is not explicitly stated); this should be harmonised. It should also be noted that lipid modification therapy is not recommended for CKD patients on dialysis without established CVD as per ESC guidelines so they should be excluded from the indicator.	Thank you for your comment.

Additional Indicators

ID	Proforma question no.	Stakeholder organisation	Comment	NICE Response
62.	N/A	HEART UK	To encourage population risk assessment consider adding a further indicator for risk assessment Denominator patients 40-74yo excluding those in comment 5 already identified as at increased risk, or FH (needs a FH indicator) or those with ASCVD Numerator with a Q-Risk score in the last 5 years Denominator patients 75-84yo excluding those in comment 5 already identified as at increased risk, or FH (needs a FH indicator) or those with ASCVD Numerator with a Q-Risk score in the last 5 years	Thank you for your comment. A separate indicator was previously discussed focussed on regular recording of CVD risk. It was not progressed because of existing reporting in relation to the NHS Health Check.