Initiating Continuous Glucose Monitoring (CGM) Using a Step-Wise Approach

Christine Richardson RN, BScN, CDE
Diabetes Nurse Educator
Children’s Hospital of Eastern Ontario
Ottawa, Ontario, Canada

Alanna Landry RN, CDE
Diabetes Nurse Educator
Markham Stouffville Hospital
Markham, Ontario, Canada

Disclosure to Participants

• Conflict of Interest (COI) and Financial Relationship Disclosures:
  – No COI/Financial Relationship to disclose

The CGM TIME Trial: Timing of Initiation of Continuous Glucose Monitoring in Established Pediatric Diabetes

• Multicentre study:
  – Children’s Hospital of Eastern Ontario (Ottawa)
  – London Children’s Hospital
  – McMaster Children’s Hospital (Hamilton)
  – Sickkids (Toronto)
  – Markham-Stouffville Hospital

Study Design

• 5-18 year olds with T1D > 1 year
• Naïve to pump therapy
• 144 children/youth randomized to simultaneous pump + CGM or standard pump therapy with addition of CGM at 6 months

Objectives

• To provide a framework to initiate CGM using a step wise approach
• To outline the use of uploaded data to adjust CGM settings and facilitate patient education
• To demonstrate an innovative tool for the adjustment of meal boluses based on rate of change arrows
CGM – 1st Generation

- March 2006:
  - Real-time CGM released in Canada but not in Europe or USA until summer of 2006

Lisa

- 14 year old girl with T1D x 4 years
- MDI management
- A1C 8.4%
- Hypoglycemic seizures

Lisa

- 14 year old girl with T1D x 4 years
- Pre CGM: A1C 8.4%, hypoglycemic seizures
- On CGM + pump: A1C 6.1%, no seizures

CGM: 2nd Generation

- April 2007:
  - Combined sensor and transmitter
  - Waterproof
  - Rechargeable

CGM Options released in Canada

- November 2013
- January 2014

CGM – 3rd & 4th Generation

- January 2013:
  - New Sensor

- Fall 2014:
  - Enhanced Sensor
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Background
- CGM provides 288 readings per day
- Interpreting all this data is difficult
- CGM use often decreases over time and A1c rises
- Pediatric studies demonstrate need to use CGM at least 6/7 days per week for improvement in A1c

1. JDRF CGM Study Group, 2008
2. Kordonouri et al, 2010

Case Study
Sarah age 8 years
Type 1 diabetes for 3 years
Initiating pump and CGM

Sarah’s goals for pump and CGM:
- Flexibility in lifestyle
- Management of glucose variability with sports

Goals when initiating CGM
- Teach most important information first
- Minimize use and frequency of alarms
- Standardize the settings
- Reinforce learning by using data uploads
- Add new information in steps
What is Important

- Differences between sensor glucose (SG) and blood glucose (BG)
- Effect of Lag Time
- Timing of readings
- Rate of Change arrows
- Trend graphs

Main Alarms

- ✓ Threshold Suspend Alarm
- ✓ Calibration Alert
- ± High and Low Glucose Alerts
- ± Predictive Alerts
- ± Rate of Change Alerts

CGM Settings: Sensor ON

- Glucose Alarms (On/Off): Set as OFF
- Glucose Limits:
  - Age 5-12 years: set at 65 - 306 mg/dl (3.6 - 17.0 mmol/L)
  - Age 13-18 years: set at 60 - 306 mg/dl (3.3 - 17.0 mmol/L)
- Hi Repeat: keep at 1 hour default
- Lo Repeat: keep at 20 minute default
- Predictive Alarms (On/Off): Set as OFF
- Rate of Change Alarms (On/Off): Set as OFF
- Threshold Suspend/Low Glucose Suspend (default Off):
  - Age 5-18 years: set at 54 mg/dl (3.0 mmol/L)
  - Age < 5 years: set at 63 mg/dl (3.5 mmol/L)
- Cal Repeat:
  - Default 30 minutes - change to 1 hour
- Cal Reminder:
  - Set at 30 minutes
- Auto Calibrate: OFF
- Weak Signal: 30 minutes
- Graph Timeout: Default 2 minutes (adjust as per family request)
- Sensor Demo: OFF
- Data Upload Settings:
  - Set glucose targets at 70-180 mg/dl (3.9-10.0 mmol/L)

Case Report of Pump with CGM

- Sarah started pump with saline and CGM on same day
- Insulin start 1 week later
- Set up follow-up with educator
Saline Start
Provides:
- Time to learn set / sensor changes
- Practice bolus utilizing ratios
- Introduce ISF and IOB
- Reinforcement of calibrations
- Ensure access to uploaded data
- Provide education tools for school

Education Strategies
• Use pump uploads in all communication
• Reinforce success by reviewing data to see effect of actions
• Do not overwhelm; stagger introduction of new settings and alarms
• View alarms as warnings; are they all needed?

Step Wise Approach
- 10 days post CGM start
  • Review current settings
  • Consider adding Glucose Alerts
  • Assess glucose limits
  • Assess need for other alerts
- 1 Month after CGM Initiation
  • Review current settings
  • Reassess glucose limits
  • Review Hi & Lo repeat alerts
  • Set other alerts as needed
- 3 months after CGM Initiation & each clinic visit
  • Review current settings
  • Assess glucose limits
  • Review all alerts
  • Teach additional pump/CGM features
10 days post CGM start

- Review current settings
- Consider adding Glucose Alerts
- Assess glucose limits
- Assess need for other alerts

1 Month after CGM Initiation

- Review current settings
- Reassess glucose limits
- Review Hi & Lo repeat alerts
- Set other alerts as needed
Timeline for adding advanced features

- Once successful with initial settings and spikes have evened out
- If and when ready to add additional features

3 months after CGM initiation & each clinic visit

- Review current settings
- Assess glucose limits
- Review all alerts
- Teach additional pump/CGM features

Innovative Tool for Rate of Change Arrows

_Trend Arrow Adjustment Tool_\(^1\) (TAAT)

\(^1\) CGM TIME Trial
Rate of Change (ROC)/Trend Arrows

- ROC/Trend arrows offer early warning system
- Voted “most helpful CGM feature”
- Lack of effective strategies for adjusting insulin based on ROC/Trend arrows

Trend Arrow Adjustment Tool - TAAT

- Tool is based on:
  - Patient’s insulin sensitivity factor (ISF)
  - Calculated using formula of 1800/TDD
  - One arrow ↑ up or ↓ down:
    - 20 to 40 mg/dL rise or decrease in SG
    - Change in SG of 30 mg/dL
  - Two arrows ↑↑ up or ↓↓ down:
    - > 40 mg/dL rise or decrease in SG
    - Change in SG of 60 mg/dL

Current Tool

<table>
<thead>
<tr>
<th>CGM Arrows</th>
<th>Interpretation of Arrows</th>
<th>10/20% Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>↑</td>
<td>Glucose is increasing by 20-40 mg/dL (1.1-2.2 mmol/L) over 20 minutes</td>
<td>Increase recommended bolus by 10%</td>
</tr>
<tr>
<td>↑↑</td>
<td>Glucose is increasing by &gt; 40 mg/dL (&lt; 2 mmol/L) over 20 minutes</td>
<td>Increase recommended bolus by 20%</td>
</tr>
<tr>
<td>↓</td>
<td>Glucose is decreasing by 20-40 mg/dL (1.1-2.2 mmol/L) over 20 minutes</td>
<td>Decrease recommended bolus by 10%</td>
</tr>
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</tbody>
</table>

Trend Arrow Adjustment Tool - TAAT

- To calculate the amount of insulin to be added:
  - One arrow is 30 / ISF
  - Two arrows is 60 / ISF
Sarah has one arrow up
Her ISF is 60
30 (for ↑) / 60 (ISF) = 0.5
Sarah would increase her bolus by 0.5 units
CONCLUSIONS

- CGM is an effective tool
- Not all settings/alarms are necessary
- Establish a time frame to review and discuss adding new settings, features & alarms
- Use uploaded data
- Addition of TAAT is easy to explain and use
- Simple math required (+)

References

- Helfeman D, et al. SPCG 2014, oral presentation