The role of evidence-based medicine in NICE's new guideline

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The term 'evidence-based medicine' was coined in 1992 by Gordon Guyatt and colleagues at McMaster University, Ontario (Guyatt et al, 1992). The underpinning principle of evidence-based medicine is that the systematic synthesis of all reliable information on a topic has greater value than traditional reviews or individual clinical papers. Through this systematic approach, evidence-based medicine is revolutionising clinical practice and is rapidly extending to many health care areas, including diabetes. Its growing utility is demonstrated by the Cochrane database where the number of such reviews continues to grow exponentially.

The Scottish Intercollegiate Guidelines Network (SIGN) was formed in 1993. Its objective, inspired by evidence-based medicine, was to improve the quality of health care for people in Scotland by reducing variation in practice and outcome, through the development and dissemination of national clinical guidelines containing recommendations for effective practice based on current evidence. They published diabetes guidance in 2001 (SIGN, 2001), with an update on type 2 diabetes anticipated in 2010. In Scotland, SIGN is a completely separate organisation from the Scottish Medicines Consortium and, hence, has side-stepped much of the rationing controversy that has surrounded NICE (Smith, 2001).

NICE is a Special Health Authority of the NHS in England and Wales. It has published guidance on diabetes in a number of areas, and primary care teams and primary care organisations are expected to implement such guidance. Since July 2006, guidance has also been reviewed locally for its applicability to Northern Ireland.

Primary care teams appraising the current NICE guidance may be struck by how little has changed from previous guidance, first published in 2002. The current QOF diabetes targets are largely based around this guidance. The introduction to this guidance would have been more relevant if the statistics used to set the UK diabetes scene could have reflected those derived from the England and Wales QOF data and their regional differences, rather than the more generic International Diabetes Federation data, which estimates the UK prevalence at 4.0% (IDF, 2006). The doctor-reported QOF data underlines the fact that type 2 diabetes is a 'disease' of social deprivation, with ethnic variations and is more prevalent in people in later life – who, ironically, might not have been included in the randomised controlled trials that underpin evidence-based medicine.

Few would argue the importance of structured education for people newly diagnosed with type 2 diabetes, although this tends to be resourced differently by PCTs, and this guidance should encourage them to recognise the value of this and implement it. Many primary care teams will be bemused by the recommendation to integrate self-monitoring of plasma glucose (SMPG) with this, as it can be time consuming to demonstrate and continuously resource.

The guidance suggests discussing appropriate HbA_{1c} targets with people with diabetes, with a guide level of 6.5%, unless contraindicated. Metformin is the medication of first choice for type 2 diabetes. Clear guidance is given about slow initiation of this treatment and appropriate creatinine and eGFR levels, below which prescribers will wish to take particular care or stop this therapy. Addition of insulin secretagogues, preferably sulphonylureas, is recommended as second-line therapy, with the usual caveats about hypoglycaemia. None of this is either surprising or controversial.

When the American Diabetes Association and European Association for the Study of Diabetes consensus statement was published (Nathan et al, 2006), it gave more prominence

to PPAR-gamma agonists than had been suggested in the 2002 NICE guidance. Given the recently disclosed problems with one of these agents, the updated NICE guidance (2008) reflects the current practice of using thiazolidinediones as third-line therapy, and more careful consideration of insulin as an alternative. The incretin mimetic exenatide is placed in context, but we will have to await further guidance on this group of agents.

Insulin therapy

There is clear guidance on the use of insulin in type 2 diabetes. NPH insulin is suggested as the first-line regimen, with basal insulins not recommended for insulin initiation, rather only for use in restricted circumstances. While keeping these analogue insulins in reserve is a cost-effective approach, this does not reflect contemporary practice in either primary or secondary care, where the convenience of use, as well as concerns about safety and hypoglycaemia, outweigh the additional costs for many healthcare professionals.

Cardiovascular risk

Cardiovascular risk is recognised and highlighted in the guidance, with careful risk assessment recommended. The blood pressure treatment of choice should be an ACE inhibitor, irrespective of age, with a target blood pressure of 140/80mmHg or lower in the presence of kidney, eye, or cerebrovascular damage. This is slightly lower than QOF targets and does not quite align to The British Hypertension Society guidance (NICE, 2006), but does reflect contemporary practice.

The guidance also recommends statin therapy for all people with type 2 diabetes over 40 years of age, suggesting simvastatin 40mg as a starting point. The guidance suggests lipid targets of <4.0mmol/l for total cholesterol and <2.0mmol/l for LDL-cholesterol, where assessed cardiovascular risk is very high. The guidance also suggests that low dose aspirin (75mg/day) be offered to all people with type 2 diabetes over 50 years of age, and to younger people at high cardiovascular risk.

Concluding remarks

Evidence-based medicine purists will find much to please them in this guidance. Pragmatic GPs and their teams may want to quibble about having to implement perceived rationing choices for individuals under their care. Everyone in primary care will be pleased that much of the guidance aligns to their everyday work in improving the quality of diabetes care by achieving contemporary QOF targets. To paraphrase one of the founding fathers of evidence-based medicine, Professor Sackett, the work of the doctor begins when the protocol is no longer of any use. Such is contemporary primary diabetes care.■

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