NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Blood glucose control in adults with type 2 diabetes: patient decision aid user guide for healthcare professionals

Implementing the NICE guideline on type 2 diabetes in adults (NG28)

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This is a user guide for healthcare professionals. It accompanies a decision aid intended to help adults with type 2 diabetes make informed decisions about taking a second medicine for blood glucose control. The decision aid and user guide are based on the NICE guideline on type 2 diabetes in adults.

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The decision aid and user guide are not NICE guidance.

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Background to patient decision aids

Patient decision aids (PDAs) are tools designed to help people participate in decision making about healthcare options. They provide information on the options and help people clarify and communicate the personal value they associate with different features of the options. PDAs do not advise people to choose one option over another, nor are they meant to replace discussions with their healthcare professional. Instead, they prepare people to make informed, values-based decisions with their practitioner (IPDAS collaboration 2012).

Complex decisions have multiple options with features that people value differently. Sometimes the scientific evidence about options is limited. Therefore the best choice depends on the personal importance the patient places on the benefits, harms, and scientific uncertainties (IPDAS collaboration 2012). The values and perceptions of individual people, and their attitudes to risk, may be different from those of their healthcare professional (Thornton 2003). Using PDAs in a consultation may help to improve a person's knowledge of the options and outcomes and give them more realistic expectations (Stacey et al. 2014).

About the type 2 diabetes patient decision aid

The PDA relates to management of blood glucose at first intensification of drug treatment in adults with type 2 diabetes, as described in the NICE guideline. It is not suitable for use at other stages of the care pathway, or for women with type 2 diabetes who are pregnant or planning to become pregnant (see the NICE guideline on diabetes in pregnancy). Healthcare professionals should explain the PDA to the person, and tailor the information to reflect the person's clinical circumstances as necessary (for example, if certain medicines are contraindicated).

The PDA was developed with input from an expert steering group of clinical experts, patient representatives and experts on PDAs.

The NICE guideline recommends that, if the HbA1c level of a person with type 2 diabetes is not adequately controlled by a single drug and rises to 58 mmol/mol (7.5%) or higher, healthcare professionals should:

- reinforce advice about diet, lifestyle and adherence to drug treatment **and**
- support the person to aim for an HbA1c level of 53 mmol/mol (7.0%) **and**
- intensify drug treatment.

However, the guideline also recommends involving the person in decisions about their individual target HbA1c level. Healthcare professionals should consider relaxing the target HbA1c level on a case-by-case basis, with particular consideration for people who are older or frail and for people:

- who are unlikely to achieve longer-term risk-reduction benefits, for example, people with a reduced life expectancy
- for whom tight blood glucose control poses a high risk of the consequences of hypoglycaemia, for example, people who are at risk of falling, people who have impaired awareness of hypoglycaemia, and people who drive or operate machinery as part of their job
- for whom intensive management would not be appropriate, for example, people with significant comorbidities.

The guideline recommends that metformin should be offered as the initial drug treatment unless it is contraindicated or not tolerated. This means that most people using the PDA will already be prescribed metformin. They will be considering whether to start taking a second medicine and, if so, which one. We have included metformin in the table of information so that people can compare the information for metformin with the information for other medicines.

If metformin is contraindicated or not tolerated, the guideline recommends that healthcare professionals should consider initial drug treatment with a dipeptidyl peptidase-4 (DPP-4) inhibitor or pioglitazone or a sulfonylurea. Repaglinide is also both clinically effective and cost effective as initial drug therapy, but it is not included in the table of information in the PDA. This is because there is no licensed non-metformin-based combination containing repaglinide that can be offered at first intensification. Anyone using the PDA who is currently taking repaglinide would therefore have to discontinue it and change to different medicines if treatment is to be intensified using a licensed combination of drugs.

Using the patient decision aid

Recommendations on good practice in shared decision-making are given in the NICE guidelines on patient experience in adult NHS services and medicines optimisation.

Healthcare professionals should present the information in a balanced way. They should make it clear that, although they may have a view on the choice they would make if they were in the

person's situation, they accept that the person may view the balance of risks, benefits and consequences of treatment in a different way.

It is important to avoid framing information in a way that results in an unbalanced picture of either benefits or harms. For example, healthcare professionals should

- State not only the possible benefits from more intensive blood glucose control on microvascular outcomes, but also the absence of effect on most macrovascular outcomes.
- State not only that (for example) 10 to 100 people in every 1000 who take a medicine will get a certain side effect, but also that this means that 900 to 990 people in every 1000 who take it will not.

Healthcare professionals should also explain that it is impossible to know what will happen to an individual person or say whether or not he or she will benefit from the treatment.

Source of data

Source of information on the advantages and disadvantages of controlling blood glucose in people with type 2 diabetes

The statements in this section of the PDA are drawn from a Cochrane review (Hemmingsen et al. 2013).

Evidence relating to blood glucose control in people with type 2 diabetes is provided by randomised controlled trials (RCTs) and epidemiological studies. The Cochrane review authors note that epidemiological studies suggest that reducing blood glucose in people with type 2 diabetes may reduce the risk of death and morbidity. However, such studies do not represent a reliable methodology to assess the effects of interventions. This is because of the inherent risk of imbalances between groups (which may be hidden and therefore uncorrectable), other than those resulting from the interventions. The Cochrane review therefore included only RCTs.

The review included 28 randomised controlled trials (RCTs) comparing intensive glucose control with conventional glucose control in participants with type 2 diabetes. The analyses included a total of 18,717 participants randomised to intensive glucose control and 16,195 to conventional glucose control. The trials were primarily conducted in Europe and Northern America. The mean duration of the intervention period varied from 3 days to 12.5 years. Only 2 trials were

considered to have low risk of bias, so the authors note that RCTs may have been included that had a high risk of overestimating beneficial effects and underestimating harmful effects.

There were no statistically significant differences between targeting intensive compared with conventional glucose control for:

- all-cause mortality (relative risk [RR] 1.00, 95% confidence interval [CI] 0.92 to 1.08; 34,325 participants, 24 trials)
- cardiovascular mortality (RR 1.06, 95% CI 0.94 to 1.21; 34,177 participants, 22 trials).

Trial sequential analysis showed that a 10% relative risk reduction could be refuted for all-cause mortality.

No statistically significant effect of targeting intensive glucose control could be shown on non-fatal stroke, cardiac revascularisation, or peripheral revascularisation.

Targeting intensive compared with conventional glucose control seemed to reduce the risks of:

- non-fatal myocardial infarction (RR 0.87, 95% CI 0.77 to 0.98; p=0.02; 30,417 participants, 14 trials)
- amputation of a lower extremity (RR 0.65, 95% CI 0.45 to 0.94; p=0.02; 11,200 participants, 11 trials)
- developing a composite outcome of microvascular diseases (RR 0.88, 95% CI 0.82 to 0.95; p=0.0008; 25,927 participants, 6 trials)
- nephropathy (RR 0.75, 95% CI 0.59 to 0.95; p=0.02; 28,096 participants, 11 trials)
- retinopathy (RR 0.79, 95% CI 0.68 to 0.92; p=0.002; 10,300 participants, 9 trials)
- retinal photocoagulation (RR 0.77, 95% CI 0.61 to 0.97; p=0.03; 11,212 participants, 8 trials).

Trial sequential analyses did not confirm a reduction in the risk of non-fatal myocardial infarction, but confirmed a 10% relative risk reduction in favour of intensive glucose control on the composite outcome of microvascular diseases. For the remaining microvascular outcomes, trial sequential analyses could not establish firm evidence for a 10% relative risk reduction.

Targeting intensive glucose control statistically significantly increased the risk of mild hypoglycaemia, but substantial heterogeneity was present. There was a statistically significant increased risk of:

- severe hypoglycaemia (RR 2.18, 95% CI 1.53 to 3.11; 28,794 participants, 12 trials)
- serious adverse events (RR 1.06, 95% CI 1.02 to 1.10; p=0.007; 24,280 participants, 11 trials).

Trial sequential analysis for a 10% relative risk increase showed firm evidence for mild hypoglycaemia and serious adverse events and a 30% relative risk increase for severe hypoglycaemia when targeting intensive compared with conventional glucose control.

Overall health-related quality of life, as well as the mental and the physical components of health-related quality of life did not show any statistical significant differences.

Source of information on adverse effects

Information on adverse effects was taken from the manufacturers' summaries of product characteristics (SPCs) as published on the electronic medicines compendium at the date the decision aid was published. Where applicable, reference has also been made to MHRA warnings published in Drug Safety Update and the DVLA At a glance guide to the current medical standards of fitness to drive. The information for classes of drugs is intended to be generally representative; there may be within-group differences in the prevalence of adverse effects. **Although the table highlights particular issues regarding use of certain medicines in renal and hepatic impairment, prescribers should consult the product literature or the BNF before prescribing any drug**.

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