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Type 2 diabetes is cardiovascular disease

Neurologists are trying to convince generalists to avoid the term cerebrovascular accident, because many of the risk factors for stroke are modifiable: to regard the condition as an act of fate encourages inertia rather than the necessary aggressive approach including rapid brain scanning and thrombolysis in selected cases.¹ Just as in myocardial infarction 'time is muscle', with an intracerebral event 'time is brain'. The term 'brain attack' serves to remind clinicians that intervention is required long before the 24 hours required for formal definition of a stroke.²

Generalists now have to be persuaded that an equally focused and aggressive approach is required in diabetes mellitus. The day of 'wait and see' is past, and the term mild diabetes should be buried forever. Gaining ground is the idea that diabetes mellitus (especially type 2 diabetes) is a 'state of accelerated cardiovascular disease that just happens to be associated with hyperglycaemia'. People with type 2 diabetes are between two and six times more likely than those without diabetes to have cardiovascular disease and are more than twice as likely to die from it.^{3,4} Among diabetologists there is a widely held belief that cardiovascular risk reduction should take precedence over reduction of blood glucose.

Whereas in type 1 diabetes the diagnosis is usually made quickly, in type 2 diabetes the patient will probably have had the disorder for 4-7 years before being formally diagnosed.⁵ Moreover, at the time of diagnosis as many as one fifth will prove to have other risk factors for cardiovascular disease modifiable by lifestyle changes or pharmacological treatment or both.^{7,8} There is now ample evidence that aspirin,^{9,10} statins,^{11,12} and angiotensin converting enzyme (ACE) inhibitors¹³ reduce the risk of death from cardiovascular disease in diabetes. Gaede and co-workers¹⁴ lately reported that, compared with 'standard care', an intensive combination of behavioural and pharmaceutical interventions in type 2 diabetes reduced the incidence of cardiovascular disease by 53%, nephropathy by 61%, retinopathy by 58% and autonomic neuropathy by 73% over a mean follow-up of 7.8 years. Today, when a person with diabetes is found to have any cardiovascular risk factor at all, there should be a good reason why they should *not* be on aspirin, a statin and an

ACE inhibitor ('aspartatapril'). Because hypertension and hypertriglyceridaemia are also widely prevalent in people with type 2 diabetes, beta blockade and fibrates may have to be added.^{15,16} These results are separate from the benefits of tight blood glucose control seen in both type 1 and type 2 diabetes.^{17,18} With epidemiological and interventional data showing that the lower the blood pressure or glucose the lower the morbidity and mortality from the complications of diabetes, target values for these indices are being revised downwards.^{19,20}

This aggressive approach is not just for primary prevention. It applies also to people who have already had a cardiovascular event, and the benefits in those with diabetes seem even more impressive than in those without.⁹ There is, of course, a down-side to this aggressive treatment. Hypoglycaemia is a hazard of intensive regimens to lower blood glucose,^{17,18} aspirin can cause gastrointestinal haemorrhage, statin therapy (especially in combination with fibrates) can result in myalgias, and ACE inhibitors can impair renal function. All these risks, however, can be limited by individual tailoring of treatment and close follow-up.^{13,21,22} The emerging epidemic of diabetes²³ demands a vigorous clinical counter-attack if its consequences are not to overwhelm our health systems.

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Rationing treatment on the NHS—still a political issue

Hard choices have to be made about how the National Health Service spends its limited budget. The Government established the National Institute for Clinical Excellence (NICE) to examine interventions and advise on whether and to what extent they should be made available. The approach is explicitly technical with the recommendation depending on health gain, measured where possible as the number of quality adjusted life years (QALYs), in relation to the cost. However, as Smith has noted, there is more to rationing than simple technical considerations.² Values also play a part, as they did in 1999 when a previous Health Secretary, faced with the potential consequences of the anti-impotence drug Viagra (sildenafil) for the allocation of funds in the NHS, issued guidance that it could only be prescribed for men with a specified list of disorders or after specialist assessment. This action was highly controversial.³ The European Union Transparency Directive⁴ says that any exclusion of a drug from a national health system requires a statement of reasons based on objective and verifiable criteria. Viagra's manufacturer, Pfizer Ltd, successfully

challenged this decision in the English High Court.⁵ The court ruled on the basis of European law that a breach of the Transparency Directive had occurred as the Health Secretary had given no reasons based on objective and verifiable criteria. The court also expressed concern about the implications of the decision for clinical freedom.

In response to the ruling the Health Secretary issued new advice, which effectively restated the earlier restrictions but emphasized that they were simply advisory. This conceded that there were limits to the power of the Health Secretary to determine what the NHS would cover where, as with Viagra, detailed assessments of cost utility had not been undertaken. However, even this more limited position was challenged by Pfizer, again on the basis of the Transparency Directive. Pfizer argued that decisions about what to fund could be made on the basis of comparative cost-utility analysis, comparisons of health gain from interventions in different disease areas, and even specified a method for assessing utilities (contingent valuation). While this may at one level be seen simply as an attack on the basis for the Health Secretary's decision, it has wider ramifications because it indicates that the pharmaceutical industry may have conceded the value of the so-called fourth hurdle to which it had previously been opposed namely, the requirement to show that new