Therapy guidelines for managing type 2 diabetes: A help or a hindrance?

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NICE guidance on type 2 diabetes can be found at:
http://www.nice.org.uk/CG87

The **AmericanDiabetes Association** and **European Association for the Study of Diabetes** joint position statement on the management of hyperglycaemia in type 2 diabetes can be found at:
http://care.diabetesjournals.org/content/35/6/1364.long

The **American Association of Clinical Endocrinologists** diabetes management algorithm can be found at:
https://www.aace.com/files/aace_algorithm.pdf

Diabetes is complex and progressive, and with the ever-increasing choice of antihyperglycaemic therapies available, selecting the most appropriate treatment, at the right time, for the right person is increasingly challenging, especially for the non-specialist. In addition to the widening array of pharmacological agents now available, more and more guidelines and recommendations are being produced that we, as healthcare professionals, are told we should base our prescribing decisions on. Both locally and nationally we have clinical guidelines, practice protocols, public health guidance, quality statements and technology appraisals, as well as prescribing formularies, to refer to. According to NICE (2014):

> "Clinical guidelines are recommendations on the appropriate treatment and care of people with specific conditions that are based on the best available evidence. They are designed to help healthcare professionals in their work, but do not replace their knowledge and skills."

This highlights that although guidelines provide a framework upon which to base our practice, they are not absolutes and we must retain the right to use our own clinical judgement. This is especially important as guidelines are not always all-encompassing and might not cover something that is widely known. For example, good glycaemic control early in diabetes (i.e. in the first 18 months since diagnosis) can improve later outcomes, including reducing the likelihood of developing complications (Holman et al, 2008), and more intensive control during this early period may thus be beneficial. However, this is not emphasised by guidance and, in my experience, is often a difficult message to convey to people, who are often asymptomatic, and this means that it may be overlooked.

Guidelines and patient-centred care

Currently, great emphasis is placed on personalised, patient-centred care and we are encouraged to fully involve patients in treatment decisions. But is this really possible if our practice is dictated by guidelines, protocols and prescribing formularies? As a practice nurse in diabetes, I believe *it is*, and this individualisation is emphasised in the NICE (2009) type 2 diabetes guideline, which states:

> "This guidance represents the view of NICE […] Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering."

In particular, colleagues often complain that they cannot prescribe certain therapies because NICE does not allow them to do so. In response to this, I would argue that NICE offers an evidence-based, cost-effective framework to guide us, which also contains the scope for the use of informed clinical judgement. For example, the 2009 guideline recommends initiating metformin where HbA_{1c} is above either 48 mmol/mol (6.5%) or a different individually agreed target after a trial of lifestyle intervention. This should be followed by the addition of a sulphonylurea if the glycaemic target is not achieved or maintained. However, the NICE guideline also states that other newer agents may be considered, providing the clinician can justify their use on the grounds that a sulphonylurea is either contraindicated or not tolerated, or the person is at significant risk of hypoglycaemia or its consequences.

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Beyond NICE – even more guidance

There are many other guidelines, in addition to those from NICE, and one difficulty that arises from this is that there are a number of subtle (and not so subtle) differences between them.

The joint position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) offers a more flexible approach for the treatment of diabetes (Inzucchi et al, 2012). This recommends that five classes of antihyperglycaemic drug should be considered for second-line use in addition to metformin, when HbA_{1c} is above target (and a similar approach is recommended for third-line treatment). Emphasis is placed on selecting therapies "within the context of the needs, preferences, and tolerances of each patient." I find this a clearer, more individualised and less prescriptive approach, with agents selected based upon the particular properties of the drugs and the person with diabetes (including disease duration, age, life expectancy, co-morbid conditions, established cardiovascular disease, and the risks associated with hypoglycaemia and other adverse events).

Type 2 diabetes is associated with various pathological defects, including insulin resistance in the muscles and liver, impaired insulin secretion due to progressive pancreatic beta-cell failure and a diminished incretin effect (Defronzo, 2009). As each class of antihyperglycaemic therapy targets particular defects, it makes sense that we would want to select agents according to the predominant pathological defect in an individual. If we take this idea a step further, then based upon the fact that most people will have more than one pathological defect, logically we would want to tackle this with a combination of therapies (each targeting a different defect) from the outset.

Interestingly, the American Association of Clinical Endocrinologists' diabetes management algorithm (Garber et al, 2013) appears, to some degree, to be based upon this principle. Choice of initial therapy is determined by HbA_{1c} level at diagnosis, so, for example, asymptomatic individuals with an HbA_{1c} greater than 75 mmol/mol (9%) are recommended to be commenced on dual, or even triple, therapy from the outset. This approach, therefore, may offer a more effective means of achieving good glycaemic following diagnosis, the benefits of which were clearly demonstrated by the UK Prospective Diabetes Study (Holman et al, 2008).

But where does this leave us?

At the *9th National Conference of the Primary Care Diabetes Society Conference*, which was held in Birmingham last November, one delegate suggested that perhaps we should completely ignore guidelines! Personally I disagree with this and believe that guidelines have a place, but it is a shame that they do not provide a consistent message.

In addition, I am not so naïve to think that we have ultimate freedom to prescribe whatever we choose whenever we like. The Quality, Innovation, Productivity and Prevention (QIPP) initiative sets out how the NHS plans to make up to £20 billion worth of efficiency savings by 2015 (Department of Health, 2014) and this has influenced the prescribing for diabetes in my area, with pressure to ensure that at least 88% of prescriptions for antihyperglycaemic agents are for metformin and sulphonylureas. However, even though newer antihyperglycaemic agents are more expensive, they may actually represent better value for money if they are more acceptable (for example, because of a lower risk of hypoglycaemia or less weight gain). This is because, as we all know, the most expensive medication is the one that is never taken, and failure to take prescribed medicines is well recognised in those with diabetes (Donnan et al, 2002). I suspect that a good deal is wasted on unwanted, unused and ineffective medicines, and that by allowing us more freedom to use our clinical judgement when selecting medications we could significantly improve both the lives of people with diabetes and their long-term outcomes, which should be more cost-effective in the longer term.

Therefore, I believe that we need to ensure that a consistent set of guidelines are developed that allow us to best use our scarce resources, while reflecting the best evidence-based practice. These guidelines must, however, allow clinicians to use their own clinical judgement and actively involve their patients in the decision-making process. Only when guidelines enable all these things do I think that they will be acceptable to all of us. ■

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