Clinical Experience with a Tubing-Free Insulin Pump System

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The use of Continuous Subcutaneous Insulin Infusion (CSII) therapy in patients with type 1 diabetes began in the late 1970’s (1-4). Insulin pump therapy improves glycemic control and reduces the development of hypoglycemia in pediatric patients with type 1 diabetes (5,6) as well as in older subjects with insulin-treated type 2 diabetes (7). For these and other reasons (e.g., a freer lifestyle, greater flexibility with meal timing and size) many patients prefer insulin pump therapy compared to multiple daily insulin injections.

Currently, there are five insulin pump manufacturers in the United States: Animas (Animas), Deltec (Cozmo), Insulet (OmniPod), Metronic Minimed (Paradigm), and Roche (Accu-Chek Spirit). Traditionally, insulin pumps have required users to manage several individual components such as insulin pumps and reservoirs, infusion sets, tubing, insertion devices, and blood glucose monitors. The OmniPod Insulin Management System features a fully-integrated design with only two components (Figure 1); a hand-held Personal Diabetes Manager (PDM) and an OmniPod (Pod). The PDM wirelessly programs the Pod with customized insulin delivery instructions, monitors the Pod’s operation, contains a fully integrated blood glucose meter, and automatically stores patient data. The Pod’s lightweight design, compact size, and absence of tubing allow it to be discreetly worn on the body completely out of sight under clothing. The Pod also includes an automated cannula insertion system designed to reduce physical discomfort resulting from insertion errors, eliminate variability in insertion angle and depth, and reduce insertion-related anxiety. While no long-
The computer search identified 87 patients who were initiated on the OmniPod insulin pump, including 59 patients in whom pump initiation occurred at least one year ago. Table 1 includes baseline patient demographic information. Forty-seven of these patients were previously receiving multiple daily insulin injections while twelve patients switched from another insulin pump. After one year of use, average A1C values decreased by a significant 0.49% (p<0.01). An A1C of <7% was obtained by 25.5% of patients on the OmniPod compared to 5.7% of patients prior to initiation of the OmniPod (p<0.001). The one-year A1C was reduced but not significantly different (0.2%; p=0.22) in the twelve patients who switched from a different insulin pump. There was one episode of DKA compared to three episodes during the prior year. There were no documented reports of hypoglycemia requiring third party assistance the year prior to or during the one-year of OmniPod therapy (both p>0.05).

Three of the 59 patients discontinued pump therapy within one year because of difficulty with pod adhesion (n=2) or weight gain. One patient switched back to his previous insulin pump after 3 months of use. One-year follow-up information was unavailable for two patients who moved out of state and for six additional patients who have not yet returned for their one-year follow-up visits. Acceptance rate for the OmniPod was 92.2%.

Discussion/Conclusions

A retrospective review of the medical records of patients with diabetes initiating continuous insulin infusion therapy with the OmniPod Insulin Management System was performed to evaluate its efficacy, safety, and patient acceptance. Mean A1C values decreased by a significant 0.49% (p<0.01) after one year of use. This is comparable to the results reported in a recent meta-analysis of continuous subcutaneous insulin infusion versus multiple daily insulin injections. (9) While no significant reduction in A1C occurred in patients previously receiving insulin

### Table 1: Patient Baseline Characteristics.

<table>
<thead>
<tr>
<th>Number</th>
<th>59</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (M/F)</td>
<td>37/22</td>
</tr>
<tr>
<td>Type 1/Type 2</td>
<td>43/16</td>
</tr>
<tr>
<td>MDI/Pump</td>
<td>47/12</td>
</tr>
<tr>
<td>Age (years)</td>
<td>37 (+/-17)</td>
</tr>
<tr>
<td>Duration of Diabetes (years)</td>
<td>14 (+/-12)</td>
</tr>
<tr>
<td>HbA1C (%)</td>
<td>8.26% (+/-1.43)</td>
</tr>
</tbody>
</table>

This is a retrospective study which was approved by the Albany College of Pharmacy Institutional Review Board. The study population consisted of diabetes patients initiating continuous insulin infusion therapy with the OmniPod Insulin Management System who previously received multiple daily insulin injections or another insulin pump device. Potential subjects were initially identified through a computerized text search of patient electronic medical records using the terms insulin pump and OmniPod. The electronic medical record of each identified patient was subsequently reviewed to determine patients who actually started on this therapy.

A data collection form was developed and utilized to collect the following patient information: baseline patient demographic information (age, weight, height, gender, race, duration of diabetes), relevant disease states (e.g., cardiovascular disease, cerebrovascular disease, congestive heart failure, chronic renal disease) and duration of those diseases, medications, and laboratory information (A1C, serum creatinine, liver function tests, and lipid profile). Efficacy was determined by comparing A1C values at baseline (prior to use of the OmniPod) to A1C values after one year of its initiation. Safety was evaluated by a comparison of rates of hypoglycemia requiring assistance and episodes of diabetic ketoacidosis (DKA) occurring the year prior to initiation of the OmniPod with rates one year after initiation of the OmniPod. Reasons for product discontinuation were also identified and reported, as were documented reports of side effects that occurred during therapy. Acceptance of the OmniPod System was determined by the number of patients continuing to use the device one year after its initiation.

Statistical Methods

Each patient served as his/her own control. Paired t-tests were utilized for statistical analysis with p-values less than 0.05 considered statistically significant.
OmniPod Insulin Management System is designed to make living with diabetes easier by taking advantage of the proven healthcare benefits of continuous subcutaneous insulin infusion therapy, while overcoming the patient’s fear of needles or unsightly tubing. The high patient acceptance, improved glycemic control, and the overall safety demonstrated in this study supports the consideration of this pump system for diabetes patients aiming for improved glycemic control.

The OmniPod Insulin Management System was well accepted by patients, and was safe and effective in improving mean A1C values. The OmniPod should be considered by clinicians as a viable option for patients who are interested in insulin pump therapy.

**Disclosure**

This study was supported by an unrestricted educational grant from Insulet Corporation, manufacturers of the OmniPod Insulin Management System.

**References**


**Figure 1: OmniPod.**

Figure 1: OmniPod.

An A1C of <7% was obtained by 25.5% of patients on the OmniPod compared to 5.7% of patients prior to initiation of the Omnipod (p<0.001) demonstrating the utility of the device in improving blood glucose control. Improved glycemic control in type 1 and type 2 diabetes patients has been associated with improved patient outcomes (10-14).

The OmniPod was found to be safe. There were no significant differences in episodes of DKA or hypoglycemia requiring assistance among patients during the one year of OmniPod use compared to the year prior to starting the therapy; this despite an improved A1C.

The overall acceptance rate for the OmniPod in this study was 92.2%. The OmniPod Insulin Management System is designed to make living with diabetes easier by taking advantage of the proven healthcare benefits of continuous subcutaneous insulin infusion therapy, while overcoming the patient’s fear of needles or unsightly tubing. The high patient acceptance, improved glycemic control, and the overall safety demonstrated in this study supports the consideration of this pump system for diabetes patients aiming for improved glycemic control.

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**References**

Technological or Cellular Assistance for Type 1 Diabetes: “One size does not fit all!”

Eric Renard,

CHU de Montpellier, Montpellier, France

As with all patients with a chronic illness, those suffering from Type 1 Diabetes wish nothing more than to be rid off it. It is indeed the case for patients with type 1 diabetes, as their illness is linked to major impediments such as: the necessity to regulate perfectly their hyperglycemia which they only feel when they reach elevated levels and which needs to be identified several times a day, ending up being as much of a pain (if not more) as the treatment itself, the risk of severe consequences in the long term due to accumulated complications, a constraining daily therapy with a lack of reward for the patient, which if not followed properly can lead to serious hypoglycemias.

A durable solution to this heavy burden, which is the daily life of many patients, has been found decades ago: pancreas transplantation. This transplant is done conjoin tally with a kidney transplant and constitutes a miracle for those who have had the chance of undergoing such an operation: no more dialysis or insulin therapy. However, one has to go through the operation and then follow a long treatment of immuno-suppressant drugs who have many secondary effects, it is however worth it! There is no proof of its benefits if there is only a pancreas transplant. Apart from some desperate cases where the prognosis of diabetes is catastrophic, offering a pancreas transplant to treat type 1 diabetes constitutes a risk which must be carefully thought through.

In order to reduce the risk of the transplant of the whole organ, of which only insulin secretion is useful to treat diabetes, islet transplantation is an attractive solution. Since the announcement of the great results of the Edmonton team nearly ten years ago, this solution has gone from being “attractive” to “possible”. Its successful procedure requires experience in isolating islets and great organization from getting the pancreas to transplanting it into the liver by minimally invasive radiology techniques. There is also a need for effective immuno-suppression after transplantation. The French teams (Lille, reseau GRAGIL) have reproduced the Canadian findings by bringing their own touch of “savoir-faire” which has led to more durable results. These results have been recently published. The simplicity of the movement, which must however be repeated consecutively two to three times, and the metabolic result of patients being rid of the effects of their severe hypoglycemias, even if insulin has not been stopped completely, must not overshadow the heavy price that the patient will have to pay. The patient has substituted a deadly condition, which had become intolerable to live with, to a more tolerable one. The risk is different but not rid of. The immuno-suppressants make the patient hypertensive and hyperlipidemic, tend to alter his kidney functions, expose the patient to possible severe infections, and in the long term, immuno-suppressants may possibly increase the risk of cancer...while diabetes remains. The monetary price to pay for this treatment is not benign and healthcare will think twice before covering such a treatment. The technology used for insulin therapy, following the promise of an artificial pancreas “in five years”, has greatly improved concomitantly with the Alberta paper. Although the insulin pumps have been questioned for a long time, they have for the past fifteen years been part of the arsenal for insulinotherapy. The availability of fast insulin analogs has increased their potential for the control of glycemia and hypoglycemia. The implantable models for insulin pumps demand a high level of expertise for which the French teams have now become a reference. The possibility for continuous glucose monitoring, which remains “invasive”, not precise and costly, has proved year after year that it is indeed very helpful. The Holy Grail that is the artificial pancreas is finally showing short term results that open the door for home use, at least to cover the anguish of night time. The chronic illness remains but technology has made it easier for the patient and might also be able to improve the prognosis.

With the great improvements that we have witnessed over the past ten years for the treatment of type 1 diabetes, for which the internet has not been the best at relaying this message to the patients, how can we inform them properly? Reading the different debates on THE therapeutic solution to treating diabetes has not been helpful for the diabetologists. The doctor treats a patient, not an illness. Classifying a patient as “failure to control” does not lead to univocal response.

To put all the patients “considered as failures” in the same basket and to compare if islet transplantation is more effective than the most sophisticated technologies of insulin therapy is fine with lab rats but not with patients. It seems to be reasonable to direct a patient toward transplantation, when his diabetes has become intolerable and when he rejects his illness and his treatment to the point where his behavior may lead to a fatal hypoglycemia. In this case, this “not so perfect” method of treatment becomes an acceptable option. The healthcare coverage of the transplantation makes it more interesting than a possible therapeutic trial. In accordance with Hippocrates’ adage “primum non nocere”, to extend transplantation to all patients would make them take a risk in the short term or at a later date. To enable a patient to have access to technology because they are discouraged with not being able to control their glycemia and/or with the constraints of a conventional insulinotherapy, is to give them a new chance to lead a better daily life. The positive and the negative must be outweighed when advising each patient. Also, patience is key, because everything changes and evolves...apart from good sense!
This article describes the development and implementation of a classroom based introductory course in Continuous Glucose Monitoring (CGM). Part 1 describes course content and format. Part 2 (next issue of Infusystems USA) will discuss participant feedback, results and future direction of CGM education.

CGM has progressed rapidly in the past three years, with the FDA approval (for adults) of four “real time” devices: the Paradigm REAL-TIME and Guardian REAL-TIME (Medtronic Minimed, Northridge, CA), Freestyle Navigator (Abbott Diabetes Care, Alameda, CA), and Dexcom SEVEN PLUS (DexCom Inc, San Diego, CA). Two of these devices (Paradigm and Guardian REAL-TIME) are currently approved for pediatric use. The challenge for clinics, already overburdened with diabetes care management, is to find the time to inform and teach families about CGM. The most efficient approach to educating families on CGM use is not currently known. If done on an individual basis, most clinics would soon be overwhelmed with the time required. As a result, our Clinic has developed a classroom based approach to introduce patients and families to CGM.

As more families investigated the use of CGM for diabetes treatment, it became apparent that a similar introductory CGM class was necessary. The primary feedback came from patients directly informing the providers that they needed more information on CGM before they decided whether they would purchase it. These comments were heard from patients using both MDI and CSII. Many patients and families were casually familiar with the technology but needed more extensive information than could be provided during clinic visits.

Figure 1: Example slide from “Introduction to Continuous Glucose Monitoring” class, available online at www.barbaradaviscenter.org.
to worry about low or high blood sugars anymore, and that the sensor values would always match the blood sugar values. Some expected that the system could be used one night per week, or one week per month and their HbA1c level would improve. Unfortunately, this was disproven in a recent large-scale study (3).

**Methods and Program Overview**

Starting in May 2008, the “Introduction to Continuous Glucose Monitoring” class was offered monthly. Logistically, our diabetes clinic staff registers patients and families for the “Introduction to CGM” class and bills their insurance. The billing code used for the class is CPT 99213 “Evaluation and Management” with a level 3 intensity (approximately $97.00 per family). Families pay their usual co-pay for the class. The cost includes the class, all handouts, and the Insulin Pump/CGM family book (2). Currently, up to 15 families are allowed to register for each class, and typically eight to ten families attend each month. The class takes approximately 60 minutes of physician time and 180 minutes of diabetes educator time (including set-up and follow-up questions). The first Wednesday afternoon of every month is routinely reserved for this class.

The Introduction to CGM course is a 1.5 hour class divided into three educational components. The first two components of the class use lecture and discussion format with a slide presentation. (Figure 1). All families are given handouts of the slide material as well as a comparison chart of CGM devices (Figure 2), two color case study reports (Figure 3), a copy of the insulin pump/CGM book (2) (available from Children’s Diabetes Foundation at http://www.childrensdiabetesfoundation.org/ or 303-863-1200), and contact information for clinic staff and CGM companies. The final component involves families migrating throughout the room speaking with different diabetes educators about specific CGM devices, and being able to handle the devices personally. The slide set is available free of charge on the Barbara Davis Center website: http://www.uchsc.edu/misc/diabetes/clin-school.html.

The details of the curriculum are presented here:

**Figure 2:** Example comparison chart of CGM systems used in Introduction to CGM class.

**Figure 3:** Case study examples used in Introduction to CGM class.

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### Parts

- **MiniMed Guardian REAL-TIME**
  - Sensor connected to transmitter
  - Wireless Receiver
- **MiniMed Paradigm REAL-TIME**
  - Sensor connected to transmitter
  - Insulin pump receiver
- **Abbott Freestyle Navigator**
  - Sensor connected to transmitter
  - Wireless Receiver
- **Dexcom SEVEN PLUS**
  - Sensor connected to transmitter
  - Wireless Receiver

### Distance of communication

- MiniMed Guardian: 6 feet
- MiniMed Paradigm: 10 feet
- Abbott Freestyle Navigator: 5 feet
- Dexcom SEVEN PLUS: 5 feet

### Sensor life

- MiniMed Guardian: 3 days
- MiniMed Paradigm: 5 days
- Abbott Freestyle Navigator: 7 days
- Dexcom SEVEN PLUS: 7 days

### Insertion device

- MiniMed Guardian: SenSerter: user loads needle/sensor into device, spring loaded entry into skin, user removes needle
- MiniMed Paradigm: Sensor/needle built into inserter, spring loaded entry and automatic removal
- Abbott Freestyle Navigator: Sensor/needle built into inserter, inserts with button push, user removes needle
- Dexcom SEVEN PLUS: Sensor/needle built into inserter, spring loaded entry into inserter, inserts with button push, user removes needle

### How it obtains BG data

- MiniMed Guardian: Medtronic link meter or manual entry
- MiniMed Paradigm: FreeStyle meter built into receiver
- Abbott Freestyle Navigator: Cable link to OneTouch Ultra or manual entry

### Initial calibration period

- MiniMed Guardian: 2 hours
- MiniMed Paradigm: 10 hours (1 hour version recently FDA approved)
- Abbott Freestyle Navigator: 2 hours

### Number of calibrations

- MiniMed Guardian: 2-4 per day
- MiniMed Paradigm: 4 in 5 days
- Abbott Freestyle Navigator: 2-4 per day

### Trend arrows

- MiniMed Guardian: Yes
- MiniMed Paradigm: Yes
- Abbott Freestyle Navigator: Yes
- Dexcom SEVEN PLUS: Yes

### High/low alarms

- MiniMed Guardian: Yes
- MiniMed Paradigm: Yes
- Abbott Freestyle Navigator: Yes
- Dexcom SEVEN PLUS: Yes

### Graphs on receiver

- MiniMed Guardian: Yes
- MiniMed Paradigm: Yes
- Abbott Freestyle Navigator: Yes
- Dexcom SEVEN PLUS: Yes

### Waterproof transmitter

- MiniMed Guardian: Yes
- MiniMed Paradigm: Yes
- Abbott Freestyle Navigator: Yes
- Dexcom SEVEN PLUS: Yes

### Reconnection of sensor and receiver

- Abbott Freestyle Navigator: Automatic
- Dexcom SEVEN PLUS: Automatic

### Power source in receiver

- MiniMed Guardian: 1 AAA battery
- MiniMed Paradigm: 2 AAA batteries
- Abbott Freestyle Navigator: Internal battery
- Dexcom SEVEN PLUS: Rechargeable battery

### Power source in transmitter

- MiniMed Guardian: Rechargeable battery (AAA in charger)
- MiniMed Paradigm: 357 watch battery
- Abbott Freestyle Navigator: Internal battery
- Dexcom SEVEN PLUS: Rechargeable battery

### Unique features

- MiniMed Guardian: Minilink transmitter can hold 40 minutes of data if transmitter and receiver lose connectivity
- MiniMed Paradigm: Meter built into CGM
- Abbott Freestyle Navigator: Hard low alarm at 55mg/dl cannot be turned off
- Dexcom SEVEN PLUS: Hard low alarm at 55mg/dl cannot be turned off

### Cost

- MiniMed Guardian: $1000 system
  - $35/sensor
- MiniMed Paradigm: $1000 sensor system + Medtronic link meter or manual entry
  - $35/sensor
  - $722/522 insulin pump
  - $35/sensor
- Abbott Freestyle Navigator: $400-1000 system
  - $60/sensor
- Dexcom SEVEN PLUS: $60/sensor

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For each family, the system would typically be used one night per week, or one week per month and their HbA1c level would improve. Unfortunately, this was disproven in a recent large-scale study (3).
PART 1: Physician session (30-45 minutes): This session explores general information about continuous glucose monitoring.

<table>
<thead>
<tr>
<th>OBJECTIVE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe what a continuous glucose monitor does</td>
<td>Provides “real time” glucose readings about trends in glucose levels</td>
</tr>
<tr>
<td>Describe what characteristics are important in determining who will be most successful in using CGM</td>
<td>Patient and family must:</td>
</tr>
<tr>
<td></td>
<td>□ Both desire to use technology</td>
</tr>
<tr>
<td></td>
<td>□ Be willing to wear a sensor and carry a receiver</td>
</tr>
<tr>
<td></td>
<td>□ Already be practicing good diabetes care</td>
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<tr>
<td></td>
<td>□ Have a sufficient social support system</td>
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<tr>
<td></td>
<td>□ Must have adequate body space to wear a sensor</td>
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<tr>
<td></td>
<td>□ Must be able to afford upkeep of technology (paying for sensors, etc.) with or without insurance</td>
</tr>
<tr>
<td>Describe reasons why CGM can be beneficial</td>
<td>□ Assists in prevention of hypoglycemia</td>
</tr>
<tr>
<td></td>
<td>□ Assists in prevention of hyperglycemia and ketones</td>
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<td></td>
<td>□ Minimizes wide glucose fluctuations</td>
</tr>
<tr>
<td></td>
<td>□ Acts as a behavior modifier</td>
</tr>
<tr>
<td></td>
<td>□ May prevent future complications</td>
</tr>
<tr>
<td>Describe the three main components of CGM and their function</td>
<td>□ Sensor: Measures subcutaneous glucose levels</td>
</tr>
<tr>
<td></td>
<td>□ Transmitter: Transmits sensor information to the receiver</td>
</tr>
<tr>
<td></td>
<td>□ Receiver: Displays glucose and trend information for the user</td>
</tr>
<tr>
<td>Describe meaning and importance of calibrations</td>
<td>□ Definition of calibration: Providing the CGM with a blood glucose value so the sensor readings can align with it</td>
</tr>
<tr>
<td></td>
<td>□ Number of calibrations vary by device</td>
</tr>
<tr>
<td></td>
<td>□ Best times to calibrate are when glucose levels are stable: before meals, before bed, etc.</td>
</tr>
<tr>
<td></td>
<td>□ Best not to calibrate when trends show glucose levels changing (i.e. arrows)</td>
</tr>
<tr>
<td>Types of “Real Time” data</td>
<td>□ Trend graphs</td>
</tr>
<tr>
<td></td>
<td>□ Alarms: including threshold and predictive alarms</td>
</tr>
<tr>
<td></td>
<td>□ Trend arrows</td>
</tr>
<tr>
<td>Types of “Retrospective data”</td>
<td>□ Modal day graphs</td>
</tr>
<tr>
<td></td>
<td>□ Pie Charts</td>
</tr>
<tr>
<td></td>
<td>□ Statistics</td>
</tr>
<tr>
<td></td>
<td>□ Provide examples, how to interpret, usefulness</td>
</tr>
<tr>
<td>Using CGM results to adjust insulin and diabetes routine</td>
<td>□ Important not to be overwhelmed by information</td>
</tr>
<tr>
<td></td>
<td>□ Make only one insulin change at a time</td>
</tr>
<tr>
<td></td>
<td>□ Look for patterns in glucose levels (2 out of 3 days) before making a change</td>
</tr>
<tr>
<td></td>
<td>□ Use to modify behavior: look for missed insulin doses, snacking, untreated low glucose levels, etc.</td>
</tr>
<tr>
<td>Case studies (added September 2008)</td>
<td>□ Families given two color modal day examples to evaluate and discuss</td>
</tr>
<tr>
<td></td>
<td>□ HCP facilitates family input on what glycemic patterns they observe, possible causes, and insulin dose changes</td>
</tr>
<tr>
<td>Misconception #1: “If I use CGM, I do not have to do BG checks anymore.”</td>
<td>□ Not FDA approved for replacement of BGs for diabetes management</td>
</tr>
<tr>
<td></td>
<td>□ BG checks needed for calibrations, testing low and high numbers, making insulin dosing decisions</td>
</tr>
<tr>
<td>Misconception #2: “CGM will make diabetes management simple.”</td>
<td>□ Initially, can be overwhelming</td>
</tr>
<tr>
<td></td>
<td>□ Can be helpful to follow an algorithm for making changes</td>
</tr>
<tr>
<td></td>
<td>□ Good initial education helps the learning curve</td>
</tr>
<tr>
<td>Misconception #3: “CGM can fix diabetes—all blood sugars will be perfect.”</td>
<td>□ Blood sugars will never be perfect</td>
</tr>
<tr>
<td></td>
<td>□ Can help reduce extreme glucose fluctuations</td>
</tr>
<tr>
<td></td>
<td>□ Can help reduce time spent in hyper- and hypoglycemia</td>
</tr>
<tr>
<td>Misconception #4: “CGM values will match BG values.”</td>
<td>□ CGM values lag behind blood glucose by ~10 minutes</td>
</tr>
<tr>
<td></td>
<td>□ CGM and BG values furthest apart with a rapid increase or decrease in glucose level</td>
</tr>
<tr>
<td></td>
<td>□ Bode found 80% of Navigator values within 20% of BG values</td>
</tr>
<tr>
<td></td>
<td>□ CGM less accurate immediately after insertion and warm up</td>
</tr>
<tr>
<td>Misconception #5 “The alarms will catch every low blood sugar so I do not have to worry about hypoglycemia anymore.”</td>
<td>□ Should always check a BG if feeling symptoms of hypoglycemia, even if the CGM does not alarm</td>
</tr>
<tr>
<td></td>
<td>□ Alarms may not be as sensitive to slowly decreasing glucose levels</td>
</tr>
<tr>
<td></td>
<td>□ Lag time could cause the CGM to read an in range number when actual BG is low</td>
</tr>
<tr>
<td>Questions/discussion</td>
<td>□ Additional information about how to make insulin dosing changes using CGM</td>
</tr>
<tr>
<td></td>
<td>□ The future of pumps and sensors</td>
</tr>
</tbody>
</table>
Families are encouraged to visit each device display to handle the systems and ask questions. Diabetes educators help explain the unique aspects of each device, and how the different CGMs would fit into each family's lifestyle. Often, the educators will place a sensor and transmitter against the patient's skin to show them what the sensor would look like, and have them carry around the receiver in their pocket. Families are also able to touch the actual demonstration sensor and look at needle sizes and insertion devices.

**References**


*This article will be continued in the next issue of Infusystems USA.*
Is this the way patients need to handle their rapid-acting insulin?

How “real world” is your patients’ rapid-acting insulin?

Can it withstand temperatures up to 86°F?

Does it require refrigeration after it’s been opened?

Does it have a low risk of clogs in the pump reservoir and distal tubing?¹

Your patients should benefit from their insulin therapy—not cater to it.
For a stable rapid-acting mealtime insulin, consider NovoLog®.

NovoLog® is an insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus.

Important safety information

NovoLog® is contraindicated during episodes of hypoglycemia and in patients hypersensitive to NovoLog® or one of its excipients. NovoLog® has a more rapid onset and shorter duration of action than regular human insulin. An injection of NovoLog® should be immediately followed by a meal within 5 to 10 minutes. Because of the short duration of action of NovoLog®, a longer-acting insulin also should be used in patients with type 1 diabetes and may be needed in patients with type 2 diabetes. When used in an external subcutaneous insulin infusion pump, NovoLog® should not be mixed with any other insulin or diluent. Hypoglycemia is the most common adverse effect of all insulin therapies, including NovoLog®. The timing of hypoglycemia usually reflects the time-action profile of the administered insulins. Any change of insulin dose should be made cautiously and only under medical supervision. Glucose monitoring is recommended for all patients with diabetes and is particularly important for patients using external pump infusion therapy. As with all insulin preparations, the time course of action of NovoLog® may vary in different individuals or at different times in the same individual and is dependent on many conditions, including injection site, local blood supply, temperature, and level of physical activity. Severe, life-threatening generalized allergy, including anaphylactic reaction, may occur with any insulin product, including NovoLog®. Adverse reactions observed with NovoLog® include hypoglycemia, allergic reactions, local injection site reactions, lipodystrophy, rash, and pruritus. Insulin, particularly when given intravenously or in settings of poor glycemic control, may cause hypokalemia. Like all insulins, NovoLog® requirements may be reduced in patients with renal impairment or hepatic impairment.

Please see brief summary of Prescribing Information on adjacent page.

For more information, visit novomediink.com/NovoLog.
NovoLog® (insulin aspart [rDNA origin] injection) 

fix only

**BRIEF SUMMARY.** Please consult package insert for full prescribing information.

**INDICATIONS AND USAGE.** NovoLog® is an insulin analog indicated to improve glycemic control in adults with type 1 diabetes. It may be used either alone or in combination with other insulin products. 

**CONTRAINDICATIONS.** NovoLog® is contraindicated during episodes of hypoglycemia and in patients hypersensitive to NovoLog® or one of its excipients. 

**WARNINGS AND PRECAUTIONS.** Administration: NovoLog® has a more rapid onset of action and a shorter duration of action than regular human insulin. An injection of NovoLog® should immediately before meals to achieve optimal glycemic control. Avoid self-injection into an area of the body that is already painful or is bruised or infected. If NovoLog® is injected into fat, insulin activity may last for up to 10 hours. 

**ADVERSE REACTIONS.** 

**Clinical Trial Experience.** 

**Hypoglycemia:** Hypoglycemia is the most common adverse effect of insulin therapies, including NovoLog®. Serious hypoglycemia may lead to unconsciousness and, if not treated promptly, may result in permanent neurologic damage or death. 

**Renal Impairment:** As with other insulins, the dose requirements for NovoLog® may be reduced in patients with renal impairment. 

**Hepatic Impairment:** As with other insulins, the dose requirements for NovoLog® may be reduced in patients with hepatic impairment. 

**Hypersensitivity and Allergic Reactions:** Local Reactions - As with other insulin therapy, patients may experience redness, swelling, or itching at the site of NovoLog® injection. These reactions usually resolve in a few days to a few weeks. In some occasions, may require discontinuation of NovoLog®. In rare instances, these reactions may be related to factors other than insulin, such as infants in a skin cleansing agent or poor injection technique. Localized reactions and generalized myalgias have been reported with injection mistakes, which is analogic in NovoLog®. 

**Systemic Reactions - Severe, Life-Threatening:** Severe allergic reactions, including anaphylaxis, may occur with any insulin therapy. Anaphylactic reactions with NPH insulin have been reported post-marketing. 

**Nutritional Information:** Patients with chronic liver disease may be at risk of hypoglycemia if they are taking ethanol. 

**Monitoring:** The frequency of insulin dose adjustments should be determined by the patient's response to treatment. The dose of insulin may need to be adjusted more frequently in patients with liver disease. 

**Hypoglycemia:** Hypoglycemia is also common in patients with diabetes. 

**Postmarketing Data:** The following additional adverse reactions have been identified during postapproval use of NovoLog®. Because these adverse reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency, and further evaluate their potential relationship to the drug. 

**OVERDOSAGE:** Excess insulin administration may cause hypoglycemia and, particularly when given intraarterially, hypokalemia. MI/MI syndrome and hepatic failure. 

**General Information:** NovoLog® is available in a concentration of 100 U/ml in 3 mL vials. 

Table 1: NovoLog® + NHPI N=918 and Human Regular Insulin + NHPI N=386

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>N (%)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoglycemia</td>
<td>448 (75%</td>
<td>505 (72%</td>
</tr>
<tr>
<td>Headache</td>
<td>70 (12%</td>
<td>28 (10%</td>
</tr>
<tr>
<td>Intraocular pressure</td>
<td>65 (11%</td>
<td>29 (10%</td>
</tr>
<tr>
<td>Nausea</td>
<td>43 (7%</td>
<td>13 (5%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>28 (5%</td>
<td>9 (3%</td>
</tr>
</tbody>
</table>

*Hypoglycemia is defined as an episode of D-dimer concentration: <45 mg/dL, with or without symptoms. See Clinical Diagnostics for the incidence of serious hypoglycemia in the individual clinical trial. 

Table 2: NovoLog® + NHPI N=918 and Human Regular Insulin + NHPI N=386

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>N (%)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoglycemia</td>
<td>99 (77%</td>
<td>53 (39%</td>
</tr>
<tr>
<td>Headache</td>
<td>10 (7%</td>
<td>6 (7%</td>
</tr>
<tr>
<td>Nausea</td>
<td>9 (7%</td>
<td>5 (5%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>8 (6%</td>
<td>6 (7%</td>
</tr>
<tr>
<td>Intraocular pressure</td>
<td>8 (6%</td>
<td>6 (7%</td>
</tr>
<tr>
<td>Nausea</td>
<td>5 (3%</td>
<td>5 (3%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>5 (3%</td>
<td>5 (3%</td>
</tr>
<tr>
<td>Intraocular pressure</td>
<td>5 (3%</td>
<td>5 (3%</td>
</tr>
<tr>
<td>Nausea</td>
<td>5 (3%</td>
<td>5 (3%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>5 (3%</td>
<td>5 (3%</td>
</tr>
</tbody>
</table>

*Hypoglycemia is defined as an episode of D-dimer concentration: <45 mg/dL, with or without symptoms. See Clinical Diagnostics for the incidence of serious hypoglycemia in the individual clinical trial. 

**More detailed information is available on request.**

**Date of Issue:** March 14, 2009

**Version:** 14

**Manufactured by**: Novo Nordisk A/S, DK-2880 Bagne, Denmark

**Manufactured for Novo Nordisk Inc., Princeton, New Jersey 08540**

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