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## Devon Primary Care Trust Effective Practice Committee Prescribing Recommendations

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**The prescribing recommendations listed were issued following  
The Effective Practice Committee Meeting held on Friday 13<sup>th</sup> March 2009**

Please note the shaded text indicates practical implementation points for primary care.

**The full set of recommendations is available on:  
Devon PCT Website - <https://www.devonpctinfo.nhs.uk/epc/>**

### 1. Update: Lipid Modification

*Revised recommendation: Effective Practice Committee lipid modification guidance*

The Effective Practice Committee has considered the following guidelines from NICE relating to lipid lowering therapy.

- NICE CG67-Lipid Modification.
- NICE TAG 94-Statins for the prevention of cardiovascular events.
- NICE CG 66- Type 2 diabetes.
- NICE TAG132- Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia.

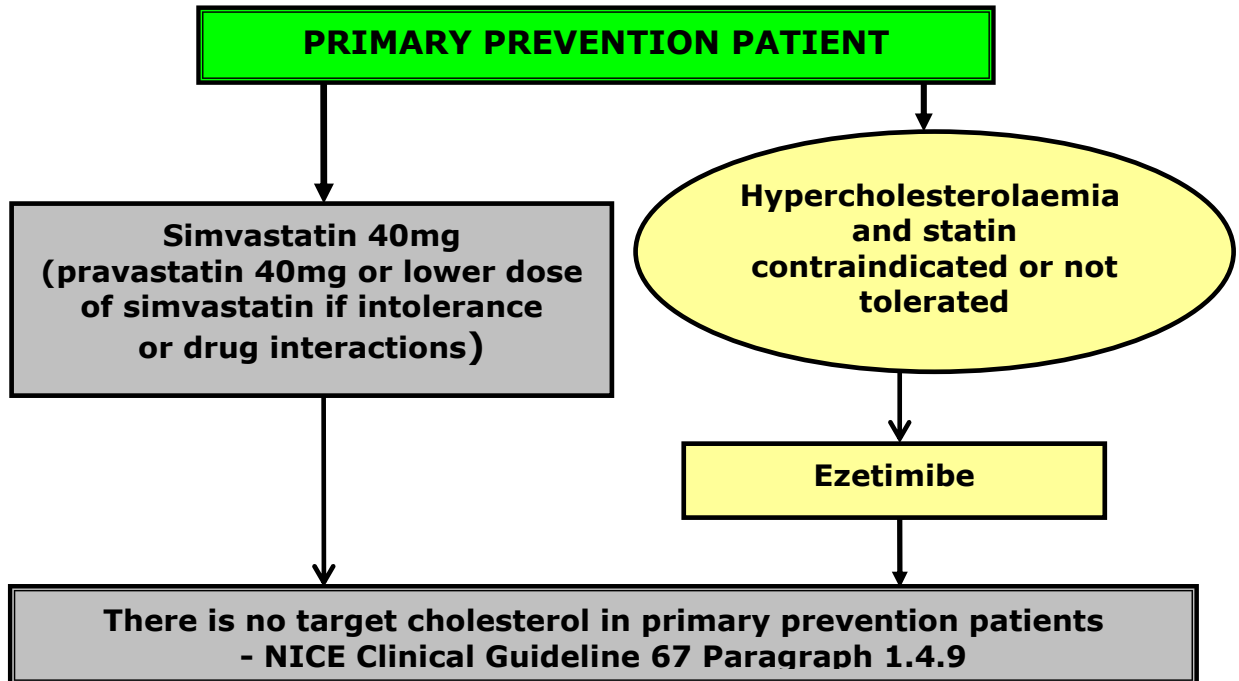
The committee note these guidelines but feel that local implementation of treatment recommendations will prove problematic. Practitioners should be conversant with these guidelines, all of which are available on the NICE website ([www.nice.nhs.uk](http://www.nice.nhs.uk)). The full guidelines contain much detail, not always adequately conveyed in the quick reference guides. They present the complexities of the issues of clinical effectiveness and cost effectiveness of the management of lipids in diverse groups of patients. The lipid modification guideline in particular may not be implemented exactly as stated by NICE. The use of drug therapy additional to that specified in this guideline was felt to be likely by clinicians attempting to reduce cholesterol concentrations to a level identified by NICE as beneficial in secondary prevention. Higher potency statins are likely to be used in particular. The committee noted that some clinicians were not content with the decision to restrict the escalation to greater potency cholesterol lowering based upon cost effective criteria. The committee advise that this will pose a substantial financial risk to the local healthcare community. The committee also note that this guidance does not address other aspects of lipid management other than cholesterol (e.g. triglycerides), despite being entitled 'lipid management'.

Despite the above misgivings the committee felt that the full lipid modification guideline contained much useful information. It presents the evidence base for reducing cholesterol in certain patient populations. This was discussed in detail which drew attention to dilemmas and subtleties contained within the guidance. The committee considered that a question and answer document reflecting the detailed discussions on these guidelines may help practitioners in their implementation of the guidelines. The following questions and answers provide appropriate guidance and explain a little of the background.

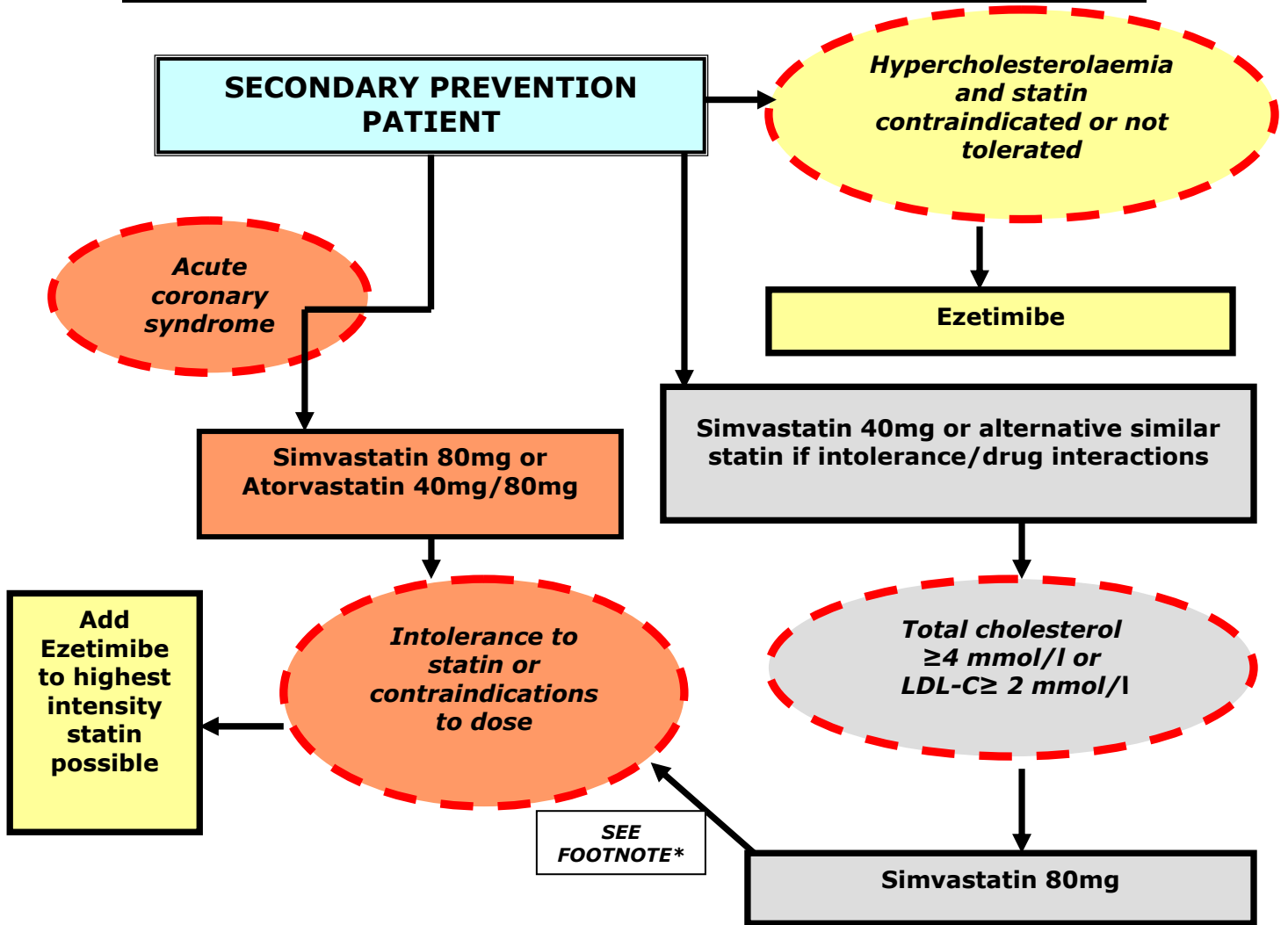
Q1. What does the guidance look like in summary

- We have produced algorithms for primary prevention, secondary prevention and type 2 diabetes

## Primary Prevention



# Secondary Prevention



**\*NICE CG67 identifies that intensification of statin therapy in secondary prevention patients should stop with simvastatin 80mg and that there are no target cholesterol concentrations expected to be achieved in all patients. The Effective Practice Committee recognise that some clinicians may wish to try an alternative statin in patients who cannot take simvastatin 80mg due to intolerance or drug interactions and recommend the use of a drug with evidence in clinical trials of a beneficial effect on CVD morbidity and mortality and of reasonable acquisition cost for this purpose, such as atorvastatin or pravastatin (if appropriate cholesterol control can be achieved).**

# Type 2 diabetes

## TYPE 2 DIABETES PATIENTS

- Age under 40 and poor CV risk profile.
- Age 40 or over and normal to high and CV risk for someone with type 2 diabetes.
- Age 40 or over and risk assessed using UKPDS risk engine as CV risk > 20% over 10 years.

**Simvastatin 40mg**  
(pravastatin 40mg or lower dose  
of simvastatin if intolerance or drug interactions)

Total cholesterol  $\geq$  4mmol/l  
(where HDL-C  $\leq$  1.4 mmol/l  
and LDL-C  $\geq$  2mmol/l)

Hypercholesterolaemia  
and statin dose  
contraindicated or not  
tolerated

Use/add  
Ezetimibe to  
maximum  
statin dose  
tolerated

**Simvastatin 80mg**

Total cholesterol  $\geq$  4mmol/l (where  
HDL-C  $\leq$  1.4 mmol/l and LDL-C  $\geq$   
2mmol/l) if there is  
existing or newly diagnosed CVD or  
increased albumin excretion rate

Consider intensifying with a more effective statin or Ezetimibe. Atorvastatin has the advantage of having been proven to reduce the risk of death/ further CV events.

**Q2. Who should be treated?**

- Primary prevention patients aged 40-74 years with >20% 10-year risk of CVD.
- Patients aged 75 years and over may be considered at increased CVD risk and likely to benefit from statins. Assessment and treatment decision should be guided by the benefits and risks of treatment, informed preference and considering any co-morbidities that may make treatment inappropriate.
- Patients with existing clinically manifest CVD.
- Type 2 diabetes patients aged under 40 with a poor CVD risk profile.
- Type 2 diabetes patients aged 40 or over with normal to high CV risk for someone with type 2 diabetes, or considered low risk but assessed at >20% over 10 years using the UKPDS risk engine (downloadable from <http://www.dtu.ox.ac.uk/index.php?maindoc=/riskengine/>)
- Patients with hypercholesterolaemia (see Q14- Effective Practice Committee recommendation for patients with familial hypercholesterolaemia).

**Q3. How should patients be identified for primary prevention?**

- Use practice held data (such as age, BP, smoking status, lipid levels) to institute a systematic strategy to prioritise those patients for whom a full risk assessment should be done.
- Conduct full assessment using risk estimators based on Framingham 1991 equations but adjust for ethnicity (multiply risk by 1.4 for a man of south Asian background), family history (multiply risk by 1.5 if one relative with premature CHD [<55 yrs in males, <65yrs in females], multiply by 2 if more than one relative affected), and socioeconomic status (take generally higher risk into account).
- If risk assessing a type 2 diabetes patient who might be considered at low risk, use the UKPDS risk engine (downloadable from <http://www.dtu.ox.ac.uk/index.php?maindoc=/riskengine/>)

**Q4. How should patients identified for primary prevention be managed?**

- Discuss lifestyle changes (diet, physical activity, smoking, alcohol).
- Use Simvastatin 40mg (use a lower dose, or pravastatin if there are drug interactions or it is not tolerated).
- Do not routinely use higher intensity statins, fibrates, anion exchange resins, fish oils, or nicotinic acid.
- Ezetimibe may be used for primary prevention in patients with primary (heterozygous-familial and non-familial) hypercholesterolaemia in patients with contraindications or intolerance to statins. NICE do not provide a specific cholesterol concentration to define hypercholesterolaemia but state the UK average total cholesterol concentration is 5.6mmol/l.

**Q5. Is there a 'target cholesterol' for primary prevention?**

- No.

**Q6. How should patients treated for secondary prevention be managed?**

- Commence simvastatin 40mg as soon as possible (use a lower dose or pravastatin if there are drug interactions or it is not tolerated).
- In patients with acute coronary syndrome use higher intensity statin, either simvastatin 80mg or atorvastatin 40mg/80mg (taking into account other therapies, co-morbidities, informed preference and risk/benefits). The clinician will need to decide on the appropriate starting dose considering the recommended start dose in the product licence and information from recent trials.

**Q7. Is there target cholesterol for secondary prevention?**

- In most secondary prevention patients there is no target cholesterol to be achieved by all patients.
- Titration to simvastatin 80 mg should occur if total cholesterol, does not fall to *below* 4mmol/l or LDL-C to *below* 2 mmol/l on standard statin therapy. It is expected that 63% of patients will not attain these low cholesterol levels despite therapy with simvastatin 80mg but NICE judge it not cost effective to intensify treatment further. An audit level of total cholesterol of 5mmol/l should be used to encourage intensification to simvastatin 80mg.
- There is specific guidance for patients with type 2 diabetes and for patients with familial hypercholesterolaemia –see also Q13 and Q14.

*An example interpretation of lipid targets/thresholds in various NICE guidelines*

Total cholesterol mmol/l	LDL-C mmol/l	Secondary prevention	Type 2 diabetes
4.1 (ie $\geq$ 4)	2.1 (ie $\geq$ 2)	Intensify	Intensify(provided HDL-C $\leq$ 1.4mmol/l)
3.9 (ie $<$ 4)	2.1 (ie $\geq$ 2)	Intensify	Do not intensify
4.1 (ie $\geq$ 4)	1.9 (ie $<$ 2)	Intensify	Do not intensify
3.9 (ie $<$ 4)	1.9 (ie $<$ 2)	Do not intensify	Do not intensify

Q8. Is there a simple way I can show patients what benefit they may gain from taking a statin?

- The National Prescribing Centre have produced a useful leaflet guide for patients, including a simple graphic representation of the magnitude of potential benefits, which clinicians may find useful when discussing lipid lowering. This is available at [http://www.npci.org.uk/therapeutics/cardio/cdlipids/resources/pda\\_Statin\\_9.pdf](http://www.npci.org.uk/therapeutics/cardio/cdlipids/resources/pda_Statin_9.pdf)

Q9. Does simvastatin 80mg carry more risks than other statins?

- Statin side effects are dose related. Myopathy rate increases from 0.08% with simvastatin 40mg to 0.53% with simvastatin 80mg. The incidence of liver enzyme rises to three times upper limit of normal increase from 0.4% to 0.9%. In general, high intensity statins have greater side effects than standard intensity whichever statin is chosen.
- NICE do not differentiate between simvastatin, atorvastatin and pravastatin on adverse events.
- NICE found increased rates of persistent elevations in liver enzymes associated with high intensity compared to standard intensity statins, but that this was not associated with clinical liver disease. Rates of myalgia were also greater with high intensity statins.

Q10. What about the use of other, non-statin, lipid lowering therapies?

- Fibrates, nicotinic acid and anion exchange resins have a role in secondary prevention patients not able to tolerate statins. These therapies also have a role in familial hypercholesterolaemia and type 2 diabetes-refer to the NICE guidelines.
- Ezetimibe may be used as monotherapy in patients with hypercholesterolaemia who cannot tolerate any statin therapy or who have contraindications. It may also be used as additional therapy in secondary prevention, type 2 diabetes, and familial hypercholesterolaemia patients who cannot tolerate dose increases in statin therapy or where the initial statin does not achieve lipid control appropriate for the relevant patient population. Whilst NICE technology appraisal 132 recommends that ezetimibe be considered in patients who need to switch statins after titration to the maximum tolerated dose of initial statin, the committee recommends using drugs for which there is appropriate trial evidence of a beneficial effect on CVD mortality or morbidity, in line with NICE clinical Guideline 67. Thus the Effective Practice Committee recommends the use of atorvastatin in such patients (or pravastatin if appropriate cholesterol control can be attained). As further trial work becomes available the range of drugs with such evidence may increase.

Q11. What is the implication if clinicians reject the NICE stance on cost effectiveness and wish to treat secondary prevention patients to a target cholesterol of 4mmol/l?

The treatment options outlined by NICE are derived from cost effective modelling applying the same criteria that NICE routinely use in decision making. If clinicians use additional therapy in pursuit of a lower target cholesterol concentration it will consume more resources and have an opportunity cost that will divert resources from more cost effective interventions.

- It more than doubles the cost and NICE consider that this not a cost effective use of resources.
- Implementing the NICE lipid modification guideline as stated by NICE is estimated to cost £2.4m. If clinicians attempt to treat all patients to a target total cholesterol of  $\leq$  4mmol/l this increases to £5m.

The key principle identified is to provide effective treatment at lowest acquisition cost. A small change in acquisition cost may result in a substantial effect on cost effectiveness and subsequent impact upon the choices made for the algorithms.

**Q12. Can clinicians choose to use higher intensity statins other than simvastatin 80mg?**

- In acute coronary syndrome NICE recommend a high intensity statin without further specification but quote simvastatin 80mg as an example. Atorvastatin 80mg is also considered cost effective in this scenario.
- For other secondary prevention patients intensification of statin therapy should be with simvastatin 80mg (or a statin of similar potency and cost-which currently does not exist) if the total cholesterol has not fallen to below 4mmol/l or LDL-C has not fallen to below 2mmol/l.
- If clinicians chose to use atorvastatin 20mg in place of simvastatin 80mg this will cost an extra £2.26m. If rosuvastatin 10mg is used this would cost an extra £1.5m.
- Rosuvastatin does not currently have clinical trial evidence of a beneficial effect on cardiovascular morbidity and mortality in patients with raised cholesterol. The newly published Jupiter study has not yet been considered in detail by the Effective Practice Committee. It has reported benefit in primary prevention patients without raised cholesterol but raised hs-CRP. It is not clear how these results should be interpreted within guidance of drug therapy to reduce cholesterol levels in routine primary care practice.

**Q13. What about patients who clinicians feel are a particularly high risk?**

- The committee were asked to consider patient groups whom local specialist opinion feels are at sufficiently increased CV risk as to warrant treatment with higher intensity statins than simvastatin 80mg if the cholesterol concentration remains above 4mmol/l. The committee noted that there is an absence of specific clinical trial data that address this question and that no conclusions on the relative benefit of applying such a policy can readily be obtained. Subgroups at highest baseline risk for a major vascular event in the Heart Protection Study were those with prior MI or CHD who also had either cerebrovascular disease or diabetes. The committee noted that NICE guidance on type 2 diabetes (CG66) recommends that clinicians consider intensifying therapy with a more effective statin than simvastatin 80mg or adding ezetimibe in patients with type 2 diabetes if there is existing or newly diagnosed cardiovascular disease, or if there is an increased albumin excretion rate, and in whom a target total cholesterol of <4mmol/l (in patients in whom the HDL-C is below 1.4mmol/l) or LDL-C <2mmol/l has not been attained. The committee note that the type 2 diabetes clinical guideline does not present data on cost effectiveness considerations of this strategy.
- The committee accept that a clinical benefit has been demonstrated using atorvastatin 80mg in the secondary prevention of stroke and TIA compared to placebo. It is unable to form a view if use would be considered cost effective by NICE compared to the recommended high intensity statin treatment of simvastatin 80mg. The committee expressed the view that to use additional ezetimibe to treat 'hypercholesterolaemia' in these patients would be less of an evidence based approach than using atorvastatin 80mg whilst incurring similar drug acquisition costs.

**Q14. What lipid lowering therapy should be used in familial hypercholesterolaemia**

The Effective Practice Committee considered the relevant NICE Guidance (CG71) and issued the following statement (November 2008).

The guidance covers the diagnosis, referral recommendations, management and drug treatment of children and adults who have raised total cholesterol concentrations (typically greater than 7.5 mmol/l).

Management in primary care includes lifestyle advice, and treatment with statins. Statins are recommended as first line treatments with the treatment goal being a 50% reduction in baseline low-density lipoprotein (LDL-C). High intensity statins or combinations with ezetimibe may be used to reach this target if required. Healthcare professionals should use cascade testing for identification of people with familial hypercholesterolaemia. Cascade testing using a combination of DNA testing and LDL-C concentration measurement is recommended to identify individuals with a clinical diagnosis of familial hypercholesterolaemia.

This guideline also provides information regarding lifestyle modification including smoking cessation, diet, physical activity, weight management and alcohol consumption. Commissioning arrangements for identification, confirmation, counselling, treatment and continued monitoring of these individuals with familial hypercholesterolaemia have yet to be determined.

**Q15 What about other lipid disorders?**

The committee notes that the lipid modification guideline does not address lipid management issues other than cholesterol (e.g. management of raised triglycerides).

**2. Clopidogrel: Potential Interaction with Proton Pump Inhibitors**

**Recommendation: Clopidogrel: potential interaction with proton pump inhibitors.**

The potential interaction between PPI and clopidogrel has been raised as a result of a publication of an observational study in the Canadian Medical Journal in January 2009. The authors of this study concluded that among patients receiving clopidogrel following acute MI, concomitant therapy with PPIs other than pantoprazole was associated with loss of the beneficial effects of clopidogrel and an increased risk of infarction. They concluded that these effects were due to inhibition of CYP2C19 by PPIs. The metabolism of clopidogrel is complex. The response to clopidogrel is influenced by a number of factors including variability in absorption, genetic polymorphisms and drug-drug interactions. The SPC for clopidogrel does not include an interaction with PPIs.

There is conflicting information as to whether PPIs interact with clopidogrel. Two observational studies have reported a significant increased risk of cardiovascular events for patients taking clopidogrel plus PPI compared with clopidogrel without PPI. The authors of the Canadian Medical Journal study recommended pantoprazole as the PPI of choice for patients taking clopidogrel. However, the analysis supporting this recommendation was not sound and may also have been influenced by small numbers of cases. The second observational study published in the JAMA provided data on individual risk for only two PPIs. There is conflicting data from a further observational study and posthoc analysis of a RCT. Data from mechanistic studies are not directly comparable but show a possible attenuation of effect for clopidogrel in patients taking omeprazole but not for pantoprazole or esomeprazole.

Much of the evidence reported to date comes from observational studies which are prone to confounding and do not confirm causality. A RCT randomizing patients with coronary artery disease to clopidogrel and aspirin plus omeprazole or placebo is being undertaken and should provide more robust data. In addition, a safety review of clopidogrel is being undertaken by a regulatory authority.



**PRIMARY CARE**



Implication for prescribers is that the evidence to date for an interaction is conflicting and there is no clear direction from the findings of the studies presented in this review. A pragmatic approach whilst waiting for the outcome of the regulatory authority review would be to prescribe a PPI for patients taking clopidogrel who have gastric pathology and are at risk of gastrointestinal haemorrhage but to avoid prescribing a PPI routinely for prophylaxis. PPI choice is unclear and should remain as defined in Joint Formulary choices.

### 3. Aliskiren in the Treatment of Hypertension.

#### Recommendation: Aliskiren in the treatment of hypertension.

Aliskiren is a direct inhibitor of renin. It is licensed for the treatment of adults with essential hypertension at a dose of 150-300mg daily either as monotherapy or in combination with other antihypertensive drugs. Meals high in fat can reduce absorption. In short term trials conducted in patients with mild to moderate essential hypertension and generally without cardiovascular co-morbidities the antihypertensive effect of aliskiren is generally comparable with ACEs and ARBs. One study has been conducted in patients with diabetic nephropathy and optimally controlled hypertension but this was only six months duration. Aliskiren decreased proteinuria to a greater extent than losartan but a long term study is required to determine whether the beneficial effects are sustained. There is no published data on the long-term use of aliskiren or its effect on cardiovascular outcomes and it is more expensive than many other antihypertensive drugs. Angioedema may occur with the use of aliskiren and it should not be used in patients who have previously had angioedema after using it. Aliskiren should be used with caution in patients taking NSAIDs, or in patients who may be at increased risk of acute renal failure such as patients with renal artery stenosis or with risk factors for renal dysfunction. Verapamil interacts with aliskiren - concomitant use is contraindicated.



#### PRIMARY CARE



There is currently no role for aliskiren in the treatment of hypertension other than for a minority of patients with resistant hypertension, in whom no other agents were found to be effective, in which case aliskiren would be initiated in secondary care only.

### 4. Aspirin for primary prevention of CVD in patients with diabetes.

#### Recommendation: Aspirin for primary prevention of cardiovascular disease in patients with diabetes

Aspirin has well-proven benefits in the secondary prevention of cardiovascular disease. It remains unclear, however, whether patients with diabetes without a history of vascular disease are at sufficient risk of vascular disease for the benefits of aspirin to outweigh the risks. This uncertainty has been reinforced by two recent trials. The Prevention of Progression of Arterial Disease and Diabetes (POPADAD) study (BMJ 2008) in which the annual event rate was well below the expected event rate resulting in a study which was underpowered to detect a plausible treatment effect. The Japanese Primary prevention of atherosclerosis with Aspirin for Diabetes (JPAD) study (JAMA 2008) was too small to provide a definitive answer. NICE acknowledge that their recommendation to prescribe aspirin for primary prevention of cardiovascular disease given in the Clinical Guidance on type 2 diabetes (CG66) was arbitrary and there was a lack of strong evidence to support their decision.



#### PRIMARY CARE



Local advice for GPs who have patients with diabetes currently taking aspirin for primary prevention is to continue treatment unless the patient wishes to stop or there are other clinical concerns. For new patients, the recommendation is for GPs to discuss with the patient what the common practice is currently and offer the patient the choice of whether to be treated with aspirin for primary prevention of cardiovascular disease or not until further evidence informs clinical practice.

## 5. Aspirin for primary prevention of CVD in patients with diabetes (continued).

### Amended statement - NICE Clinical Guideline CG66 Type 2 diabetes - The management of type 2 diabetes.

NICE Clinical Guideline 66 Type 2 diabetes: the management of type 2 diabetes (update) has revised its guidance on the management of type 2 diabetes from 2002, incorporating updates to technology appraisals published since then.

Key points and changes from earlier guidance include:

- Offer structured education to every person and/or their carer at and around the time of diagnosis, with annual reinforcement and review. This should be delivered through for example the diabetes education and self-management for ongoing and newly diagnosed (DESMOND) programme.
- Provide individualised and ongoing specialist nutritional advice.
- Involve the person in decisions about their individual HbA1c target level, which may be above that of 6.5% set for people with type 2 diabetes (T2DM) in general.
- Self-monitoring of blood glucose should be offered to a patient newly diagnosed with T2DM only as an integral part of his/her self-management education. Its purpose should be discussed and there should be agreement how the results should be interpreted and acted upon.
- Use aspirin 75 mg in higher-risk patients and those aged 50 and older, whose blood pressure is less than 145/90 mmHg. Clopidogrel is an alternative only in those with clear aspirin intolerance.

NICE acknowledge that this advice is not based upon conclusive evidence of benefit in type 2 diabetes patients treated for primary prevention. The Effective Practice Committee considered the use of antiplatelets in type 2 diabetes – please look at the statement ‘aspirin for primary prevention of cardiovascular disease in patients with diabetes’.

- Metformin is the first-choice oral hypoglycaemic in overweight patients and may be considered in the non-overweight.
- Sulphonylureas of a low acquisition cost (but not glibenclamide) may be considered in the non-overweight, or if metformin is contraindicated or not tolerated. Once daily, long acting sulphonylureas may be offered if drug concordance is a problem.
- Glitazones are third-line, as dual therapy or triple therapy with metformin and/or a sulphonylurea if HbA1c targets are not reached, but note the cardiovascular and higher risk fracture concerns relating to glitazones.
- Exenatide is not recommended for routine use but an option if body mass over 35 kg/m<sup>2</sup> and inadequate blood glucose control (HbA 1c  $\geq$  7.5%). Exenatide should be continued only if there is at least a 1% reduction in HbA1c at 6 months and a weight loss of at least 5% at 1 year and that these metabolic responses are maintained.
- When starting basal insulin therapy continue with metformin and the sulphonylurea (and acarbose if used). Insulin therapy should be initiated from a choice of a number of insulin types and regimens.
- First-choice antihypertensive drug is a once-daily generic ACE-inhibitor (plus a diuretic and/or calcium channel blocker in people of African-Caribbean descent or in people whose blood pressure is not controlled to target on monotherapy) with other drugs added as needed. A calcium channel blocker is recommended for women who may become pregnant. Substitute with angiotensin 2 receptor antagonist for the ACE inhibitor if intolerant to ACE inhibitor (other than renal deterioration or hyperkalaemia).
- Initiate generic simvastatin 40 mg for most people aged 40 or older (unless their 10-year cardiovascular disease (CVD) risk has been estimated at less than 20%), and younger people if their CV risk factor profile seems particularly poor. Increase the dose to 80 mg if a total cholesterol of less than 4 mmol/L or LDL-cholesterol of less than 2 mmol/L is not attained. Aim for these targets by changing statin or adding ezetimibe if there is new or existing CV disease or increased albumin excretion.
- Screen for eye and kidney damage annually.

### Amended statement - NICE Clinical Guideline CG66 Type 2 diabetes- The management of type 2 diabetes (continued).

NICE also includes advice on management of depression, nerve damage, diabetic neuropathic pain, gastroparesis, erectile dysfunction and other aspects of autonomic neuropathy. Locally it was noted that there was limited structured education and dietary advice available for newly diagnosed diabetics which needed to be addressed by the commissioning arrangements of the PCT. The Committee noted that the continuation of the sulphonylurea with metformin on the initiation of basal insulin therapy should only be prescribed if there was evidence of endogenous pancreatic function. Consideration could be given to adding a proton pump inhibitor to aspirin if in higher-risk patients and those aged 50 and older, whose blood pressure is less than 145/90 mmHg who are intolerant to aspirin, prior to starting clopidogrel.

## 6. NICE CG 76: Medicines Adherence - Involving Patients in Decisions About Prescribed Medicines and Supporting Adherence.

### Recommendation: NICE clinical guideline 76 Medicines Adherence.

This guidance offers best practice advice on how to involve patients in decisions about prescribed medicines and how to support adherence. It also recommends that the initial decision to prescribe medicines, the patient's experience of using the medicines and the patient's needs for adherence support should be reviewed regularly. Healthcare professionals involved in prescribing, dispensing or reviewing medicines should ensure that there are robust processes for communicating effectively with other healthcare professionals involved in a patient's care particularly when patient care is transferred and when medicines reviews are carried out.

The guidance has the potential to impact key areas of medicine management, such as prescribing, dispensing, patient understanding of their medication, medicines waste and patient safety. Improving and encouraging a partnership approach to medicines taking will help to improve these areas and others, resulting in a medication regimen that is more likely to be adhered to by the patient. It will help patients make informed decisions about their medication to use appropriate treatment to best effect. Adherence to therapies averages between a third and a half for medicines prescribed for long term conditions. Medicines adherence is defined as the extent to which the patient's action matches the agreed recommendations.

## 7. Revision of the Effective Practice Committee recommendation- erectile dysfunction therapies.

### Recommendation: Erectile dysfunction therapies

Only men suffering from one of the specified medical conditions outlined in HSC 1999/148 and HSC 199/177 are eligible to receive treatments for erectile dysfunction on the NHS. These are men with erectile dysfunction due to:

- Having diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis, prostate cancer, severe pelvic injury, single gene neurological disease, spina bifida or spinal cord injury.
- Receiving dialysis for renal failure.
- Have had radical pelvic surgery, prostatectomy (including transurethral resection of the prostate) or kidney transplant.
- Were receiving Caverject®, Erecnos®, MUSE®, Viagra® or Viridal® for erectile dysfunction at the expense of the NHS on the 14 September 1998.
- Are suffering severe distress as a result of impotence.

In all other cases impotence treatment should be provided by private prescription from the patients GP. With regard to HSC, 199/177, GPs are advised that no patient should be referred to secondary care psychiatric services, if the basis of the referral is just 'severe distress caused by impotence'. It is expected that patients will be referred to secondary care psychiatric services only if their general condition warrants a referral and impotence is but one feature of their condition.

Oral agents: Phosphodiesterase type-5 inhibitors (PDE5) – Where a PDE5 is indicated, sildenafil remains the first choice agent. Tadalafil and vardenafil can be considered as second line options for men who would benefit from a longer duration of action. A trial of therapy should consist of 12 doses to assess efficacy. It is preferable to start with a high dose and titrate downwards. When these oral treatments were first introduced they were intended to be taken prior to anticipated sexual activity and not for continuous daily use. Recently tadalafil 2.5mg and 5mg (Cialis Once-A-Day®) has become available. This is designed to be taken as a daily regimen in men who have responded to the on-demand regimen, and who have intercourse more than once a week. Cialis Once-A-day® may be a suitable choice in that small number of patients requiring phosphodiesterase type-5 inhibitors more than twice a week, upon discussion of risk and benefits with the patient. The appropriateness of continued use of daily regimen should be assessed periodically.

Vacuum devices: Vacuum devices are a very cost-effective option for the management of erectile dysfunction, but only if tested in specialist clinic first to assess acceptability. Once found to be an acceptable option to the patient, the device could be prescribed in primary care. The use of vacuum devices may be particularly beneficial for elderly patients or men who have had a radical prostatectomy or who have diabetes. They have been found to be less acceptable to men with serious spinal injury. Men who are taking anticoagulants should not use vacuum devices.

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Endorsed by: The Devon Primary Care Trust Effective Practice  
Committee on Friday 22<sup>nd</sup> May 2009

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