Rotherham Guideline for the management of Non-Familial Hypercholesterolaemia

Recommendations taken from NICE Clinical Guideline 181: Lipid Management, December 2014

Primary Prevention

- **Type 1 Diabetes**
  - Offer lifestyle advice

- **Chronic Kidney Disease (CKD) eGFR < 60mls/min and/or albuminuria**
  - Over 40yrs of age?
  - Diabetic for more than 10 years?
  - Established nephropathy?
  - Other CVD risk Factors?
  - **NO**
    - Consider whether statin treatment is appropriate based on clinical judgement.
  - **YES**
    - Give **Atorvastatin 20mg** OD if not contraindicated (plus other interventions, as appropriate)

- **Patients aged 85yrs and over**
  - Assess CVD risk using QRISK2 tool*, obtain baseline lipid profile and LFTs
  - Risk > 10% over 10 years
  - Risk < 10% over 10 years
  - **Risk > 10% over 10 years**
    - Offer lifestyle advice and reassess as appropriate
  - **Risk < 10% over 10 years**
    - Monitor lipid profile 3 months after initiation. Is there >40% reduction from baseline?
      - **YES**
        - Maintain current statin prescription
      - **NO**
        - Discuss adherence and timing of statin dose
        - Optimise diet and lifestyle measures
        - Consider increasing Atorvastatin if not already on maximal dose

- **Other Patients**
  - Consider whether statin treatment is appropriate based on clinical judgement.

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*CVD risk using QRISK2 may be underestimated in the following patient groups:
- Those treated for HIV
- Those with serious mental health problems
- Those taking medicines which may predispose to hyperlipidaemia such as corticosteroids, antipsychotics or immunosuppressants.
- Those already taking lipid modification or antihypertensive therapies.
- Those who have recently stopped smoking
- BMI > 40kg/m²

NB - All patients on statins should have their treatment reviewed on an annual basis.
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Secondary Prevention

Established Cardiovascular Disease (CVD)

Are there potential drug interactions or high risk of adverse effects with statins?

NO

Give Atorvastatin 80mg OD (unless patient expresses a preference for a lower dose)

Monitor lipid profile 3 months after initiation. Is there >40% reduction from baseline?

YES

Give Atorvastatin at 40mg/20mg/10mg OD as appropriate given potential interactions or risk factors

- Discuss adherence and timing of statin dose
- Optimise diet and lifestyle measures
- Consider increasing Atorvastatin if not already on maximal dose review in 3 months

Maintain current statin prescription

All patients on statins should have their treatment reviewed on an annual basis
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Management of Intolerance to Statin Treatment

Statin intolerance
Studies so that when statins have been stopped for intolerance in the absence of a clinical reason up to 92% of patients are able to tolerate satins when re-challenged. (Annals of Internal Medicine 158; 526-534)

Strategy for reintroducing a statin
• Stop the statin and restart once symptoms have resolved to check if the symptoms are statin related
• Reduce the dose of the current statin if appropriate
• Change to an alternative statin within the same intensity group
• Change to an alternative statin within a lower intensity group

Intolerance is not a class effect. Hence where intolerance to a second statin is evident, other statins should be tried before considering alternative agents. The agents with the best tolerability profiles are pravastatin, atorvastatin (if not already tried), the lipid lowering potential and acquisition cost should also be considered. When initiating atorvastatin or rosuvastatin in previously intolerant patients, start at the lowest available dose and up-titratre.

Ezetimibe:
• Ezetimibe monotherapy should only be considered for prevention of CVD if multiple statins and fibrate treatment has not been tolerated (or in primary hypercholesterolaemia as per NICE TA 132) since there is minimal outcome data regarding its effectiveness in reducing morbidity or mortality in CVD.
• Ezetimibe may be added to statin treatment if recommended by a specialist, where treatment with statins alone has not produced optimal lipid lowering.

Other lipid lowering agents:
• Nicotinic acid derivatives, bile acid sequestrants and omega-3 fatty acids are not recommended for use in primary or secondary prevention of CVD.

Reduction in low density lipoprotein cholesterol (LDL)
Atorvastatin, simvastatin & Pravastatin have consistently the statins with the lowest acquisition costs

<table>
<thead>
<tr>
<th>Dose (mg/day)</th>
<th>5mg</th>
<th>10mg</th>
<th>20mg</th>
<th>40mg</th>
<th>80mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluvastatin</td>
<td>-</td>
<td>-</td>
<td>21%</td>
<td>27%</td>
<td>33%</td>
</tr>
<tr>
<td>Pravastatin</td>
<td>-</td>
<td>20%</td>
<td>24%</td>
<td>29%</td>
<td>-</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>-</td>
<td>27%</td>
<td>32%</td>
<td>37%</td>
<td>*42%</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>-</td>
<td>37%</td>
<td>43%</td>
<td>49%</td>
<td>55%</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>38%</td>
<td>43%</td>
<td>48%</td>
<td>53%</td>
<td>-</td>
</tr>
</tbody>
</table>

• 20-30% low intensity
• 31-40% medium intensity
• Above 40% high intensity
* Advice from the MHRA is that there is an increased risk of myopathy associated with 80mg dose of simvastatin. This dose should only be considered in patients with severe hypercholesterolaemia and high risk of cardiovascular complications who have not achieved their treatment goals on lower doses, and where the benefits are expected to outweigh the risks.
Lipid measurement and referral (Primary prevention)

Recommendations taken from NICE Clinical Guideline 181: Lipid Management, December 2014

Before starting lipid therapy take at least 1 lipid sample, this need not be fasting this should include

- Total cholesterol
- HDL cholesterol
- non-HDL cholesterol
- Triglycerides

Also Check
- Smoking status
- Alcohol status
- HbA1c
- BMI
- Liver transaminases
- TSH

Triglyceride concentration

- Between 10 and 20 mmol/litre, repeat with a fasting sample after 5 days but within 2 weeks
- Between 4.5 and 9.9 mmol/litre CVD risk may be underestimated

Exlude common causes of secondary dyslipidaemia such as
- Excess alcohol
- Uncontrolled diabetes
- Hypothyroidism
- Liver disease
- Nephrotic syndrome

Refer for specialist advice if;
- Total cholesterol is above 9 mmol/litre
- Or non-HDL cholesterol is above 7.5 mmol/litre.
- Triglyceride concentration above 20 mmol/litre (urgent referral)

Consider familial hypercholesterolaemia and refer if
- Total cholesterol more than 7.5 mmol/litre
- A family history of premature coronary heart disease

Always use Non-HDL cholesterol for all risk assessment calculations

= Total Cholesterol – HDL Cholesterol
Monitoring patients on statins

Has the patient experienced generalised unexplained muscle pain whether or not associated with previous statin therapy?

Yes

Measure creatine kinase
- If 5 times upper of normal re-measure after 7 days

Are creatine kinase levels still 5 times above normal

No

But creatinine kinase levels are still raised

Start statin therapy but at a lower dose

No

Do not start statin therapy

If patients report muscle pain or weakness and have a raised creatine kinase explore and consider other causes if they have tolerated statin therapy for more than 3 months

Commence statin advise patient to report immediately any muscle symptoms (pain, tenderness, weakness). If this occurs measure creatine kinase

Do not measure creatine kinase routinely in asymptomatic patients
Monitoring patients on statins
Recommendations taken from NICE Clinical Guideline 181: Lipid Management, December 2014

Liver transaminase

Measure liver transaminase
• At baseline before statin starting therapy
• within 3 months of starting statin therapy
• 12 months after starting therapy
• Do not measure again unless clinically indicated

• Do not routinely stop statin therapy in patients that have raised transaminases but are less than 3 times the upper limit.

Blood Glucose / HbA1c

Do not stop statins because of an increase in blood glucose levels of HbA1c

Pregnancy

Stains are contraindicated in pregnancy
Advise omen of childbearing age of the potential teratogenic risk of statin
Advise woman considering pregnancy to stop stains 3 months prior to attempt to conceive.