

NICE statins guidance will save lives but leaves room for improvement



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On 24 January 2006, the National Institute for Health and Clinical Excellence (NICE; formerly the National Institute for Clinical Excellence) published its highly anticipated Technology Appraisal on statins for the prevention of cardiovascular events (NICE, 2006; see *Table 5* on page 18). This guidance, which recommends the use of statins to reduce the risks of heart attacks and strokes, means that more than 3 million new patients will benefit from this treatment. Most importantly for people with diabetes, it highlights their increased risk of developing cardiovascular disease (CVD) and reaffirms the need for clinicians to consider using statin therapy for all individuals with diabetes (both type 1 and type 2).

Initially envisioned as a Technology Appraisal on the prevention of coronary events, the document's scope was expanded to include cardiovascular events owing to the existence of substantial clinical evidence to support the benefit of statin treatment in reducing strokes and peripheral vascular disease as well as coronary events (e.g. Sever et al, 2003).

In many ways, the NICE guidance is the latest step forward in the Government's drive to reduce the national burden of diabetes, which began with the publication of the National Service Framework (NSF) for diabetes in 2001 (Department of Health, 2001). The NSF, which set out the first ever series of national standards for the treatment of diabetes in the UK, states that:

'reducing cholesterol levels in people with diabetes who have raised cholesterol levels may reduce their risk of CVD.'

Since the NSF, an overwhelming body of evidence gathered from primary prevention studies involving people with type 2 diabetes, such as the Collaborative Atorvastatin Diabetes Study (CARDS; Colhoun et al, 2004) and the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT; Sever et al, 2003), has shown that these individuals face a higher absolute risk of CVD than those without diabetes. This thinking

has been accepted by NICE and reflected in the guidance, which states that all patients with diabetes should be considered for treatment with a statin. For the general population, the guidance recommends that statins be used either where there is clinical evidence of CVD or where the risk of an individual developing CVD within 10 years is estimated to be 20% or greater.

The NICE guidance echoes the recently published Joint British Societies' guidelines on prevention of cardiovascular disease in clinical practice (JBS 2; British Cardiac Society et al, 2005), which state that most patients with type 1 and type 2 diabetes (that is, everyone over 40 years of age and anyone between 18 and 39 with at least one complication) should be on a statin.

I am confident that increased access to statins will lead to thousands more lives being saved. However, it is a shame that NICE did not take that extra step to emphasise the importance of treating patients to clinically recognised cholesterol targets, once they have been started on a statin. Based on evidence showing that the greater the reduction of low-density lipoprotein (LDL)-cholesterol, the greater the reduction in cardiovascular (CV) risk (Baigent et al, 2005), the JBS-2 guidelines recommend that clinicians aim to get high-risk patients down to a total cholesterol target of 4.0 mmol/l and an LDL-cholesterol target of 2.0 mmol/l.

NICE also fails to acknowledge that statins differ in terms of their potency, side effects, half-lives and contraindications. It is important that these differences are taken into account when deciding which statin to use for each individual. Ignoring cholesterol targets and the properties of different statins could mean that patients remain at greater CV risk for longer than is necessary.

Conclusion

Although it is encouraging that NICE has accepted that people with diabetes are at increased risk of CV events, I would like to see the next set of guidance acknowledge the importance of clinically recognised cholesterol targets and their role in the prevention of heart attacks and strokes. ■

Baigent C, Keech A, Kearney PM et al (2005) Efficacy and safety of cholesterol-lowering treatment. *Lancet* **366**(9493): 1267–78

British Cardiac Society et al (2005) JBS 2. *Heart* **91**(Suppl 5): v1–v52

Colhoun HM, Betteridge DJ, Durrington PN et al (2004) Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS). *Lancet* **364**(9435): 685–96

Department of Health (DoH; 2001) *National Service Framework for Diabetes: Standards*. DoH, London

National Institute for Health and Clinical Excellence (NICE; 2006) *Statins for the prevention of cardiovascular events in patients at increased risk of developing cardiovascular disease or those with established cardiovascular disease*. NICE, London

Sever PS, Dahlof B, Poulter NR et al (2003) Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower-than-average cholesterol concentrations. *Lancet* **361**(9364): 1149–58

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