

Global Guideline

for Type 2 Diabetes

Chapter 7: Clinical monitoring

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Recommendations

■ Standard care

- MO1 Monitor blood glucose control by high-precision methods of HbA_{1c} performed every 2 to 6 months depending on level and stability of blood glucose control, and change in therapy.
- MO2 Report all HbA_{1c} results DCCT-aligned, pending internationally concerted policy changes.
- MO3 Provide site-of-care measurement of HbA_{1c} or laboratory measurement before clinical consultation.
- MO4 Communicate the HbA_{1c} result to the person with diabetes. The term 'A1c' may be useful in some populations.
- MO5 Use appropriate alternative measures where HbA_{1c} methods are invalidated by haemoglobinopathy or abnormal haemoglobin turnover.
- MO6 Do not use fructosamine as a routine substitute for HbA_{1c} measurement; it may be useful where HbA_{1c} is not valid.
- MO7 Site-of-care capillary plasma glucose monitoring at random times of day is not generally recommended.

■ Comprehensive care

- MO_c1 This would be as for *Standard care*, but continuous glucose monitoring is an additional option in the assessment of glucose profiles in people with consistent glucose control problems, or with problems of HbA_{1c} estimation.
- MO_c2 HbA_{1c} estimation would be available at each visit, and provided in electronic or paper diary form to the person with diabetes.

■ Minimal care

MO_M1 Fasting plasma glucose measurement could be used for monitoring.

MO_M2 Site-of-care capillary blood glucose meters should be quality controlled by reference to laboratory methods.

MO_M3 Visually read glucose test strips have a role in emergency and remote situations where maintenance of functional meters is not feasible.

Rationale

Type 2 diabetes shows progression of hyperglycaemia with time, and causes organ damage through controllable hyperglycaemia. Accordingly hyperglycaemia has to be monitored. Some of this will be performed by the person with diabetes, some by site-of-care tests, and some by laboratory methods which can be referenced to studies of control and complications.

Evidence-base

In general the major national guidelines do not address this area in detail. An exception is the 2004 NICE guideline for Type 1 diabetes [1]. This can be seen as applicable in terms of the methods proposed for clinic and office monitoring, and in particular for people using insulin therapy. Other guidelines and the ADA standards [2] do also centre on the HbA_{1c} assay for clinic/office monitoring of glucose control, while laboratory guidelines address available methods and their quality implementation [3].

The central role for the HbA_{1c} assay largely derives from its position in the reports of the major outcomes studies (the DCCT [4] and the UKPDS [5]). These provide the main method by which clinicians can relate individual blood glucose control to risk of complication development [6], and make HbA_{1c} mandatory where affordable/available. The laboratory and site-of-care assays are precise and accurate if appropriately controlled and aligned with international standards. However, a number of issues still surround the results reported, including problems affecting haemoglobin itself (turnover or structural abnormalities [7]) and the absolute assay standard used. These issues in turn affect the recommendation to use HPLC-based assays where feasible,

in order to detect haemoglobin variants. Additionally there are recommendations in the published guidelines on site-of-care testing, and on communication of the result to the person with diabetes.

Random clinic plasma glucose testing is not seen as having a role in quality diabetes care. Where HbA_{1c} is unavailable, timed glucose levels are often recommended as a substitute (see also *Self-monitoring*). Recommendations are then made over the quality control of devices used to make such site-of-care tests. Continuous ambulatory blood glucose monitoring has become available in recent years. There is still no good evidence-base for its use, particularly in people with Type 2 diabetes.

Consideration

The central role for site-of-care quality-controlled DCCT-aligned HbA_{1c} testing was found to be solid. Blood glucose testing per se, using quality controlled methods, was noted to have a role in certain circumstances. The role of continuous monitoring remains to be established.

Implementation

There should be access to a laboratory or site-of-care test that participates in a certified quality assurance scheme for measurement of HbA_{1c}. People for whom HbA_{1c} measurement is inappropriate must be identified; HPLC can detect haemoglobinopathies. Organization to allow site-of-care or prior-to-visit sampling is also needed. Provision of capillary blood glucose meters and strips needs to be assured (if used). It is essential to establish whether meters report values for plasma or blood and to ensure that schemes for monitoring the quality of their output are in place.

Evaluation

This is of the presence of records of HbA_{1c} results in patient records, and documented evidence of the quality of performance of the assay system.

References

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