

Technology

Can we predict which individuals will make most use of continuous glucose monitoring?



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Almost constant use of real-time continuous glucose monitoring (CGM) can be effective in optimising glycaemic control, but requires a significant investment, both financially and in terms of the commitment the individual must put in. Therefore, user selection is crucial to the cost-effectiveness of CGM. Can we identify which people with type 1 diabetes will be able to use CGM effectively? And if so, is successful use of CGM sustained?

The Juvenile Diabetes Research Foundation (JDRF) CGM Study Group (2008) confirms the evidence of previous smaller studies that for CGM to be effective it must be used at least 6 days per week, and that this was most likely to occur when the user was in the >25-year-old age group; with lack of such adherence with CGM in the adolescent group in particular, resulting in no obvious benefits of CGM for this group as a whole.

Two further articles from the JDRF CGM Study Group in *Diabetes Care* (2009a, summarised alongside; 2009b, summarised overpage) provide more detailed analyses of certain aspects of the study, helping to answer the questions about successful user identification and sustainability of CGM efficacy. In the first article (JDRF CGM Study Group, 2009a) the factors associated with greater CGM usage were analysed. The study population comprised 82% insulin pump users, with the remainder using multiple daily injections. A total of 53% of the subjects used CGM for at least 6 days per week during the sixth and final month of the study. As previously described, there was a strong association with age, with 79% of those over the age of 25 years using CGM with this frequency.

The other significant association was with self-reported frequency of blood glucose monitoring prior to the study. The mean number of daily measurements for the group as a whole was 6.6 ± 2.3 , but only 28% of those measuring between three and five times daily were using CGM at least six times daily in month six, compared with 61% of those measuring between six and eight times daily, and 68% of those

measuring nine or more times daily. There was a trend towards an association of baseline HbA_{1c} <7.0% (<53 mmol/mol) with greater CGM use, but not after adjustment for age and frequency of blood glucose monitoring. Other factors such as gender, insulin delivery modality, education level or frequency of severe hypoglycaemia did not show a significant association with CGM use.

The second paper (JDRF CGM Study Group, 2009b) reports the outcomes for a sub-group of the 232 participants from the first study who took part in an extension study for a further 6 months. Of the 83 participants, 49 had a baseline HbA_{1c} level of >7.0% (>53 mmol/mol) and their reduction in HbA_{1c} at 6 months was sustained, the mean change from baseline to 12 months being $-0.4 \pm 0.6\%$. The 34 participants with a baseline HbA_{1c} level of <7.0% (<53 mmol/mol) had a stable mean HbA_{1c} level of 6.4% (46 mmol/mol) throughout the study. Perhaps the most striking finding, however, was that the rate of severe hypoglycaemic events fell from 21.8 per 100 person years in the first 6 months to 7.1 in the last 6 months of the study. In the group with baseline HbA_{1c} level of <7.0% (<53 mmol/mol) the corresponding figures were 23.6 and 0 events per 100 person years.

Thus, we can identify those who will use CGM to its greatest effect on the basis of their age and frequency of blood glucose monitoring. Furthermore, the improvement in HbA_{1c} level in those using CGM almost continuously was sustained for at least 12 months, and there was a striking reduction in the frequency of severe hypoglycaemia with more prolonged use, particularly in those with near-normal baseline glycaemic control.

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Tamborlane WV, Beck RW et al (2008) Continuous glucose monitoring and intensive treatment of type 1 diabetes. *N Engl J Med* **359**: 1464–76

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Beck RW, Buckingham B et al (2009a) Factors predictive of use and of benefit from continuous glucose monitoring in type 1 diabetes. *Diabetes Care* **32**: 1947–53

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Bode B, Beck RW et al (2009b) Sustained benefit of continuous glucose monitoring on A1C, glucose profiles, and hypoglycemia in adults with type 1 diabetes. *Diabetes Care* **32**: 2047–9

DIABETES CARE

Near-daily use of CGM reduces HbA_{1c}

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

1 Factors associated with successful use of continuous glucose monitoring (CGM) were assessed in this randomised clinical trial carried out by the Juvenile Diabetes Research Foundation.

2 A total of 232 people with type 1 diabetes (duration >1 year, aged 8–73 years), treated with either an insulin pump or at least three insulin injections per day and with an HbA_{1c} level of <10% (<86 mmol/mol) were randomised to the CGM group.

3 Regression models were used to evaluate any association of baseline characteristics and CGM use at the beginning of the study with CGM use more than 6 days per week and change in HbA_{1c} after 6 months.

4 Baseline factors associated with greater CGM use after 6 months were more frequent blood glucose meter readings prior to the study ($P < 0.001$) and being ≥ 25 years of age ($P < 0.001$).

5 Across all age groups there was a statistically significant association between frequent CGM use and reduction in HbA_{1c} level from baseline ($P < 0.001$).

6 Adults used CGM more than 6 days per week more frequently than adolescents or children did. In all groups, use of CGM more than 6 days per week was associated with a similar reduction in HbA_{1c} level.

7 The authors concluded that frequency of blood glucose monitoring and regular use of CGM initially may help predict long-term use and benefit of CGM.

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Beck RW, Buckingham B et al (2009) Factors predictive of use and of benefit from continuous glucose monitoring in type 1 diabetes. *Diabetes Care* **32**: 1947–53

DIABETES CARE

Benefit of CGM sustained for 12 months

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓✓✓

1 Long-term use of continuous glucose monitoring (CGM) in participants of a previous 6-month study was assessed in this 6-month extension study.

2 Participants were 83 individuals with type 1 diabetes ≤ 25 years of age who were initially randomised to receive CGM in one of two baseline HbA_{1c} groups (those with an HbA_{1c} level of $\geq 7.0\%$ [≥ 53 mmol/mol; $n=49$], or $< 7.0\%$ [< 53 mmol/mol; $n=34$]).

3 An insulin pump was used by 75 participants and multiple daily injections by 8. Participants were provided with the following CGM devices: DexCom SEVEN, MiniMed Paradigm REAL-Time System and FreeStyle Navigator.

4 After 6 months, participants were using CGM a median of 7.0 days per week, and 6.8 days per week at 12 months.

5 HbA_{1c} levels remained within the target range for the whole 12 months in those who initially had an HbA_{1c} level of $< 7.0\%$ (< 53 mmol/mol).

6 The incidence of severe hypoglycaemia decreased from 21.8 events per 100 person-years in the first 6 months to 7.1 in the last 6 months.

7 The time spent each day within the target blood glucose range (3.95–10 mmol/L) significantly increased from baseline to 12 months ($P=0.02$).

8 It was concluded that the use and benefit of CGM can be sustained for 12 months in intensively treated adults with type 1 diabetes.

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Bode B, Beck RW et al (2009) Sustained benefit of continuous glucose monitoring on A1C, glucose profiles, and hypoglycemia in adults with type 1 diabetes. *Diabetes Care* **32**: 2047–9

DIABETES TECHNOLOGY & THERAPEUTICS

CSII effective both in T1D and T2D

Readability	✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

1 This retrospective analysis looked at data from 33 people using insulin pump therapy (17 people with type 1 and 16 with type 2 diabetes).

DIABETES TECHNOLOGY & THERAPEUTICS

CGM to detect inpatient hypos?

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

1 This case study investigated the potential of continuous glucose monitoring (CGM) for the detection of hypoglycaemia in an inpatient with type 1 diabetes.

2 The day after the inpatient (a 32-year-old woman) had a moderate hypoglycaemic event, she was fitted with

DIABETES TECHNOLOGY & THERAPEUTICS

Fewer severe hypos with CGM

Readability	✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓✓

1 The HYPO-Score (a measure of the frequency of hypoglycaemic episodes) was used to assess whether continuous glucose monitoring (CGM) could decrease episodes of hypoglycaemia.

2 Sixteen people with type 1 diabetes with problematic hypoglycaemia were observed for 1 month to gather data for the HYPO-Score, and then used CGM for 2 months.

3 The long-term benefit of CGM was assessed with a 3-month period of

2 When HbA_{1c} levels before CSII therapy were compared with after, a statistically significant reduction was found (10.7% [93 mmol/mol] vs. 8.3% [67 mmol/mol], $P<0.001$). The frequency of episodes of severe hypoglycaemia reduced and no DKA was recorded.

3 CSII was found to be effective for people with diabetes who are poorly controlled with other treatments.

Sudhakaran C, Anjana RM, Rao K et al (2009) Role of continuous subcutaneous insulin infusion in patients with recalcitrant diabetes in South India. *Diabetes Technol Ther* **11**: 733–7

a CGM system measuring interstitial glucose levels every 5 minutes.

3 Both the hospital staff and the inpatient were blinded to the CGM data and glucose meter measurements were taken as per hospital protocol.

4 A severe episode of hypoglycaemia was detected by the CGM the next day. Blood glucose levels had dropped below 4 mmol/L for 4.5 hours before nursing staff treated it.

5 CGM may be able to detect hypoglycaemia in hospital sooner than infrequent glucose meter measurements.

Ryan MT, Savarese VW, Hipszner B et al (2009) Continuous glucose monitor shows potential for early hypoglycemia detection in hospitalized patients. *Diabetes Technol Ther* **11**: 745–7

data collection after the 2-month trial period, to calculate a final HYPO-Score.

4 The modified HYPO-Score decreased from 857 ± 184 to 444 ± 92 ($P=0.055$). The HYPO-Score decreased from 857 ± 184 to 366 ± 86 ($P=0.023$) when it was analysed further, just including times when the CGM was functioning and being worn.

5 Episodes of severe hypoglycaemia < 3.0 mmol/L decreased from 8.6 ± 1.5 to 4.7 ± 0.9 during CGM use ($P=0.01$).

6 In this study, CGM significantly decreased the number of severe hypoglycaemic events and the HYPO-Score when it was being worn.

Ryan EA, Gormsheid J (2009) Use of continuous glucose monitoring system in the management of severe hypoglycemia. *Diabetes Technol Ther* **11**: 635–9

“Frequency of blood glucose monitoring and regular use of CGM initially, may help predict long-term use and benefit of CGM.”