West Yorkshire & Harrogate
Joint Committee of Clinical Commissioning Groups

Summary report			
Date of meeting: 1st October 2019		Agenda item: 51/19	
Report title:		Healthy Hearts project: Paper A – Approval of Cholesterol Treatment Guidance Paper B - Implementation Update	
Joint project sponsors:		Amanda Bloor (Chief Officer, North Yorkshire CCGs) Dr Steve Ollerton (Chair, Greater Huddersfield CCG)	
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Presenters:		Amanda Bloor (Chief Officer, North Yorkshire CCGs) Dr Steve Ollerton (Chair, Greater Huddersfield CCG)	
Purpose of report: (why is this being brought to the Committee?)			
Decision	✓	Comment	✓
Assurance	✓	For Information	

Executive summary

This report is presented in two sections:
Paper A - Approval of Cholesterol Treatment Guidance
Paper B - Implementation Update.

Paper A

The purpose of this paper is to recommend to the Joint Committee of CCGs that it supports the introduction of standardised and simplified treatment guidance for patients with high cholesterol.

The Cholesterol Treatment Guidance (Appendix A) has been developed for use in primary care and has been created following extensive stakeholder engagement across West Yorkshire and Harrogate. The guidance has been agreed by the Elective Care and Standardisation of Commissioning Policies Programme Board, the West Yorkshire and Harrogate Pharmacy Leadership Group and the WY&H Area Prescribing Committees.

The proposed treatment guidance supports delivery of the second phase of the West Yorkshire and Harrogate Healthy Hearts project. The project was approved by the Joint Committee of CCGs on 5th June 2018. The project aims to reduce the chance of patients developing conditions affecting their heart or blood vessels, improve the outcomes of patients already living with these conditions, and improve outcomes for those living with diabetes.

Phase two of the Healthy Hearts project is focused on improving the treatment of patients with high cholesterol currently medicated by switching their statin medication if their current statin is not the most effective; and initiating statin treatment of patients at risk of a heart attack or stroke not presently medicated. High cholesterol is a significant risk factor for diseases affecting the heart or blood vessels. Too much 'bad' cholesterol can be harmful because it sticks to the inside of the arteries; this makes it harder for blood to flow, which can lead to a heart attack or a stroke. Statin therapy reduces cholesterol and reduces heart attacks and strokes by almost a quarter.

Paper B

The purpose of this paper is to update the Joint Committee of CCGs on aspects of the implementation of the Healthy Hearts project to date, and to highlight proposed changes to its delivery timescales.

Recommendations and next steps

The Joint Committee of CCGs is asked to:

Paper A

a) Review and comment on the proposed Cholesterol Treatment Guidance and supporting information (see Appendices A and B respectively)
b) Approve the use of the Cholesterol Treatment Guidance across the whole of the West Yorkshire and Harrogate Health and Care Partnership

Paper B

c) Review and support the amended timeframes for the implementation of phases two and three of the Healthy Hearts project.

Delivering outcomes

Health and Wellbeing: Decrease in deaths, decrease in heart attacks and strokes
Care and Quality: Increase the number of people with, or at risk of developing, conditions affecting their heart or blood vessels, and diabetes receiving beneficial interventions
Finance and Efficiency: Decrease the amount of resources spent on conditions affecting the heart or blood vessels and diabetes

Impact assessment – Paper A only	
Clinical outcomes:	As Health and Wellbeing above, see also appendices C (Cholesterol Background Paper) and E (Quality and Equality Impact Assessment)
Public involvement:	See section 4
Finance:	See section 7
Risk:	Should the Joint Committee of CCGs not approve the simplified guidance, all nine CCGs will be required to do so individually, which will be less efficient, and may delay implementation
Conflicts of interest:	None

Paper A

West Yorkshire and Harrogate Healthy Hearts Project
Approval of Cholesterol Treatment Guidance

1. Introduction

1.1. This paper seeks to recommend to the Joint Committee of CCGs that it approves the introduction of standardised and simplified treatment guidance for patients with high cholesterol within West Yorkshire and Harrogate (WY&H).

1.2. The proposed treatment guidance supports delivery of the second phase of the WY&H Healthy Hearts project. The second phase is focused on improving the treatment of patients with high cholesterol currently medicated by switching their statin medication if their current statin is not the most effective; and initiating statin treatment of patients at risk of a heart attack or stroke not presently medicated.

1.3. It is important to support patients in reducing their cholesterol levels as high cholesterol is a significant risk factor for diseases affecting blood vessels and the heart. Too much 'bad' cholesterol can be harmful because it sticks to the inside of the arteries. This makes it harder for blood to flow, which can lead to a heart attack or stroke.

1.4. The project is based on successful work carried out in CCGs in WY&H, including Bradford. A key part of Bradford's success in reducing cholesterol levels was through creating standardised and simplified guidance for GPs, nurses, pharmacists and other members of the primary care team to use; as existing guidance, including that issued by NICE, was more involved for the patient and their clinicians.

1.5. The Cholesterol Treatment Guidance (Appendix A) has been developed for use in primary care and has been created following extensive stakeholder engagement across WY&H. GP leaders from each of the nine CCGs have reviewed and adapted Bradford's original guidance to make it applicable across the whole of WY&H. The evidence and rationale for the guidance is given at Appendix C.

2. Background

2.1. Following recommendation from the Clinical Forum, the Joint Committee of CCGs meeting of 5th June 2018 recommended that the WY&H CCGs adopt the Healthy Hearts project to reduce the chances of patients developing conditions affecting their heart or blood vessels; improve the outcomes of patients already living with these conditions, and improve outcomes for those living with diabetes.

2.2. The project is being delivered in three phases:

1. Better identifying those with high blood pressure and controlling it more effectively
2. Better identifying those with high cholesterol levels, and managing their cholesterol more effectively
3. Better management of patients with diabetes.

2.3. Problems of the heart and blood vessels account for one in four deaths in England. Yearly healthcare costs in England relating to poor health of the heart

and blood vessels are estimated at £7.4 billion, with an annual cost to the wider economy of £15.8 billion.

2.4. The West Yorkshire and Harrogate Health and Care Partnership's (HCP) plan includes a target to 'Reduce the number of people experiencing a CVD incident *(such as a heart attack or stroke)* by 10% across the area by 2021.' If this target were met, there would be over 1,100 fewer of these incidents by 2021.

2.5. High cholesterol is a significant risk factor for diseases of the heart and blood vessels. Positive lifestyle choices such as good diet, not smoking, being physically active and maintaining appropriate body weight all contribute to reducing the incidence of high cholesterol levels. The many local and WY&H wide projects supporting healthy living choices support the prevention of high cholesterol levels.

2.6. When patients do have elevated cholesterol levels, the treatment guidance is clear that advice to patients as to how to reduce their cholesterol levels by improving their diets, losing weight, increasing their physical activity and stopping smoking is a key early intervention. In some cases, patients self-managing their condition by following this advice will be all that is required to lower their cholesterol levels, while for others a blended approach of self-management and statin therapy will be required. Statin therapy reduces the risk of heart attacks and strokes by almost a quarter.

2.7. The estimated adult population across WY&H, with a 20% risk of a heart attack or stroke in the next 10 years, is 175,000[1] and of those almost 90,000 are not treated with a statin. If this project identified and treated just 10% of those not treated with a statin an estimated 250 to 400 events, such as hearts attacks and strokes, would be prevented over five years[2].

2.8. The approach that Bradford took resulted in 6,000 patients on a statin, whose cholesterol was not effectively controlled, switching to a more effective statin and achieved a significant lowering of their 'bad' cholesterol in just over three months. In addition to this, 7,000 new patients who had a potential risk of heart attack or stroke of either 10% or more took up the offer of statin medication.

3. Proposal

3.1. The WY&H Healthy Hearts project aims to improve care beyond current levels by utilising the impact of existing primary care resource, and maximising engagement of clinicians with a large-scale improvement project.

3.2. Feedback from GPs and nurses, particularly those involved in phase one of Healthy Hearts (high blood pressure) indicated that many clinicians liked the use

[1] This calculation uses the same benefit (Numbers Needed to Treat NNT) and savings estimation as PHE Size of the Prize https://www.healthcheck.nhs.uk/commissioners_and_providers/data/size_of_the_prize_and_nhs_health_check_factsheet/

[2] (NNT 22 – 40 Cochrane Review 2013, Cholesterol treatment trialists review Lancet 2012)

of specific medicines and doses in guidance that streamlined the prescriber's approach.

3.3. To fully implement NICE guidance for lipids across the WY&H population using traditional implementation methods would require hundreds of thousands of extra appointments. Current treatment with statins in primary care results in more than half of patients failing to reach NICE cholesterol targets.

3.4. The WY&H Healthy Hearts Cholesterol Treatment Guidance (Appendix A) and supporting information (Appendix B) seek to maximise the impact of existing primary care resource, and build on feedback from clinicians about the previous WY&H Healthy Hearts guidelines for treating high blood pressure, and to maximise engagement of clinicians with a large-scale improvement project.

3.5. The local Cholesterol Treatment Guidance (Appendix A) and supporting information (Appendix B) are aligned to NICE guidance and only differ in two small respects:

1. The WY&H Healthy Hearts Cholesterol Treatment Guidance advises usually starting people with 40mg Atorvastatin (NICE states 20mg initially and then to increase up to 80mg thereafter if not to cholesterol target) but provides suggested alternative of 20mg in two scenarios: 1) Dosage concerns; 2) Potential sensitivity of those of South Asian or East Asian heritage.

2. NICE recommends a discussion with people who are stable on a low or middle intensity statin about the likely benefits and potential risks of changing to a high-intensity statin. This cohort of patients are not included in the WY&H Healthy Hearts guidance document: This decision was taken due to the reduced absolute benefit from interventions in these patients. The project is also mindful of the aim to maximise the impact of existing primary care resource.

3.6. As is standard practice, shared decision making remains the norm and multiple sources of information can help this. Localities will be supported and encouraged to use services such as:

- West Yorkshire and Harrogate Healthy Hearts website
- local community pharmacy services
- *me +my medicines*

Together these resources support patients to understand and use their medications effectively; provide information on what cholesterol is, what a statin is, and how statins can help reduce risk; and details of further advice and support.

4. Patient engagement

4.1. The patient voice is key to ensuring phase two of the project is successful. It is important to ensure patients understand why they are being prescribed statins and why cholesterol management is important. It is important to understand the barriers which may exist which prevent patients from taking statins, and to understand the types of information and support patients find beneficial to them in being able to make informed decisions about statin therapy.

4.2. In order to do this the project team gathered public feedback to help shape the materials and supportive information including letter templates that will be used in phase two and will be provided to patients by clinicians.

4.3. The engagement activity took place during June and July 2019. Working with the engagement leads of all nine of the CCGs within WY&H the project secured more than 200 responses, with some completing an online questionnaire and others giving their feedback in focus groups.

4.4. The aim was to gather public and patient feedback on several areas including:

- Their views on the cholesterol work of the Healthy Hearts project
- Their views on the draft statin switch and new statin initiation template letters that some GP practices may choose to send out
- Where they are likely to turn to for advice and guidance if they felt the switch in statin medication or the issue of a new statin had caused them concern or a problem
- Where they would normally go for advice and guidance on leading a healthier lifestyle.

4.5. The engagement process was presented to the Joint Committee of CCGs Patient and Public Involvement Assurance Group on 10th June 2019 for comment and the findings of the engagement were presented to the Group on 12th August 2019. Appendix F provides a summary of the key findings and details the next steps which will be taken. A full engagement report will be produced and published in due course.

5. Clinical (and other) engagement in development of guidance

5.1. The Cholesterol Treatment Guidance and supporting information has been developed following extensive consultation with clinicians and other stakeholders.

5.2. The engagement has been led in each of the nine CCGs by the lead GP for Healthy Hearts; they have engaged with fellow GPs, nurses and pharmacists at primary care level, as well as secondary care colleagues, Area Prescribing Committees and Local Medical Committees.

5.3. The central project team have ensured other key stakeholders such as Public Health England, British Heart Foundation and the Local Pharmacy Committees have been engaged. Full details of who has been engaged with are given at Appendix D.

5.4. A key outcome of the engagement was that consensus has been reached by lead clinicians across WY&H on what should be included and excluded from the Cholesterol Treatment Guidance to ensure it is effective and clear.

6. Quality and Equality Impact Assessment

6.1. A Quality and Equality Impact Assessment (QEIA) has been completed, and its summary is attached at Appendix E. In respect of quality the project will have a positive impact on the quality and effectiveness of patient care and outcomes through the creation of support resources for professionals, particularly GP practices. These resources will help practices identify patients in need of treatment, give patients the most effective treatment and provide further patient advice and support through the Healthy Hearts website.

6.2. The assessment shows that, the project will exclude those who are pregnant and those within childbearing age (i.e. under the age of 55). The guidance is predominantly aimed at people aged 84 and under; which is consistent with NICE guidance, however the guidance includes information that supports treatment for those aged 85 and over.

6.3. The QEIA concludes that the exclusions listed above are on the grounds of clinical safety and that these patients are not excluded from cholesterol treatment – which will be provided through normal GP clinical provision. In addition, all patients will be able to benefit from the Healthy Hearts website with the aim of ensuring key documents produced are in an easy read format to support those with a learning disability or those with low literacy levels.

6.4. A key consideration of the project is improving access to appropriate, evidence-based treatment. By implementing the guidance, it is intended to reduce inequalities in health outcomes for the population of WY&H, particularly through ensuring ethnicity and deprivation are considered in order to target those at a greater risk.

6.5. By using tools such as the QRISK calculator which identifies patients based on their level of risk, those from BAME communities who have a greater risk will positively benefit, meaning they may more likely be identified for treatment.

7. Financial Impact

7.1. NHSE/I and PHE have agreed a target of 45% of people aged 40 to 74 identified as having a 20% or greater 10-year risk of having a heart attack or stroke be treated with statins by 2029. Currently this proportion in WY&H is 42%.

7.2. The CVD Prevention Return on Investment Tool[3], designed by Public Health England and Sheffield University, has been used to understand and estimate the potential impact of phase two of the Healthy Hearts project on the prevention of heart attacks and strokes.

[3] Available at https://cvd-prevention.shef.ac.uk/

7.3. The tool estimates the population across WY&H with a 10% or greater risk of heart attack or stroke as c655,000 (32% of the total population) and estimates that achieving PHE's 45% target would result in a reduction of 202 heart attacks and strokes over the following five years with a net saving of £2.1m.

7.4. The cost of the Healthy Hearts project to each place will depend on the nature of the demography, and the intensity of implementation of the project, of that place. As implementation are place-based decisions and are yet to be made, it is not possible to calculate a full HCP wide cost estimate. However, to give an indication of cost the central team has modelled the outputs of Bradford District's work described at 2.7. It is noted that Bradford District's population of c321,000 is an eighth of the HCP's total population.

7.5. The cost of the 6,000 patients on a statin, whose cholesterol was not effectively controlled, switching to a more effective statin would be an additional £17,940pa[4]. The cost of putting the 7,000 new patients who had a potential risk of heart attack or stroke of 10% or more onto a statin would be £111,930pa[5].

7.6. In total Bradford District's work would cost it £129,870pa (this is an overestimate as where there is a range of costs, the highest has been used). It is noted that Bradford District targeted those with a 10% or greater risk of heart attack or stroke; however, some places may choose to target those with a 20% or greater risk resulting in a reduced target population with associated reduction of cost of at least 50%.

7.7. While the financial investment in statins will not be insignificant, the reduction in personal cost to individuals, social cost to communities, and financially to the health and care system of not having to treat avoidable heart attacks and strokes will substantially outweigh the costs of the statins.

8. Governance

8.1. The development of the Cholesterol Treatment Guidance is following the HCP's governance route for the approval of clinical guidance associated with the Healthy Hearts Project, as presented to the Joint Committee of CCG development session on 6th August 2019.

8.2. The Cholesterol Treatment Guidance has been presented to the Area Prescribing Committees (APCs) in WY&H for review and the APCs recommended that the Pharmacy Leadership Group (PLG) should support the proposal.

[4] Based on Regional Drug and Therapeutics centre cost comparison chart January 2019. Comparing the per patient cost difference of switching 40mg of Simvastatin to 40mg of Atorvastatin (£2.99) and switching 20mg of Simvastatin to 20mg of Atorvastatin (£2.73)

[5] Based on the per patient cost of Atorvastatin 40mg being £15.99 as quoted in the Regional Drug and Therapeutics centre cost comparison chart January 2019

8.3. The PLG reviewed the Cholesterol Treatment Guidance at its meeting of 20th August 2019 and recommended that the Elective Care and Standardisation of Commissioning Programme Policies Board should support the proposal.

8.4. Members of the Elective Care and Standardisation of Commissioning Programme Policies Board reviewed the Cholesterol Treatment guidance at their meeting of 17th September 2019 and recommended that the Joint Committee of CCGs should support and agree to the Cholesterol Treatment Guidance being implemented across the HCP.

8.5. Adopting this HCP level governance process avoids each of the nine CCGs having to take the decision through their own individual governance routes.

8.6. It should be noted that the use of the guidance will be at the discretion of individual clinicians. Agreement of the guidance by the APCs, PLG, Elective Care and Standardisation of Commissioning Policies Programme Board and Joint Committee of CCGs, will not mandate clinicians to use it. If clinically appropriate, flexibility can and should continue to be used by primary care clinicians at each treatment step, as would be expected as standard for all aspects of medical care.

8.7. The local guidance is simply proposed as a facilitator to quality improvement within a healthcare system that has limited capacity for extra workload. Clinicians will be expected to continue to use their clinical judgement on how best to treat their patients, drawing on this guidance and other relevant guidance to support them to make the best treatment decisions for their patients.

9. Conclusion and Recommendations

9.1. The WY&H Healthy Hearts Cholesterol Treatment Guidance (Appendix A) and supporting information (Appendix B) seek to maximise the impact of existing primary care resource at scale, to support streamlining the management of cholesterol in patients with the aim of reducing diseases of the heart and blood vessels.

9.2. The Joint Committee of Clinical Commissioning Groups is asked to:

a. Review and comment on the proposed Cholesterol Treatment Guidance and supporting information (see Appendices A and B respectively)
b. Approve the use of the Cholesterol Treatment Guidance across the whole of the West Yorkshire and Harrogate Health and Care Partnership.

Appendices

Appendix A: Cholesterol Treatment Guidance
Appendix B: Cholesterol Guidance Supporting Clinical Information
Appendix C: Cholesterol Background Paper
Appendix D: Cholesterol Stakeholder Feedback and Engagement
Appendix E: Quality and Equality Impact Assessment summary page
Appendix F: Summary of Patient and Public Engagement Feedback

Paper B

West Yorkshire and Harrogate Healthy Hearts Project implementation update

1. Introduction

1.1. The purpose of this report is to update the Joint Committee of Clinical Commissioning Groups on aspects of the implementation of the Healthy Hearts project to date, and to highlight proposed changes to its delivery timescales.

2. Implementation of phase one – high blood pressure (hypertension)

2.1. Phase one is live and being implemented within each of the nine CCGs in West Yorkshire and Harrogate Health and Care Partnership.

2.2. Initial quarterly data indicates that in the period 1st April 2019 to 30th June 2019 an additional 3,789 patients were added to hypertension registers, and 967 more patients had their blood pressure controlled to 140/90 or better.

2.3. Informal feedback from those involved in the project is positive, a workshop to more formally review implementation is to be held on 20th November 2019, which will be reported to Clinical Forum in December 2019.

3. Implementation of phases two and three – improved management of cholesterol and diabetes respectively

3.1. Implementation of the second and third phases were due to go live in October 2019 and April 2020 respectively; however, based on feedback from the place-based clinical leads, the pace of implementation has been reviewed.

3.2. To allow clinicians sufficient time to implement and embed the three phases of the project it is proposed that the implementation timeframes are amended to allow greater flexibility, by permitting a date range over which implementation can take place, rather than the present fixed dates – with places choosing the best time at which to implement the second and third phases. This change will support clinicians to exercise their discretion over when to implement, allowing them to best manage their workload and resources to achieve the best outcomes for patients.

3.3. It is therefore proposed that the implementation of phases two and three be changed as follows:

- Phase two – Cholesterol: Implementation to begin in the period October 2019 to April 2020, rather than October 2019
- Phase three – Diabetes: Implementation to begin in the period April 2020 – October 2020, rather than April 2020.

3.4. For both phases two and three all documentation including clinical searches, treatment protocols and supporting materials will be in place and available to allow clinicians to commence implementation at the earliest opportunity.

4. Recommendation

4.1. The Joint Committee of Clinical Commissioning Groups is asked to:

a) Review and support the amended timeframes for the implementation of phases two and three of the Healthy Hearts project.

West Yorkshire and Harrogate HEALTHY HEARTS

Guidance: Lipid management for patients with CVD and risks of CVD (up to and inc. 84 years exc. frailty / women of child bearing age <55 years)

Details provided on website (in progress) inc. NICE Me&My Medicines

Shared Decision Making
Outline the risks and benefits of statin treatment, taking into account lifestyle modifications, comorbidities, polypharmacy, general frailty and life expectancy

Show patients the QRISK 2/3 risk assessment tool and/or JBS3

Lifestyle
Lifestyle to be considered fundamental to this guidance. Lifestyle helps to reduce future CVD risk. Statins are effective at reducing cholesterol. Both important.

Details provided on website (in progress)

Primary Prevention

- CKD 3 and above (regardless of cholesterol level or risk of CVD)
- QRISK2 >10% 10 year Cardiovascular Risk
- Diabetes Type 1 who are older than 40 or nephropathy or had DM for more than 10 years or other CVD risk factors

Usually
Atorvastatin 40mg

Sometimes
Atorvastatin 20mg

Scenarios
1) Concerns about dosage
2) Potential sensitivity of those of South Asian / East Asian (e.g. Chinese and Japanese)

Secondary Prevention

- Established CHD/IHD/MI
- Ischemic Stroke & TIA,
- PAD

Recommended
Atorvastatin 80mg

Aim for Total cholesterol <4mmol/l or >40% reduction in baseline non-high density lipoprotein (HDL) with up-titration to 80mg Atorvastatin if required **(see supporting info)**

Second Line (Those intolerant to Atorvastatin)
Initiate one month of Rosuvastatin 5 mg once daily (doubled to 10 mg daily for primary prevention on repeat prescription after one month if no reported side effects) For secondary prevention up to 20 mg once daily, dose to be increased gradually at intervals of at least 4 weeks

Before starting lipid modification therapy take full lipid profile and check ALT

Repeat lipid profile and ALT after 3 months

Show patients targets / progress to help behaviour change

If target not achieved discuss adherence/understanding and timing of dose / diet and lifestyle- If commenced on 20mg atorva, consider increase to 40mg

Total / (HDL) / non-HDL / Triglycerides. A fasting sample is *not* needed.

Check ALTs at baseline and at 3 months. No further checks required after starting statin unless clinical concern (e.g. liver disease)

Please Consider:

- Familial hypercholesterolaemia and Hyperlipidaemia in anyone with a total cholesterol >7.5mmol/L or LDL >4.9 mmol/ - Talk to patients to get family history
- Familial hypercholesterolaemia affects c.1 in 325. NHS Long Term Plan commitment to improving the genetically confirmed detection of FH from 7% to 25% by 2024 (January 2019)
- See pathway for further information about the above

West Yorkshire and Harrogate HEALTHY HEARTS

51/19 Appendix B - West Yorkshire and Harrogate Cholesterol Guidance - Supporting Clinical Information

The guidance and supporting information has been agreed (TBC) across West Yorkshire and Harrogate HCP. It should not be seen as mandatory and clinical judgement can always be exercised as usual.

1. As well as QRISK2 calculators within S1 or EMIS, clinicians may wish to consider the online JBS3 for lifetime risks or European SCORE Risk Charts (The European cardiovascular disease risk assessment model) when making clinical decisions with patients. QRISK3 to be used where/when available.

2. Measure a full lipid profile after 3 months of treatment (total cholesterol, high-density lipoprotein (HDL) cholesterol, and LDL *or* non-HDL cholesterol (total cholesterol minus HDL cholesterol)). The aim of treatment is to achieve a pragmatic target of <4 mmol/l of total cholesterol (since many practices are only measuring total cholesterol), or ideally, a more precise target of >40% reduction in baseline LDL or non-HDL levels. If the clinician prefers to aim for absolute targets in LDL, the European Society of Cardiology (ESC) targets are a great evidence-based choice:

Primary Prevention	*LDL-C <3 mmol/L in moderate risk patients* *LDL-C <2.5 mmol/L in high risk patients*
Secondary Prevention	*LDL-C <1.8 mmol/L*

3. If muscle **pains develop**:
   - Check creatine kinase (CK).
   - If CK normal and pains intolerable, stop statin for 6 weeks and then re-challenge with statin at the same or lower dose .
   - If truly intolerant to atorvastatin, try rosuvastatin as second line.
   - If still intolerant, reducing to once or twice weekly dosing is worthwhile

   See further information on statin intolerance

   ✓ If CK raised, you may wish to consider Advice and Guidance/e-consult from Specialist Lipid Service, or if not available then Cardiology or local lipid clinic in DGHs in your CCG:
   If CK < 3x ULN (<600 females, <960 for males), can continue statin if minimal /no persisting symptoms, with regular monitoring CK (e.g. 2-3 monthly)
   ✓ If CK 3-5x upper normal limit, treatment could be continued with careful monitoring if tolerated. (We advise seeking specialist advice from local lipid service)
   ✓ If CK is significantly elevated (5-10x upper normal limit or 1,000-2,000 for females, 1,600-3,200 for males) = myositis, treatment should be stopped immediately and seek urgent specialist advice.
   ✓ If CK > 10x upper normal limit (CK>2,000 for females or >3,200 for males) = rhabdomyolysis, needs urgent discussion with hospital to consider urgent admission.

4. Additional Lipid Lowering Agents –There is evidence of reduced mortality in secondary prevention by driving LDL below a target of 1.8. GPs may wish to prescribe additional cholesterol lowering medications to achieve this target, as per NICE guidance.

5. In Secondary prevention of CVD, this guidance is for ischemic stroke only, not haemorrhagic – since atorvastatin can increase risk of haemorrhagic stroke.

6. Provide annual medication reviews for people taking statins. *Consider* an annual non-fasting full lipid profile to inform the discussion (if needed to assess or support adherence/response)

7. Women of childbearing potential can still have statin dose optimisation, but they should be invited to speak to a health professional about teratogenic risks of statins and precautions that need to be taken. Statins are contra-indicated in pregnancy and precautions should be continued for 1 month after stopping a statin. Statins are less commonly routinely prescribed to women under the age of 55 as they tend to have lower 10yr CVD risks.

8. Guidance is aimed at <84 years. For people 85 years or older consider atorvastatin 20 mg as statins may be of benefit in reducing the risk of nonfatal myocardial infarction, taking into account patient choice, comorbidities, polypharmacy, general frailty and life expectancy.

9. Consider A&G/e-consult if high-risk patients and intolerant to 3 different statins e.g. CVD (MI, CVA, TIA, PAD), CKD 3b or more, type 1 diabetes, type 2 diabetes or genetic dyslipidaemias.

West Yorkshire and Harrogate HEALTHY HEARTS

Statin Background Document

Amendment History

Version	Date	Amendment History
0.1	01/3/19	For comment to Monthly Project Group
0.2	15/6/19	Added in alignment with NICE Appendix 1 Added in detail similar to Hypertension doc
0.3	17/6/19	YB revisions and sign off
0.4	3/9/19	Formatting revisions
1.0	6/9/19	Final Copy

West Yorkshire and Harrogate HEALTHY HEARTS

Table of Contents

Summary

- High cholesterol is one of the most significant risk factors for CVD
- Raised cholesterol can also be caused by genetic conditions, where cholesterol is elevated from birth to very high levels, such as Familial Hypercholesterolaemia (FH). FH affects approximately 1 in 300
- The estimated adult population across West Yorkshire and Harrogate with a greater than 2 in 10 chance of a future heart attack or stroke is 175,000. Of those, just over half (89,250) aren't treated with a statin
- Statin therapy reduce cholesterol and reduces risk of CVD events by almost a quarter
- Data from UK general practice shows that **over half** of patients on statins do not reach their NICE cholesterol targets
- West Yorkshire and Harrogate Health Care Partnership (along with the nine CCGs) have developed a local treatment guidance and supporting information document for use in Primary Care; under the Healthy Hearts project.
- The local guidance and supporting information is well aligned to NICE and only differs in two small areas:
  1. Local Lipid guidance advises usually starting people with 40mg Atorvastatin (NICE states 20mg initially and then to increase up to 80mg thereafter if not to cholesterol target) but provides suggested alternative of 20mg in two scenarios: 1) Dosage concerns; 2) Potential sensitivity of those of Asian or Chinese heritage.
  2. NICE recommend a discussion with people who are stable on a low or middle intensity/strength statins the likely benefits and potential risks of changing to a high-intensity statin. This cohort is not included in this guidance document: the searches that support the work have excluded people with reasonably controlled cholesterol. This is due to the reduced absolute benefit from interventions in the "managed/controlled groups" and we are also mindful of the aim to maximise the impact of existing primary care resource, and maximising engagement of clinicians with a large-scale improvement programme.

1. Introduction

1.1. Poor cardiovascular (CVD) health can cause heart attacks, strokes, heart failure, chronic kidney disease, and the onset of vascular dementia. It disproportionately affects people from the poorest communities. CVD deaths still account for 1 in 4 of all deaths in England - the equivalent to 1 death every 4 minutes. Yearly healthcare costs in England relating to CVD are estimated at £7.4 billion, with an annual cost to the wider economy of £15.8 billion.

1.2. High cholesterol is one of the most significant risk factors for CVD. Too much bad cholesterol (non-HDL cholesterol) can be harmful because it sticks to the inside walls of the arteries. This can lead to fatty material (atheroma) building up - this process is known as atherosclerosis. It makes it harder for blood to flow through, which can lead to a heart attack or a stroke.

1.3. Raised cholesterol can also be caused by genetic conditions, where cholesterol is elevated from birth, such as Familial Hypercholesterolaemia (FH). FH affects approximately 1 in 300. If untreated, about 50% of men and 30% of women with FH will develop coronary heart disease by the time they are 55.

1.4. Encouraging healthy lifestyle changes such as improving diet, stopping smoking or reducing weight can help to lower cholesterol levels and reduce the risk of CVD. NICE guidelines advise offering lifestyle advice and statins to those people with high cholesterol and high CVD risk. NICE advise starting a high-dose statin in those who already have CVD.

1.5. Statin therapy reduce cholesterol and reduces risk of CVD events by around a quarter.

1.6. The estimated adult population across West Yorkshire and Harrogate with a greater than 2 in 10 chance of a future heart attack or stroke is 175,000. Of those, over half (89,250) aren't treated with a statin.

1.7. West Yorkshire and Harrogate Health Care Partnership (along with the nine CCGs) have developed a local treatment guidance and supporting information document for use in Primary Care; under the Healthy Hearts project.

1.8. The project aims to identify and treat at least 10% of eligible adults (9000 people), aiming for an estimated 220 to 400 CVD events prevented over 5 years.

Sources:

- https://www.gov.uk/government/publications/health-matters-preventing-cardiovascular-disease/health-matters-preventing-cardiovascular-disease

- https://www.healthcheck.nhs.uk/commissioners-and-providers/data/size-of-the-prize-and-nhs-health-check-factsheet/

2. Rationale for the Local Clinical Guidance

2.1. Data from UK general practice shows that over half of patients on statins do not reach their NICE targets after 2 years of statin therapy.

2.2. Feedback from many GPs and nurses, in particular on phase one of Healthy Hearts (hypertension), has indicated that many liked the use of specific medicines and doses in a guidance since it streamlines the prescriber's approach.

2.3. Current NICE guidance was written in 2014 and is five years old. It is currently being reviewed and subject to changes.

2.4. In this Healthy Hearts programme across West Yorkshire, we want to improve care beyond current levels and we wish to maximise the impact of existing primary care resource, and maximising engagement of clinicians with a large-scale improvement programme.

Sources:

- https://www.nice.org.uk/guidance/cg181/resources/surveillance-report-2018-cardiovascular-disease-risk-assessment-and-reduction-including-lipid-modification-2014-nice-guideline-cg181-4724759773/chapter/Surveillance-decision?tab=evidence
- Akyea RK, et al. Heart 2019;105:975–981

3. What evidence base has been used in the local guidance

3.1. CTT evidence

Cholesterol Treatment Trialist's (CTT) collaborators 2009 - meta-analyses of mortality and morbidity from all relevant large-scale randomised trials of statin therapy. Findings were:

- Lipid lowering with statins confers similar CV risk reduction across all ranges of baseline dyslipidaemia
- Clinical benefit is related to the absolute reduction in LDL-C
- For secondary prevention, intensive therapy is safe and arrests atherosclerosis and provides further clinical benefit with CV risk reduction and hospitalisations for heart failure
- In acute coronary syndromes, high-dose statins provide a rapid early reduction in clinical events which may be related to non-LDL-C dependent anti-inflammatory effects

Further details of the CTT findings were:

- Data on 90,056 individuals from 14 trials were combined. Mean follow-up of 5 years
- Almost a half-million person years of observation
- Significant 12% reduction in all-cause mortality per 1mmol/l reduction in LDL-C
- 19% reduction in coronary mortality
- 24% reduction in the need for revascularisation
- 17% reduction in stroke
- 21% reduction in any major vascular event.

Importantly a similar proportional benefit was observed in different age groups, across genders, at different levels of baseline cholesterol/lipids (including triglycerides and high-density lipoprotein cholesterol) and equally among those with prior coronary artery disease (heart attacks, angina) and cardiovascular risk factors as in those without. This was important since it showed that relative risk reductions were equivalent in all patients studied.

Finally, the magnitude of clinical benefit in the CTT meta-analysis appeared related to the magnitude of LDL cholesterol reduction and is independent of the initial cholesterol/lipid readings or other baseline characteristics.

3.2. Safety

The safety data presented in CTT come from randomised control trials:

- Risk of rhabdomyolysis (serious muscle inflammation) was 3/100,000 person years
- Myopathy (muscle inflammation) was 11/100,000 person years
- Peripheral neuropathy (nerve damage) 12/100,000 person years
- Liver disease even rarer.

The authors conclude that side effects are rare and likely to be more common when drugs which block certain liver pathways (the CYP3A4 pathway) are given at the same time as statins.

3.3. NICE guidance

A review of NICE Clinical Guideline [CG181] Cardiovascular disease: risk assessment and reduction, including lipid modification has taken place (Appendix 1) The local guidance and supporting information that has been created makes only two small pragmatic changes to NICE guidance. These are as follows:

NICE: 1.3.18 Offer atorvastatin 20 mg for the primary prevention of CVD to people who have a 10% or greater 10year risk of developing CVD. Estimate the level of risk using the QRISK2 assessment tool. [new 2014]

Local Lipid guidance makes reference to usually starting people with 20mg and uptitrating to 40mg daily after two weeks since over half of patients will not achieve lipid targets, and provides suggested alternative of 20mg in two scenarios 1) Dosage concerns 2) Potential sensitivity of those of Asian or Chinese heritage.

NICE 1.3.30 Discuss with people who are stable on a low or middle intensity statin the likely benefits and potential risks of changing to a high-intensity statin when they have a medication review and agree with the person whether a change is needed. [new 2014]

This cohort is not included in this guidance document: the searches that support the work have excluded people with reasonably controlled cholesterol. This is due to the reduced absolute benefit from interventions in the "managed/controlled groups" and we are also mindful of the aim to maximise the impact of existing primary care resource, and maximising engagement of clinicians with a large-scale improvement programme.

Statins are grouped in this guideline as seen in Table 36. This grouping was agreed by GDG consensus, informed by analyses in the literature. This grouping is discussed further in Section 11.8.

Table 36: Grouping of statins

	% reduction in low-density lipoprotein cholesterol				
Dose (mg/day)	**5**	**10**	**20**	**40**	**80**
Fluvastatin	10%[1]	15%[1]	21%[2]	27%[2]	33%[3]
Pravastatin	15%[1]	20%[2]	24%[2]	29%[2]	33%[1]
Simvastatin	23%[1]	27%[2]	32%[3]	37%[3]	42%[4*]
Atorvastatin	31%[1]	37%[3]	43%[4]	49%[4]	55%[4]
Rosuvastatin	38%[3]	43%[4]	48%[4]	53%[4]	58%[1]

It is noted that NICE classifies atorvastatin 20mg as high intensity whilst European Society of Cardiology lipid guidance classifies atorvastatin 20mg as weaker medium intensity and atorvastatin 40mg as high intensity. Both guidelines agree that treatment with statins should usually be "high intensity" not lower.

Regarding the choice of atorvastatin dose for primary prevention, NICE state that:

The base case analysis was based on an assumption of equivalent effectiveness between all high-intensity statins, due to a lack of evidence comparing the effectiveness of the different doses within the high-intensity class in terms of reducing clinical end points, although there is evidence of differing effectiveness of different doses in terms of reducing LDL-cholesterol levels. On this basis the cheapest high-intensity statin – atorvastatin 20 mg – was predicted to be the most cost effective. However, an additional threshold analysis showed that atorvastatin 40 mg would be cost effective compared to atorvastatin 20 mg if it was 1% relatively more effective in decreasing CV events than atorvastatin 20 mg and if there was no loss in utility due to increases in adverse events. It also showed that atorvastatin 80 mg would be cost effective compared to atorvastatin 20 mg if it was 2% relatively more effective than atorvastatin 20 mg in decreasing CV events and if there was no loss in utility due to increases in adverse events.

4. Conclusion

NICE recognises that primary care has limited capacity and lowering the QRISK2 threshold to include 10-20% has resulted in an extra 4.5 million people in the UK becoming eligible for statins and lifestyle advice. To fully implement NICE guidance for lipids across the WY&H population using traditional implementation methods would require hundreds of thousands of extra appointments. Current treatment with statins in primary care results in more than half of patients failing to reach NICE cholesterol targets. Local HCP guidance seeks to maximise the impact of existing primary care resource, to build on feedback from clinicians about previous HCP guidelines, and to maximise engagement of clinicians with a large-scale improvement programme.

5. Guidance Adoption / Shared Decision Making

It is noted that no guidance should be expected to be mandatory for all patients at all times: if clinically needed, flexibility can and should continue to be used by primary care clinicians at each treatment step, as would be expected as standard for all aspects of medical care. A local guidance is simply proposed as a facilitator to quality improvement within a healthcare system that has limited capacity for extra workload.

As is standard practice, informed decision making remains the norm and multiple sources of information can help this: localities will be supported and encouraged to use services such as:

- West Yorkshire and Harrogate Healthy Hearts website
- local community pharmacy services
- *me +my medicines* .

6. Author

Dr Youssef Beaini

- Clinical Lead - West Yorkshire and Harrogate Healthy Hearts
- Clinical Lead - Cardiovascular Disease, Bradford Districts CCG, Bradford City CCG, and Airedale, Wharfedale and Craven CCG

- Board member - Primary Care Cardiovascular Society UK
- Honorary Senior Lecturer, University of Bradford

June 2019

Programme Support provided by:
Yorkshire and Humber Academic Health Science Network
Contact: Pete Waddingham (Programme Manager) Pete.waddingham@yhahsn.com

Appendix 1 Key Points of alignment with NICE Clinical Guideline [CG181]

This document outlines the key points of alignment between West Yorkshire and Harrogate Healthy Hearts – Lipid Guidance and NICE Clinical Guideline [CG181]. Cardiovascular disease: risk assessment and reduction, including lipid modification. Clinical guideline [CG181] Published date: July 2014 Last updated: September 2016 https://www.nice.org.uk/guidance/cg181

1.1 Identifying and assessing cardiovascular disease (CVD) risk

Full formal risk assessment

1.1.8 Use the QRISK2 risk assessment tool to assess CVD risk for the primary prevention of CVD in people up to and including age 84 years. **[new 2014]**

Included in Lipid guidance document

1.2 Lifestyle modifications for the primary and secondary prevention of CVD

West Yorkshire and Harrogate Healthy Hearts website has links to cholesterol and lifestyle information

1.3 Lipid modification therapy for the primary and secondary prevention of CVD

1.3.18 Offer atorvastatin 20 mg for the primary prevention of CVD to people who have a 10% or greater 10year risk of developing CVD. Estimate the level of risk using the QRISK2 assessment tool. **[new 2014]**

Local Lipid guidance makes reference to usually starting people with 40mg but provides suggested alternative of 20mg in two scenarios: 1) Dosage concerns; 2) Potential sensitivity of those of Asian or Chinese heritage.

1.3.19 For people 85 years or older consider atorvastatin 20 mg as statins may be of benefit in reducing the risk of non-fatal myocardial infarction. Be aware of factors that may make treatment inappropriate (see recommendation 1.3.12). **[new 2014]**

Local lipid guidance aimed at <85 years – but supporting information has made reference to this recommendation.

1.3.2 When a decision is made to prescribe a statin, use a statin of high intensity[5] and low acquisition cost. **[new 2014]**

Lipid guidance makes reference to high intensity statins. Note – proposed switch of Simvastatin to Atorvastatin is consistent with NICE as only 80mg Simvastatin is considered as a high intensity statin by some guidelines but other data shows that 80mg of simvastatin is no more clinically effective in routine care than 40mg but has increased risk of side effects, hence resulting in the following MHRA warning:

Advice from the MHRA (The Medicines and Healthcare products Regulatory Agency) there is an increased risk of myopathy (muscle weakness) associated with high dose (80 mg) simvastatin. The 80 mg dose should be considered only in patients with severe hypercholesterolaemia and high risk of cardiovascular complications who have not achieved their treatment goals on lower doses, when the benefits are expected to outweigh the potential risks.
https://www.nice.org.uk/guidance/cg181/chapter/appendix-a-grouping-of-statins

Lipid measurement and referral

1.3.4 Before starting lipid modification therapy for the primary prevention of CVD, take at least 1 lipid sample to measure a full lipid profile. This should include measurement of total cholesterol, HDL cholesterol, non-HDL cholesterol and triglyceride concentrations. A fasting sample is not needed. **[new 2014]**

Included in lipid guidance document

1.3.7 Consider the possibility of familial hypercholesterolaemia and investigate as described in familial hypercholesterolaemia (NICE guideline CG71) if they have:
- a total cholesterol concentration more than 7.5 mmol/litre **and**
- a family history of premature coronary heart disease. **[new 2014]**

1.3.8 Arrange for specialist assessment of people with a total cholesterol concentration of more than 9.0 mmol/litre or a non-HDL cholesterol concentration of more than 7.5 mmol/litre even in the absence of a first-degree family history of premature coronary heart disease. **[new 2014]**

1.3.9 Refer for urgent specialist review if a person has a triglyceride concentration of more than 20 mmol/litre that is not a result of excess alcohol or poor glycaemic control. **[new 2014]**

1.3.10 In people with a triglyceride concentration between 10 and 20 mmol/litre:
- repeat the triglyceride measurement with a fasting test (after an interval of 5 days, but within 2 weeks) **and**
- review for potential secondary causes of hyperlipidaemia **and**
- seek specialist advice if the triglyceride concentration remains above 10 mmol/litre. **[new 2014]**

1.3.11 In people with a triglyceride concentration between 4.5 and 9.9 mmol/litre:
- seek specialist advice if non-HDL cholesterol concentration is more than 7.5 mmol/litre. **[new 2014]**

FH / Specialist Lipid Pathway provides advice on referring to special lipid clinic in these scenarios

Primary prevention

1.3.14 Before offering statin treatment for primary prevention, discuss the benefits of lifestyle modification and optimise the management of all other modifiable CVD risk factors if possible. **[new 2014]**

1.3.15 Recognise that people may need support to change their lifestyle. To help them do this, refer them to programmes such as exercise referral schemes. (See the NICE guidelines on behaviour change: individual approaches and physical activity: exercise referral schemes.) **[new 2014]**

Included in Lipid Treatment Guidance and Behaviour change principles document

Follow up of people started on statin treatment

1.3.28 Measure total cholesterol, HDL cholesterol and non-HDL cholesterol in all people who have been started on high-intensity statin treatment (both primary and secondary prevention, including atorvastatin 20 mg for primary prevention) at 3 months of treatment and aim for a greater than 40% reduction in non-HDL cholesterol. If a greater than 40% reduction in non-HDL cholesterol is not achieved:

- discuss adherence and timing of dose
- optimise adherence to diet and lifestyle measures
- consider increasing the dose if started on less than atorvastatin 80 mg and the person is judged to be at higher risk because of comorbidities, risk score or using clinical judgement. **[new 2014]**

Included in Lipid Treatment Guidance and supporting information.

1.3.29 Provide annual medication reviews for people taking statins.

- Use these reviews to discuss medicines adherence and lifestyle modification and address CVD risk factors.
- Consider an annual non-fasting blood test for non-HDL cholesterol to inform the discussion. **[new 2014]**

Two points above not referenced in supporting information document.

1.3.30 Discuss with people who are stable on a low or middle intensity statin the likely benefits and potential risks of changing to a high-intensity statin when they have a medication review and agree with the person whether a change is needed. **[new 2014]**

Not include in guidance document. Searches have excluded people with managed/reasonably controlled cholesterol. This is to maximise the impact of existing primary care resource, and maximising engagement of clinicians with a large-scale improvement programme.

Advice and monitoring for adverse effects

1.3.31 Advise people who are being treated with a statin:

- that other drugs, some foods (for example, grapefruit juice) and some supplements may interfere with statins **and**

- to always consult the patient information leaflet, a pharmacist or prescriber for advice when starting other drugs or thinking about taking supplements. **[new 2014]**

Not included in guidance but support information on website will cover these areas.

Intolerance of statins

1.3.41 If a person is not able to tolerate a high-intensity statin aim to treat with the maximum tolerated dose. **[new 2014]**

1.3.42 Tell the person that any statin at any dose reduces CVD risk. If someone reports adverse effects when taking high-intensity statin discuss the following possible strategies with them:

- stopping the statin and trying again when the symptoms have resolved to check if the symptoms are related to the statin
- reducing the dose within the same intensity group
- changing the statin to a lower intensity group. **[new 2014]**

1.3.43 Seek specialist advice about options for treating people at high risk of CVD such as those with CKD, type 1 diabetes, type 2 diabetes or genetic dyslipidaemias, and those with CVD, who are intolerant to 3 different statins. Advice can be sought for example, by telephone, virtual clinic or referral. **[new 2014]**

Included in Lipid Guidance

ENDS

West Yorkshire and Harrogate HEALTHY HEARTS

51/19 Appendix D Cholesterol Stakeholder Feedback and Engagement

Revisions to Lipid Guidance and Supporting Information

This document provides a summary of the key changes to the local lipid guidance, following the stakeholder meeting on 12th June 2019. The feedback comments, received after 12 weeks of engagement across primary, secondary and commissioning stakeholders, were discussed and changes agreed by CCG Clinical Leads (with representation from Secondary Care).

Further information on any of the comments below can be obtained by contacting:

Dr Youssef Beaini (Clinical Lead - West Yorkshire and Harrogate Healthy Hearts) Youssef.Beaini@bradford.nhs.uk or Pete Waddingham (Programme Manager) Pete.waddingham@yhahsn.com

- Age to be up to and including 84 (no lower limit as per NICE)
- Exclusion to be women under 55 (childbearing age) but supporting info will provide more guidance
- To add for Second line "Everyone on Rosuvastatin 5mg with 10mg put on repeat after a month – if no issues"
- Removed the reference to Asian origin for Rosuvastatin as 5mg now recommended, and this is applicable to this patient group.
- Add in section on further info on suspected intolerance to second line section
- Removed referenced to Type 2 Diabetes in primary prevention as this is picked up in QRISK 2
- CKD left in (this will be covered in QRISK3 – not yet mainstream in clinical systems)
- Changed definitions of established CVD to CHD / IHD / MI
- Changed Stroke to Ischaemic Stroke
- Changed "check LFTs at baseline" to "check ALT and at 3 months"
- Include some guidance on ALT
- Changed wording of "Recommended 40mg Atorvastatin and Alternative 20mg" to "Usually 40mg - sometimes 20mg in these scenarios 1) Concerns about dosage 2) Potential sensitivity of those of Asian heritage
- Changed / Add Target = Non HDL reduction 40% which is consistent with NICE
- Use Lipid targets from ESC
- Changed guidance to be aimed at QRISK >10%
- Added in "Provide annual medication reviews for people taking statins. *Consider* an annual non fasting full lipid profile to inform the discussion (if needed to assess adherence/response)
- Moved shared decision making to the top. Merged with lifestyle and added "Lifestyle helps to reduce future CVD risk. Statins are effective at reducing cholesterol. Both important."
- Added in supporting notes "Ezetimibe – is a consideration for secondary line but due to lack of evidence is not part of this guidance"
- Added "Patients to be advised that if any experience of intolerance / side effects that not taking the statin every day is still a beneficial strategy - See further information on statin intolerance"
- Added Advice and Guidance /e-consult from local lipid service or if not available cardiology.
- Adopted Yorkshire and Humber FH / Specialist Lipid Pathway
- Adopted the Leeds Teaching Hospital supporting information on Statin Intolerance.

Main Feedback Comments not included

Patients with hypertension who are treated with amlodopline should be treated with Atorvastatin 20mg maximally and not 40mg. –

- Response – It is Simvastatin that has the adverse interaction with amlodopline not atorvastatin. This has been confirmed Mike Mansfield – Consultant Leeds Teaching Hospital.

Add reference to Kidney function <30ml/min

- Response - This does not need to be in guidance as covered already by CKD.

Add in "and calculated LDL – cholesterol"

- Response – all LDL is calculated so does not need to be added.

Add in periodic LFT monitoring

- Response – No evidence base and local hepatology advice is do not need to monitor LFTs.

Secondary prevention could be stepped down from 80mg atorva to 40mg - or is this not the case from these guidelines - if the medication is tolerated

- Response - No stepping down - this is old advice. NICE do not say to step down. This was an original cost reason.

Only the ALT was to be tested for statin monitoring

- Response – Compromise agreed to test ALT once after statin initiation at 3 months and no further testing required based on FDA guidance that is evidence-based.

SPC recommends periodic LFT monitoring which the guidance doesn't, baseline only.

- Response – NICE recommendation has no evidence base and American guidance is evidence-based. Local expert consultant hepatology advice is that we do NOT need to monitor LFTs

No Re-check LFTs, especially as the scheme advocates the use of statin doses up to Atorvastatin 80mg.

- Response See above – FDA evidence base.

1. **Stakeholder Engagement**

Clinical Engagement has taken place with a variety of stakeholders on the Lipids / Cholesterol Guidance and supporting information including (but not limited to)

- Healthy Hearts Project Group (Clinical and Locality Leads)

Organisation	Name
Airdale Wharfedale and Craven CCG	Graeme Summers
Airedale Wharfedale and Craven CCG	Teresa Birks
Bradford City	Youssef Beaini
Bradford City	Kath Helliwell
Bradford Districts	Dr Youssef Beaini
Bradford Districts	Kath Helliwell
Calderdale CCG	Dr James Gray
Calderdale CCG	Andrew Bottomley
Calderdale CCG	Shelly Porter
Greater Huddersfield CCG	Steve Ollerton
Greater Huddersfield CCG	Steve Ollerton
Greater Huddersfield CCG	Sarah Rothery
Harrogate and Rural District CCG	Bruce Willoughby
Harrogate and Rural District CCG	Chris Ranson
Leeds CCG	Bryan Power
Leeds CCG	Lindsay Springall
North Kirklees CCG	Sarah Rothery
Wakefield CCG	Dr Pravin Jayakumar
Wakefield CCG	Anna Staples

Clinical Commissioning Groups

- NHS Airedale, Wharfedale and Craven CCG
  - ✓ Council of Members
  - ✓ CVD Right Care
  - ✓ AWC GPs

- NHS Bradford City CCG / NHS Bradford Districts CCG#
  - ✓ Clinical Commissioning Forums
  - ✓ Joint Practice Nurse Forum

- NHS Calderdale CCG
  - ✓ Care Closer to Home Programme
  - ✓ Medicines Management
  - ✓ SMT
  - ✓ Clinical Team
  - ✓ CCG Forum

- NHS Greater Huddersfield CCG / NHS North Kirklees CCG
  - ✓ Clinical Strategy Group
  - ✓ Commissioning for Value meetings / Primary Care Cluster meetings
  - ✓ Practice Quality & Contracting Group
  - ✓ Meds Management Team
  - ✓ Secondary Care – Cardiologist
  - ✓ CCG Communications team
  - ✓ Launch planned for Practice Protected Time (PPT)
  - ✓ Quality team
- NHS Harrogate and Rural District CCG
  - ✓ Council of Members
  - ✓ All GP commissioning leads
  - ✓ CCG patient group
- NHS Leeds CCG
  - ✓ Leeds CVD Operational Steering Group
  - ✓ Leeds LMC
  - ✓ Leeds Area Prescribing Committee
- NHS Wakefield CCG
  - ✓ Stroke / CVD Group
  - ✓ Clinical Cabinet;
  - ✓ Meds Optimisation
  - ✓ Cardiology Consultant - Mid Yorkshire Hospital NHS Trust
  - ✓ Stroke Consultant - Mid Yorkshire Hospital NHS Trust
  - ✓ Connecting for Prevention Group (hosted by Public Health – multi-agency attendance)
  - ✓ Public Health key team members
  - ✓ Comms and Engagement, CCG
  - ✓ Patient Representative Groups
  - ✓ Livewell Wakefield – for feedback from groups accessing social prescribing
  - ✓ Community Pharmacy West Yorkshire – Wakefield locality

Key Supporting Stakeholders

Along with Project Team and CCG engagement a number of key stakeholders have also been engaged (see below)

- Dr Rani Khatib Consultant Pharmacist in Cardiology & Cardiovascular Clinical Research Leeds Teaching Hospitals NHS Trust
- Dr Gaye Sheerman-Chase - Principal Medical Adviser for Medicines Optimisation Commissioning Team - NHS Leeds Clinical Commissioning Group
- Mike Mansfield - Consultant Lipidologist - Leeds Teaching Hospitals NHS Trust
- Tracey Gaston - Head of Medicines Optimisation - NHS Bradford City Clinical Commissioning Group & NHS Bradford Districts Clinical Commissioning Group
- Leeds Area Prescribing Committee
- Harrogate and Rural Districts Area Prescribing Committee
- South West Yorkshire Area Prescribing Committee
- West Yorkshire and Harrogate Pharmacy Leadership Group

Key Engagement Stakeholders

- Airedale NHS Foundation Trust
- Bradford Teaching Hospitals NHS Foundation Trust
- Calderdale and Huddersfield NHS Foundation Trust
- Harrogate and District NHS Foundation Trust
- Leeds Teaching Hospitals NHS Trust
- The Mid-Yorkshire Hospitals NHS Trust
- NHS England
- Public Health England
- West Yorkshire Association of Acute Trusts (WYAAT)
- British Heart Foundation
- Community Pharmacy West Yorkshire / Community Pharmacy North Yorkshire
- Local Medical Council (Calderdale, Kirklees, Wakefield and York)

51/19 Appendix E: Quality and Equality Impact Assessment summary page

This summary sheet provides an overview of the summary of the findings. This assessment consists of five domains: Patient Experience, Patient Safety, Effectiveness, Equality and Workforce.

West Yorkshire and Harrogate Health and Care Partnership
Quality and Equality Impact Assessment

Title of Scheme:	West Yorkshire and Harrogate Healthy Hearts - Phase Two - Cholesterol		
Project Lead:	Pete Waddingham (Yorkshire and Humber Academic Health Science Network)		
Clinical Lead:	Dr Youssef Beaini	Programme Lead:	Jenny Hamer (Y&H AHSN)
Senior Responsible Officer:	Shane Hayward-Giles	Date:	24/05/2019

Proposed change:

Brief Background

West Yorkshire and Harrogate Health Care Partnership (HCP) aim to 'Reduce the number of people experiencing a Cardiovascular Disease incident by 10% across the area by 2021.' This would mean over 1,100 fewer CVD incidents. The HCP Clinical Forum identified the opportunity to make significant improvements in outcomes through joint working across the area, sharing resources and spreading learning. The WY&H Joint Committee of CCGs (JCC) in May/June 2018 agreed to a three phased approach. Phase 1 will focus on Hypertension, followed by Lipid/Cholesterol management (phase 2) and diabetes in phase 3. Phases will run from 2018 – 2021. The project is known as 'Healthy Hearts'. This assessment relates to the second phase of the project - Cholesterol.

Brief Description

Phase two of the West Yorkshire and Harrogate Healthy Hearts Project aims to identify and treat, at scale, patients whose cholesterol may be better controlled through switching to a high intensity statin, and also initiating a statin in those patients at risk of developing CVD. High cholesterol is a key risk factor in heart attacks and strokes. Statins are one of the most evidence based treatments for reducing cholesterol.

Phase Two

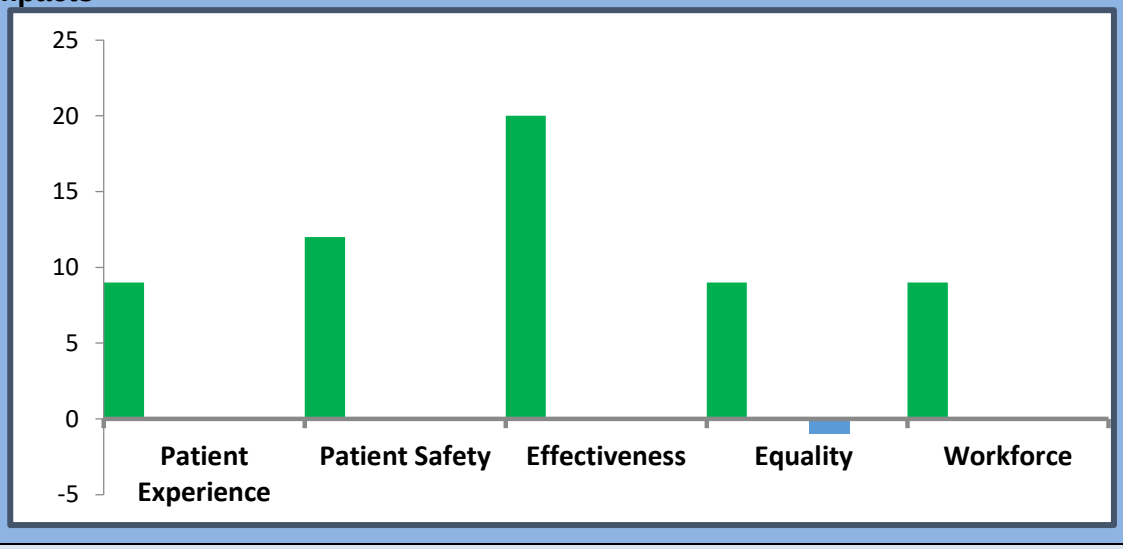
In order to help GP practices, an implementation resource has been created which includes; clinical searches, agreed local treatment guidance, information which can be used when communicating with patients. It is these resources that are subject to this QEIA. In addition to these resources there is a supporting website for patients, the public and professionals containing key information and signposting to further support - this is not part of this QEIA. This work will support current clinical process and practice, and not replace the hard work that is already taking place in Primary Care on Cardiovascular/cholesterol management.

Outcomes and Impact

The estimated adult population across West Yorkshire and Harrogate with a 10-year CVD risk > 20% is 175,000, and of those 89,250 aren't treated with a statin. If this project identified and treated 10% -8,925 people would receive treatment and an estimated 225 to 400 CVD events would be prevented over 5 years. Further analysis using the CVD ROI has identified the population with a 10-Year QRISK >=10% as 655,000 (32%) and suggests if a proportion of these were treated with statins then there could be anywhere from 262 to 1344 CVD events prevented over the next 5 years with a net saving of between £2.2m and £11.5m.

https://cvd-prevention.shef.ac.uk/

Summary of Impacts



Summary of findings:

This QEIA has concluded that the biggest quality impact is likely to be in terms of Effectiveness. The streamlined guidance should have a positive impact on workforce by making it simpler to treat patients with uncontrolled cholesterol or initiating the treatment for those at a future risk of cardiovascular disease. There is negative impact identified under Equality, as the clinical searches and treatment guidance excludes people aged 85 and over and those who are pregnant or of child bearing age, While this represents a disadvantage when compared to the general population, this is consistent with National Clinical Guidance (NICE CG181) and these patients will continue to receive treatment in line with existing clinical practice. These patients will also benefit from the increased clinical focus that this project will bring upon cholesterol and will be able to access various resources e.g. website (see Equality tab for further info)

Summary of Next Steps:

The cholesterol treatment guidance is undergoing engagement across various stakeholders including Primary, Secondary Care, Area Prescribing Committees, LMC, Medicine Optimisation Teams. Assuming all stakeholders and WY&H Joint Committee of CCGs of October 2019 are content with it, the guidance shall be offered as support to primary care to support the achievement of the Healthy Hearts project's objectives.

Has this been incorporated into the project documentation?		Yes

West Yorkshire and Harrogate HEALTHY HEARTS

51/19 Appendix F

Summary of Patient and Public Engagement Feedback

1. What we did

1.1. The engagement activity took place between June and July 2019. Working with engagement leads from across all nine of the CCGs within West Yorkshire and Harrogate, the engagement was undertaken using an online questionnaire and attendance at focus groups.

1.2. The engagement asked people about:

- Their views on the cholesterol work of Healthy Hearts Project
- Their views on the draft statin switch and new statin letters that some GP practices may choose to send out
- Where they are likely to turn to for advice and guidance if they felt the switch in statin medication or the issue of a new statin had caused them concern or a problem
- Where they would normally go to for advice and guidance on leading a healthier lifestyle.

1.3. Through this activity more than 200 responses were received with over 250 individual comments. The responses and comments were received by both the online questionnaire and 15 patient focus groups.

1.4. Feedback from respondents covered 50 out of 78 postcodes within the West Yorkshire and Harrogate area.

2. Findings

2.1. Nearly a quarter of responses were from those of minority ethnic heritage. The median age of respondents was 57 with the youngest being 18 and the oldest 100. Of the respondents 62% were female and 32% were male.

2.2. On reviewing the responses, a key finding was that those consulted were largely supportive of the aims of the project and approach being taken. 88% of those who completed the questionnaire felt the second phase of the project would benefit local people.

2.3. When asked ‘If you were a patient, whose GP wanted to change your statin prescription, do you think this letter explains those changes and why they are being made’ 80% said yes.

2.4. When asked ‘If you were a patient, whose GP wanted to start you on a statin because you were at risk of a heart attack or stroke, do you think the letter provided explains clearly why?’ 76% of respondents said yes.

2.5. Responses showed that overwhelmingly patients would wish to speak to their GP or a Practice Nurse if they had any issues or causes of concern in relation to statins.

2.6. As part of the engagement a number of individual comments were received. These have been grouped to allow themes to be identified. Themes include:

- **Wording / tone of Letter** - what people did or did not like about the letters or the process of writing out to patients about switching their statin medication or putting them on statin medication
- **Support and resources** - general comments about how people access information
- **Barriers** and **Concerns** what would stop someone from taking a statin and more general comments about the project

3. Next Steps

3.1. Revisions will be made to the language and wording of the patient letters which will be used in phase two of the project. A patient user group will be used to make the final revisions to ensure the letters are in 'Plain' language, easy to understand and patient centred. The revisions to the letter will seek to address concerns raised in relation to the tone and level of detail contained within the letter.

3.2. Supporting resources and information will be reviewed alongside comments received to understand how these can be made more accessible, in appropriate formats and to ensure they cover the range of areas highlighted through the engagement including:

- The role of community pharmacy
- Dietary / lifestyle advice
- What statins are – benefits, possible side effects.

3.3. Patients will not be sent a letter automatically putting them on statin medication - they will have the opportunity to actively agree to this first. The letter will make it clear patients can see their GP / health professional before making a final decision about their medication.

3.4. The findings of the patient and public engagement will be shared with CCG colleagues and Primary Care clinicians linked to the project to ensure that this rich source of patient feedback that has been captured can be used to its full potential.

3.5. Further areas which will be explored based on the feedback received will include:

- Establishing champions and community webinars, to support work the work of the project and in reducing heart attacks and strokes
- Use and role of community groups in providing information on the work of the project and in reducing heart attacks and strokes
- Creation of a Frequently Asked Questions resource based on the questions and concerns received