

Continuous glucose monitoring: consensus statement on the use of glucose sensing in outpatient clinical diabetes care

Introduction

Continuous glucose monitoring (CGM) generates an average glucose value every few minutes. The majority of these devices are inserted subcutaneously and measure interstitial fluid glucose. They require calibration with capillary blood glucose measurements. CGM can be used in adults and children with diabetes.

CGM can be performed retrospectively, where there is no contemporaneous display of sensor readings, or in real-time where the user can view readings on a monitor allowing immediate adjustment to therapy. Real-time monitors show trends in glucose levels on an LCD display and have alarms which can warn of impending hypoglycaemia or hyperglycaemia.

It is important to recognise that there is a lag between the blood and interstitial glucose levels of at least 15 minutes. This lag increases when blood glucose levels are changing rapidly. Trends in interstitial glucose are representative of blood glucose changes, but absolute interstitial glucose values are not always co-incident with blood glucose levels. The absolute value should be confirmed with a capillary blood glucose measurement before taking any therapeutic action.

CGM (retrospective and real-time) allows:

- Identification of glycaemic excursions, both above and below the individual's target range.
- Analysis of the causes of excursions can be made by reconciling the sensor data with the user record of:
 - Insulin doses
 - Food and drink
 - Exercise

Real-time monitoring additionally allows the user to take immediate action in response to adverse glucose trends.

Indications for CGM

Proven clinical indication:

Therapeutic – continuous use of real-time glucose sensors

- To lower HbA1c, when this remains above the individual's target despite optimised use of intensive insulin regimens¹⁻³ (MDI or insulin pump therapy)

Potential clinical indications:

On the basis of trial evidence and personal experience the following indications for CGM were reached by consensus. They are divided into “diagnostic” indications, where a specific problem is solved and treated, or “therapeutic”, where CGM can allow a persistent problem to be addressed

Diagnostic use (retrospective and real-time) – this will usually involve intermittent use of sensors and helps to identify patterns of glucose excursion to guide therapeutic change

- Suspected nocturnal hypoglycaemia and/or early morning hyperglycaemia
- Suspected unrecognised hypoglycaemia eg exceptionally low HbA1c without reported hypoglycaemia
- HbA1c above individualised target despite intensified insulin therapy apparently optimised with self-monitoring
- Persistent disabling hypoglycaemia despite conversion from MDI to CSII
- In pregnancy when HbA1c \geq 6.1% or problems with recurrent hypoglycaemia despite optimised intensive insulin therapy

Therapeutic use (real-time) – this requires continuous use of sensors and users need time to develop their strategy of use

- Further optimisation of pump therapy regimens when HbA1c cannot be consistently lowered below 7.5% (or 6.1% in pregnancy)
- Protection against recurrent disabling hypoglycaemia, and for those with hypoglycaemia unawareness or debilitating fear of hypoglycaemia
- Need to ensure avoidance of even modest hyperglycaemia eg pregnancy

When continuous use does not result in any clinical improvement, either in terms of glycaemic control or patient-related benefit, CGM should be discontinued.

1. Garg S et al. Improvement in Glycemic Excursions With a Transcutaneous, Real-Time Continuous Glucose Sensor: A randomized controlled trial. *Diabetes Care* 2006;29:44-50
2. Deiss D et al. Improved Glycemic Control in Poorly Controlled Patients with Type 1 Diabetes Using Real-Time Continuous Glucose Monitoring *Diabetes Care* 2006;29:2730-2732

3. The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. *New Engl J Med* 2008;359:1464-1476.

Appendices

Definitions

Retrospective monitoring – analysis of blood glucose trends in retrospect; this can be done with retrospective CGM, where there is no contemporaneous display of sensor readings (blinded CGM), or by looking at historical data from a real-time monitor either directly or after downloading onto a PC

Real-time monitoring – use of a glucose sensor with a contemporaneous display of blood glucose values; often there is also a display of glucose trends and alarm functions to warn of impending adverse glucose levels

Intermittent use of CGM – this includes use of retrospective CGM (blinded CGM) or real-time CGM over a limited period; the latter may involve the wearing of several sensors eg 4 over 24 days; intermittent use is for diagnostic purposes (see below)

Continuous use of CGM – the expectation is that the user will continuously wear sensors for at least 6 days per week; continuous use will usually be for therapeutic purposes (see below)

Diagnostic use of CGM – this is use of sensing to identify specific glucose excursions with the expectation that these can be corrected with a change in therapy without the need for ongoing sensing

Therapeutic use of CGM – this is ongoing use of sensing to complement insulin therapy and allow the user to make real-time changes in response to adverse glucose trends

Devices

Currently available in UK

Enzyme tipped catheters inserted subcutaneously

- **iPro** (Medtronic) – retrospective monitoring system; requires calibration with 4 capillary blood glucose measurements daily; sensor life 6 days
- **Guardian-REAL-Time/Paradigm REAL-Time** (Medtronic) – real-time system; requires calibration with 4 capillary blood glucose measurements daily; high/low alarms; trend and predictive functions; 6 day sensor life;
- **Freestyle Navigator** (Abbott) – real-time system; requires calibration with capillary blood glucose measurements at 10, 12, 24 and 72 hours; high/low alarms; trend and predictive functions; 5 day sensor life

Microdialysis system inserted subcutaneously

- **Glucoday** (Menarini) – real-time system; requires a one-off calibration with a capillary blood glucose measurement; high/low alarms; 2 day sensor life

Additionally available in the USA, enzyme-tipped catheter

- **Dexcom SEVEN** (Dexcom) - real-time system; requires calibration 12 hourly with capillary blood glucose measurements by One-Touch meter; high/low alarms; trend function; 7 day sensor life

NICE advice on CGM (Clinical Guideline 15)

- Continuous glucose monitoring systems have a role in the assessment of glucose profiles in adults with consistent glucose control problems on insulin therapy, notably:

- repeated hyper- or hypoglycaemia at the same time of day
 - hypoglycaemia unawareness, unresponsive to conventional insulin dose adjustment
- and in children and young people with Type 1 Diabetes who have persistent problems with hypoglycaemia unawareness or repeated hypoglycaemia or hyperglycaemia