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1. Introduction and objectives

1.1 Coronary and other heart diseases are the second leading cause of death in Hong Kong, accounting for 14.1% of all deaths in the year 2001¹. From the public health standpoint, much of the burden of Cardiovascular disease is preventable since many predisposing risk factors can be prevented or controlled through the adoption of appropriate lifestyle changes and treatment. In order to optimize the control of coronary risk factors, the active involvement of the medical profession as a whole, and primary care physicians in particular is of utmost importance. As doctor, we are in a very good position to reinforce healthy lifestyle messages to our patients, and to encourage them to take appropriate actions.

Hyperlipidaemia is a major risk factor for Cardiovascular disease, which is very commonly encountered in general practice. At present, the management of hyperlipidaemia especially in relation to the indication of drug treatment is not unified among the four clinics of PDQA Department of Health. In view of this, the clinical audit/guideline development group of PDQA produces this clinical practice guideline to assist primary care doctors in the assessment and management of these patients.

1.2 Methodology

In preparing this guideline, the guideline development group has identified and make reference to local and international guidelines including (1) Clinical management guidelines of Department of Medicine & Therapeutics, The Chinese University of Hong Kong (2) Joint British recommendation on prevention of Cardiovascular disease in clinical practice (3) Recommendation of the second joint task force of European and other societies on coronary prevention (4) Clinical practice guidelines on lipid from Singapore (5) Third report of the National Cholesterol Education Program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III) (6) National Clinical Guideline for Type 2 Diabetes, National Institute of Clinical Excellence (7) Guideline on lipids and primary prevention of Cardiovascular disease, Scottish Intercollegiate Guidelines Network and (8) Guideline on Assessment and Management of Cardiovascular Risk Factor by New Zealand Guidelines Group.

1.3 Objectives

The aim of this guideline is to assist primary care physicians in clinical decision-making by providing well-balanced information on the lipid management in primary prevention of Cardiovascular disease and to encourage a unified approach to the management of hyperlipidaemia among clinics of PDQA.

This is only a guideline to clinical practice without restricting the physician’s individual clinical judgment. Each physician is ultimately responsible for the management of his/her unique patient based on the clinical data presented by the patient and the diagnostic and treatment options available.
2. Laboratory lipid measurements

2.1 Who should be tested?

The major risk factors for Cardiovascular disease (CVD) are: Established CHD, other major atherosclerotic vascular disease, hypertension, dyslipidaemia, diabetes mellitus, family history of premature CHD, cigarette smoking or a combination of these risk factors\textsuperscript{3,4}.

Recommendation:

A lipid profile consisting of total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C) and triglyceride (TG) should be obtained in the following individuals:

- Patients with coronary heart disease (CHD), cerebrovascular or peripheral artery disease (PVD).
- Diabetic patients.
- Individuals with a family history or clinical evidence of familial hyperlipidaemia. (A)

It is also reasonable to test individuals with other risk factors for CVD:

- A family history of CHD or PVD (especially before age 55)
- Hypertension
- Obesity
- Chronic renal disease
- Smoking habits

2.2 What is the procedure of blood testing?

Serum TC and HDL-C levels can be measured at any time of the day in the non-fasting state. However, TG levels must be obtained after 10-12 hours of fasting. TC, HDL-C and TG are measured directly.

\textit{LDL-C is calculated using the Friedwald formula}:

\[
\text{LDL-C (mmol/L)} = \text{TC} - (\text{HDL-C} + \text{TG}/2.2)
\]

This formula cannot be used if the TG is $\geq 4.5$ mmol/L (400 mg/dL).
2.3 What are the precautions to be taken?

- 10-12 hours of fasting is necessary for the estimation of TG.
- The individual’s posture should be consistent i.e. either always sitting (usual practice) or always lying.
- Defer tests for at least 2 weeks after a febrile illness.
- For patients suffering from acute myocardial infarction, the cholesterol level may be depressed between 24 hours to about 3 months after the infarction.
- Since cholesterol and TG levels show biological variability, it is advisable to obtain at least 2 consecutive estimations (1-8 weeks apart) before deciding on any therapeutic intervention.

3. Risk assessment

3.1 Assessment of risk status

The first step is to assess the individual’s risk status. The basic principle of prevention of CVD is that the intensity of risk-reduction therapy should be adjusted to the person’s risk of developing future coronary events. Conventional tools for cardiovascular risk assessment, based on Framingham risk equations, tend to grossly overestimate risk for Chinese based on a large cohort study in China. Clinicians should take a balanced view in applying tools based on Framingham equations such as New Zealand Cardiovascular Risk Prediction Charts, Joint British Societies Charts and New Sheffield Table.

In some people, a high risk can be assumed on the basis of history, symptoms, or signs alone, including symptomatic cardiovascular disease (as defined above), left ventricular hypertrophy on electrocardiography, previous angioplasty or coronary artery bypass grafts, genetic lipid disorders, or diabetic nephropathy (albuminuria >300 mg/day). Risk factors not included in the charts are family history of cardiovascular disease, physical inactivity, obesity, and left ventricular hypertrophy diagnosed by echocardiography. There are no standard definitions for these risk factors, and the magnitude of their independent predictive value is unclear; their presence should influence treatment decisions for patients at borderline treatment levels.
3.2 Risk factors

The major risk factors are:

- CVD and other clinical forms of atherosclerotic vascular disease
- Diabetes mellitus
- Cigarette smoking
- Hypertension (BP $\geq 140/90$ mmHg or on anti-hypertensive medication)
- Dyslipidaemia* (low HDL-C $< 1.0$ mmol/L [40 mg/dL])**
- Family history of premature CHD (CHD in male first degree relative $< 55$ years; CHD in female first degree relative $< 65$ years)
- Age (men $\geq 45$ years; women $\geq 55$ years)

* LDL-C is an important risk determinant.
** HDL-C $\geq 1.6$ (60 mg/dL) counts as a negative risk factor.

Other risk factors are:

- Excess weight
- Sedentary lifestyle
- Atherogenic diet
- Impaired fasting glucose

4. Cardiovascular disease risk group calculation

4.1 The risk assessment tools that can be used for risk stratification are:

- Joint British Societies Coronary Risk Prediction Chart$^6$ [Appendix 1]
- Cardiac Risk Assessor of Joint British Societies [http://www.bhsoc.org/]
- New Sheffield Table$^7$ [Appendix 2]
- New Zealand cardiovascular risk prediction charts$^{40}$ [Appendix 3]
- Charts or computer programs based on Chinese Multi-provincial Cohort Study (CMCS) equation derived by Lam et al. 2005 (to be published in Feb 2005 in Hong Kong Practitioner). [Appendix 4]
Most of these risk assessment methods use the Framingham risk equation to determine the risk of an event. Each assessment method has its particular merits and demerits. A Scottish randomized controlled study that compared the calculations from 3 risk assessment tools (New Zealand table, old Sheffield table, and Joint British chart) with each other, rather than with full Framingham equation estimates, and provided information about the feasibility of using these tools in clinical practice. In this study, doctors and nurses preferred New Zealand tables and Joint British charts over the Sheffield tables and found them easier to use. The group recommends the use of New Zealand tables as it is easy to use, take into account of diabetes status and it is more relevant to the aged population as it predicts 5 year cardiovascular risk. However, the clinician may apply other tools which they found appropriate.

Although Chinese Multiprovincial Cohort Study (CMCS) achieved good/acceptable internal and external validity, it is uncertain whether the new charts based on CMCS can be directly applied to Hong Kong. They new tools based on CMCS study only serve to introduce a balanced view on decision making and for explanation of the relatively lower risk for Chinese at the same lipids level to patients. Therefore the charts are still not recommended as the basic tool for risk assessment until more evidence on local Hong Kong population emerge.

5. Management

5.1 Lifestyle changes

Life style modification is the mainstay of treatment in population based primary prevention strategies.

*Evidence*:

Meta-analysis have unanimously confirmed that cholesterol lowering whether by diet or diet and drugs, decreases CVD risk. *(Ia)*

In the Family Heart Study, a small average reduction in risk factors concealed much larger gains for those who were at highest risk initially, appropriate lifestyle measures should always be attempted before resorting to drug therapy. *(Ib)*

*Recommendation*:

Lifestyle measure remain the first priority in the primary prevention of Cardiovascular disease *(A)*

Before considering lipid lowering drug therapy for primary prevention, lifestyle measures to reduce CVD risk should normally be pursued for a period of 3-6 months, and should be continued irrespective of the need for drug treatment. *(C)*
5.1.1 Cigarette smoking

**Evidence:**

The evidence linking cigarette smoking with coronary and other atherosclerotic vascular disease is incontrovertible\(^28,29\). (IIa)

Stopped smoking significantly reduces CVD risk, although it may be several years before the risk is reversed\(^32\). (III)

Meta-analysis of RCTs showed that education and counseling help patients make behavioural changes. The percentage improvement of an average member of the experimental group (who received specific education and counseling) over an average member of the control group for smoking was 44\(^%\)\(^45\). (Ia)

**Recommendation:**

Smokers should be advised to stop smoking (B)

Repeated brief and supportive advice on smoking cessation should be given to patients by primary care team. (B)

5.1.2 Weight reduction

**Evidence:**

Obesity has an adverse influence on a number of cardiovascular risk factors including blood pressure, plasma cholesterol, triglycerides, glucose tolerance and thrombogenesis\(^41,42\). (III)

Overweight compounds the Cardiovascular disease risk of elevated lipids, blood pressure or diabetes and therefore needs to be addressed independently of these related risk factors\(^43\). (III)

Optimal body mass index (BMI) should be achieved by dietary intervention and regular exercise. Ko et al (1999) studied 1513 Hong Kong Chinese, the risk of diabetes, hypertension, dyslipidaemia and albuminuria starts to increase at a BMI of about 23 kg/m\(^2\). For Asian, the proposed classification from World Health Organization is:

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI</th>
<th>Risk of Co-morbidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt;18.5</td>
<td>Low (but increased risk of other clinical problems)</td>
</tr>
<tr>
<td>Normal Range</td>
<td>18.5-22.9</td>
<td>Average</td>
</tr>
<tr>
<td>Overweight</td>
<td>&gt;=23</td>
<td>Increased</td>
</tr>
<tr>
<td>At Risk</td>
<td>23-24.9</td>
<td>Moderate</td>
</tr>
<tr>
<td>Obese I</td>
<td>25-29.9</td>
<td>Severe</td>
</tr>
<tr>
<td>Obese II</td>
<td>&gt;=30</td>
<td></td>
</tr>
</tbody>
</table>
Recommendation:

Realistic targets of 5-10% weight loss should be set for overweight and obese individuals. (B)

5.1.3 Diet

Evidence:

A recent Cochrane Database of Systemic Review concluded that dietary change to reduce or modify dietary fat intake appears to reduce the incidence of combined cardiovascular events when the dietary modification is followed for at least two years\(^\text{14}\). The extent of this protection appears similar in both high and low risk populations, although the relationship does not achieve statistical significance in low risk participants\(^\text{14}\). (Ia)

Recommendation:

Advice to reduce or modify dietary fat intake should be given to all patients. (A)

In local setting, a general guideline has been set up in the Hospital Authority Diet Manual\(^\text{15,16}\). [Appendix 4]

5.1.4 Exercise

Evidence:

Meta-analysis showed that physical activity, either at work or in leisure time, is associated with a lower risk of CVD in both men and women\(^\text{24}\). (Ia)

Adopting a lifestyle that includes moderate physical activity in middle age appears to have a beneficial effect on CVD risk with a reduction in total and LDL cholesterol and a concomitant increase in HDL cholesterol\(^\text{38,39}\). (Ib, III)

Recommendation:

For those who are currently inactive or not regularly active, aim to accumulate 30 minutes of moderate intensity physical activity on most days. (B)

For those who are already active, vigorous intensity aerobic exercise of 20-30 minutes three times per week is recommended. *(B)

* Vigorous physical activity is rhythmic repetitive physical activities that use large muscle groups at 70% or more of maximum heart rate for age. Maximum heart rate equals roughly 220 beats per minute minus age\(^\text{46}\).
5.1.5 Alcohol restriction

*Evidence*: Heavy drinking elevates blood pressure and triglyceride, contributes towards obesity, and increases both cardiac and total mortality\(^ {33,34} \). *(III)*

*Recommendation*: Men drinking more than 21 units weekly and women drinking more than 14 units weekly should reduce their consumption. *(B)*

5.2 Drug therapy

5.2.1 Priority for drug treatment

Priorities for drug treatment are recommended, based on the level of risk, which patients express in clinical practice\(^ {17} \). In order of decreasing risk, these are:

1. Individuals with established Cardiovascular disease.
2. Individual with established atherosclerotic disease in other sites such as carotid or peripheral vascular disease.
3. Individuals with other major risk factors. The priorities for treatment should be based on the CVD risk calculation.
4. Individuals with lipid abnormalities in the absence of risk factors.

*Evidence*: Evidence from clinical trials has unequivocally shown that individuals with an absolute CVD risk as low as 15% over 10 years do benefit from blood pressure and lipid lowering therapies that reduce coronary and cardiovascular morbidity and mortality. The scientific evidence justifies lifestyle and therapeutic interventions in the population, at least down to a 15% absolute risk. *(Ib)*

Drug treatment has been shown to reduce the relative risk of cardiovascular events in groups of patients with blood pressure >150 mm Hg systolic or 90 mmHg diastolic, and those patients with blood cholesterol >5.0 mmol/l\(^ {53,54} \). *(Ib)*

Drug treatment reduces combined cardiovascular disease mortality and morbidity by about one third, whatever the pretreatment absolute risk, assuming a reduction in blood pressure of about 10-15/5-8 mm Hg or cholesterol reduction of about 20%\(^ {53,54} \). *(Ib)*

Cut-off value for initiation of drug therapy varies between different guidelines, which reflects the complexity of the management of dyslipidemia. Our workgroup has made a consensus on the cut-off value after considering recommendations and on practical ground.
Recommendation:

A patient should be considered for lipid lowering drug therapy for primary prevention, usually following a trial of lifestyle measures and other appropriate interventions for at least 3 months, when the serum total cholesterol is \( \geq 5.0 \text{ mmol/L} \) AND the 5-year risk of CVD is \( \geq 20\% \) using the New Zealand cardiovascular disease risk assessment charts. \( \text{GPP} \)

The Sheffield and Joint British Societies Risk Prediction Charts could also be considered for risk factor assessment, if preferred. \( \text{C} \)

5.2.2 Lipid lowering drug

Evidence:

There is evidence from large, randomized placebo-controlled trials that statins, fibrates and resins all reduce the risk of non-fatal myocardial infarction in persons without symptomatic Cardiovascular disease. Only statins have been shown also to reduce total mortality\(^9\). \( \text{lb} \)

Two primary prevention studies- the West of Scotland Coronary Atherosclerosis Prevention Study (WOSCOPS) and the Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS) using statin have shown clinically and statistically significant falls in fatal and non-fatal CHD. The WOSCOPS was also able to show significant reductions in all cause mortality\(^{47}\). \( \text{lb} \)

Meta-analysis of published randomized trials of statin drugs demonstrates large reductions in cholesterol and clear evidence of benefit on stroke and total mortality. There was a large and significant decrease in CVD mortality, but there was no significant evidence for any increases in either non-CVD deaths or cancer incidence\(^{48}\). \( \text{la} \)

Recommendation:

For primary prevention of CVD, statins are drugs of first choice for lowering lipids. \( \text{A} \)

Statins\(^{18,19}\)

These HMG Co-A Reductase inhibitors have substantial reduction in LDL-C (reduce by 15-60%), with significant beneficial effect on triglyceride (reduce by 10-20%) and HDL-C level (increase by 5-10%)

Most common side effects are:

- GI upset, headache and sleep disturbance
- Myopathy
- Liver transaminase elevation.
**Myopathy:**

- Rhabdomyolysis and acute renal failure secondary to myoglobinuria had been reported (approximately 1 in 100,000), with increased chance in patient with renal failure and hypothyroidism.

- Statins are metabolized by cytochromeP450 liver enzyme system. When statins are co-administrated with other liver enzyme inhibitor, such as: azole antifungals (itraconazole & ketoconazole), erythromycin or clarithromycin, HIV protease inhibitor, or cyclosporin, drug interaction will occurred and increased risk of myopathy.

- Incidence of myopathy is also raised when statin is used with other lipid lowering drug, such as fibrates & nicotinic acid.

- Statins & Calcium Antagonists: Verapamil & diltiazem are weak inhibitor of liver enzymes. Cases of rhabdomyolysis have been reported with the association of diltiazem with atorvastatin & simvastatin. Caution is needed when these drugs are used simultaneously.

- Patients should be advised to report unexplained muscle pain. Creatinine kinase (CK) level should then be measured and drug discontinued if CK level is more than 5 times the upper limit of normal.

**Liver transaminase elevation:**

- Controlled trials show statins increases serum transaminase values to more than 3 times of upper limit of normal (3X ULN) in approximately 1% of patients. The incidence of this abnormality is dose related. At low dose of statins, the incidence of liver transaminase elevation is similar to that of placebo\(^9,13,47,57\). The majority of liver abnormalities occur within the first 3 months of therapy. Special precautions should be taken in patients with history of liver disease or high alcohol intake.

- Liver function tests should be checked before and within 1-3 months of starting treatment. Thereby half yearly review of liver function tests for the first year.

- Treatment should be discontinued if serum transaminase concentration raise and persist at three time of upper limit of reference range.

- There is one meta-analysis on statins and liver toxicity. 49275 patients from 13 trials were reviewed. It found proportion of patients having LFT abnormalities was low for pravastatin, lovastatin & simvastatin. However, fluvastatin was associated with a significant increase in the odds of having LFT abnormalities. It concluded that patients taking low to moderate doses statins are not associated with significant risk of LFT abnormalities\(^59\).

- One retrospective review of statin use in primary care practice questions the usefulness of routine measurement of transaminase\(^57\). This revealed no case of significant or moderately abnormal in transaminaes level.
 Recommendation from drug companies for subsequent monitoring of LFTs are varies. Some drug companies recommended periodically monitoring after initiation of statins. For example, Manufacturer of Atorvastatin (Lipitor) recommended LFT should be performed “before the initiation of treatment and periodically thereafter”, or when patients “develop any signs or symptoms suggesting liver injury”. Whereas some drug companies recommended periodically monitoring of LFTS only for those whose taking high dose statin. Manufacturer of Simvastatin (Zocor) recommended LFTs be performed before treatment begins and then when “clinically indicated” in patients who receiving low dose statins (<80mg daily). If patients titrated to the 80-mg dose of zocor, they should have an additional test prior to titration, 3 months after titration to the 80-mg dose, and periodically thereafter (e.g. semiannually) for the first year.

Physicians should determined on individual basis for the needs & frequency of subsequent LFTs monitoring.

Congenital anomalies have been reported when used in pregnant women. Contraception should be used during and one month after treatment.

**Fibrates**

Mechanism of this group of drugs remained incompletely understood. It is thought to have stimulating activities on hepatic lipase and reduce secretion of VLDL.

They reduce triglyceride by 20-50%, LDL-C by 5-25% and increase HDL-C by 10-20%.

Their main side effects are GI upset, headache, fatigue, myositis-like syndrome especially in patients with impaired renal function. Myopathy usually occurs within two months of starting treatment. Increased risk of gallstone formation has reported in clofibrate but it has not been conclusive in other fibrates.

Absolute contraindication includes hepatic impairment, renal dysfunction and they should be avoided in diabetes nephropathy. Special precaution should be taken in alcoholism, gallstone and pregnancy.

Drug interaction may occur with increase anticoagulation effect of pregnancy. On starting fibrate treatment, warfarin dosage may need to be reduced by 1/3 with monitoring of Prothrombin time.

**Resin (Bile Acid Sequestrants)**

This group of drugs reduces LDL-C by 15-30%, increase HDL-C by 3-5% but may increase level of Triglycerides.

On long term use, their effect may be reduced due to increase cholesterol synthesis in liver.

GI upset is common including constipation, bloating, epigastric fullness and flatulence.
They are contraindicated in complete biliary obstruction, high fasting Triglyceride (>5.6mmol/L absolute contraindication, >2.3 relative contraindication).

Special precaution should be taken for diabetic patients with GI autonomic neuropathy (increase constipation and risk of fecal impaction).

Drug interactions include reduction in absorption of fat soluble vitamins and folic acid. Increase in bleeding tendency may occur with vitamin K deficiency. Resins can bind to oral drugs including warfarin, digoxin, thyroxine, oral hypoglycaemic agent, thiazide and NSAIDs. Resins should therefore be taken one hour after or four hours before these agents.

**Nicotinic Acid**

- It is a water-soluble Vitamin B Complex.
- The mechanism of action is not well understood. It decreases LDL-C by 5-25%, Triglyceride by 20-50% and increase HDL-C by 15-35%.
- Nicotinic Acid is usually not well tolerated due to flushing, skin itching, GI irritation, deranged liver transaminases, increase glucose level and increase in uric acid level. Severe liver toxicity was reported.
- Contraindications of this drug include hypersensitivity reaction to this drug, liver disease impaired glucose tolerance, diabetes mellitus and gouty arthritis.

5.3 Management of hypertension in primary CVD prevention

**Evidence**:

Hypertension is an important risk factor for CHD and stroke. Randomized controlled trials have shown convincingly that lifestyle measures plus antihypertensive drugs reduce the risk of stroke at all ages and of coronary disease in the elderly. *(lb)*

**Recommendation**:

Treatment of hypertension is recommended to reduce the risk of both CHD and stroke. *(A)*

The management of hypertension is considered in more detail in the Hypertension Management Guideline PDQA 2004.
5.4 Use of Aspirin in primary CVD prevention

**Evidence**:

There is no clear evidence that antiplatelet therapy is indicated for routine use in primary prevention subjects at low risk of occlusive vascular events\(^{22}\). The results of two trials support the use of prophylactic aspirin in selected high risk individuals\(^{20,21}\). In the HOT trial, low dose aspirin (75 mg) further reduced cardiovascular risk in well-controlled hypertensive patients who already had atherosclerotic complications, or who had target organ damage such as left ventricular hypertrophy, proteinuria or renal impairment\(^{25}\). (II)

Aspirin is contraindicated in people with aspirin allergies or intolerance, active peptic ulceration, and uncontrolled blood pressure and in people with other major bleeding risks\(^{56}\).

Aspirin treatment for primary prevention is safe and worthwhile at coronary event risk \(\geq\) 1.5%/year; safe but of limited value at coronary risk 1%/year; and unsafe at coronary event risk 0.5%/year\(^{58}\). (I)

Advice on aspirin for primary prevention requires formal accurate estimation of absolute coronary event risk\(^{58}\). (I)

**Recommendation**:

Patients with a 5-year cardiovascular risk greater than 15%, should be considered on low-dose aspirin (75 – 150 mg/day) if there are no contraindications\(^{56}\). (A)

Aspirin is contraindicated in people with aspirin allergies or intolerance, active peptic ulceration, uncontrolled blood pressure and in people with other major bleeding risks\(^{56}\). (A)

6. Goal lipid level

**Evidence**:

A non-randomized analysis from WOSCOPS of the relation between reduction in cholesterol and all cardiovascular event rates suggests that there may be little to be gained in primary prevention by lowering total serum cholesterol much below 5.0 mmol/l. The trial data suggest that a 1 mmol/l reduction in serum total cholesterol sustained over five years will reduce the incidence of non fatal MI or fatal CHD by 20-25% irrespective of baseline cholesterol and baseline risk\(^{9,36,37}\). (II)

**Recommendation**:

The treatment target total cholesterol level for primary prevention in patients on drug therapy should be less than 5.0 mmol/l, together with a fall in total cholesterol of at least 1 mmol/l. (B)
7. Special groups

7.1 Elderly patients

Evidence:
Both PROSPER and Heart Protection Study showed benefit of cholesterol lowering in terms of reduction in risk of major vascular events in individuals 70-82 and 75 years of age respectively\textsuperscript{10,23}. (Ib)

Recommendation:
For primary prevention, advance age is not a contraindication for lipid lowering drug therapy. (B)
Patients on lipid lowering therapy should not have their drugs stopped on account of age. (C)

7.2 Diabetes mellitus

Evidence:
The development of proteinuria in diabetes mellitus is a particular strong predictor of CVD risk and patients with this complication should be treated as in secondary CVD prevention\textsuperscript{26}. (III)
A 7-year prospective study of a hospital-based cohort confirms that after adjustment for age only, microalbuminuria is a strong predictor for all-cause and CHD mortality\textsuperscript{44}. (III)

Recommendation:
In Type 2 diabetic with nephropathy, lipid lowering drug therapy should be considered at a lower risk threshold in these individuals. (C)

7.3 Renal disease

- Starting dose of statin in chronic renal failure should be low and creatinine kinase and renal function should be closely monitored.
- Fibrates can be used in mild or moderate renal failure with reduced dosage and monitoring of side effect.
- Risk of myopathy and rhabdomyolysis may be increased in renal transplant patients on immunosuppressive therapy.
7.4 Liver disease

- Liver Function should be screened on two consecutive occasions with chronic liver disease due to hepatitis B or alcohol abuse.
- Transaminases of less than 1.5 times the upper limit of normal, statin can be used with caution.
- The starting dose should be low.
- Fibrates can be given whose transaminase level is less than three times the upper limit of normal range, but at a lower starting dosage.
- Careful monitoring of liver function is required.

8. Summary of recommendation on lipid management in primary prevention of CVD

A A lipid profile consisting of total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C) and triglyceride (TG) should be obtained in the following individuals:

- Patients with Cardiovascular disease (CVD), cerebrovascular or peripheral artery disease (PVD)
- Diabetic patients
- Individuals with a family history or clinical evidence of familial hyperlipidaemia

A Lifestyle measure remain the first priority in the primary prevention of Cardiovascular disease.

C Before considering lipid lowering drug therapy for primary prevention, lifestyle measures to reduce CVD risk should normally be pursued for a period of 3-6 months, and should be continued irrespective of the need for drug treatment.

B Smokers should be advised to stop smoking.

B Repeated brief and supportive advice on smoking cessation should be given to patients by primary care team.

B Realistic targets of 5-10% weight loss should be set for overweight and obese individuals

A Advice to reduce or modify dietary fat intake should be given to all patients.

B For those who are currently inactive or not regularly active, aim to accumulate 30 minutes of moderate intensity physical activity on most days.

B For those who are already active, vigorous intensity aerobic exercise of 20-30 minutes three times per week is recommended.

B Men drinking more than 21 units weekly and women drinking more than 14 units weekly should reduce their consumption.
A patient should be considered for lipid lowering drug therapy for primary prevention, usually following a trial of lifestyle measures and other appropriate interventions for at least 3 months, when the serum total cholesterol is $\geq 5.0$ mmol/L AND the 5-year risk of CVD is $\geq 20\%$ using the New Zealand cardiovascular disease risk assessment charts. (GPP).  

The New Zealand cardiovascular disease risk assessment charts could also be considered for risk factor assessment, if preferred.

The treatment target total cholesterol level for primary prevention in patients on drug therapy should be less than 5.0 mmol/l, together with a fall in total cholesterol of at least 1 mmol/l.

Treatment of hypertension is recommended to reduce the risk of both CHD and stroke.

Patients with a 5-year cardiovascular risk greater than 15\%, should be considered on low-dose aspirin (75 – 150 mg/day) if there are no contraindications. (A)  

Aspirin is contraindicated in people with aspirin allergies or intolerance, active peptic ulceration, uncontrolled blood pressure and in people with other major bleeding risks. (A)

For primary prevention, advance age is not a contraindication for lipid lowering drug therapy.

Lipid lowering treatment should not be stopped at any particular age.

In Type 2 diabetic with nephropathy, lipid lowering drug therapy should be considered at a lower risk threshold in these individuals.
# 9. Ranking of evidence and grade of recommendation

Adapted from the US Agency of Health Care Policy and Research\textsuperscript{30}

<table>
<thead>
<tr>
<th>Level</th>
<th>Type of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ia</td>
<td>Evidence obtained from meta-analysis of randomized controlled trials</td>
</tr>
<tr>
<td>Ib</td>
<td>Evidence obtained from at least one randomized controlled trial</td>
</tr>
<tr>
<td>IIa</td>
<td>Evidence obtained from at least one well-designed controlled study without randomization</td>
</tr>
<tr>
<td>IIb</td>
<td>Evidence obtained from at least one other type of well-designed quasi-experimental study</td>
</tr>
<tr>
<td>III</td>
<td>Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grading</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Requires at least one randomized controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)</td>
</tr>
<tr>
<td>B</td>
<td>Requires the availability of well-conducted clinical studies but no randomized clinical trials on the topic of recommendation. (Evidence levels IIa, IIb, III)</td>
</tr>
<tr>
<td>C</td>
<td>Requires evidence obtained from expert committee reports or opinion and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)</td>
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<tr>
<td>GPP</td>
<td>Recommended best practice based on clinical experience of Guideline Development Group.</td>
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</table>
10. References


4. Executive summary of the third report of the National Cholesterol Education Program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol on adults (Adult Treatment Panel III). JAMA, May 16, 2001; Vol 285, No. 19


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11. Members of the clinical audit and guideline working group

1. Dr Christie Chan
2. Dr Lisa Cheng
3. Dr Anthony Ho
4. Dr Linda Hui (Chairman)
5. Dr Lam Wing Kwun
6. Dr Lau Kam Tong
7. Dr Ng Mei Yee
8. Dr Charmaine Tse

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Correspondence to: Dr Linda Hui
Address: Ngau Tau Kok Family Medicine Training Centre, 2/F, Ngau Tau Kok Polyclinic, 60. Ting On Street, Ngau Tau Kok, Kowloon.
Fax: 2753 9555
E-mail: smo_pdqa@dh.gov.hk

Footnotes
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✧ Competing interest: None
✧ Last modified: May 2005
✧ Comments and suggestions are welcomed and should be addressed to the chairman of the group.

Disclaimer

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12. British societies (JBS) coronary risk prediction chart (Appendix 1)

**Nondiabetic Men**

**Non-smoker**

**Age under 50 years**

**Age 50 - 59 years**

**Age 60 years and over**

**Smoker**

SBP = systolic blood pressure mmHg

TC : HDL = serum total cholesterol to HDL cholesterol ratio

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How to use the Cardiovascular Disease Risk Prediction Charts for Primary Prevention

These charts are for estimating cardiovascular disease (CVD) risk (non-fatal myocardial infarction [MI] and stroke, coronary and stroke death and new angina pectoris) for individuals who have not already developed coronary heart disease (CHD) or other major atherosclerotic disease. They are an aid to making clinical decisions about how intensively to intervene on lifestyle and whether to use antihypertensive, lipid lowering medication and aspirin.
The use of these charts is not appropriate for the following patients groups. Those with:

- CHD or other major atherosclerotic disease
- Familial hypercholesterolaemia or other inherited dyslipidaemias
- Chronic renal dysfunction
- Type 1 and 2 diabetes mellitus

The charts should not be used to decide whether to introduce antihypertensive medication when blood pressure (BP) is persistently at or above 160/100 or when target organ damage (TOD) due to hypertension is present. In both cases antihypertensive medication is recommended regardless of CVD risk. Similarly the charts should not be used to decide whether to introduce lipid-lowering medication when the ratio of serum total to high density lipoprotein (HDL) cholesterol exceeds 7. Such medication is generally then indicated regardless of estimated CVD risk.

To estimate an individual's absolute 10 year risk of developing CVD choose the table for his or her gender, smoking status (smoker/non-smoker) and age. Within this square define the level of risk according to the point where the coordinates for systolic blood pressure (SBP) and the ratio of total cholesterol to HDL-cholesterol meet. If no HDL cholesterol result is available, then assume this is 1.00mmol/l and the lipid scale can be used for total serum cholesterol alone.

Higher risk individuals (red areas) are defined as those whose 10 year CVD risk exceeds 20%, which is approximately equivalent to the CHD risk of >15% over the same period indicated by the previous version of these charts. As a minimum those at highest CVD risk (greater than 30% shown by the line within the red area) should be targeted and treated now. When resources allow, others with a CVD risk of >20% should be progressively targeted.

The chart also assists in the identification of individuals whose 10 year CVD risk moderately increased in the range 10-20% (orange area) and those in whom risk is lower than 10% over 10 years (green area).

Smoking status should reflect lifetime exposure to tobacco and not simply tobacco use at the time of assessment. For example, those who have given up smoking within 5 years should be regarded as current smokers for the purposes of the charts.

The initial BP and the first random (non-fasting) total cholesterol and HDL cholesterol can be used to estimate an individual's risk. However, the decision on using drug therapy should generally be based on repeat risk factor measurements over a period of time.

Men and women do not reach the level of risk predicted by the charts for the three age bands until they reach the ages 49, 59, and 69 years respectively. Everyone aged 70 years and over should be considered at higher risk. The charts will overestimate current risk most in the under forties. Clinical judgement must be exercised in deciding on treatment in younger patients. However, it should be recognised that BP and cholesterol tend to rise most and HDL cholesterol to decline most in younger people already possessing adverse levels. Thus untreated, their risk at the age 49 years is likely to be higher than the projected risk shown on the age-less-than 50 years chart.
These charts (and all other currently available methods of CVD risk prediction) are based on groups of people with untreated levels of BP, total cholesterol and HDL cholesterol. In patients already receiving antihypertensive therapy in whom the decision is to be made about whether to introduce lipid-lowering medication or vice versa the charts can act as a guide, but unless recent pre-treatment risk factor values are available it is generally safest to assume that CVD risk is higher than that predicted by current levels of BP or lipids on treatment.

CVD risk is also higher than indicated in the charts for:-

- Those with a family history of premature CVD or stroke (male first degree relatives aged <55 years and female first degree relatives aged <65 years) which increases the risk by a factor of approximately 1.5
- Those with raised triglyceride levels
- Women with premature menopause
- Those who are not yet diabetic, but have impaired fasting glucose (6.1-6.9mmol/l)

In some ethnic minorities the risk charts underestimate CVD risk, because they have not been validated in these populations. For example, in people originating from the Indian subcontinent it is safest to assume that the CVD risk is higher than predicted from the charts (1.5 times).

The charts may be used to illustrate the direction of impact of risk factor intervention on estimated level of CVD risk. However, such estimates are crude and are not based on randomised trial evidence. Nevertheless, this approach maybe helpful in motivating appropriate intervention. The charts are primarily to assist in directing intervention to those who typically stand to benefit most.
### 13. Sheffield table for primary prevention of cardiovascular disease (Appendix 2)

Showing serum total-HDL cholesterol ratios conferring estimated risk of coronary heart disease events of 15% and 30% over 10 years.

#### Men: Total: HDL cholesterol ratio

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#### Women: Total: HDL cholesterol ratio

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Clinical Audit & Guideline Working Group
NOTE: READ BEFORE USING TABLE.

INSTRUCTIONS

- Do not use for secondary prevention: patients with MI, angina, PVD, non-hemorrhagic stroke, TIA, or diabetes with microvascular complications have high CHD risk. Treat mild hypertension: treat with aspirin; and treat with statin if serum cholesterol \( \geq 193 \text{ mg per dL (5.0 mmol per L)} \).
- Treat hypertension above mild range (average \( \geq 160 \) or \( \geq 100 \text{ mm Hg} \)).
- Treat mild hypertension (140 to 159 or 90 to 99 mm Hg) with target organ damage (LVH, proteinuria, renal impairment) or with diabetes (type 1 or 2).
- Consider drug treatment only after 6 months of appropriate advice on smoking, diet and repeated BP measurements.
- Use average of repeated total: HDL-C measurements. If HDL-C is not available, assume 46 mg per dL (1.2 mmol per L).
- Those with total:HDL-C ratio \( \geq 8.0 \) may have familial hyperlipidemia.
- The table underestimates CHD risk in:
  - LVH on ECG (risk doubled; add 20 years to age)
  - Family history of premature CHD (add 6 years)
  - Familial hyperlipidemia
- British Asians
- Choose table for men or women.
- Hypertension means SBP \( \geq 140 \text{ mm Hg} \) or DBP \( \geq 90 \text{ mm Hg} \) or on antihypertensive treatment.
- Identify correct column for hypertension, smoking and diabetes.
- Identify row showing age.
- Read off total:HDL-C ratios at intersection of column and row. If there is an entry, measure serum cholesterol:HDL ratio. If no entry, lipids need not be measured unless familial hyperlipidemia is suspected.
- If total:HDL-C ratio confers CHD risk of 15%, consider treatment of mild hypertension (SBP 140 to 159 mm Hg or DBP 90 to 99 mm Hg) and with aspirin.
- If total:HDL-C ratio confers CHD risk of 30%, consider statin if serum cholesterol \( \geq 193 \text{ mg per dL (5.0 mmol per L)} \).
- Decision on statin at CHD risk between 15% to 30% depends on local policy.
- The table can be used to assess CHD risk at an older age.

HDL = high-density lipoprotein; CHD = coronary heart disease; MI = myocardial infarction; PVD = peripheral vascular disease; TIA = transient ischemic attack; LVH = left ventricular hypertrophy; BP = blood pressure; HDL-C = high-density lipoprotein cholesterol; ECG = electrocardiograph; SBP = systolic blood pressure; DBP = diastolic blood pressure.
New Zealand Cardiovascular Risk Calculator
adapted with permission from New Zealand Guidelines Group

How to use the risk calculator
Find the colour block which best describes your patient’s:
- gender
- age (age shown is mean for that category e.g. 60 represents those 55–64 years old)
- smoking status (regular daily smoking or having stopped in the previous 12 months)
- diabetes status (on insulin, oral hypoglycaemics, or fasting blood glucose > 8.0 mmol/L)
- BP (mean of two readings on at least two occasions)
- total cholesterol/HDL-cholesterol ratio.

Cell colour estimates a person’s absolute 5-year risk of a cardiovascular event i.e. newly diagnosed angina, myocardial infarction (MI), coronary heart disease death, stroke or transient ischaemic attack (TIA).

Who does not need their risk calculated?
Very high-risk patients as determined clinically do not need to have their risk calculated. These patients are assumed to have a cardiovascular disease (CVD) risk > 20% over 5 years.
- All patients with symptomatic CVD
- Those with diagnosed left ventricular hypertrophy
- Those with genetic lipid disorders
- Those with diabetes and evidence of renal disease.
For age > 75 years, the absolute risk of a cardiovascular event is > 15% at 5 years in nearly all individuals.

Where risk may be underestimated
The following patient groups are likely to be at greater risk than the tables indicate. For these patients, consider increasing estimated risk by one colour level or treating at a lower CVD risk level:
- Those with a strong family history of CVD (first degree relative) i.e. a male with CVD before 55 years, or female before 65 years
- Those of Aboriginal, Torres Strait Islander, Maori or Pacific Islander origin and people from the Indian sub-continent
- Those who are obese (BMI ≥ 30 kg/m²)
- Those with very high levels of total cholesterol (> 8.5–9 mmol/L)
- Those with very high blood pressure (> 170/100 mmHg).

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http://www.healthevidence.nhmco.org.au

Familial hypercholesterolaemia, familial defective ApoB and familial combined dyslipidaemia.

Microalbuminuria > 10 micrograms and/or proteinuria > 200 mg/day and/or glomerular filtration rate (GFR) < 60 ml/min.

National Prescribing Service ACN 082 034 393
Level 7 / 418A Elizabeth Street Surry Hills NSW 2010
Phone: 02 8217 8700 | Fax 02 9211 7578 | email: info@nps.org.au | net: http://www.nps.org.au

February 2004
New Zealand Cardiovascular Risk Calculator
Assessing cardiovascular risk and treatment benefit

Cells with this marker (*) indicate patients with either a very high total cholesterol or very high blood pressure. In these patients the tables may underestimate true risk.

### Absolute 5-year CV risk

<table>
<thead>
<tr>
<th>Category</th>
<th>Risk Level</th>
<th>5-year CV risk (fatal and non-fatal)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very high</td>
<td>&gt; 30%</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>25-30%</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>15-20%</td>
</tr>
<tr>
<td></td>
<td>Mild</td>
<td>10-15%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5-10%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.5-5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt; 2.5%</td>
</tr>
</tbody>
</table>

### Risk level

<table>
<thead>
<tr>
<th>Risk level</th>
<th>5-year CV risk (fatal and non-fatal)</th>
<th>Benefits: NNT* for 5 years to prevent one event^2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 intervention (25% risk reduction)</td>
<td>2 interventions (45% risk reduction)</td>
</tr>
<tr>
<td></td>
<td>3 interventions (55% risk reduction)</td>
<td></td>
</tr>
<tr>
<td>30%</td>
<td>13 (7.5 per 100)</td>
<td>7 (14 per 100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 (16 per 100)</td>
</tr>
<tr>
<td>20%</td>
<td>20 (5 per 100)</td>
<td>11 (9 per 100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>9 (11 per 100)</td>
</tr>
<tr>
<td>15%</td>
<td>27 (4 per 100)</td>
<td>15 (7 per 100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 (8 per 100)</td>
</tr>
<tr>
<td>10%</td>
<td>40 (2.5 per 100)</td>
<td>22 (4.5 per 100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>18 (5.5 per 100)</td>
</tr>
<tr>
<td>5%</td>
<td>80 (1.25 per 100)</td>
<td>44 (2.25 per 100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 (3 per 100)</td>
</tr>
</tbody>
</table>

* Number needed to treat

^2 Based on the conservative estimate that each intervention: aspirin, blood pressure treatment (≥ SBP by 10 mmHg) or lipid modification (LDL-cholesterol by 20%) reduces CV risk by approximately 25% over 5 years.
15. Risk prediction charts based on Chinese Multiprovincial Cohort Study equation (Appendix 4)

The charts in Appendix 4 only apply to primary prevention of iCVD in Chinese in the age range of 35-64. First select the chart according to the patient's HDL level. Choose the chart section corresponding to the person's sex, diabetic status, smoking status, and age. ("Age 50" in a chart indicates the age range of 45-55 years.) Find the cell nearest to the person's blood pressure (the average of two measurements on the right arm) and value of total cholesterol. When systolic and diastolic blood pressures fall in different categories, the higher category applies. Compare the color of the cell with the risk level color key and read the predicted ten-year risk of iCVD.

For example, to estimate the 10 year iCVD risk of a 49 year old male diabetic patient who is a smoker with TC 5.2 mmol/L, HDL 1.0 mmol/L and BP 120/90 mmHg, the chart would give a color key corresponding to a 10-15% risk level for fatal and nonfatal cardiovascular event (including heart attack and stroke) over 10 years.
Chinese Ischemic Cardiovascular Risk Charts

HDL 1.04-1.56 mmol/L

Risk levels:
- CHD risk % over 10 years
  - >30%
  - 25-30%
  - 20-25%
  - 15-20%
  - 10-15%
  - 5-10%
  - 2.5-5%
  - <2.5%

**Men**

No diabetes
- Non-smoker
- Smoker

Diabetes
- Non-smoker
- Smoker

Age 60
- Blood Pressure: 180/110
- HDL: <4.1
- Total Cholesterol: 4.1-6.16
- Blood Pressure: 140/90

Age 50
- Blood Pressure: 180/110
- HDL: <4.1
- Total Cholesterol: 4.1-6.16
- Blood Pressure: 140/90

Age 40
- Blood Pressure: 180/110
- HDL: <4.1
- Total Cholesterol: 4.1-6.16
- Blood Pressure: 140/90

**Women**

No diabetes
- Non-smoker
- Smoker

Diabetes
- Non-smoker
- Smoker

Age 60
- Blood Pressure: 180/110
- HDL: <4.1
- Total Cholesterol: 4.1-6.16
- Blood Pressure: 140/90

Age 50
- Blood Pressure: 180/110
- HDL: <4.1
- Total Cholesterol: 4.1-6.16
- Blood Pressure: 140/90

Age 40
- Blood Pressure: 180/110
- HDL: <4.1
- Total Cholesterol: 4.1-6.16
- Blood Pressure: 140/90
Chinese Ischemic Cardiovascular Risk Charts

Risk level:
- CHD risk % over 10 years:
  - >30%
  - 25-30%
  - 20-25%
  - 15-20%
  - 10-15%
  - 5-10%
  - <5%
  - <2.5%

HDL > 1.56 mmol/L

Men
- No diabetes
  - Non-smoker
  - Smoker
- Diabetes
  - Non-smoker
  - Smoker

Women
- No diabetes
  - Non-smoker
  - Smoker
- Diabetes
  - Non-smoker
  - Smoker

1. This diet limits the total fat intake to less than 30% of total energy. The following proportions of fatty acids are recommended:
   - Total fat: Less than 30% of total calories
   - Saturated fatty acids (SFAs): Less than 10% of total calories
   - Polyunsaturated fatty acids (PUFAs): Up to 10% of total calories
   - Monounsaturated fatty acids (MUPAs): Remaining of 30% of total calories

2. Dietary cholesterol intake should not exceed 300 mg/day. Cholesterol rich foods are restricted. No more than 3 egg yolks per week is allowed. The amount of lean meat and fish is limited to 150g-180g (5 oz-6oz) per day.

3. Strict prohibition of seafood is not necessary. Seafood when eaten in moderation (100g or 3-4 oz/day) can be allowed in a low-cholesterol diet. Squid and cuttlefish containing high level of cholesterol should be limited and only be exchanged for egg yolk.

4. Dietary fibre, particularly soluble fibre, should be encouraged in the diet.

5. It is necessary to maintain ideal body weight by adjusting energy intake.

6. Reduce alcohol intake if it is excessive. For patients with Type V hyperlipidaemia, alcohol should be excluded.