NHS Greater Glasgow and Clyde

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.

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Important Note:

The online 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

Offer statin to the following patient groups without risk scoring:

- **Patients with type 1 diabetes mellitus if they are >40 years old, or they have had diabetes for >10 years, or they have established nephropathy or other cardiovascular risk factors.**
- **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. Patients with diabetes mellitus type 2 should have their risk score calculated.

Random (non-fasting) lipids: total cholesterol (TC), LDL-C, HDL and triglycerides

TC≥5.5mmol/L

TC<5.5mmol/L

Assess and manage secondary causes such as BMI>25, excess alcohol consumption, uncontrolled diabetes mellitus, hypothyroidism, liver disease and nephrotic syndrome.

Provide dietary and lifestyle advice. **Repeat lipid profile after 3 months** to confirm. Check TFTs and HbA1c if not already done.

If 2 separate total cholesterol measurements 3 months apart >7.5 mmol/L and history of CVD in a 1st degree relative aged <60, (or TC >9.0 mmol/L without a family history) **refer to lipid clinic** for familial hypercholesterolaemia assessment

Calculate individual risk using ASSIGN2, QRISK3, or other established risk calculator

NB Risk calculators may under-estimate lifetime risk in younger patients.

NB QRISK3 should be used for non-caucasian patients for greater accuracy.

For patients with a 10-year cardiovascular event risk ≥ 10%, first line treatment is to offer atorvastatin 20mg daily as primary prevention

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

- **All patients should be advised of the benefits of lifestyle modification including smoking cessation, diet, weight loss, increased activity, and reduced alcohol consumption and manage other modifiable cardiovascular risk factors.**
- **Recheck lipids and LFTs within 3 months then consider annually as best practice to optimise compliance. Check CK if patient reports myalgia.**
- **Best practice suggests aim for 40% or greater reduction in LDL cholesterol for primary prevention. Statin therapy can be intensified to achieve this.**
- **Consider comorbidities, life expectancy and treatment goals when considering statin therapy in patients with frailty.**

- **Most reported statin intolerance is due to an expectation of side-effects. Consider a reduction in atorvastatin dose or switch to rosuvastatin if an alternative statin is required. There is more evidence for prognostic benefit with statin treatment than for other drug classes.**
- **For individuals intolerant of statins please refer to Appendix 9.**

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 cholesterol concentration

This includes patients with coronary calcification or atherosclerosis reported incidentally on non-cardiac imaging eg CT imaging. It also includes patients with previous MI, CABG or PCI, angina, proven coronary artery disease (invasive or CT angiography), ischaemic stroke or TIA and peripheral arterial disease.

Random (non-fasting) total cholesterol, LDL-C, HDL and triglycerides

If TC>5.5mmol/L, also assess and manage secondary causes such as BMI>25, excess alcohol consumption, uncontrolled diabetes mellitus, hypothyroidism, liver disease and nephrotic syndrome.

If 2 separate total cholesterols >7.5 mmol/L and history of CVD in a 1st degree relative aged <60, (or total cholesterol >9.0 mmol/L without a family history) refer to lipid clinic for familial hypercholesterolaemia assessment

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 activity 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.**
- **For patients with coronary artery calcification, give 40mg or 80mg atorvastatin depending on patient characteristics (Refer to Appendix 3).**
- **Recheck lipids and LFTS within 3 months then consider annually as best practice to optimise compliance. Check CK if patient complains of myalgia.**

Treatment targets are LDL-C goal of <2 mmol/L (non-HDL <2.6 mmol/L)

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.

Patients who are intolerant of atorvastatin should be trialled on rosuvastatin (Refer to Appendix 9).

Refer to lipid clinic if LDL remains >3.5mmol/L despite optimised lipid lowering therapy for consideration of PCSK9-inhibitor or other drug therapy.

Note that coronary calcification or atherosclerosis reported on CT alone is insufficient indication for consideration of PCSK9 inhibitor therapy.

Consider comorbidities, life expectancy and treatment goals when considering statins in patients with frailty.

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
8. Failure to reach cholesterol targets
9. Statin intolerance
10. Advice on raised triglycerides
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12. Lipid lowering drugs not recommended for routine use in GGC
13. GGC Lipid Clinic referral information

1. MAIN CHANGES TO THE GUIDELINE

- Risk threshold for statin therapy for primary prevention has been reviewed to align with current risk tools and national guidelines.
- Indication for statin therapy in patients with diabetes updated to reflect national guidelines.
- Introduction of total cholesterol threshold for reviewing secondary causes of elevated cholesterol, with repeat lipid profile being recommended at 3 months.
- Target LDL and non-HDL cholesterol updated for primary and secondary prevention to align with national guidelines.
- More specific recommendations for patients with incidental coronary calcification noted on non-coronary CT scan.
- Emphasis on the use of ezetimibe to support achieving LDL targets in secondary prevention.
- Advice around statin intolerance has been updated to provide titration plans and indications for referral to lipid clinic for consideration of alternative therapies (eg bempedoic acid). Updated reference for statin intolerance.
- Links for risk calculators updated.
- Update on underestimation of lifetime risk in younger patients when using risk calculators.
- New statement that lipoprotein(a) is not for routine use in NHSGGC.
- Introduction of a second lipid profile prior to referral to lipid clinic for possible familial hypercholesterolaemia.
- Indication for inclisiran reviewed and clarified only under a specialist lipid clinic.
- Algorithms updated to reflect reviewed guidelines.
- Updated lipid clinic details.
- Updated working group membership.

2. PRELIMINARY COMMENTS REGARDING CARDIOVASCULAR RISK REDUCTION

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

- Relevent 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 10% or more over 10 years. ASSIGN2 or QRISK3 are recommended for calculation of baseline cardiovascular risk. ASSIGN2 is the most commonly used model locally, and represents an update to the original ASSIGN score.

ASSIGN: https://www.assign-score.com/

QRISK3: https://qrisk.org/

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 ASSIGN2.

It should be noted that both these models may underestimate lifetime risk in younger patients. These tools should inform discussions with younger patients who may be approaching risk thresholds and who may wish to consider statin therapy if lifestyle measures do not sufficiently improve their lipid profile.

Treatment of frail or very elderly people with statins should be guided by individual circumstances and co-morbidities and need not follow guideline recommendations. Review statin if limited life expectancy or if falling due to weakness. Additional considerations in severe frailty: review statin/do not initiate if limited life expectancy or if the priority is symptomatic relief.

Lipoprotein (a) is not recommended for routine use in NHSGGC outside of lipid or cardiology services.

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

"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)".

Williams et al, Reporting incidental coronary, aortic valve and cardiac calcification on non-gated thoracic computed tomography, a consensus statement from the BSCI/BSCCT and BSTI, British Journal of Radiology, Volume 94, Issue 1117, 1 January 2021, https://doi.org/10.1259/bjr.20200894

Patients with incidental findings of coronary calcification should be managed as secondary prevention guidelines using statins and ezetimibe. Patients should be given atorvastatin 40mg or 80mg depending on patient characteristics and severity of calcification. Note that coronary calcification or atherosclerosis reported on CT alone is insufficient indication for consideration of PCSK9 inhibitor therapy.

5. FAMILIAL HYPERCHOLESTEROLAEMIA

Referral Pathway

All patients with suspected Familial Hypercholesterolaemia (FH) should be referred to a Lipid Clinic for confirmation of the diagnosis, assessment and management (see Section 13 for current clinics). This should be after at least two lipid profiles, ideally taken 3 months apart, which have demonstrated a sustained elevated cholesterol above the thresholds used in the Simon Broom Criteria. Consideration should be given to secondary causes of hypercholesterolaemia and their management. Repeat lipid profiles at 3 months should ideally be taken following a period of lifestyle counselling and intervention if indicated.

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

6. CHOLESTEROL / LIPID ASSAYS

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:

LDL-C = TC – HDLc – (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.

Equation for calculating non-HDL cholesterol

Calculated non-HDL cholesterol = TC – HDLc (Target <2.6 mmol/L in high risk patients).

7. CHOLESTEROL TARGETS

Primary prevention includes patients with a 10 year risk of cardiovascular events ≥10%, patients ≥40 years of age who have diabetes type 1, patients who have had diabetes type 1 for >10 years or who have established nephropathy or cardiovascular risk factors, and patients who have CKD stage 3-5 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. Best practice suggests to aim for 40% or greater reduction in LDL cholesterol for primary prevention. Statin therapy may be intensified to achieve this.

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 coronary calcification or atherosclerosis reported on non-cardiac imaging).

This NHSGGC Guideline recommends a target LDL-C concentration of <2mmol/L for secondary prevention.

The previous iteration of this guideline recommended LDL<1.8mmol/L. Subsequent NICE guidelines, supported by economic analysis, have recommended targets of LDL<2mmol/L. ESC and other clinical guidelines recommend lower LDL targets and these may be appropriate for individual patients based on specialist advice.

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

NICE recommends a target of a 40% reduction in non-HDL cholesterol within 3 months af 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:

Best practice suggests to aim for 40% or greater reduction in LDL cholesterol for primary prevention. It may be reasonable to intensify statin therapy to achieve this.

Secondary prevention

Check and encourage concordance if patients fail to reach LDL-C targets using atorvastatin 80mg (LDL-C target <2mmol/L) .

Offer the addition of ezetemibe 10mg daily as the next step.

If the LDL remains >3.5mmol/L despite maximal tolerated statin and ezetimibe therapy, referral to lipid clinic may be appropriate for consideration of PCSK9-inhibitors or other agents. If patients are unable to tolerate statin therapy, they should be referred to the lipid clinic for advice on alternative therapies.

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:

"Statin therapy caused a small excess of mostly mild muscle pain. Most (>90%) of all reports of muscle symptoms by participants allocated statin therapy were not due to the statin. The small risks of muscle symptoms are much lower than the known cardiovascular benefits."
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01545-8/fulltext

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.

Note rosuvastatin has a maximum licensed dose of 20mg daily in patients of Asian origin.

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:- if intolerant of Atorvastatin (20, 40 or 80mg dose), stop statin therapy for 2-3 weeks and then recommence Atorvastatin 10mg. If intolerant, stop for 2-3 weeks then trial rosuvastatin at 2.5mg daily (half a 5mg tablet) for 4 weeks and titrate up to 5mg and then 10mg at 4 weekly intervals until a maximally tolerated dose is determined. If a higher dose is not tolerated, stop for 2-3 weeks and recommence at the last tolerated dose and recheck lipid profile.

If familial hypercholesterolaemia is suspected, 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 retry same statin after period of abstinence first and if side effects remerge then try different statin preparations and/or lower than usual doses - for example:- if intolerant of Atorvastatin (20, 40 or 80mg dose), stop statin therapy for 2-3 weeks and then recommence Atorvastatin 10mg. If intolerant, stop for 2-3 weeks then trial rosuvastatin at 2.5mg daily (half a 5mg tablet) for 4 weeks and titrate up to 5mg and then 10mg at 4 weekly intervals until a maximally tolerated dose is determined. If a higher dose in not tolerated, stop for 2-3 weeks and recommence at the last tolerated dose and recheck lipid profile. If necessary combine a lower dose of statin with ezetimibe.

If genuinely intolerant of statin offer monothreapy with ezetimibe. If the patient is intolerant to statins and ezetimibe, or if targets not met with ezetimibe monotherapy for secondary prevention, then seek advice from a lipid clinic (via SCI referral) regarding alternative therapies.

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.

Raised triglycerides are most commonly due to secondary causes, e.g. BMI>25, diabetes, alcohol excess, medicines. Note that BMI targets should take ethnicity into account.

Any secondary causes of hypertriglyceridaemia should be identified and treated, then a further sample arranged, after a period of lifestyle intervention.

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 CV risk threshold.

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

Address secondary causes and consider referral to lipid clinic for advice if triglycerides remain persistently >10mmol.

Patients should be counselled about the risk of pancreatitis. They should be advised to follow a low refined carbohydrate and saturated fat diet.

11. LIPID-LOWERING DRUGS

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 atorvastatin 10mg or simvastatin 40mg).
- 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.

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

Ezetimibe

Ezetemibe 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.

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 ≥5.0mmol/L for primary prevention of cardiovascular events.

- patients with HeFH and LDL-C ≥3.5mmol/L for secondary prevention of cardiovascular events.
- patients at high risk due to previous cardiovascular events and LDL-C ≥4.0mmol/L.
- patients with recurrent or poly-vascular disease and LDL-C ≥3.5mmol/L.

At the time of writing, 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 ≥5.0mmol/L for primary prevention of cardiovascular events.
- patients with HeFH and LDL-C ≥3.5mmol/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 In patients thought to be potential candidates for treatment with bempedoic acid, advice should be sought from the lipid clinic (via SCI referral).

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

Inclisiran has similar indications to monoclonal PCSK9 inhibitors per SMC guidance but lacks cardiovascular outcome data. Its use is restricted to patients attending a lipid clinic eligible for a monoclonal PCSK9 inhibitor but unable to take one due to side effects.

12. DRUGS NOT RECOMMENDED FOR ROUTINE USE IN GGC

Other classes of lipid lowering drugs

The following lipid-lowering drugs have a limited evidence and outcome data. Consequently they are not recommended for routine use:

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

13. LIPID CLINIC REFERRALS

Indications for referral include:
- Patients with known or suspected familial hypercholesterolaemia.
- Failure to meet GG&C cholesterol targets in patients with atherosclerotic arterial disease.
- Intolerance to multiple statins (and ezetimibe) in the context of secondary prevention, for advice only regarding primary prevention.
- Patients with markedly raised triglycerides after management of secondary causes.

GGC Lipid clinics and Consultant Staff

QEUH (QEUH and Victoria ACH referrals)	Dr Iain Jones
Gartnavel General Hospital	Dr Caroline Millar/Dr Alison Kelly
Stobhill	Dr Maurizio Panarelli
GRI	Dr Alison Kelly/Professor Naveed Sattar
Vale of Leven Hospital	Dr Christina Kanonidou
RAH	Dr Colleen Ross

NHS GREATER GLASGOW AND CLYDE

CORONARY HEART DISEASE AND STROKE
PRIMARY AND SECONDARY PREVENTION GUIDELINES REVISION 2025

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