



## CLINICAL GUIDELINE

# Coronary Heart Disease and Stroke, Primary and Secondary Prevention Guideline (Cholesterol)

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

<b>Version Number:</b>	6
<b>Does this version include changes to clinical advice:</b>	Yes
<b>Date Approved:</b>	11 <sup>th</sup> May 2022
<b>Date of Next Review:</b>	30 <sup>th</sup> May 2025
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### Important Note:

The Intranet version of this document is the only version that is maintained. Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

# Primary prevention of coronary heart disease and stroke

## High risk patients (predicted cardiovascular event rate 20% or more over 10 years) should be offered treatment with a statin

Treat all patients  $\geq 40$  years of age who have diabetes, and patients  $< 40$  years who have had diabetes  $> 20$  years or have target organ damage, without additional risk assessment. Aspirin is not routinely indicated for patients with diabetes who do not have known atherosclerosis.

Treat patients with chronic kidney disease (CKD 3-5) without additional risk assessment. There is no evidence of cardiovascular benefit for initiation of statins in patients already established on dialysis.

Random non-fasting test for total cholesterol, LDL-C, HDL and triglycerides plus LFT's TSH and HbA1c

If total cholesterol  $> 7.5$  mmol/L and there is a history of CVD in a 1<sup>st</sup> degree relative aged  $< 60$ , (or if total cholesterol  $> 9.0$  mmol/L even without a family history) refer to lipid clinic for genetic screening for familial hypercholesterolaemia.

Assess and manage secondary causes of hyperlipidaemia, such as obesity, excess alcohol consumption, uncontrolled diabetes mellitus, hypothyroidism, liver disease, and nephrotic syndrome.

Calculate individual risk using ASSIGN, QRISK3, or other established risk calculator  
NB Risk calculators may under-estimate lifetime risk in younger patients

## For patients with a 10-year cardiovascular event risk $\geq 20\%$ offer atorvastatin 20mg daily as primary prevention

See BNF for cautions, contra-indications, and clinically important drug interactions

- NB All patients should be advised of the key benefits of lifestyle modification including smoking cessation, diet, weight loss, increased exercise, and reduced alcohol consumption.
- Ensure optimal management of other modifiable cardiovascular risk factors including blood pressure and glycaemic control if appropriate.
- Recheck lipids and LFTs within 3 months then annually. Check CK if patient complains of myalgia. The aim should be to reduce cholesterol concentrations substantially, and failure to do so may be a marker of poor concordance. Although there is no formal GGC LDL-C target for primary prevention, it may be reasonable to increase atorvastatin to 40mg or 80mg in high-risk patients.
- Consider switching patients established on lower intensity statins such as simvastatin to atorvastatin 20mg unless there is a history of intolerance, or patient preference.
- Most reported statin intolerance is due to an expectation of side-effects, but consider a reduced dose of atorvastatin if necessary, and switch to rosuvastatin if an alternative statin is required. There is more evidence for prognostic benefit with statin treatment than for other drug classes.
- Treatment of frail or very elderly people with statins should be guided by individual circumstances and co-morbidities and need not follow guideline recommendations.

See Appendix for additional comments

# Secondary prevention of coronary heart disease and stroke

## Patients with established atherosclerotic arterial disease are at high risk and should be offered treatment with a statin regardless of total blood cholesterol concentration

Includes patients with previous MI, previous CABG or PCI, angina, proven coronary artery disease (invasive or CT angiography) ischaemic stroke or TIA, or peripheral arterial disease. Also includes patients with significant coronary calcification or atherosclerosis reported on non-cardiac imaging.

Random non-fasting test for total cholesterol, LDL-C, HDL and triglycerides plus LFT's TSH and HbA1c

If total cholesterol >7.5 mmol/L and there is a history of CVD in a 1<sup>st</sup> degree relative aged <60, (or if total cholesterol >9.0 mmol/L even without a family history) refer to lipid clinic for genetic screening for familial hypercholesterolaemia.

Assess and manage secondary causes of hyperlipidaemia, such as obesity, excess alcohol consumption, uncontrolled diabetes mellitus, hypothyroidism, liver disease, and nephrotic syndrome.

## For patients with atherosclerotic disease offer atorvastatin 80mg daily as secondary prevention

See BNF for cautions, contra-indications, and clinically important drug interactions

- All patients should be advised of the key benefits of lifestyle modification including smoking cessation, diet, weight loss, increased exercise, and reduced alcohol consumption, as appropriate.
- Ensure optimal management of other modifiable cardiovascular risk factors including left ventricular systolic dysfunction, blood pressure and glycaemic control if appropriate.
- Recheck lipids and LFTs within 3 months then annually. Check CK if patient complains of myalgia.
- The target for treatment of new patients is a reduction in LDL cholesterol by  $\geq 40\%$  from baseline for secondary prevention, or an LDL-C goal of <1.8 mmol/L (non-HDL <2.5 mmol/L) for patients already established on treatment. NB Failure to reduce cholesterol concentrations significantly may be a marker of poor concordance.
- If cholesterol targets are not met offer ezetimibe 10mg daily in addition to the maximal tolerated dose of high-intensity statin.
- Consider switching patients established on lower intensity statins such as simvastatin to atorvastatin 80mg unless there is a history of intolerance, or LDL-C targets are met.
- Most reported statin intolerance is due to an expectation of side-effects, but consider a reduced dose of atorvastatin if necessary, and switch to rosuvastatin if an alternative statin is required. NB There is better evidence for prognostic benefit with statin treatment than for other drug classes.
- Refer to a lipid clinic if PCSK9-inhibitors or other drug options are being considered.
- Treatment of frail or very elderly people with statins should be guided by individual circumstances and co-morbidities and need not follow guideline recommendations.

See Appendix for additional comments

## **APPENDIX – EXPANDED ADVICE**

### **CONTENTS:**

1. Main Changes to the Guideline
2. Preliminary comments regarding cardiovascular risk reduction
3. Risk assessment for primary prevention
4. Inclusion criteria for secondary prevention
5. Familial hypercholesterolaemia
6. Cholesterol and lipid assays
7. Cholesterol targets
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9. Failure to reach targets
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11. Lipid lowering drugs – formulary comments
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13. GGC Lipid Clinic referral information

### **1. MAIN CHANGES TO THE GUIDELINE**

- Advice regarding risk stratification in primary prevention has been refined.
- The lack of evidence for the use of statins for primary prevention in dialysis patients is noted.
- The presence of coronary calcification or other atherosclerosis on non-cardiac imaging is now included under the category of secondary prevention as an indication for treatment.
- GGC guidance on the management of familial hypercholesterolaemia (FH) has been incorporated.
- All routine requests for cholesterol or lipids will result in a biochemistry report which includes total cholesterol (TC), calculated LDL-C (LDL-C), HDL cholesterol (HDLc), and triglycerides (TG) – planned introduction 2022.
- It is recommended that LDL-C concentrations should be re-checked following statin initiation for primary prevention (good practice point).
- LDL-C targets have been updated for secondary prevention to better reflect current national and international guidelines.
- Addition of ezetimibe is recommended for secondary prevention of atherosclerotic arterial disease if LDL-C targets are not met with the maximum tolerated dose of high intensity statin.
- The role of the placebo effect as a key cause of apparent statin intolerance is highlighted.
- Ezetimibe monotherapy is recommended off-label as the initial choice for secondary prevention of atherosclerosis if there is genuine statin intolerance.
- Enhanced guidance on the role of PCSK9-Inhibitors and newer lipid-lowering drugs is provided.
- Advice regarding referral to lipid clinics is included.

### **2. PRELIMINARY COMMENTS REGARDING CARDIOVASCULAR RISK REDUCTION**

**NB** It is important to emphasise that prevention and management of atherosclerotic arterial disease requires control of all risk factors including lifestyle and co-morbidities:

- Relevant dietary and lifestyle advice and support should be offered (e.g. smoking cessation, safe alcohol limits, exercise prescription, weight management).
- Ensure other forms of treatment for the secondary prevention of vascular disease has been optimised (e.g. anti-platelet therapy, ACE-inhibitors, beta-blockers).
- The management of comorbidities should be re-assessed and optimised as appropriate (e.g. glycaemic control in diabetes, blood pressure control in hypertension, treatment of LVSD or AF).

Nonetheless the introduction of lipid-modification therapy **should not be delayed for high risk individuals** while these measures are being addressed.

### 3. RISK ASSESSMENT FOR PRIMARY PREVENTION

The suggested threshold for introduction of statin therapy in GGC is a predicted cardiovascular event rate of 20% or more over 10 years. ASSIGN or QRISK3 are recommended for calculation of baseline cardiovascular risk. ASSIGN is the most commonly used model locally, but has been temporarily unavailable in 2020/2021.

ASSIGN: <https://www.assign-score.com/estimate-the-risk/>

QRISK3: <https://www.qrisk.org/three/>

**NB** Additional factors should be taken into account for selected patient groups.

Serious mental illness, corticosteroid use, inflammatory or autoimmune disorders such as RA or SLE, anti-psychotic use, and erectile dysfunction are all markers of enhanced risk. These factors are incorporated into QRISK3, but should also be taken into account when using ASSIGN.

It should also be noted that both these models may under-estimate lifetime risk in younger patients, and adjustment may be particularly appropriate in those aged <50 if 10 year risk > 10%.

### 4. INCLUSION CRITERIA FOR SECONDARY PREVENTION

Secondary prevention includes patients with previous MI, CABG, or PCI, patients with angina, proven atherosclerotic coronary artery disease (invasive or CT coronary angiography), ischaemic stroke or TIA, or peripheral arterial disease.

This category now also includes patients with coronary calcification or significant atherosclerosis reported on non-cardiac imaging, following the publication of new reporting advice for radiologists in 2020:

*“Suggested report text: Mild / moderate / severe coronary artery calcification, indicating the presence of coronary artery disease. If the patient has associated symptoms recommend management as per chest pain guidelines (eg NICE CG95, SIGN 151). If the patient is asymptomatic consider reviewing modifiable risk factors and managing as per prevention guidelines (eg NICE CG181)”*

<https://www.birpublications.org/doi/epub/10.1259/bjr.20200894>

### 5. FAMILIAL HYPERCHOLESTEROLAEMIA

#### Referral Pathway

All patients with suspected FH should be referred to a Lipid Clinic for confirmation of the diagnosis, assessment and management (see Appendix 13.)

## Simon Broom Criteria for diagnosis of FH

### Definite FH

Required laboratory = high cholesterol levels:

- Adult = Total cholesterol > 7.5 mmol/L or LDL-C > 4.9 mmol/L
- Child <16 years = Total cholesterol > 6.7 mmol/L or LDL-C > 4.0 mmol/L

Plus at least one of the two:-

- Physical finding = tendon xanthomas, or tendon xanthomas in first or second degree relative
- DNA-based evidence of an LDL-receptor mutation, familial defective apo B-100, or a PCSK9 mutation.

### Possible FH

Required laboratory = high cholesterol levels:

- Adult = Total cholesterol > 7.5 mmol/L or LDL-C > 4.9 mmol/L
- Child < 16 years = Total cholesterol > 6.7 mmol/L or LDL-C > 4.0 mmol/L

Plus at least one of the two:-

- Family History: MI <60yrs in 1<sup>st</sup> degree or <50yrs in 2<sup>nd</sup> degree relative
- Family History of elevated total cholesterol
  - TC >7.5 mmol/L in adult 1<sup>st</sup> or 2<sup>nd</sup> degree relative
  - TC > 6.7 mmol/L in child or sibling aged <16 years.

## 6. CHOLESTEROL / LIPID ASSAYS

From 2022 it is planned that all routine requests for cholesterol or lipids will result in a biochemistry report which includes:

- Total cholesterol (TC) mmol/L
- HDL cholesterol (HDLc) mmol/L
- Triglycerides (TG) mmol/L
- Calculated LDL (LDL-C) mmol/L

### Friedewald equation for calculating LDL-C:

$$\text{LDL-C} = \text{TC} - \text{HDLc} - (\text{TG}/2.2)$$

### Indices to guide treatment and risk assessment

The **TC/HDLc ratio** is a better marker of cardiovascular risk for primary prevention than TC alone and there is an inverse relationship between HDLc concentration and CVS risk, at least up to 2.3mmol/L.

- A TC/HDLc ratio >6.0 indicates high risk
- A TC/HDLc ratio <4.0 indicates low risk
- Ratios in-between indicate intermediate risk.

**LDL-C** is a better target than TC alone to guide treatment (Target <1.8 mmol/L in high risk patients)

### Equation for calculating non-HDL cholesterol

Calculated non-HDL cholesterol = TC – HDLc (Target <2.5 mmol/L in high risk patients)

## 7. CHOLESTEROL TARGETS

**Primary prevention** (including patients with a 10 year risk of cardiovascular events  $\geq 20\%$ , patients  $\geq 40$  years of age who have diabetes, patients <40 years of age who have had diabetes >20 years or who have target organ damage, and patients who have CKD3-5 without known atherosclerotic arterial disease, but not those established on dialysis)

It is good practice to re-check cholesterol concentrations within 3 months of initiation of treatment. The aim of statin therapy is to induce a substantial reduction in LDL-C concentrations, and failure to do so may be a marker of poor concordance.

**Secondary prevention** (including patients with previous MI, previous CABG or PCI, angina, proven coronary artery disease (invasive or CT angiography) ischaemic stroke or TIA, or peripheral arterial disease, and also patients with significant coronary calcification or atherosclerosis reported on non-cardiac imaging)

Background: Most national and international guidelines now recommend using non-HDL cholesterol, or LDL-C in preference to TC to guide treatment. NICE and SIGN recommend a target of a greater than 40% reduction in non-HDL cholesterol within 3 months of treatment initiation. ESC guidelines recommend a target of at least a 50% reduction from baseline, and an LDL-C goal of <1.4mmol/L.

**GGC Guideline comments:** The previous GGC Coronary Heart Disease and Stroke, Primary and Secondary Prevention Guideline (2017) recommended a target for total cholesterol of <4.0mmol/L, or a reduction of TC of at least 40% from baseline. The guidelines have now been updated and recommend that the target should now be a reduction in LDL-C cholesterol of >40% from baseline or an LDL-C concentration of <1.8mmol/L.

## 8. FAILURE TO REACH CHOLESTEROL TARGETS

**NB** Failure to reduce cholesterol concentrations significantly with high intensity statins is often a marker of poor concordance to treatment.

### Primary prevention

There is limited evidence for the benefits of dose titration of statins from individual primary prevention trials, while there is good evidence for the efficacy of fixed dose “high intensity” statins in this setting. Nonetheless NICE recommends a target of a 40% reduction in non-HDL cholesterol within 3 months of treatment initiation for primary prevention, while ESC guidelines recommend the use of LDL-C targets graded according to baseline risk (“very high risk” <1.4 mmol/L, “high risk” <1.8mmol/L, “moderate risk” <2.6mmol/L, “low risk” <3.0mmol/L based on the SCORE risk algorithm).

### **GGC Guideline comments:**

Although there is no formal GGC target at present, the Guideline Group considers it reasonable to offer an increased dose of atorvastatin (40 or 80mg) to higher risk primary prevention patients who do not achieve a substantial reduction in LDL-C following initiation of atorvastatin 20mg daily, despite good concordance (e.g. younger patients with 10 year CVS event risk >30%).

### Secondary prevention

Check and encourage concordance if patients fail to reach LDL-C targets using atorvastatin 80mg (>40% reduction from baseline in new patients, LDL-C target <1.8mmol/L in existing patients).

- Offer the addition of ezetimibe 10mg daily as the next step.
- Consider a switch from atorvastatin to rosuvastatin 20mg (consider titrating to a maximum of 40mg if tolerated in order to reach target).

In the event of failure to reach lipid lowering targets on maximal tolerated statin / ezetimibe therapy, referral to lipid clinic may be appropriate for consideration of the use of PCSK9-inhibitors.

## 9. STATIN INTOLERANCE

**The majority of side-effects attributed to statins are due to “nocebo” effect** (i.e. an expectation of adverse side-effects purely related to the act of taking a tablet, rather than an adverse effect of the active ingredient *per se*). The following paper provides a useful reference for discussions with patients:

***N-of-1 Trial of a Statin, Placebo, or No Treatment to Assess Side Effects: “In patients who had discontinued statin therapy because of side effects, 90% of the symptom burden elicited by a statin challenge was also elicited by placebo”*** <https://www.nejm.org/doi/full/10.1056/NEJMc2031173>

**NB** The evidence base for improved cardiovascular outcomes with the use of statins is much more robust than for other agents for both primary and secondary prevention of cardiovascular disease. It

is important to emphasise this to patients, and to ensure that there is genuine intolerance before considering an alternative.

### **Primary prevention**

Ensure patients are genuinely intolerant of statin before making any changes. If necessary patients should be encouraged to try different statin preparations and/or lower than usual doses - for example:- atorvastatin 20mg → atorvastatin 10mg → rosuvastatin 5mg

There is insufficient evidence to support the routine use of agents other than statins for primary prevention. If familial hypercholesterolaemia is suspected however, the patient should be referred to a lipid clinic for specialist advice.

### **Secondary prevention**

Ensure patients are genuinely intolerant of statin before making any changes. Patients should be encouraged to try different statin preparations and/or lower than usual doses - for example:- atorvastatin 80mg → atorvastatin 40mg → atorvastatin 20mg → rosuvastatin 10mg → rosuvastatin 5mg. If necessary combine a lower dose of statin with ezetimibe.

If genuinely intolerant of statin offer monotherapy with ezetimibe (off-label indication - accepted for use on NHS GGC formulary). If the patient is intolerant to statins and ezetimibe for secondary prevention, or if targets not met with ezetimibe monotherapy, then refer to a lipid clinic.

## **10. ADVICE ON RAISED TRIGLYCERIDES**

Triglycerides can be measured on a random sample as part of a full lipid profile. Elevated triglyceride levels on a random sample may be due to the presence of dietary triglycerides.

**NB** A raised triglyceride level should be repeated on a fasting sample to confirm.

Raised triglycerides are most commonly due to secondary causes, e.g. obesity, diabetes, alcohol excess, medicines.

*Any secondary causes of hypertriglyceridaemia should be identified and treated, then a further fasting sample arranged.*

A lipid clinic referral should be arranged for any patient with a suspected familial dyslipidaemia, e.g. patients with high lipid levels and a family history of premature ischaemic heart disease or pancreatitis.

**For patients with moderately raised fasting triglycerides, e.g. 5 to 10 mmol/L**

There is a modest increase in cardiovascular risk due to the raised triglycerides alone. Address secondary causes and then consider treatment with atorvastatin at a lower than usual calculated CVS risk threshold (e.g. 15%)

**For patients with markedly raised triglycerides, e.g. > 10 mmol/L**

Address secondary causes and consider referral to lipid clinic if triglycerides remain persistently >10mmol (urgent referral if > 20mmol/L unless due to alcohol excess or poor glycaemic control)

## **11. LIPID-LOWERING DRUGS – GGC FORMULARY COMMENTS**

### **Statins**

NICE categorise statins into 3 intensity categories:

- Low: LDL reduction 20-30% (e.g pravastatin or fluvastatin up to 40mg)



- Medium: LDL reduction 31-40% (e.g simvastatin 40mg or atorvastatin 10mg)
- High: LDL reduction >40% (e.g atorvastatin 20mg or higher, rosuvastatin 10mg or higher)

In GGC atorvastatin is recommended for first line use at a dose of 20mg for primary prevention, and 80mg for secondary prevention. Ensure generic prescribing. Dose reduction should be considered in patients with CKD, or if there is intolerance.

Rosuvastatin is the preferred alternative if atorvastatin is not tolerated, and is an alternative option if lipid targets are not met with atorvastatin.

Simvastatin, and pravastatin are also listed on the GGC formulary.

**NB** The use of simvastatin 80mg is not recommended due to the increased risk of rhabdomyolysis. Patients currently on simvastatin 80mg should be switched to atorvastatin 80mg daily or rosuvastatin 20mg daily.

### **Ezetimibe**

Ezetimibe 10mg daily is indicated:

- as an add-on to statin therapy for secondary prevention if cholesterol goals are not achieved on the maximum tolerated dose of statin
- as monotherapy for secondary prevention in the event of persistent statin intolerance (off-label indication, approved for use on the NHSGGC Formulary November 2021)

### **PCSK9-inhibitors**

**NB** Patients thought to be potential candidates for treatment with PCSK9-inhibitors should be referred to the lipid clinic.

SMC advice: Alirocumab and evolocumab are accepted for restricted use in Scotland for the following indications:

- patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C  $\geq 5.0$ mmol/L for primary prevention of cardiovascular events
- patients with HeFH and LDL-C  $\geq 3.5$ mmol/L for secondary prevention of cardiovascular events
- patients at high risk due to previous cardiovascular events and LDL-C  $\geq 4.0$ mmol/L
- patients with recurrent or poly-vascular disease and LDL-C  $\geq 3.5$ mmol/L

NHSGGC Formulary: PCSK9-inhibitors are approved for use on the on the advice of a lipid specialist in accordance with local protocols and implementation plan in the following:

- patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C  $\geq 5.0$ mmol/L for primary prevention of cardiovascular events
- patients with HeFH and LDL-C  $\geq 3.5$ mmol/L for secondary prevention of cardiovascular events

Use of alirocumab and evolocumab results in a substantially greater reduction in LDL cholesterol than statins alone. They offer modest benefits in terms of clinical outcomes when used in addition to statins, but at a much higher cost. Patients who are thought to be potential candidates for treatment with PCSK9 inhibitors should be referred to a lipid clinic for initiation and follow-up.

### **Bempedoic acid / Bempedoic acid with ezetimibe**

**NB** Patients thought to be potential candidates for treatment with bempedoic acid should be referred to the lipid clinic.

Restricted to use only on the advice of a lipid specialist in accordance with the SMC advice and restrictions on use noted below. Advice regarding its use will be subject to regular review as further clinical trial evidence emerges.

SMC advice:

- statin intolerant or for whom a statin is contra-indicated, and...
- where ezetimibe alone does not appropriately control LDL-C, and...
- where proprotein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors are not appropriate

Additional comments: Where indicated, the use of the combined bempedoic acid with ezetimibe preparation should be used in preference to the two separate constituents.

### **Inclisiran**

**NB** Patients thought to be potential candidates for treatment with inclisiran should be referred to the lipid clinic.

Restricted to use only on the advice of a lipid specialist in accordance with the SMC advice and restrictions on use noted below. Advice regarding its use will be subject to regular review as further clinical trial evidence emerges.

SMC advice: for specialist use only in patients at high cardiovascular risk as follows:

- patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C  $\geq 5.0$ mmol/L, for primary prevention of cardiovascular events
- patients with HeFH and LDL-C  $\geq 3.5$ mmol/L, for secondary prevention of cardiovascular events
- patients with high risk due to previous cardiovascular events and LDL-C  $\geq 4.0$ mmol/L
- patients with recurrent/poly-vascular disease and LDL-C  $\geq 3.5$ mmol/L.

Additional comments: At present there is no agreed mechanism for administration within GGC.

## **12. DRUGS NOT RECOMMENDED FOR ROUTINE USE IN GGC**

### **Other classes of lipid lowering drugs**

The following lipid-lowering drugs are not recommended for routine use, except under specialist advice (e.g. Lipid Clinic):

- Anion exchange resins
- Fibrates
- Omega-3 preparations (including icosapentyl ethyl)

## **13. LIPID CLINIC REFERRALS**

Indications for referral include:

- Patients with known or suspected familial hypercholesterolaemia
- Failure to meet cholesterol targets in patients with atherosclerotic arterial disease
- Intolerance to multiple statins (and ezetimibe) in patients with atherosclerotic arterial disease
- Patients with markedly raised triglycerides after management of secondary causes

### **GGC Lipid clinics and Consultant Staff**

QEUH (QEUH and Victoria ACH referrals)	Dr Giles Aldsworth/Dr Alison Kelly
West Glasgow ACH	Dr Caroline Millar
GRI / Stobhill	Dr Maurizio Panarelli
Vale of Leven Hospital	Dr Iain Jones
RAH / IRH	Dr Colleen Ross

# NHS GREATER GLASGOW AND CLYDE

## CORONARY HEART DISEASE AND STROKE

### PRIMARY AND SECONDARY PREVENTION GUIDELINES REVISION 2022

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