

## Editorials

# In pursuit of normoglycaemia:

the overtreatment of type 2 diabetes in general practice

The prevalence of type 2 diabetes is rising each year,<sup>1</sup> with the World Health Organization warning of an emerging global epidemic. The number of people with diabetes at my practice has increased by 36% in the past 5 years. More than 1 in 20 of the practice population now have a diagnosis of diabetes, and about 75% are aged  $\geq 60$  years. The cost of treating these extra patients is rising too. In 2013–2014 in England we spent over £800 million on items prescribed to lower and monitor blood glucose,<sup>2</sup> and in addition there are the costs associated with extra consultations in primary and secondary care. It would be good to know that this was money well spent.

### DIABETES AS A RISK FACTOR

Raised blood glucose is just one component of a complex assortment of metabolic abnormalities in this thing we call type 2 diabetes, and with the laboratory standardisation of HbA1c, this surrogate has proved a convenient tool for easy diagnosis and the monitoring of blood glucose levels. Most people I see with a new diagnosis of type 2 diabetes have no symptoms. They will have had a simple blood sample taken for HbA1c, usually as a consequence of ad hoc screening, instead of the palaver of a glucose tolerance test to see where they lie along the continuum of glucose metabolism. If they pass an arbitrary threshold they turn overnight into a patient with a diagnosis. What has really happened is that a risk factor has been identified. The UK Prospective Diabetes Study (UKPDS) observational study showed that poor levels of diabetic control, as measured by HbA1c, are associated with an increased risk of macrovascular and especially microvascular complications.<sup>3</sup> HbA1c joins cholesterol and blood pressure as continuous biological variables whose level can be used to predict the risk of future events. The UKPDS risk engine can be used to calculate the risk of future cardiovascular disease in people with diabetes depending on their HbA1c level. The leap of faith is that any drug that lowers HbA1c also lowers the risk.

### THE CURSE OF CODING AND THE TYRANNY OF TARGETS

Clinical records in general practice are almost totally computerised, and

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information is recorded as Read Codes, which have come to dominate our lives. Before computerisation, patients could be managed in a way that reflected the uncertainty of diagnosis and the complexities of the human condition. A patient who only just crossed an arbitrary diagnostic threshold could be managed less aggressively than others. There is no uncertainty with a Read Code. You either have it or you do not, and if you have the Read Code for type 2 diabetes, since 2004 both you and your GP are managed according to the rules of the Quality and Outcomes Framework (QOF). We receive financial incentives for diagnosing more cases and for meeting targets, including blood pressure, cholesterol, and HbA1c levels. Our diabetic QOF scores are in the public domain and have formed part of the array of performance management indicators, including the Care Quality Commission's Intelligent Monitoring report. This report assigned practices to one of six bands based on an amalgamation of publicly-available practice-specific data. The banding process needed to be revised once because of flaws in the methodology and has now been withdrawn. There are three QOF indicators related to targets for lowering HbA1c. Initially the lower target was set at 7.5% (59 mmol/mol), the assumption being that the lower the HbA1c the lower the risk of complications. This target was lowered to 7.0% (53 mmol/mol) in 2009, but cracks had already opened up in this glucocentric approach to diabetes in 2008 with the publication of the ACCORD study that failed to demonstrate an improvement in cardiovascular outcomes with intensive

control in older patients, and in fact showed an increase in mortality rate.<sup>4</sup> Later that year the ADVANCE study also failed to show a cardiovascular benefit,<sup>5</sup> and I expected that the QOF target would be quickly relaxed to reflect this. It was not, despite calls for a change,<sup>6</sup> and as time went on the VADT trial gave the same result.<sup>7</sup> A large retrospective cohort study in 2010 showed an increase in all cause mortality at HbA1c levels  $< 7.5\%$ .<sup>8</sup> I found it bewildering to continue to be pressurised to act contrary to the evidence by a system supposedly concerned with quality. It was not until April 2011 that the QOF target returned to 7.5%, although before this GPs may actually have been receiving financial incentives to harm their patients. National Institute for Health and Care Excellence (NICE) guidelines<sup>9</sup> still recommend adding in an extra drug in addition to metformin to reach a target of 6.5% (48 mmol/mol), or other agreed target, although in the new draft guidelines<sup>10</sup> this figure is relaxed to 7.0% if the lower target is not reached with a single drug. It is difficult not to lose confidence in the clinical appropriateness of targets set by QOF and NICE.

### THE DRIVE FOR NORMOGLYCAEMIA AS A MARKETING OPPORTUNITY

Most of the effort in diabetes care now relates to driving down HbA1c levels, although other risk factors such as blood pressure and cholesterol level appear to be much more worthwhile targets when it comes to reducing cardiovascular risk.<sup>11</sup> Antihypertensives and statins are easier to use and do not have the effects of weight gain and hypoglycaemia that sulphonylureas

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and insulin have, nor do they demand daily blood monitoring. Blood pressure and cholesterol are established cardiovascular risk factors that can be managed with cheap and effective generic drugs. HbA1c is not so easy, so for the pharmaceutical industry, glycaemia has moved into the spotlight with opportunities to promote to a growing market an increasing range of new and expensive drugs on the grounds that they lower glucose levels. It is virtually impossible to open a medical magazine now without coming across an advertisement for a medication that promises to reduce HbA1c. To help GPs meet their targets, the pharmaceutical industry generously funds 'educational' meetings and initiatives to promote 'good practice', as they used to do for statins before these drugs became available as generics. They support specialist diabetic nurses in secondary care. No other risk factor is privileged to receive so much attention. Practice nurses, who are now often responsible for much of the chronic disease management, are fair game for the manufacturers of blood glucose testing strips who compete for a market currently worth £172 million in England.<sup>2</sup>

### UNKNOWN RISKS AND BENEFITS

I have no idea whether these drugs will benefit my patients at all, and I feel uncomfortable about prescribing them. Following the withdrawal of rosiglitazone, because of concerns that it lowered HbA1c but increased cardiovascular risk, the US Food and Drug Administration requires new drugs to demonstrate short-term cardiovascular safety but, as yet, there is no evidence that the modest reductions in HbA1c have any clinically-meaningful benefit, or that there are no significant harms. Every now and then there are rumblings about new side effects such as pancreatitis or bladder cancer.<sup>12</sup>

Because the treatment burdens of glucose-lowering therapies are significant, and the limited benefits take a long time to accrue, a recent study<sup>13</sup> modelled the benefits of glucose-lowering compared to the reduction in quality of life from treatments. It concluded that for patients

aged  $\geq 50$  years, efforts to reduce the HbA1c below 9% (75 mmol/mol) may not be worthwhile. This conclusion depends to a large extent on the patient's view of the inconvenience of treatment, but patients are rarely given the opportunity or the freedom to make a genuine choice. They are more concerned about quality of life, heart attacks, and strokes than microvascular changes.

Surely it is time to devote our limited resources to helping younger patients and those with very high HbA1c levels. In older patients we should be avoiding overtreatment by concentrating on established risk factors rather than trying to drive down the HbA1c just that little bit more with expensive drugs which have little or no proven clinical benefit and uncertain risks.

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