

In the US providers have not been compelled to spend the extra money they receive for higher dependency patients on patient care. Nor have they been required to maintain higher levels of staffing: in US long term care settings 37% of expenditure is on staff; in the NHS the figure is 65%.<sup>8,9</sup> The US experience also shows how tying reimbursement to levels of disability can provide perverse incentives for homes to accept residents who are more disabled and allow them to become more so.<sup>10</sup> A similar picture is emerging in Australia.<sup>11</sup> Before 1997 a set percentage of the funding received by care home owners had to be spent on care and could not be diverted to non-care staff, capital maintenance, or profit. This requirement was removed in 1997, and staffing levels have since fallen, with experienced nurses being replaced by those who are less costly to employ. This has led to scandals about the quality of care and claims by the Australian Nursing Federation that the industry is facing a quality of care crisis.<sup>12</sup>

A government committed to a universal, comprehensive, high quality NHS would not embark on this path. It would restore the risk pooling model of universal provision by bringing the nursing and care elements of the workforce in the private sector under NHS control. This would bring it into line with its policies for the rest of the NHS, where under the private

finance initiative bricks and mortar are owned and operated by the private sector but clinical services remain under the control of the NHS.

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## Controlling glucose and blood pressure in type 2 diabetes

### *Starting treatment earlier may reduce complications*

Strategies for treating disorders of public health interest such as high blood pressure, dyslipidaemia, and hyperglycaemia have been debated ever since they were considered to be conditions for medical interventions. The main questions have been when should we start treatment, what is the target level during treatment, and what is the best method of treatment? Since there are no obvious cut-off points for blood pressure or glucose or cholesterol concentrations that would guide clinical decisions, the justification must come from clinical and epidemiological research.

Data from randomised clinical trials are considered necessary these days for defining treatment practice, but there are limits on the generalisability of their results.<sup>1</sup> These results are important in proving causality between risk factors and outcomes and in showing the reversibility of the disease process by therapy. Observational data, on the other hand, are needed to describe the target population included in the trials and thus to inform doctors how the trial results may be best translated to the community. This is particularly important for defining treatment strategies in disorders where many patients are asymptomatic, such as type 2 diabetes, hypertension, and dyslipidaemia.

The evidence from previous clinical trials has established that it is beneficial to treat hypertension and hypercholesterolaemia.<sup>2,3</sup> Only recently have the results of randomised controlled trials shown the ben-

efit of reducing blood pressure in isolated systolic hypertension.<sup>4,5</sup> Comparisons with observational data have shown, for instance, that antihypertensive drugs reduce the risk of stroke as predicted, but the reduction in the risk of myocardial infarction is less than expected.<sup>2</sup> Treatment of hypercholesterolaemia with statins reduces the risk of myocardial infarction as predicted, whereas the effect on the risk of stroke seems to be larger than expected.<sup>6</sup>

The good news from the United Kingdom prospective diabetes study (UKPDS) in this week's *BMJ* (p 412) is that patients with type 2 diabetes whose hypertension is tightly controlled reduce their risk of macrovascular complications to a greater extent than estimated by observational analysis.<sup>7</sup> Also, in the Systolic Hypertension in Europe trial antihypertensive treatment in patients with diabetes with isolated systolic hypertension got rid of their excess cardiovascular risk related to diabetes.<sup>8</sup>

There are recommendations about the target levels for glycaemia, blood pressure, and lipids in the treatment of patients with type 2 diabetes.<sup>9</sup> These are based largely on expert opinions, with only limited evidence from trials. The degree to which these target levels can be reached depends mainly on two factors: the intensity of treatment and the level of these variables at the start of treatment. The epidemiological data clearly show that there are no natural thresholds under which the risk of microvascular and macrovascu-

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lar complications in diabetes are fully prevented, but the risk increases steadily with rising levels of risk factors. The new analysis of the UKPDS data confirms this notion for both glycaemia and blood pressure.<sup>7-10</sup> The findings from the observational analysis and the trial effects are concordant, which is reassuring and emphasises the need for more effective control of glucose concentrations and blood pressure in patients with type 2 diabetes. The lower the level of blood glucose, HbA<sub>1c</sub>, or blood pressure, the lower the risk of complications. Thus, artificial target levels are not necessarily useful since they may sometimes incorrectly lead both patients and physicians to think that reaching such levels fully protects against late complications of diabetes.

We know that it is difficult to maintain reductions in glucose concentrations and blood pressure even when using multiple pharmacological agents that in short term trials have produced excellent results. This was also confirmed in the UKPDS. Thus, the alternative possibility would be to start treatment at lower levels than those currently used as thresholds. The guidelines for antihypertensive treatment have been drastically shifted in this direction over the past decades.<sup>11</sup> Guidelines for the treatment of hyperglycaemia should be also evaluated from this perspective.

Disappointing results from lowering high concentrations of blood glucose may be due to the use of inappropriate diagnostic tests. A large European epidemiological study showed that the postprandial glucose concentration is a better predictor of mortality than is fasting glucose.<sup>12</sup> Mortality was already increased in people with impaired glucose tolerance. The present UKPDS data show that the lower the concentration of glucose the lower risk of complications.<sup>11</sup> Therefore, we must seriously ask whether treatment to lower raised blood glucose should be started much earlier. Perhaps impaired glucose tolerance should be

an indication for treatment. There is a need to carry out controlled clinical trials to find out whether lowering glucose concentrations at the levels of impaired glucose tolerance will reduce microvascular and macrovascular complications.

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## Herbal medicines: where is the evidence?

*Growing evidence of effectiveness is counterbalanced by inadequate regulation*

Sales of herbal medicines are booming. This is particularly true in the United States, where the market for herbal supplements is now approaching \$4bn a year. The fastest growth has been recorded for St John's wort, a herbal antidepressant whose sales increased in one year by 2800%.<sup>1</sup> Faced with such figures doctors are inclined to ask where the evidence is. Are there rigorous trials to show that herbal treatments work?

Single studies are unlikely to convince sceptics, but an increasing body of evidence is now emerging from systematic reviews and meta-analyses of randomised clinical trials. These suggest that some herbal medicines are efficacious. The increased demand for St John's wort, for instance, was triggered by press reports of a meta-analysis of 23 randomised trials of 1757 patients with mild or moderate depression. The authors concluded that extracts of hypericum were significantly more effective than placebo (odds ratio 2.67; 95% confidence interval 1.78 to 4.01) and as effective as

conventional antidepressants (odds ratio 1.10; 93 to 1.31) in alleviating the symptoms of mild to moderate depression.<sup>2</sup> Since this article was published, at least nine further randomised trials have appeared, all of which confirm the efficacy of this herbal antidepressant.<sup>3</sup>

Systematic analyses of other herbal medicines followed and drew similarly positive conclusions. A review of all nine placebo controlled, double blind randomised trials of ginkgo biloba for dementia, covering 1497 patients, showed that ginkgo was more effective than placebo in delaying the clinical course of dementia.<sup>4</sup> A meta-analysis of 18 randomised controlled trials (2939 patients) of saw palmetto as a symptomatic treatment for benign prostate hyperplasia showed that it improved urological symptoms and flow measures significantly more than placebo.<sup>5</sup> Saw palmetto was as effective as finasteride and had fewer adverse effects. A systematic review of horse chestnut seed extracts for chronic venous insufficiency included eight placebo controlled and five comparative randomised trials with a

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A full list of systematic reviews of trials of herbal medicines appears on the BMJ's website

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