NORTH EAST QUALITY OBSERVATORY SERVICE (NATIONAL COLLABORATING CENTRE FOR INDICATOR DEVELOPMENT)

FOR

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INDICATOR DEVELOPMENT PROGRAMME

Feedback report on piloted indicators

Topic areas: Cardiovascular disease (CVD)

Pilot period: January – March 2022

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Output: Findings from qualitative pilot to contribute towards recommendations for NICE indicator menu

Contents

Summary of pilot findings

Indicator 1: Lifestyle modification in people with high CVD risk

The percentage of patients with a cardiovascular disease (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.

Acceptability assessment

71% of survey respondents (24/34) agreed that this indicator would improve the quality of care for patients and 73% (24/33) supported it being financially incentivised. Interview participants were supportive of providing lifestyle modification advice to patients but felt that for this to be most clinically relevant it needed to be done with patients with a ≥10% CVD risk assessment score rather than ≥20%. Additionally, the level of lifestyle advice and support provided needed to be sufficient to motivate patients and result in actual lifestyle changes so that this did not become a tick-box exercise.

Implementation assessment

There were some key concerns with implementation, as outlined in the table below. Specifically, providing tailored lifestyle advice to patients would significantly increase workload (especially if a ≥10% CVD risk assessment score was to be used). Practices were clear that further resources, such as an increased number of social prescribers, nurses, and in some cases, doctors, would be needed to implement this indicator successfully. There may also be capacity issues with external referral programmes that would need to be considered.

Issues to be resolved prior to implementation

Issue	Detail	Mitigating activity
Appropriateness of using a CVD risk assessment score of ≥20%	Although the indicator only refers to newly identified patients with a ≥ 20% risk assessment score, practices viewed lifestyle modification as an insufficient intervention by itself at this level of risk. A ≥10% score would increase the clinical relevance of this	Reduce the risk assessment score to ≥10%. Potential mitigation for the workload: start with ≥20% risk first, before moving to ≥10%?

	indicator but would increase workload.	
Timescale for providing advice	A three-month cut-off for providing lifestyle advice was considered too short. A longer time frame, such as 6 months, was considered more appropriate.	Remove or amend the 3-month specification in definition. (NB not to be confused with the 3 month timescale within the pathway for repeating lipid measurement after initiation of lifestyle modifications).
Lack of clear definition of 'advice and support'	To ensure this is not a 'tick-box' exercise and to increase likelihood for improvements to patient lifestyles, it is paramount that a sufficient level of dialogue and intervention is provided. Mitigations proposed here could also help improve patients' ability to engage with lifestyle modifications when previous attempts have been unsuccessful.	Greater clarity on 'advice and support' required. Include consistent messaging / a template to ensure adequate level of advice and support is provided by all clinicians. Locally, more signposting to available services may be required. Specify use of patient-led/ motivational interviewing approach, as opposed to information-only approaches.
Suspension of health checks during COVID-19	Practices advised that health checks would need to be resumed to support this indicator.	Resume health checks.
Clinical workload increase	Providing sufficient lifestyle advice and support will cause a significant increase in workload.	Increased PCN staff budget. Resources to increase numbers of other clinical staff such as social prescribers and nurses.
Capacity levels of external referral programmes	Referral programmes may not have the capacity to provide the necessary support for lifestyle modifications.	
Ability to monitor lifestyle changes	Monitoring uptake and impact of lifestyle programmes would be helpful (as long as not an indicator requirement). However, the use of external referral programmes and possibility of patients who self-refer may make this difficult.	

Indicator 2: Lipid modifying therapy for primary prevention of CVD

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

In patients with a high risk of CVD, for whom lifestyle changes are ineffective or inappropriate, and in whom the risks and benefits of starting lipid modifying drug therapy have been discussed with their healthcare professional, the proportion who are taking lipid modifying therapy.

Acceptability assessment

Survey responses showed that 65% (22/34) felt that this indicator would improve the quality of care for patients and a similar proportion (67%, 22/33) thought it should be financially incentivised.

Participants in the interviews expressed mixed opinions about the acceptability of this indicator; a couple of practices felt they were already doing this with their patients but a few felt that the indicator was not suitable as currently defined (focusing on uptake of therapy rather than discussion with patients).

Implementation assessment

Participants felt that there were little to no issues with implementation – starting lipid modifying therapy would be done in a standard appointment time (providing patients were given information beforehand). Practices interviewed agreed that financial reimbursement should be given based on discussions with patients about treatment rather than treatment uptake. Practices did generally consider that indicator 2 overlaps with the planned PCN DES indicator for 2022/23 (CVD-03)[1].

Issues to be resolved prior to implementation

Issue	**Detail**	**Mitigating activity**
Appropriateness of using a CVD risk assessment score of ≥20%	Practices felt it was more appropriate to reduce the risk assessment score to ≥10%, in line with NICE guidance.	Reduce the risk assessment score to ≥10%. See indicator 1 for other workload mitigations. (See

[1] CVD-03 Percentage of patients aged between 25 and 84 years inclusive and with a CVD risk score (QRISK2 or 3) greater than 20 percent, who are currently treated with statins.

		also resumption of health checks in support). Additionally, potentially lower achievement thresholds to mitigate the workload impact.
Payment based on uptake of lipid modifying therapy may be problematic	Clinicians may have discussions with patients and offer treatment, but the patient may decline treatment or not ultimately take up prescribed treatment.	Base payment on the clinician having had a discussion with regards to starting lipid modifying therapy rather than on whether or not there was patient uptake. Exemption criteria for non-uptake.
Definition of 'currently treated'	Practices considered treatment for 6 to 12 months as sufficient for being 'currently treated'.	For indicator guidance (assuming the indicator remains as based on uptake of treatment).
Overlap with planned PCN DES indicator CVD-03[1] for 2022/23	Practices considered that having both indicators would be unnecessary. Indicator 2 is preferred due to inclusion of all lipid modifying therapies (and possibly also absence of age range).	

<u>Indicator 3: Lipid modifying therapy for secondary prevention of CVD</u>

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

Acceptability assessment

Survey respondents felt that this indicator would either 'improve' (68%, 23/34) or cause 'no change' (32%, 11/34) in the quality of care for patients. Approximately three quarters of respondents thought indicator 3 should be financially incentivised (76%, 25/33). Practices felt that this would be an acceptable indicator especially as it was believed that patients who fit into this group should already be receiving lipid modifying therapy. Some clinicians suggested that the definition for this indicator should not include heart failure as a subgroup as this may not be caused by CVD and may not require treatment with statins.

Implementation assessment

There were no concerns with the implementation of this indicator.

Issues to be resolved prior to implementation

Issue	Detail	Mitigating activity
Indicator definition	Some interviewees noted heart failure is not always caused by CVD and treatment of heart failure with statin may not be required.	Remove heart failure from the indicator definition of CVD? (see paper 5d)

Indicator 4: Lipid modifying therapy for people with Chronic Kidney Disease (CKD)

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

Acceptability assessment

Survey respondents felt that this indicator would either 'improve' (68%, 23/34) or cause 'no change' (32%, 11/34) in the quality of care for patients. Most respondents (79%, 26/33) were supportive of the indicator being financially incentivised. Overall, practices were supportive of this indicator.

Implementation assessment

There was a consensus across practices that this indicator should focus on patients already identified in the QOF CKD register (CKD005) however one practice felt the current coding of CKD is poor.

Issues to be resolved prior to implementation

Issue	Detail	Mitigating activity
Indicator definition	Practices felt that this indicator should focus on patients already identified in CKD005.	Amend 'existing CKD' to 'patients with CKD on the register'
Coding accuracy for CKD / CKD QOF register	Current coding of CKD is felt to be poor.	Consider findings from CKD topic piloted indicators (see paper 6c)

Background

As part of the NICE indicator development process, all clinical and health improvement indicators for general practice proposed for inclusion in the NICE Indicator Menu are piloted, using an agreed methodology, in a representative sample of GP practices across England.

The aim of piloting is to test whether indicators work in practice, have any unintended consequences and are fit for purpose.

The full background to the inclusion of this topic in the pilot, including a list of piloted indicators, is presented in Appendix A, along with a description of the method and approach to piloting.

Practice recruitment

A summary of the general practice recruitment methodology is shown in Appendix B.

Number of practices recruited, ready to commence pilot (January 2022)	**27**
Final number of practices in the pilot	**16**
Number of practices participating in feedback	**16**

Feedback was obtained via interviews and an online survey, and it was possible for individuals to participate in both the survey and the interviews. At least one survey was completed by each of the 16 participating practices. The quantitative responses to the online survey are shown in Appendix F[2].

The table below indicates the practice participation in the pilot specifically for the lipid management topic.

[2] Note that an error was identified in some of the survey data relating to Lipid Management Indicator 4 and this data has been excluded from this analysis. This is further explained in Appendix F.

Feedback participation by role and method

Staff role	**Interviews - number of participants**	**Survey - number of respondents**
GP	7	16
Practice manager	5	5
Other senior management	4	2
Pharmacist	1	2
Practice Nurse	1	4
Practice administrative staff	1	5
Number of participants	**19** From 12 practices # *	**34****

As described in Appendix A, not all interviews covered all topics and only 12 out of the 16 practices were asked questions about lipid management in their interviews.

* Only 10 practices provided interview feedback about indicator 1, and 8 of these practices also provided interview feedback about indicators 2, 3 and 4 with an additional two practices who had not provided interview feedback on indicator 1 also providing feedback.

** Not all respondents completed all of the lipid management-related indicator questions (see note in Appendix A).

Assessment of clarity, feasibility, reliability and acceptability

Clarity

There were no significant problems with ambiguity for any of the four indicators, although greater clarity on what 'advice and support' should include for indicator 1 is required. Some specific amendments to indicator definition/wording were suggested in both the interviews and survey with pilot practices (see relevant section, p24). It was suggested by some practices that the cardiovascular disease (CVD) risk assessment score of ≥20% should be changed to ≥10% in indicators 1 and 2 but other practices expressed concerns over the workload implications resulting from this; these indicators may require additional refinement or testing prior to widespread implementation.

Feasibility and reliability

There was a common view that it would be easy to identify patients with a high risk of CVD (indicator 1) and that it would be relatively straightforward to record in the clinical system when lifestyle advice had been given, particularly if a template was provided. However, one practice noted that this indicator necessitates a CVD score being recorded within the clinical system. In the interviews, a few practices implied that this is not routine practice, potentially resulting in only those patients coming into the practice, for example to attend a health check[3] (see below), being identified and some eligible patients being missed. One practice suggested adding an additional indicator to address this issue:

"You said about targeting the people who have had a CVD risk score calculated, I don't think, in practice, that is going to happen very often. So, I think, actually, you are not targeting enough people with this. I almost wonder whether or not any severe kind of indicator before this, similar to the blood pressure ones where you kind of target saying "X percentage of your practice population, should have a CVD risk score calculated in the last five years" or something. (…) I suspect this [the indicator currently proposed] is just going to be picked up on people you are just doing health

[3] https://www.nhs.uk/conditions/nhs-health-check/

checks for (…) I just wonder whether or not (…) the denominator group needs to be expanded a little bit more, so you are actually targeting more people." [GP, Interview]

It was also highlighted by another practice that the only way of identifying the patient group for indicator 1 would be via health checks, which have not been carried out in the last few years due to Covid-19:

"At the moment I would think the only way of getting this group of patients is through the health check programme. I don't think we routinely do this other than if they have had a health check, which is what that was set up to find this group of people. And obviously health checks for the last two years have not been happening and yes, I am not really sure how we are going to identify this cohort of patients." [Practice Manager, Interview]

The issues identified above would also impact on the ability to identify patients for indicator 2.

There was a common view that it would be easy to identify patients with existing CVD (indicator 3). However, one practice expressed concerns over coding issues and requested further clarification on eligible codes for this patient group:

"It does happen though that some codes falsely come with secondary prevention like mild … atheroscnerosis." [Practice Manager, Interview]

Practices were asked for their views on whether indicator 4 should focus on all patients with CKD or only those on the CKD register (CKD005) (see p32 for detail).

Regarding feasibility of identifying all patients with CKD, one GP commented that patients could be identified by running a search on eGFR (estimated glomerular filtration rate) measurements.

"I think identifying them would be relatively straightforward because then you can just run a search on eGFRs." [GP, Interview]

However, one practice raised concerns on the coding of CKD patients (for indicator 4) which could impact on the identification of patients eligible for inclusion in the indicator. The practice proposed that, to address this, the indicator could instead be looked at again following use of the CKD indicators currently also being piloted:

"Well, I think obviously the first set of indicators is all around CKD and its diagnosis, I think the […] with this is that I suspect there's really poor coding of CKD around in all sorts of places, not only in my practice. So, I think this isn't a bad indicator but

maybe an indicator that will be better a few years down the line having used the next set of indicators for a while." [GP, Interview]

In general, the pilot practices were more concerned about the feasibility and reliability of indicator 1 compared to the other indicators (as outlined below).

Acceptability

This section summarises practice views from the interviews and the survey on the acceptability of the topic; on the potential impact on quality of care; the importance of the issues covered by the indicators for patients and families; the role of financial incentivisation; and, separately for each indicator, any specific acceptability issues identified.

Topic feedback

There was overall support for this topic, with practices recognising the potential benefits of the indicators on the quality of care for patients. Some practices noted that they were already fulfilling the work specified within the indicators.

While there was support, in theory, for all four indicators, some concerns around the implementation specifically of indicators 1 and 2 were highlighted in the survey and interviews.

Indicator-level feedback

<u>Quality of care</u>

Most respondents to the survey thought the lipid management-related indicators would improve the quality of care for patients, particularly for indicator 1 where 70.6% (24/34) respondents believed this (Table 1). Two respondents (5.9%) thought that indicators 1 and 2 would 'worsen' the quality of care for patients.

Table 1: Views on the impact of quality of care of lipid management-related indicators (survey)

What impact do you think the following indicators could have on the quality of care for patients?				
	Improve	No change	Worsen	Total
Indicator 1: Lifestyle modifications in people with high CVD risk	24 (70.6%)	8 (23.5%)	2 (5.9%)	34
Indicator 2: Lipid modifying therapy for primary prevention of CVD	22 (64.7%)	10 (29.4%)	2 (5.9%)	34
Indicator 3: Lipid modifying therapy for secondary prevention of CVD	23 (67.6%)	11 (32.4%)	0 (0.0%)	34
Indicator 4: Lipid modifying therapy for people with CKD	23 (67.6%)	11 (32.4%)	0 (0.0%)	34

Value to patients

Practices were asked whether they thought the indicators represented an important issue for patients, families and carers (Table 2). Most survey respondents agreed that the four indicators are important to patients, with relatively low proportions stating this is not the case. (For brevity, the rest of the results in this section are reported as relating to ‘patients’ rather than ‘patients, families, and carers’).

Table 2: Views on the importance of the lipid management-related indicators to patients, families and carers (survey)

Do you think the following indicators represent an issue that is important for patients, families and carers?				
	Yes	No	Unsure	Total
Indicator 1: Lifestyle modifications in people with high CVD risk	23 (67.6%)	3 (8.8%)	8 (23.5%)	34
Indicator 2: Lipid modifying therapy for primary prevention of CVD	21 (61.8%)	4 (11.8%)	9 (26.5%)	34
Indicator 3: Lipid modifying therapy for secondary prevention of CVD	26 (76.5%)	3 (8.8%)	5 (14.7%)	34
Indicator 4: Lipid modifying therapy for people with CKD	21 (61.8%)	4 (11.8%)	9 (26.5%)	34

There were mixed views from practices interviewed around the value of lifestyle modifications for patients with high CVD risk (indicator 1), with some raising concerns that by the time a patient has a CVD risk score of ≥20% more than lifestyle advice would need to be offered (e.g. statins). Around two thirds of survey respondents (67.6%, 23/34) thought this indicator represented an issue that is important to patients. However, nearly a quarter (23.5%, 8/34) were 'unsure' and 3 respondents (8.8%) believed it was not of value to patients.

Some practices reported at interview that they had received some direct feedback from patients on how they feel about being given advice/support for lifestyle changes. Some of these practices raised concerns relating to the extent of advice and support that that could be given: for example, whether offering standard health checks, providing a leaflet, or giving one-off advice would be of much value to patients and/or could be deemed repetitive:

"People in this cohort would have health reviews somewhere along the line and a lot of the reviews have these things within them. So, you know, diabetes or mental health views, or we do health checks, we just do normal health checks and things like that. And these things are, kind of, already in there so you may have a danger of it being repetitive." [Practice Manager, Interview]

One interviewee also highlighted patients may perceive advice on lifestyle changes as a 'tick-box' exercise by healthcare professionals, and other practices raised similar concerns:

"It is hard really – because I think some patients are really appreciative of the lifestyle advice that you give them but I do think sometimes they see it as a tick-box exercise so maybe they don't sort of take it on board what you say." [Practice Nurse, Interview]

"There's no meaningful way to actually do anything apart from ticking the box … it's a waste of each other's time." [GP, Interview]

Advice and support for lifestyle modification was considered to be valued more when it involves regular support, as this can motivate patients to make the lifestyle changes needed. This regular support may require more involvement from clinicians, but as noted later in the report, practices raised concerns regarding feasibility of this due to workload implications.

"…the views are that the amount of time we're offering people is not enough, the amount of support we're giving people is not enough. We know who our lifestyle ticking bombs are, we just, besides advice, which clearly doesn't work year after year. […] I can think of quite a few names straight-away, and they are in theory really willing to do something, but it's just in human nature that unless there is support, regular, not just somebody given one-off advice, it doesn't work, I don't think." [GP, Interview]

"Patients would appreciate that [lifestyle advice] and they would value that. We've set up a walk with your GP group part of lifestyle changes etc, and a GP goes out every Wednesday for a 1-hour walk with the patients around the canals […] The feedback that we're getting from the patients is that they enjoy the walk, like going out with the doctor and it's fresh because some of the patients are lonely, elderly, and some just want to get fit. […] The feedback is really good. They understand the lifestyle changes." [Practice manager, Interview]

A few practices discussed other ways, such as through groups or videos, to provide lifestyle advice to patients which patients may 'value'. However, concerns were raised about the feasibility of this:

"The doctors did, it was a 30-minute Zoom call, there are 3 doctors who are there, question and answer etc, we do 5-minute presentation. (…)So, it's like one of those patient groups that you have for chronic diseases etc that we've put together, but it's on Zoom. But then you've got your 3, 4 GPs joining as well because they are enjoying it, patients are enjoying it and our staff join in as well. Everybody's getting to understand that lifestyle element of being." [Practice Manager, Interview]

"We did set up a walking group before COVID that was quite good, but then COVID happened, and obviously it's all stopped now, we've not been able to start it again just yet, but yes, definitely, some group …" [Practice Manager, Interview]

"we did have a walking group, but who would have thought there will be so many legal considerations? (…) it's all great, but again, it's just time consuming." [GP, Interview]

Indicators 2 and 4 were considered to be of moderate value to patients with 61.8% (21/34) of survey respondents indicating that they could be important to patients. A further 26.5% (9/34) were unsure of the value of these indicators to patients and 11.8% (4/34) believed they were not of value. Offering lipid modifying therapy for the secondary prevention of CVD (indicator 3) was considered of most value to patients,

with 76.5% (26/34) of survey respondents suggesting this would be important to their patients, families, and carers.

Practices did not report any direct feedback from patients on the value of indicators 2, 3, and 4 in the interviews.

Financial incentivisation

Most respondents to the survey were supportive of financial incentives for the lipid management-related indicators. Approximately three quarters of respondents thought indicators 1, 3 and 4 should be financially incentivised (Table 3). There was slightly less support for incentivising indicator 2 (66.7%, 22/33) when compared with the other indicators, with seven respondents (21.2%) reporting the indicator should not be incentivised while a further four (12.1%) were unsure.

Table 3: Views on financial incentivisation of lipid management-related indicators (survey)

Do you think the following indicators should be financially incentivised?				
	Yes	No	Unsure	Total
Indicator 1: Lifestyle modifications in people with high CVD risk	24 (72.7%)	5 (15.2%)	4 (12.1%)	33
Indicator 2: Lipid modifying therapy for primary prevention of CVD	22 (66.7%)	7 (21.2%)	4 (12.1%)	33
Indicator 3: Lipid modifying therapy for secondary prevention of CVD	25 (75.8%)	6 (18.2%)	2 (6.1%)	33
Indicator 4: Lipid modifying therapy for people with CKD	26 (78.8%)	4 (12.1%)	3 (9.1%)	33

Within the interviews, discussions around financial incentivisation centred on indicator 2. Some practices felt that payment should not be based on medication uptake and instead that evidence of a discussion around starting lipid modifying therapy should suffice for payment. One practice suggested that financial incentivisation should be based on issuing a prescription and some practices suggested that exemption code should be used for patients who choose not to start lipid modifying therapy, because the GP would still have had the discussion with them.

"I think if practices are done, step one, two, and three but the patient's ultimately decided that they don't want to be on medication but they've chosen a different route to manage things, then surely that should be just as good as them going on medication anyway. It's what, you know, they've gone through the process with the practice, and the practice has clearly identified everything and done everything, then I think that that should be taken into account for payment […] we can't control what patients want to do." [Practice Manager, Interview]

"But how many people will actually take their script or cash their script? I don't know, to be honest, what you want to count. I think it's fair to say as long as they were counselled properly and a prescription was issued." [Practice Manager, Interview]

"I think, if we've done the work to get them on it, we probably should be reimbursed for that." [GP, Interview]

Practices were asked their views on the potential impact of including performance thresholds within the draft pilot indicator as well as with regard to the similar indicator planned to be introduced into the 2022/23 PCN DES Investment and Impact Fund (IIF)[4] which states a lower performance threshold of 48% and an upper threshold of 58%. The inclusion of this performance threshold and potential impact on over– or under– treatment was discussed in a few interviews. There were mixed views on this with one practice saying thresholds would not lead to overprescribing whilst another thought it might:

"GP: Is the question whether it would make us give more people statins, for no reason?
Moderator: Potentially.
GP: No, I don't think it would.
Moderator: No?
GP: Yeah, it wouldn't." [Interview]

"I think that's something that we would be concerned about, you know, we wouldn't want to be, 'Oh, we've got to hit this target, we've got to hit this target, so we're going to whack these patients on this medication just because we want to get paid.' So, I think that's something that wouldn't be good practice … So I think in terms of payment, that might need to be looked at …' [Practice Manager, Interview]

[4] https://www.england.nhs.uk/wp-content/uploads/2022/03/B1357-investment-and-impact-fund-2022-23-updated-guidance-march-2022.pdf

One GP suggested that rather than financially incentivising the indicators, another approach to drive delivery would be to create a 'prescribing initiative scheme', with comparisons being made between practices:

"…yes a threshold will drive delivery, yes. But another way to drive delivery is making it a prescribing indicator where there's a softer approach (…) with comparisons between practices. Which one does at, sort of, local levels tend to work quite well at driving these things as well. So, delivery through a prescribing incentive scheme would have the same thing but it's a bit more flexible." [GP, Interview]

At least two additional practices were content with the use of thresholds within indicator 2 but discussed the importance of being able to use exemption codes (termed Personalised Care Adjustments in QOF since April 2019[5]) within this:

"I think it is important to have the thresholds … I think you can exclude patients if you have had the conversation with them and they- for whatever reason – don't want to go on a statin – you can exclude them as long as you have had the proper discussion and you use the exemption codes as you should be doing …" [GP, Interview]

Quality improvement

The survey showed mixed views as to whether the lipid management-related indicators could be suitable for quality improvement without incentivisation.

Approximately half of respondents overall thought the indicators were suitable for quality improvement without incentivisation although this varied by indicator (Table 4), ranging from only 45.5% (15/33) in support of indicator 1, and 51.5% (17/33) for indicator 2, with slightly greater support for indicator 4 (54.4%, 18/33) and the highest proportion agreeing that indicator 3 could be suitable for quality improvement (57.6%, 19/33). Around one quarter to a third of respondents did not feel the indicators were suitable for quality improvement without incentivisation, with the remaining respondents being unsure (Table 4).

[5] https://www.england.nhs.uk/wp-content/uploads/2018/07/quality-outcome-framework-report-of-the-review.pdf

Table 4: Views on suitability of lipid management-related indicators for quality improvement (survey)

Do you think the following indicators could be suitable for quality improvement, without financial incentive?				
	Yes	No	Unsure	Total
Indicator 1: Lifestyle modifications in people with high CVD risk	15 (45.5%)	12 (36.4%)	6 (18.2%)	33
Indicator 2: Lipid modifying therapy for primary prevention of CVD	17 (51.5%)	10 (30.3%)	6 (18.2%)	33
Indicator 3: Lipid modifying therapy for secondary prevention of CVD	19 (57.6%)	9 (27.3%)	5 (15.2%)	33
Indicator 4: Lipid modifying therapy for people with CKD	18 (54.4%)	8 (24.2%)	7 (21.2%)	33

Indicator 1 – Lifestyle modification for primary prevention of CVD – specific issues identified in interviews and survey

Lifestyle modifications

As noted previously, there were mixed views on the value and rationale for an indicator relating to changing lifestyle factors in those with a high CVD risk. Some practices felt they were already doing this with their patients:

"I think this is something that we already do. We do it over 10% most of the time anyway." [GP, Interview]

However other practices, although recognising the value and rationale of changing lifestyle factors in the prevention of CVD, felt that at a CVD risk of ≥20% lifestyle modifications would not be sufficient:

"If you have got a CVD of over 20% you are not going to be changing that to 10% with diet and lifestyle … So, those patients, even though you have to give lifestyle advice to them – will probably be on statins if they have reached that stage." [Unknown, Interview]

"I think over 20% I hope we're offering more than just lifestyle …" [GP, Interview]

"… this is a completely circular conversation we have with patients the whole time, which goes along the lines of, 'Your CVD risk is 20%. You need to change your lifestyle and you should go on a statin,' 'Oh, can't I just eat less cheese and have my cholesterol checked in three months' time?' To which the answer is, 'Yes, you can, but you're not going to be younger, your risk is going to go up. You've crossed a line that is a one-way line.' So, the idea that the lifestyle interventions drops people down

to a pre-statin, it just doesn't happen, it never happens, and it's confusing to make people think it does …" [GP, Interview]

Advice and support

Practices also referred to other barriers to implementation, such as capacity to provide consistent and intervention-level advice (as opposed to information provision only) and patient compliance. There was also concern that, without monitoring the outcomes of patient lifestyle changes, this could devalue the indicator and reduce it to a 'tick-box' exercise:

The potential for the definition of 'advice and support' to be interpreted differently by practices – leading to a variation between practices in how the indicator is fulfilled – is outlined later (see 'Suggested amendments to indicator definitions' section). A common concern for participants was that ensuring patients were given enough thorough advice and support to facilitate meaningful lifestyle changes would be time-consuming for clinicians:

"We thought this was do-able, but was it a good use of time that seems to be quite short? I mean, I think all practices are struggling, and if you do this well, it's going to be quite time-consuming, and if you do it as a tick-box, why do it, and why is this not public health?" [GP, Interview]

There was a belief that, unless patients were given meaningful advice and tailored support, it would be a waste of time for practices and patients:

"…but the problem I see with those indicators is that there's no meaningful way to actually do anything apart from ticking the box […] unless there is a thought-through pathway for those people, because year after year I see the same faces saying, "Your BMI is up," you know, "You are sitting on your bum," and they say yes, and we see each other in a year, and it's a waste of each other's time. My whole […] problem with those indicators is everything is so disjointed that I think it would be nice to think something through. [GP, Interview]

One practice specifically suggested that the monitoring and measuring the impact of the advice given to patients would increase the value of the indicator. Seeing measurable changes could also address the other issue of patient compliance, by increasing motivation to change lifestyle factors:

"The only observation I'd make is that is the effect going to get measured? […] there used to be something called PAM scores, patient activation measures, where they

ask them about 10 questions before you started to put them through, and then 6 months later you asked them the same 10 questions to see if their physical activity has increased or not. Is it going to be something like that? Because […] if patients can see the benefit of what they're actually doing, it keeps their motivation going. Otherwise, it just becomes a tick-box exercise […] If you're actually looking to make some sort of impact, how is that going to be measured?" [Other Senior Management, Interview]

However, a few practices noted the difficulty in being able to measure outcomes following onward referral to an outside organisation for advice/support, due to a lack of time and the different ways that patients may access such services, and urged that it should not be expected for practices to evidence these outcomes as part of the indicator:

"Obviously we are not looking for the outcome of what happens to the patient once they have been referred to an outside organisation. So, yes, as long as it's not dependent on what happens to the patient when they have been referred, then it is OK." [Practice Manager, Interview]

"I think if you end up having to have evidence that they had been referred to a local stop smoking group or they had been referred to a local weight loss group, that is going to be very difficult because of the way people can access it." [GP, Interview]

One Practice Manager noted that social prescribers may be better able to monitor patients following referral to services for lifestyle modification, but that GPs would not have the capability to check the impact of any advice and support received following onward referral:

"…quite a good person (…) to manage this would be, like, our social prescriber or something like that. Because, you know, when they do onward referrals, they tend to keep an eye on those kinds of things more than the clinician does because obviously, they haven't got the time, have they? (…) if they wanted more bolted on this lifestyle check, then that's great but you definitely need somebody else to be able to follow that up really. And we wouldn't have the capability to make sure that anything further would be done." [Practice Manager, Interview]

Some practices noted the potential lack of capacity within the local community to manage an increase in referrals to services providing advice and support with lifestyle modification (see 'Barriers to implementation' section).

Indicator 2 – Lipid modifying therapy for primary prevention of CVD– specific issues identified in interviews and survey

Focus of indicator

Participants expressed mixed opinions regarding the rationale for indicator 2. A couple of practices mentioned that they were already doing this with their patients:

"This one, I've got the least concerns about. This has kind of been in QOF in one way or another for years now, so it sits very naturally with the work that we do in terms of long-term condition checks, attention reviews etc. So, you know, I'm quite pleased to see it, actually, because I think it's something that we're pretty much doing anyway." [Pharmacist, Interview]

However, a few questioned the approach of the indicator:

"I think this is the wrong approach. The wrong approach with the wrong target." [GP, Interview]

"There should not be a percentage of patient(s), as patients should have the right to decline medication, especially for primary prevention." [Practice Manager, Interview]

"Should be about how many patient-led discussion(s), not about starting events …" [GP, Interview]

Furthermore, some respondents questioned the rationale surrounding the ≥20% risk assessment score. This is considered further in the 'amendments to indicator definitions and/or wording' section.

As discussed previously, some practices felt it would be unfair to base financial incentivisation on patient uptake of lipid management medication as, in their opinion, it was out of their control if patients took their advice.

There were also mixed reviews regarding the need and usefulness of a patient decision aid (discussed in more detail in p34-35).

Indicator 3– Lipid modifying therapy for secondary prevention of CVD– specific issues identified in interviews and survey

Focus of indicator

All practices interviewed agreed that there was sound rationale for indicator 3. Some noted that patients in this group should already be on lipid modifying therapy and so practices should already be providing this treatment.

"*Yes, we're absolutely happy with it. No problem." [Deputy Practice Manager, Interview]*

"They all should be on it, and it should be part of a current chronic disease (you know) review." [GP, Interview]

Although supportive of this indicator, one GP was interested to hear the evidence behind it as they are not currently doing this within their practice.

"Yes, absolutely needs to be there. No question. Stick it in. It's for-, it's evolving practice. We weren't quite sure what the evidence was before […] if the evidence is there, it would be useful to have in because it's something we don't do at the moment." [GP, Interview]

Indicator 4– Lipid modifying therapy for people with CKD – specific issues identified in interviews and survey

Focus of indicator

At least five practices were supportive of indicator 4 and felt it was clinically relevant and/or that they were already doing this.

"I think it is becoming more and more known isn't it about the CKD risk for CVD so I think it is reasonable […] I think if there is evidence behind it, which there clearly is then I think it is worth doing." [GP, Interview]

"I would think it's similar to the indicator three as well. We're probably already doing it hopefully. So, I don't see it as a big problem." [Practice Manager, Interview]

"I think it's a clinically valid target, potentially a vulnerable group of patients […] I think that is a worthwhile group to be looking at, there's no doubt about that." [Pharmacist, Interview]

It was noted by the GP quoted above that this cohort are already likely to be receiving lipid modifying therapy due to comorbidity, but that it is a worthwhile indicator for identifying patients who have hypertension but are not on lipid modifying therapy.

"I think it is quite rare that patients have CKD and no other chronic disease so the chances are that most of these patients will be on statins anyway, but I think it is good to have – young group of patients perhaps who have got hypertension and CKD that might not be on a statin." [GP, Interview]

Data quality issues

However, one GP felt that it might be worth delaying the introduction of this indicator until the other CKD indicators (see CKD topic paper 6c) have had time to take effect, due to the likelihood of current poor coding of CKD in some practices.

"I think the problem with this is that I suspect there's really poor coding of CKD around in all sorts of places, not only in my practice. So, I think this isn't a bad indicator but maybe an indicator that will be better a few years down the line having used the next set of indicators for a while […] I think at the moment you'd end up with a lot of focus on a lot of people who perhaps shouldn't be in the group and some people who should be in the group and a lot of people who didn't realise they were in the group because there's a lot of that." [GP, Interview]

At least one additional practice also emphasised the importance of giving practices sufficient time to implement this indicator:

"I think that's a bit more difficult because it's not something we've been routinely doing. (…) if we were given sufficient notice, it should be okay." [GP, Interview]

Suggested amendments to indicator definitions and/or wording

Indicator 1 – Lifestyle modification for primary prevention of CVD

Some issues with the definition and wording of indicator 1 were highlighted by practices in both the survey and interviews. Over a quarter of respondents (27.3%, 9/33) thought the wording of this indicator should be changed, and a further 18.2% (6/33) were unsure. The suggested changes outlined in their freetext comments centred on amending the CVD risk score from ≥20% to ≥10% and removing the 3-month requirement (these issues are discussed further below).

"The CVD risk should be 10 percent, not 20 percent" [GP, Survey]

"LM1 - it is not clear why there is a 3-month requirement, this should be within the year. It should also contain an option to include information being sent to the patient (as often patients want this)" [GP, Survey]

A few respondents also felt the indicator was 'too wordy':

"LM1 - SUGGEST LIFESTYLE ADVICE- CURRENT IS TOO WORDY" [GP, Survey]

"The others [LM & CKD] are too wordy and mean little to staff without detailed knowledge and so for patients they'll never understand" [Practice Manager, Survey]

The appropriateness of using a CVD risk assessment score of ≥20%

There were mixed views about the appropriateness of using a ≥20% CVD risk assessment score for the provision of lifestyle advice. Some questioned the clinical relevance of this cut-off point, as by 20% they 'hoped' that more than lifestyle advice would have been offered to patients with one stating that lifestyle changes at this point would not reduce the risk to a pre-statin level. (To note that practices were not probed in the interviews about whether this point applied regardless of whether these are newly identified patients at risk, as intended by this indicator, and therefore less likely to be already treated with statins). However another practice, while acknowledging this point, emphasised that lifestyle changes are still the first priority:

"Yes, I think as a clinician, I want to do as best as I can, but I think […] the minimum standard is lifestyle education. If you find that their QRISK is more than 20% you might actually want to clinically put them on the statin sooner, but I think the lifestyle and education and smoke stop, is by far the key and the most important thing. We do it with our diabetics, we do it with our hypertensives quite often. So, it is just continuing already what we are doing." [GP, Interview]

Some practices were already providing lifestyle modification advice at a ≥10% level and felt that this score should be maintained. Similarly, existing NICE guidance uses a ≥10% risk level, and some participants felt this cut-off should be used here too.

"Using 20% risk cut-off is confusing when guidance is based at 10%. Confusing target in my opinion leads to generally poor management." [GP, Survey]

"It doesn't really seem logical to have NICE guidance saying one thing, and us being incentivised to do something else. [GP, Interview].

And from the same GP, later in the interview (*…) everyone who's got to 20% has got there five, six, seven years later than they got to the 10% risk, which is the risk-, the level at which they would have been recommended-, they should have been recommended treatment " [GP, Interview].*

Although using a ≥10% risk score for indicator 1 was felt to be more clinically relevant, there was concern that the workload to do this would be too great. Some suggestions offered to remedy this included:

- start small with a ≥20% risk first and move to ≥10% when there is increased capacity
- use a ≥15% risk assessment score, or

- change the score to ≥ 10% but lower the threshold to achieve the indicator.

"I did think is 20% a bit too high? I think it would be a massive workload if you went with 10%. Maybe something in-between, I don't know. I'm not sure the numbers would be that high for over 20%. Yes, I don't know whether 15% might be better." [Practice Manager, Interview]

"In terms of patient populations, it's very good but I think in this initial setup, in this launch, you probably want to focus on a smaller pool first. And then, see how that goes and then, you could branch it out to the 10%." [Practice Manager, Interview]

"10% does seem more logical because that's been the guidance for some time now, but 20% would be easier to achieve as a target. You've got 2 options. You either go for 10% and have a lower target or you go for 20% and you go with a higher target, but yes, because we'll probably carry on using 10% as the cut-off." [GP, Interview]

Providing a meaningful level of advice and support

Some interviewees raised concerns that the definition of 'advice and support' could be interpreted differently by practices leading to a variation between practices in how the indicator is fulfilled:

"…a lot of other practices might just send an accurate test to patients, saying this is the lifestyle advice – not actually doing a holistic approach, whereas I think, our practice is good at doing what [practice nurse] has just said. So, I suppose to make sure the practice is doing it thoroughly – I suppose is something that perhaps needs to be thought about" [Unknown, Interview]

There was a suggestion for greater clarity on what 'advice and support' should include, to ensure practices provided meaningful advice that would lead to lifestyle changes. It was clear that this advice needed to include dialogue and conversation with patients and not just the provision of information. One practice suggested that the wording may include the use of the term "personal", to ensure advice is tailored to the patient, whilst another suggested specifying the use of patient led/ motivational interview-style discussions.

"I think there can be quite a lot of variation with practices as to what advice you would be giving. I was just wondering if something like this came through, you would probably just want to say – use the word 'Personal' in there, so you would be offered personal advice because that way you wouldn't then have to send them – you would have the conversation with them somehow to sort of tailor the advice and that would potentially be a blanket way of making sure you actually had a – with the patient and actually making this a worthwhile intervention." [GP, Interview]

"Might there be more population health gains to be made by incentivising doing more CVD risk assessments on a wider population & having high quality patient led / motivational interviewing influenced discussion about change as a result?" [GP, additional email feedback]

A couple of practices suggested the use of templates (see page 34 for detail) or consistent messaging to reduce the potential variation in the advice received by patients:

"…some consistent simplified messaging, and even some instructions, practice directions on how to implement that consistent messaging, I think would be really good." [GP, Interview]

"If you, kind of, just free-flow it, one patient, it might be different to another. Whereas if it's structured and they can just, you know, say, 'Leaflet given, signposted to this, done this, done this, done this.' And you know that everything's been done." [Practice Manager, Interview]

Timeframe for providing advice

A couple of interviewees questioned the use of a three-month cut-off for providing lifestyle advice. As lifestyle modifications were not considered 'urgent', a longer timeframe, such as 6 months, was considered more appropriate (and would allow for patients going on holiday, for example):

***"**This is not an urgent matter and therefore the time limit seems artificial" [Practice Manager, Interview]*

"I would just say to make that [timeframe] a little bit more flexible – like six months. Because we have certain practitioners that do smok[ing] and alcohol advice – it is not GPs – it's our health care professionals – so we don't have a plethora of them that are available every day of the week. It would be appointment schedules – so three months is a little bit tight." [GP, Interview]

These views were reiterated in the survey responses by members of the same practices quoted above.

Consideration of indicator scope

Some practices were asked if there were any other ways in which the focus of Indicator 1 should be limited, such as by age. There was a shared view that limiting the focus of the indicator by age was unnecessary, with a couple suggesting frailty may be a more important exclusion:

"I'm not sure age, but frailty would probably be important to exclude, so leave frailty as, 'Yes, you're not going to achieve much by trying to intervene with them,' but I don't think it's an age thing."[GP, Interview]

"It's more the person's ability, rather than their age." [Senior Manager, Interview]

Indicator 2 – Lipid modifying therapy for primary prevention of CVD

Two thirds of respondents (66.7%, 22/33) did not think the wording should be changed for this indicator and a further 18.2% (6/33) were unsure. Five respondents (15.2%) thought the wording should be changed. Of those who provided a written explanation, the issues appeared to be with the assessment score of ≥20% and the need to take into consideration those that have declined treatment:

"LM1 and 2 - I don't think these are suitable indicators. Using 20% risk cut-off is confusing when guidance is based at 10%. Confusing target in my opinion leads to generally poor management. I think these issues should be approached in an entirely different way by Health Promotion Campaign and messaging rather than using 1:1 clinician time. Nearly all men reach 10% risk threshold within a year either side of 60; and for women the age is 70. Simple messaging about statins at these age thresholds, messages direct to patients from national Health Promotion, would save loads of medical time (and let's face it we have a massive shortfall of doctors and nurses so any help here very much needed" [GP, Survey].

"LM2 - this should have option for patients to have declined (and this therefore taken into consideration as a whole of the % indicator)". [GP, Survey]

"LM2. ≥10% and offered lipid modifying therapy". [Senior Management, Survey]

The appropriateness of using a CVD risk assessment score of ≥20%

As with indicator 1, there were mixed views about the use of a ≥20% risk score for indicator 2 and many felt that a ≥10% score would be more useful. Some practices highlighted they currently offered patients lipid modifying therapy/statins at a ≥10% risk score, with one practice explicitly stating that this would be offered at ≥10% alongside the lifestyle modification guidance. Furthermore, as the NICE guidance uses a ≥10% score, it was felt that this indicator should match it.

"10% is not a magic number, it's a round number […] The whole risk calculator is not an individualised risk. So, we make some very black lines around something that is completely fuzzy, and so, well, if we just come back to the 10 versus the 20%, why

have guidance that is set at 10%, and then QOF indicators set at 20%? Doesn't make sense to me." [GP, Interview]

"Again, because we're using 10% as a cut off, almost everybody with 20% would probably end up on a statin automatically. We'd probably do the lifestyle advice and the statin at the same time, for the vast majority. If it was 10% as a cut off, then there might be a smaller percentage that go through to statins straight away, but with 20%, I think almost 100% of them would be going onto statins." [GP, interview]

However, one interviewee suggested that if the score was to be reduced to ≥10% it would be appropriate to reduce the threshold required to achieve the indicator:

"Doctors were happy to do that. They would actually go, even though there's a much higher number of patients, they would go for 10%, so they're both aligned, but lower the threshold of achievement for full points." [Deputy Practice Manager, Interview]

In contrast to those suggesting a reduction to ≥10%, one GP thought that a score of ≥20% would be appropriate and argued there is a risk of discouraging lifestyle modifications if lipid modifying therapy was offered when the CVD risk assessment score is ≥10%.

"I think for Indicator 2, probably, I would go for 20% because I would think that a lot of people in the 10 to 20%, in my experience, sort of, will want to say, 'I want to start trying to do this in my lifestyle first.' Now, actually, you can disincentive the lifestyle change if you're saying, well, 10% are going to performance manage, putting everybody up on the statin." [GP, Interview]

Consideration of indicator scope

One GP did not think the indicator should be limited by age but noted a lack of evidence to support the prescribing of statins for those aged over 80. However, it was felt that GPs should determine the most appropriate way to manage this older patient cohort:

"I suppose the only thing would be the very old patients because there is not a lot of data to back up managing – you know – statins and things in patients over the age of 80, but I think it is important for us to make that decision but to still be able to do the risk (…) So, I don't think it should be split into only looking at patients between, I don't know, 40 and 60 or something." [GP, Interview]

Timeframe for patients to be on lipid modifying therapy

The general consensus amongst interviewed practices was that between 6 and 12 months was a sufficient period for a patient on lipid modifying therapy to be included in the indicator. Some felt that 3 months would be reasonable, but any less time would not be appropriate:

"Once you've started it [statin], you're going to repeat the cholesterol and the liver function tests after three months, so it can't be possibly any less than that, because it's at the three-months marker you make a decision as to whether or not they're tolerating the therapy and then adjust it accordingly. I've got in my mind really somewhere between six and twelve months. A lot of the time, people will be started on a statin, they take it for a couple of months, and then give up on it for one reason or another. So, I think if this is going to carry some value, plucking a figure out the air, I'm thinking around six months." [Pharmacist, Interview]

"I suppose if someone has been on Statins for 6 months, you could safely say that they are not going to stop it due to side effects – I suppose a year probably – they will have gone through an annual review then. So, you'll - there will be some patients that have perhaps stopped it but we have not been aware of that but that would be picked up at the annual review. So, I suppose between 6 months and a year." [GP, Interview]

"I think 3 months sounds reasonable." [GP, Interview]

However, as previously discussed some practices felt that as long as practices had appropriately counselled the patient this should be sufficient for payment irrespective of whether the patient started lipid modifying therapy.

Agreement with using the term 'lipid modifying therapy' (Indicators 2-4)

There was agreement from practices that the wording 'lipid modifying therapy' was more suitable than demarcating 'statins' specifically, as these medications do not suit all patients. One practice also mentioned that other lipid modifying therapies rather than statins, like Inclisiran, were starting to be used more in general practice so should be included:

"I personally think it's probably better, because we've had this in the past with other indicators around is it just a statin, and then you find that they're on something else and that doesn't count, and you think, well, why doesn't it count? So, I would've thought, yes, it's good to have that broader therapy use." [Practice Manager, Interview]

"I think it has to be, because you've mentioned Inclisiran there, there's no doubt that is going to be one of the big therapies moving forward, so it can't just be about statins anymore. Statins don't suit everyone. In fact, one of the reasons that we don't always get to 100% on this type of scoring is because some people don't tolerate statins, so we need to bring the alternative factors into that, the alternative therapy." [Pharmacist, Interview]

"Yes, it should have a broad definition because, at the moment, things like fibrates are not included either. Some people can't tolerate statins and we're already using other drugs. It should be any lipid treatment, really." [GP, Interview]

Indicator 3 - Lipid modifying therapy for secondary prevention of CVD

Most survey respondents (81.8%, 27/33) did not think the wording of this indicator needed changing and 15.2% (5/33) were unsure. Only 1 respondent (3.0%) thought the wording needed changing, citing that it should state 'offered/discussed':

"LM3 - this should be offered/discussed, as patients may initially be trialled on lifestyle modification/decline treatment." [GP, Survey]

Definitions of subgroups

Nine practices discussed the subgroups of patients that would be defined under Indicator 3 (CHD, heart failure, peripheral arterial disease, stroke, and TIA). Five interviewees were happy for all these subgroups to be included. However, three practices questioned the inclusion of 'heart failure' within this definition:

"Heart failure probably shouldn't be because heart failure isn't always caused by cardiovascular disease. I'm not sure that should be in the indicator. Apart from that, I think everything else sounded fine to me." [GP, Interview]

"Also, sometimes cardiologists do not recommend statin for heart failure, depending on primary cause or patients with heart failure are very frail, elderly and statin not indicated." [Practice manager, Interview]

One GP thought it was best to consider the conditions as one group.

"I think bundling it on all together under the work secondary prevention is better than dividing it into individual diseases." [GP, Interview]

Indicator 4 - Lipid modifying therapy for people with CKD

No survey respondents thought the wording of this indicator required amendment.

Appropriateness and feasibility of including all stages of CKD

Practices were asked to consider the value of focusing indicator 4 only on patients captured by CKD005 (i.e., patients with stages 3a-5 CKD on the QOF CKD register), or whether it would be possible to capture all patients with CKD for the proposed indicator.

Of the 9 practices that were asked, there was a shared view that the indicator should continue focusing on those captured by CKD005. It was felt unfeasible to include all patients due to 'huge' implications on workload from the high numbers involved. One practice who discussed the 'absolutely huge' workload impact that expanding the indicator to include all patients with CKD would have involved, also questioned whether their prescribing budget would be increased. Expanding the indicator to include all patients with CKD was also considered clinically irrelevant and could run the risk of over-treatment:

"I would have to convince myself it would be an appropriate management for these people. I really can see just over-treating lots of people. I think, you know, early stages would definitely benefit from lifestyle, and just to make sure they are not on anti-inflammatories long-term, some other reasons why their kidneys are not happy. But not, sort of, going heavy duty on statins" [GP, Interview]

"…if someone's eGFR can bounce around so much, I think if we're going to be incorporating other people who have a very diminished renal function, the numbers are going to expand hugely and I think we're better off focusing on three to five. I really do. Because I think those are the people who would benefit most from this intervention." [Pharmacist, Interview]

One GP explained that it would be possible to identify the expanded cohort, but that it would increase the workload significantly. The feasibility of offering all patients with existing CKD lipid modifying therapy was regarded to be dependent on the level of reimbursement and the amount of time that could be allocated:

"It would be a significant amount of work, probably, at first. It depends on how well it's remunerated and if it's reimbursed well then it should be okay. I think identifying them would be relatively straightforward because then you can just run a search on

eGFRs. If it's 4% of the population, that would be a lot of work (…) we'd probably be looking at around 1,000 patients, (…) again, it depends on the reimbursement and how much time we can commit [to whether this was feasible]." [GP, Interview]

It was suggested by one GP that this indicator should focus on those patients with higher risk elements of CKD, rather than those who have CKD and no other chronic illnesses. It was further noted that it may not be appropriate to prescribe lipid modifying therapy for patients with severe CKD.

"…the really severe ones who are on dialysis and they don't want to be giving them drugs that are going to screw up their renal treatment, if they're heading towards that. I don't know whether there is anything there but it just needs to be taken into account." [GP, Interview]

A different GP felt that if patients did not have other comorbidities in addition to CKD they should not be included in the indicator:

"…….*we do have quite a significant population of people in their 90s who've travelled the world and they have dodgy kidneys but probably will die with them, and they're not on any other medication. I would hate offering them statins because it would be totally silly." [GP, Interview]*

Practice views on implementation issues and impact

This section covers practice views on: training requirements; workload, resource utilisation (including which healthcare professionals would be involved) and costs (including impact on appointment times); any changes required to practice organisation (e.g. setting up and use of clinical system protocols, recall systems and templates); any barriers to implementation; assessment of overlap with and/or impact on existing QOF indicators or local schemes; and any other overall views on implementation of the indicators (including unintended consequences).

Training requirements

Practices in the survey and interviews were asked whether staff would need any additional training or guidance to implement the lipid management-related indicators. Half of the survey respondents (15/30, 50.0%) thought that clinical staff would need to undertake additional training if the indicators were introduced. A higher proportion (19/30, 63.3%) reported that administrative staff would require additional training or guidance to implement the indicators.

Within the interviews, questions about training were asked in relation to the provision of lifestyle modification therapy (indicator 1). Some practices felt that their staff had adequate training to provide lifestyle information, as this would be similar to health checks given for a range of health issues such as diabetes. Nonetheless, some practices may value more information about the services available for patients to be signposted to.

"I think the majority would be fine, wouldn't need much more training. I think maybe they'd need to understand what other services are available to be referred to, to help them with their lifestyle changes, making sure that we've got an up-to-date directory of, you know, where and what we can do." [Practice Manager, Interview]

It was suggested by a couple of interviewees that a template could be used to ensure the provision of consistent structured advice and monitoring of information:

"I mean, my healthcare assistant is fairly new but she's done plenty of NHS health checks and things, so this would be fine. As long as she's got a template to follow, it will be okay." [Practice Manager, Interview]

Patient decision aid

As a way of exploring shared decision making, some interviewees were asked about their views on using a patient decision aid to help patients in conversations with regard to starting lipid modifying therapy for primary prevention (indicator 2). Two practices referred to already using decision aids and thought that automating the distribution of these aids would assist practices:

"Our system we've set up recently is that when an HCA gets to a point of finding somebody with a risk of over 10% they send them a text with the statin decision aid and they can then from that go to our website and send something back into us saying thank you I've read the statin decision aid, I do want I don't want or I would like to discuss statins further. And, you know, it's just how to automate a process that everyone is going to cross." [GP, Interview]

"[In reference to using patient decision aids] Sometimes we do … I guess, yes, if there was a straightforward, at-a-glance aid for people, we could maybe send them a link, like an accuRx link ... something that they could make admin part of it easier." [GP, Interview]

A different practice already sent information, in the form of a leaflet, to patients and felt having an official tool would be helpful.

"We already have something. It would be good if there was something official that came out, so that we could send those to patients before we actually consult, so we're only consulting with the ones that actually want advice." [GP, Interview]

It was felt to be important by some interviewees that a general discussion was sufficient and one practice emphasised that it was important that a patient decision aid did not replace a discussion with a clinician about starting new medication:

"I think if information is made available that facilitates those conversations, you know, there's some good examples of decision trees and things like that out there, so that you can explain to people the risk factors that are associated with these things. They're all useful, but I would say general discussion is quite adequate. That's what we're doing at the moment and that seems to work." [Pharmacist, Interview]

One interviewee questioned whether the NICE patient decision aid would be accessible in multiple languages and noted the importance of being able to communicate with patients in a culturally sensitive way.

"…some of the stuff the NHS does, does it in a range of languages, and there's other stuff that it doesn't, for some reason. All health problems affect everybody, so I'm just wondering because being an ethnic minority area, inner city, that's one of the fundamental problems that we come across. It's not just getting the message across to them, it's getting the message across to them in a language and culturally sensitive way." [Other Senior Management, Interview]

Workload, resource utilisation and costs

Clinical workload

Most survey respondents thought the requirements relating to the lipid management indicators would generate additional clinical workload, either 'definitely' or 'to some extent' (Table 5). A slightly higher proportion of respondents (16/31, 51.6%) reported that indicator 1 would 'definitely' create additional clinical workload when compared with the other indicators (Table 5).

Table 5: Views on additional clinical workload generated by each indicator (survey)

Will the requirements relating to each indicator generate additional clinical workload? *					
	Yes, definitely	Yes, to some extent	No	Unsure	Total
Indicator 1: Lifestyle modifications in people with high CVD risk	16 (51.6%)	8 (25.8%)	5 (16.1%)	2 (6.5%)	31
Indicator 2: Lipid modifying therapy for primary prevention of CVD	15 (48.4%)	5 (16.1%)	7 (22.6%)	4 (12.9%)	31
Indicator 3: Lipid modifying therapy for secondary prevention of CVD	13 (41.9%)	7 (22.6%)	8 (25.8%)	3 (9.7%)	31

* Note that no response is displayed for indicator 4 due to data quality concerns (see Background section, p8)

Some interviewed practices noted concern around the workload required to implement indicator 1. A few practices expressed that they did not have the capacity to provide the level of lifestyle advice required and to implement this indicator successfully, more staff resources would be needed. It was also mentioned that the indicator should allow for the utilisation of different staff roles (for example, social prescribers and nurses) rather than specifying that a GP had to provide the advice to the patient:

"We don't have capacity, we don't have nurses, we don't have doctors. Last week, I was alone manning the surgery because of these unexpected health issues of my colleagues, and yes, so unless there is more planning, all of this is just a joke." [GP, Interview]

"And you know what would have been really-, like, quite a good person would be to manage this would be, like, our social prescriber or something like that. And social prescribers have a bit more ongoing, you know, they tend to look at things like if they referred a patient to the gym to help them with their diet or weight loss, and stuff. They'll keep a track on that more than a clinician. We don't get that much of a social prescriber's time here in our practice. I know some practices have their own social prescribers and some don't. But I think that would be-, you know, if they wanted more bolted on this lifestyle check, then that's great but you definitely need somebody else to be able to follow that up really." [Practice Manager, Interview]

"We have only just had this excellent nurse team in the last couple of years and that is what has revolutionised – if GPs are managing it, they are not going to do it properly! […] so, the key is the nurse team" [GP Partner, Interview]

Practices also commented that using social prescribers or the nursing team may allow for more continued care and tailored advice than providing this through a clinician appointment:

"… quite a good person would be to manage this would be, like, our social prescriber … because, you know, when they do onward referrals, they tend to keep an eye on those kinds of things more than the clinician …" [Practice Manager, Interview]

"We have got a very strong nursing team in our practice whereas I think a lot of practices don't do that and I think a lot of the GPs do some of the chronic disease management which I don't think we do very well …" [GP, Interview]

One interviewee also made the point that this may not be the right time to implement the indicator, as practices are still recovering from backlogs resulting from the Covid-19 pandemic.

"Yes I am just obviously looking at it from a workload issue. I don't think it is practical for most practices to be doing this just at the moment. Yes, we should all be doing it anyway but thinking about where we are at right now in post Covid and everything getting back to normal and QOF coming back and all the new initiatives, it may not be do-able at the moment." [Practice Manager, Interview]

It was suggested by one practice that Integrated Care Partnerships could, in the future, offer a solution to providing support to patients around lifestyle changes.

"These incoming integrated care partnerships […] have access to loads of social activities, that we could refer people on to […] I think there's some sort of tie up with the wealth of organisations and city council funds, that provide social activities, and then people can refer to them as well, in terms of people taking some sort of activity up from a personal interest point of view, it might find more broader, long-term benefits for patients" [Other Senior Management, Interview]

Two practices also referred to the use of PCN budgets (and specifically the Additional Roles Reimbursement scheme, ARRS) to aid with the demand either in reference to the indicator or following onward referral:

"Well, I think there's delivery of that certainly through our PCN, and so if the demand is growing, then at least, with an increasing PCN staff budget, then the service can grow." [GP, Interview]

"I think we need to be looking using our ARRS roles more, so using social prescribers and looking at the lifestyle of patients and how we can change that by using these new roles that we've all got as part of our network." [Practice Manager, Interview]

Practices were asked in the survey which staff groups would be most affected by the clinical requirements of the indicators. Differences between the indicators was evident (Table 6); a higher proportion reported that 'nursing' and 'other clinical' staff groups would be most affected by the clinical requirements of indicator 1 when compared with the other indicators. In contrast, whilst 74.2% (23/31) of respondents thought GPs would be affected by the clinical requirements of indicators 2 and 3, only 25.8% (8/31) thought this would be the case for indicator 1.

Table 6: Views on staff groups affected by the clinical requirements (survey n=31*)

Which staff group(s) would be most affected by the clinical requirements of the lipid management indicators? #						
	GP	Nursing	Pharmacist	Other Clinical	Unsure	Total respondents*
Indicator 1: Lifestyle modifications in people with high CVD risk	8 (25.8%)	21 (67.7%)	9 (29.0%)	11 (35.5%)	1 (3.2%)	31
Indicator 2: Lipid modifying therapy for primary prevention of CVD	23 (74.2%)	18 (58.1%)	12 (38.7%)	3 (9.7%)	1 (3.2%)	31
Indicator 3: Lipid modifying therapy for secondary prevention of CVD	23 (74.2%)	15 (48.4%)	14 (45.2%)	4 (12.9%)	2 (6.5%)	31

* This is a multiple response question, so the number of responses per indicator/row totals more than 31, as respondents could select more than one response

Note that no response is displayed for indicator 4 due to data quality concerns (see Background section, p8)

Administrative workload

Over half of survey respondents (59.4%, 19/32) thought indicator 1 would 'definitely' generate additional administrative workload, with a further 21.9% (7/32) reporting it would 'to some extent' (Table 7). Although slightly lower proportions of respondents felt indicators 2 and 3 would 'definitely' increase administrative workload (43.8% and

37.5% respectively), when combined with those that responded 'yes to some extent' the majority still felt these indicators would generate additional administrative work.

Table 7: Views on additional administrative workload generated by each indicator (survey)

Will the requirements relating to each indicator generate additional administrative workload? *					
	Yes, definitely	Yes, to some extent	No	Unsure	Total
Indicator 1: Lifestyle modifications in people with high CVD risk	19 (59.4%)	7 (21.9%)	4 (12.5%)	2 (6.3%)	32
Indicator 2: Lipid modifying therapy for primary prevention of CVD	14 (43.8%)	11 (34.4%)	6 (18.8%)	1 (3.1%)	32
Indicator 3: Lipid modifying therapy for secondary prevention of CVD	12 (37.5%)	11 (34.4%)	8 (25.0%)	1 (3.1%)	32

* Note that no response is displayed for indicator 4 due to data quality concerns (see Background section, p8)

In the interviews some practices identified administrative workload issues with identifying patients within the four indicators. Regarding indicator 1, this was due to it not currently being routine practice to calculate the risk score. One practice mentioned the 'significant' workload required to identify a potentially large number of patients for indicator 4, whilst two practices raised potential coding issues relating to indicators 3 and 4 respectively, which could result in workload implications.

Time pressure, appointment capacity and appointment type/length

There was variation in the perceived time pressure issues relating to each of the indicators. Seventy percent (21/30) of survey respondents thought there were time pressure issues relating to indicator 1. As discussed previously, practices expressed concern over the time and resources required to provide the level of lifestyle advice required. The proportion reporting time pressure issues for the other two indicators reported was lower than for indicator 1, although more than 45% of respondents still thought there were time pressure issues (Table 8).

Table 8: Views on time pressure issues in the practice relating to the indicators (survey)

Can you foresee any other time pressure issues in the practice relating to the indicators? *				
	Yes	No	Unsure	Total
Indicator 1: Lifestyle modifications in people with high CVD risk	21 (70.0%)	7 (23.3%)	2 (6.7%)	30
Indicator 2: Lipid modifying therapy for primary prevention of CVD	17 (56.7%)	11 (36.7%)	2 (6.7%)	30
Indicator 3: Lipid modifying therapy for secondary prevention of CVD	14 (46.7%)	14 (46.7%)	2 (6.7%)	30

* Note that no response is displayed for indicator 4 due to data quality concerns (see Background section, p8)

Most respondents to the survey did not think the appointment type would need to be changed for implementing the indicators, particularly for indicator 3 where two thirds (66.7%, 20/30) said no changes were needed (Table 9). Similarly, for indicators 2 and 3, over half the respondents did not think the length of the appointment would need to change. In contrast, only 26.7% (8/30) of respondents thought the appointment length would not require changing for indicator 1, with 56.7% (17/30) believing it would need to change.

Table 9: Views on any changes needed to appointment type/length relating to the indicators (survey)

Do you think there would need to be any changes to appointment TYPE for the following indicators? *				
	Yes	No	Unsure	Total
Indicator 1: Lifestyle modifications in people with high CVD risk	10 (33.3%)	13 (43.3%)	7 (23.3%)	30
Indicator 2: Lipid modifying therapy for primary prevention of CVD	8 (26.7%)	18 (60.0%)	4 (13.3%)	30
Indicator 3: Lipid modifying therapy for secondary prevention of CVD	6 (20.0%)	20 (66.7%)	4 (13.3%)	30

Do you think there would need to be any changes to appointment LENGTH for the following indicators? *				
	Yes	No	Unsure	Total
Indicator 1: Lifestyle modifications in people with high CVD risk	17 (56.7%)	8 (26.7%)	5 (16.7%)	30
Indicator 2: Lipid modifying therapy for primary prevention of CVD	9 (30.0%)	17 (56.7%)	4 (13.3%)	30
Indicator 3: Lipid modifying therapy for secondary prevention of CVD	8 (26.7%)	18 (60.0%)	4 (13.3%)	30

* Note that no response is displayed for indicator 4 due to data quality concerns (see Background section, p8)

Questions about appointment times in the interviews were only considered in relation to starting a patient on lipid-modifying therapy (indicator 2). Most practices agreed that this would be done in a standard appointment in-person or over the phone. Five practices mentioned that the appointment length would be 10 minutes. However, one of these practices did suggest a 20-minute appointment but believed this would depend on how much pre-work (blood tests, conversations about risks) had been done. Otherwise, for starting patients on lipid modifying therapy, a standard 10-minute appointment would be sufficient:

“I mean I think we would book it as a routine ten-minute appointment. It doesn't feel like a good use of time.” [GP, Interview]

“It does depend exactly how much pre-work is being done before that. If it's literally just to talk about whether or not someone started on a statin, that could be done in ten minutes, definitely, I would agree with that. I think if it's more comprehensive conversation about risk etc., additional blood tests, then 20.” [Pharmacist, Interview]

One practice noted that they would probably manage such appointments within a dedicated clinic to allow consistency in the appointment type between patients:

“We like having set clinics with the doctor so we would probably have, like, a set number of appointments for these patients to be booked into. So, it's consistent, so they're not slotted into, you know, twelve other routine appointments, it would be all the same clinical appointments, so you've got that consistency going through it (…)because that way you'd be able to run a search, give a list to reception, call the patients in, book them into the clinic.” [Practice Manager, Interview]

Changes in practice organisation

To fulfil indicator 1, it is likely practices would need to resume undertaking health checks following Covid-19 to identify the eligible patient group. A couple of practices suggested the use of templates or consistent messaging to ensure the provision of consistent structured advice, and monitoring lifestyle advice and support information.

Barriers to implementation

For indicator 1, there was concern that onward referral programmes may lack the capacity to provide lifestyle modification to patients. Some of these capacity concerns may be related to a backlog from the Covid-19 pandemic, but some may be linked to high numbers of patients.

"There is no capacity now, it's all saturated." [GP, Interview]

"We always tend to get that fact that there's not enough capacity from that side." [Practice Manager, Interview)

"If it was two years ago, I probably would have a clearer idea to say, yes, these services would be okay to pick this up, but at the moment it's quite difficult to say because, you know, there is a backlog from COVID." [Practice Manager, Interview]

Other potential barriers to providing advice and support for lifestyle modification have already been outlined.

Assessment of Personalised Care Adjustment reporting rates

One interviewee queried whether there could be an exemption for those patients that had already received a lifestyle check for another condition, due to the difficulty of getting their engagement for another discussion around lifestyle modifications (indicator 1):

"There might be another health lifestyle check again. So, maybe it's something that maybe, like, if they've already had a lifestyle check before or a health check in another domain, would you exclude that patient from this check because you won't want them repeating it and they won't come in, to be honest with you. If they've already had it, they won't come in again." [Practice Manager, Interview]

As previously noted, for indicator 2 there was a call from some practices to include an exemption code to exclude patients that declined to have lipid modifying therapy following a discussion with a healthcare professional and/or those for whom the medication could not be tolerated.

"I think you can exclude patients if you have had the conversation with them and they – for whatever reason – don't want to go on a statin – you can exclude them as long as you have had the proper discussion and you use the exemption code as you should be doing, not just to get your appointments up." [GP, Interview]

"….would that not include the not indicated, the not tolerated, etc, even though we would've done the work to establish that." [Data Quality Staff Member, Interview]

Assessment of overlap with and/or impact on existing QOF indicators or local schemes

Nine practices were asked for their views on whether there was any value in having both the proposed indicator 2 and the planned PCN DES for 2022/23 CVD-03[1]. It was noted that the only difference between the indicators was the specification of age group and statin in the PCN DES indicator and that having both was unnecessary. Indicator 2 was deemed preferable to the PCN DES indicator by two practices due to the inclusion of patients on all lipid modifying therapies.

"… the lipid modifying group is better. There's no point having both [indicators], really." [GP, Interview]

Furthermore, a couple of practices noted that they did not like the age restrictions imposed on the PCN DES indicator. One of these practices mentioned that perhaps frailty should be considered:

"I don't think there is any value in having both. I wouldn't go with age, I would go with frailty …" [Deputy Practice Manager, Interview]

Whilst one practice did not offer a view on the potential overlap between the indicators, they did comment that the planned PCN DES indicator should also not use the ≥20% risk score due to its conflict with NICE guidance, as discussed earlier.

There are already two QOF indicators (DM022[6] and DM023[7]) that focus on statin treatment for people with diabetes. Some interview respondents were asked if there may be any drawbacks to having indicator 3 in addition to the DM indicators and the proposed indicator. The consensus from practices was that there would be no issues although one practice suggested merging the indicators:

"I wouldn't see any drawbacks. I mean some people could be in both, but that's just because they are doubly important. So, I wouldn't see. We have searches that tell us high-cost interventions. So, a patient if you get them on a statin is going to score multiple points becomes the priority patient so it doesn't do any harm." [GP, Interview]

"I think you can exclude the diabetes from your indicator but in some ways you are best to have it twice than not at all." [GP, Interview]

"It doesn't really make a difference. You probably don't need DM23 after this, because everybody with CVD should have a statin or should have lipid lowering therapy. It probably doesn't make a difference for DM22, because that's a separate indicator." [GP, Interview]

Other overall views on implementation of the indicators (including unintended consequences)

Most survey respondents were either unsure or did not think there would be any unintended (positive or negative) consequences if the lipid management indicators were introduced (Table 10). Of the minority who did predict some unintended consequences, a slightly larger number thought they would be positive, particularly for indicator 3 (Table 10).

[6] DM022 The percentage of patients with diabetes aged 40 years and over, with no history of cardiovascular disease and without moderate or severe frailty, who are currently treated with a statin (excluding patients with Type 2 diabetes and a CVD risk score of <10% recorded in the preceding 3 years).
[7] DM023 The percentage of patients with diabetes and a history of cardiovascular disease (excluding haemorrhagic stroke) who are currently treated with a statin.

Table 10: Views on potential unintended consequences relating to the indicators (survey)

Are there any unintended positive or negative consequences that you can think of that could be experienced locally if these indicators were introduced nationally? *					
	Yes, positive	Yes, negative	No	Unsure	Total
Indicator 1: Lifestyle modifications in people with high CVD risk	5 (16.7%)	4 (13.3%)	10 (33.3%)	11 (36.7%)	30
Indicator 2: Lipid modifying therapy for primary prevention of CVD	6 (20.0%)	5 (16.7%)	9 (30.0%)	10 (33.3%)	30
Indicator 3: Lipid modifying therapy for secondary prevention of CVD	8 (26.7%)	3 (10.0%)	10 (33.3%)	9 (30.0%)	30

* Note that no response is displayed for indicator 4 due to data quality concerns (see Background section, p8)

Via freetext comments, respondents who predicted negative unintended consequences if the indicators were introduced noted issues relating to workload, funding, labelling patients, and prescribing statins:

"LM1: GPs may feel that is a lot work to do and may not be equip to do it. I feel this is an important indicator for public health and you should make it financially attractive to do this." [GP, Survey]

"Crossover issues could mean double funding accusations." [Practice Manager, Survey]

"Diversion of fixed amount of resource away from other care to focus on incentives. Unless there is a cunning plan to fix the primary care workforce crisis that we haven't been told about yet..." [GP, Survey]

"LM2: The percentage of patients with a CVD risk assessment score of ≥20% who are currently treated with a lipid modifying therapy. As I said before I feel like statin should be optional for patients for primary prevention and I don't think GPs should be seen as rewarded to prescribe." [GP, Survey]

"LM1 and 2 - as before: not the right approach in my opinion." [GP, Survey]

"Side effects. Labelling patients with a diagnosis, the significance of which is still debated within medical profession." [GP, Survey]

Comments relating to perceived positive consequences noted the beneficial impacts for patients:

“CVD - improve CHD outcomes, educate patients re diet and lifestyle - positively impact on other chronic disease such as diabetes, mental health etc.” [Nurse, Survey]

“All indicators are reasonable and would improve patient experience with a more structured approach.” [Practice Manager, Survey]

“With lipid management, it will lead to proactively identifying patients with CVD.” [GP, Survey]