# How to achieve the new QOF diabetes indicators

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### Article points

- In terms of diabetes, the main changes to the Quality and Outcomes Framework (QOF), introduced on 1 April 2009, relate to HbA<sub>1c</sub> indicators.
- Up-titrate or add medications as necessary every 3 months. Once the agreed HbA<sub>1c</sub> target has been achieved, review the individual every 6 months.
- 3. Frail older people, those with terminal illness and those with significant comorbidities should be excluded from QOF. In the author's experience, a 10% exclusion rate to cover such groups in whom achieving QOF indicators may be medically inappropriate is realistic.

### Key words

- QOF
- HbA<sub>1c</sub>
- Glucose-lowering therapies
- Optimal glycaemic

Roger Gadsby is GP and Associate Clinical Professor, Warwick Medical School; Pam Gadsby is Practice Diabetes Nurse, Warwickshire. In terms of diabetes, the main changes to the Quality and Outcomes Framework (QOF), introduced on 1 April 2009, relate to HbA<sub>1c</sub> indicators. This article explains the changes to clinical indicators and gives suggestions as to how to meet these new, tighter, glucose control targets, from the perspective of the GP and practice diabetes nurse. Over 90% of people with diabetes seen in general practice will have type 2 diabetes (Yorkshire and Humber Public Health Authority and National Diabetes Support Team, 2006), but many of the principles discussed in this article will be applicable to people with well controlled type 1 diabetes, some of whom are now being cared for in general practice.

he changes to the Quality and Outcomes Framework (QOF) indicators (*Box 1*) mean that there is more pressure to have more people with diabetes achieving lower HbA<sub>1c</sub> targets. The aim is to encourage better glycaemic control, but the downside could be that there will be an increasing number of people experiencing hypoglycaemia, as they are encouraged to take more glucose-lowering medications to try to attain HbA<sub>1c</sub> levels that may be individually unrealistic or inappropriate for them.

The NICE guidance for type 2 diabetes, published in May 2008, recommends that the  $\mathrm{HbA}_{\mathrm{lc}}$  target for people using lifestyle interventions to manage their diabetes, oral monotherapy or dual therapy should be 6.5%, but if a third agent is needed, this should only be started if the  $\mathrm{HbA}_{\mathrm{lc}}$  level is  $\geq$  7.5% (National Collaborating Centre for Chronic Conditions [NCCCC], 2008). However, these guidelines also advocate that the above targets should be

agreed with the individual, taking their personal situation into account.

### Diagnose people early

The earlier people are diagnosed in the course of their diabetes, the lower the initial  $HbA_{1c}$  level is likely to be at diagnosis. They should be able to maintain an  $HbA_{1c}$  level below 7% with lifestyle changes for longer. The more of such people we have registered, the easier it will be to achieve clinical indicator DM 23 (see *Box 1*).

Most practices will screen for diabetes as part of investigations for cardiovascular disease, hypertension, and tiredness clinical presentations. The planned national vascular screening programme, which is, at present, being piloted in some PCT areas (Department of Health [DH], 2008), should help to identify asymptomatic individuals with diabetes or other "milder" abnormalities of glucose metabolism such as impaired fasting glucose.

Annual follow-up of people diagnosed as having impaired fasting glucose, impaired glucose tolerance, or those with a history of gestational diabetes, is good clinical practice as 50% of these people will develop diabetes within 10 years (DeVegt et al, 2001). Annual screening will highlight those who have developed type 2 diabetes since their last screen and their HbA $_{\rm lc}$  is still likely to be low. It is important to ensure that these people with prediabetes are on registers and that the practice has a call and recall system for their annual screening and lifestyle advice.

# Regularly review those with diagnosed diabetes

Review people who are not reaching their individually agreed HbA<sub>1c</sub> target every 3 months.

At each consultation it is important to agree with the person with diabetes an appropriate HbA<sub>1c</sub> target and document the plans to try to reach that target within the next 3 months. The "Year of Care" initiative (NHS Diabetes, 2009)

### Box 1. Changes introduced to the QOF indicators.

To achieve maximal points for glycaemic control under the previous clinical indicators (DM 20 and DM 7), 90% of people registered as having diabetes needed to have an HbA $_{1c}$  level of 10% or less, and 50% needed to have an HbA $_{1c}$  of 7.5% or less. From 1 April 2009, there are three indicators for HbA $_{1c}$  at 7%, 8% and 9%.

### Diabetes Quality Indicator 23 (DM 23; replaces DM 20)

The percentage of people with diabetes in whom the last  $HbA_{1c}$  is 7% or less (or the equivalent test or reference range depending on the local laboratory) in the previous 15 months.

- Minimum threshold: 40%.
- Maximum threshold to earn the full 17 available points: 50%.

### Diabetes Quality Indicator 24 (DM 24; new indicator)

The percentage of people with diabetes in whom the last  $HbA_{1c}$  is 8% or less (or the equivalent test or reference range depending on the local laboratory) in the previous 15 months.

- Minimum threshold: 40%.
- Maximum threshold to earn the full 8 available points: 70%.

### Diabetes Quality Indicator 25 (DM 25; replaces DM 7)

The percentage of people with diabetes in whom the last  $HbA_{1c}$  is 9% or less (or the equivalent test or reference range depending on the local laboratory) in the previous 15 months.

- Minimum threshold: 40%.
- Maximum threshold to earn the full 10 available points: 90%.

Source: NHS Employers and the General Practitioners Committee (2008)

is designed to encourage such personcentred consultations and goal setting. Patient-held records can facilitate this.

### Alter therapies as needed

Up-titrate or add medications as necessary every 3 months. Once the agreed HbA<sub>1c</sub> targets have been achieved, review the individual every 6 months.

### Agree targets for weight loss

Negotiate realistic targets for weight loss with the individual. An agreed plan to lose 1 stone in 3 months for someone who weighs 16 stone is likely to be regarded by them as achievable. In the author's experience, slow, steady weight loss of around 1 lb per week achieved by lifestyle change is more likely to be permanent than rapid loss achieved by an extreme diet.

# Reinforce the importance of physical activity

Remember to stress the importance of physical activity at each consultation. Most people can realistically agree to try to walk a mile a day initially. The aim (recommended by the British Heart Foundation [BHF]) is for 30 minutes of brisk physical activity 5 days per week (BHF, 2009). People need encouragement to achieve and continue a form of physical activity that they enjoy, especially where mobility is restricted.

# Use glucose lowering therapies wisely Initial monotherapy

Metformin is the initial monotherapy of choice for the majority of people with type 2 diabetes with the exception of thin or highly symptomatic people newly diagnosed with type 2 diabetes who should be managed differently (see section below).

The author's usual approach is to prescribe one 500 mg tablet of metformin twice a day, but suggest that the person just takes 500 mg daily for the first 2 weeks to minimise the risk of abdominal

pain, bloating and diarrhoea. Warn about the side-effects and explain that they will usually settle. Up-titrate to two 500 mg tablets twice a day if and when necessary. Consider a trial of extended-release metformin in those for whom gastrointestinal tolerability prevents the continuation of metformin therapy.

# For a small subgroup of people, consider sulphonylurea as the initial monotherapy

There are a small number of people newly presenting with type 2 diabetes who are thin, eating a healthy diet, exercising well, and who have significant hyperglycaemic symptoms of thirst and polyuria. In the authors' opinion, beta-cell dysfunction, rather than insulin resistance, probably plays the most important part in the aetiology of diabetes in this group of people. A choice of sulphonylurea as the initial monotherapy using, for example, one gliclazide 80 mg tablet twice daily is likely to improve symptoms within a few days.

A close watch needs to be kept on such people by seeing them every few weeks, monitoring the effects of the sulphonylurea therapy by measuring fasting glucose levels. The dose of gliclazide can be titrated up to two 80 mg tablets twice daily in a few weeks until the fasting glucose is controlled. If the maximum doses fail to control glycaemia, and the addition of metformin does not enable good glycaemic control to be achieved, it may be necessary to consider the early introduction of insulin therapy.

### **Dual therapy**

When the maximally tolerated dose of metformin does not give optimal glycaemic control, NICE (NCCCC, 2008) recommends that a sulphonylurea should be the second therapy to be added for most people with type 2 diabetes. The most commonly prescribed sulphonylurea in the UK is generic gliclazide (The Information Centre and Yorkshire and Humber

### Page points

- 1. When optimal glycaemic control an HbA<sub>1c</sub> ≤7.5% is not obtained with maximal tolerated doses of metformin plus a sulphonylurea, NICE recommends a number of options.
- 2. There is no strong evidence base to determine for any individual exactly when insulin therapy should be introduced, but data suggest that it should be considered as an option for people who have poor glycaemic control as evidenced by persistently elevated HbA<sub>1c</sub> levels over 7.5%, who are currently receiving maximal dosage of metformin plus sulphonylurea agents, and who have already had optimised lifestyle changes.
- 3. A key factor that will need to be addressed is the individual's views, attitudes and fears. These may involve worries about the fear and pain of injections, and the risks of hypoglycaemia.

Public Health Observatory, 2007). The initial dose is often given as 40 mg twice a day. This is done by splitting an 80 mg tablet in two. The author's usual next titration is up to one 80 mg tablet twice a day, then to two tablets (160 mg twice daily). NICE stipulates that a meglitinide or a thiazolidinedione (TZD) may be alternative second-line options in certain people.

### Third-line therapy

When optimal glycaemic control – an HbA<sub>1c</sub> ≤7.5% (NCCCC, 2008) – is not obtained with maximal tolerated doses of metformin plus a sulphonylurea, NICE recommends a number of options, detailed below (NCCCC, 2008).

### a) Add a TZD (triple oral therapy)

- Triple therapy with metformin, sulphonylurea plus a TZD has become quite widely used.
- It may defer the need for insulin, and is especially helpful for people who have a reluctance to initiate insulin perhaps as a result of employment concerns, for example public service vehicle drivers.

### b) Add basal insulin

• If people with type 2 diabetes require insulin, NICE recommends that once- or twice-daily neutral protamine Hagedorn (NPH) insulin is the initial regimen of choice, although other approaches are recommended if NPH insulin is not a suitable option (NCCCC, 2008).

### c) Add exenatide

NICE recommends that exenatide be considered as an option if an individual fulfils the following criteria:

- A BMI over 35 kg/m<sup>2</sup> in those of European descent, with appropriate adjustment for other ethnic groups.
- Specific problems of a psychological, biochemical or physical nature arising as a result of a high body weight.
- Inadequate blood glucose control (HbA<sub>1c</sub> ≥ 7.5%) with conventional oral agents following a trial of metformin and sulphonylurea.
- Other high-cost medication, such as a TZD or insulin injection therapy, would otherwise be initiated.

The choice of which of these options is most suitable needs to be made in consultation with the person with diabetes, taking into account their individual circumstances.

### Other agents

A rapid update of the glucose-lowering section of the NICE guideline is being undertaken. This will consider the dipetidyl peptidase-4 (DPP-4) inhibitors and the long-acting analogue insulin detemir, and will reconsider guidance on the TZDs. This was due for publication at the end of March 2009 but has been delayed; a draft version was published for comment on the NICE website in autumn 2008 (NICE, 2008).

If the published version is similar to the draft, it will position the DPP-4 inhibitors as an option for second-line therapy in combination with either metformin or a sulphonylurea for people meeting specific criteria. The draft also positions DPP-4 inhibitors as a third-line, triple therapy option in combination with metformin and a sulphonylurea. Sitagliptin has a license to be used in this way (Electronic Medicines Compendium, 2008).

### Initiating insulin when appropriate

There is no strong evidence base to determine for any individual exactly when insulin therapy should be introduced, but data suggest that it should be considered as an option for people who have poor glycaemic control as evidenced by persistently elevated HbA<sub>1c</sub> levels over 7.5%, who are currently receiving maximal dosage of metformin plus sulphonylurea agents, and who have already had optimised lifestyle changes.

### Overcoming obstacles to insulin therapy

A key factor that will need to be addressed is the individual's views, attitudes and fears. These may involve worries about the fear and pain of injections, and the risks of hypoglycaemia. The needles used for insulin injections today are very short and thin, and as a result, injections are less painful than in the past.

# Teach self-monitoring of blood glucose if this is not yet being undertaken

Individuals starting on insulin need to be monitoring their glycaemic control by measuring their blood glucose levels with a meter. This may need to be taught, but if people have already been self-monitoring, it should be reviewed and reinforced.

### Choosing the right device

Pen injection devices may have disposable cartridges or the whole pen device may be disposable. The author's approach is to demonstrate the various devices, enabling the person to choose the one that they feel is appropriate for them. In the authors' experience, most people choose disposable pens.

The techniques of how to dial up the correct dose of insulin from a pen device, giving the injection, rotating injection sites, and adjustment of insulin dosage should all be demonstrated, and taught. The person newly starting on insulin should be observed giving an injection with the chosen device.

# Discussion of medico-legal implications and treatment of hypoglycaemia

Issues around driving, insurance, and recognition and management of hypoglycaemia should be discussed.

### Choosing the right insulin

NICE (NCCCC, 2008) recommends continuing on oral metformin and sulphonylurea and preferably beginning insulin therapy with oncedaily long-acting NPH insulin taken at bedtime or twice-daily according to need. Alternatively, NICE suggests consideration of a once-daily long-acting analogue (insulin glargine) if:

- The person requires assistance to administer insulin injections.
- A person's lifestyle is significantly restricted by recurrent symptomatic hypoglycaemic episodes.
- A person otherwise needs twice-daily basal insulin injections in combination with oral glucose-lowering medication.

### Follow-up

People initiating insulin with a once-daily basal insulin regimen will need close support and supervision over the first few days and weeks as they titrate up their insulin dose in response to their home monitored fasting blood glucose

results. In the author's practice, this is usually achieved by a combination of telephone support and clinic visits. An  $HbA_{1c}$  level estimation 3 months after insulin initiation will demonstrate the improvement in glycaemic control on insulin.

NICE (NCCCC, 2008) summarises its recommendations for a structured programme for insulin initiation by advising that such a programme should encompass:

- Structured education.
- Continuing telephone support.
- Frequent self-monitoring.
- Dose titration to target.
- Dietary understanding.
- Management of hypoglycaemia.
- Management of acute changes in plasma glucose control.
- Support from experienced and appropriately trained healthcare professionals.

### Exclude people appropriately

Treating glycaemia reduces the risk of developing microvascular and macrovascular complications (DH, 2001). For some patient groups, for example frail older people, the quality of their remaining life is more important than the quantity. The most important thing will be to ensure that they are free of symptoms of hypoglycaemia or hyperglycaemia, rather than being treated aggressively to a low HbA<sub>1c</sub> target to achieve a good QOF score. Frail older people, those with terminal illness and those with significant comorbidities should therefore be excluded from QOF. In the author's experience, a 10% exclusion rate to cover such groups in whom achieving QOF indicators may be medically inappropriate is realistic.

### Conclusion

A person with diabetes should be treated as an individual and decisions about their care, including setting  $HbA_{lc}$  targets, should be shared between the healthcare professional and the individual. However, the new QOF indicators intend to motivate healthcare professionals to improve diabetes services and, if the methods outlined in this article are used, each aspect of the care of people with diabetes in general practice could be improved on, and QOF indicators achieved.

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