

# **Insulin Pump Therapy: Guidelines for Successful Outcomes**

*American Association of Diabetes Educators 2008 Consensus Summit  
September 18, 2008 • Chicago, Illinois*

This white paper was developed by AADE and is supported by an independent educational grant from LifeScan and Medtronic Inc.

**AADE** American Association  
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50% of salary from the National Institute of Health  
Stock shareholder: Amylin Pharmaceutical, Inc, Dex Com, Patton Medical Devices  
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Honoraria: Novo Nordisk; Abbott; Takeda; Seattle Medical, Home Diagnostics; Animas; AgaMatrix; Eli Lilly; Amylin Pharmaceuticals; Animas  
Speakers' Bureau: Amylin; Lilly; Novo Nordisk; Lilly-Amylin Alliance  
Grants/Research Support: NIH: 2 research studies; Eli Lilly; Amylin Pharmaceuticals

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No disclosures stated

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*The authors wish to thank Melissa P. Ford for her contribution to the writing of this white paper.*

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## Introduction

Industry estimates indicate that the estimated number of continuous subcutaneous insulin infusion (CSII, “insulin pump therapy”) users in the United States has grown from 70,000 to over 300,000 since 1998. Technological advances have increased the appeal of pump therapy to both patients and clinicians. As the number of pump users and potential users expands, diabetes educators may face new challenges and opportunities to improve their patients’ lives with diabetes. In September 2008, the American Association of Diabetes Educators (AADE) convened a multidisciplinary expert panel to discuss guidelines for achieving optimal outcomes in patients with diabetes using insulin pumps.

The panel included certified diabetes educators (CDEs), board certified advanced diabetes management educators (BC-ADMs), endocrinologists, certified nurse practitioners, an exercise physiologist, a clinical pharmacist, and a registered dietitian, each with extensive experience in caring for patients with diabetes mellitus (DM) using insulin pumps.

The panel discussed several aspects of insulin pump use, including the rationale for therapy, patient selection, pre-pump and ongoing management and education, use of pump therapy in different age groups, and the role of the diabetes educator in facilitating successful outcomes in CSII therapy.

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## **Rationale for Insulin Pump Therapy**

Since the first human trials of insulin pump therapy in the late 1970s<sup>1</sup>, numerous studies have demonstrated the potential for insulin pump therapy to minimize hypoglycemia and maintain long-term glycemic control compared to multiple daily injections (MDI), defined as >3 daily insulin injections.<sup>2-7</sup> In 1993 the Diabetes Control and Complications Trial (DCCT) established that intensive insulin therapy in type 1 diabetes (T1DM), either with an external insulin pump or MDI, in conjunction with frequent self-monitoring of blood glucose (SMBG) and delayed the onset and slowed the progression of diabetes complications including retinopathy, nephropathy, and neuropathy, compared with conventional therapy (1 or 2 daily insulin injections).<sup>8</sup>

Although the theory has not been confirmed *in vivo*, *in vitro* studies and retrospective analyses of human data suggest that fluctuations between hypo- and hyperglycemia are more damaging to cells than elevated glucose alone.<sup>9</sup>

## **Advantages and Potential Challenges of CSII**

The chief benefit of insulin pump therapy is customized, flexible basal and bolus dosing to meet patients' individual insulin requirements while reducing the risk of severe hypoglycemia.<sup>10</sup> Insulin delivery via pump is more consistent and precise than delivery by syringe or injection pen.

With a pump, basal insulin can be adjusted in increments as small as 0.25-unit, depending on the model of pump. Bolus insulin can be dosed to within 0.1-unit increments or even 0.05-unit

increments on some pumps. More precise and accurate insulin dosing can better regulate blood glucose levels.<sup>11</sup>

Patients and care providers can face challenges as they seek to optimize therapy. Conscientious patient selection is key to realizing the potential advantages of pump therapy, as is thorough patient training. Insulin pump therapy requires more training than other forms of insulin delivery. Thorough training builds patients' understanding of pump therapy principles, as well as how best to use the technology to manage their diabetes. Patients starting insulin pump therapy must be motivated to improve their glucose control and willing to work with their health care team to pursue mutually agreed objectives of therapy.

Frequent (up to 6-8 times daily) self-monitoring of blood glucose (SMBG) is the foundation of intensive diabetes management. Diabetic ketoacidosis (DKA) is rare among pump users who perform SMBG adequately, but can develop quickly because of the short half-life of rapid-acting insulin analogues (lispro, aspart, glulisine) commonly used in pumps.<sup>11</sup> The panelists concurred that the advantages of insulin pump therapy outweigh its potential disadvantages.

## **Current Insulin Pump Technology**

All available traditional insulin pumps are about the size of a pager, water resistant, and relatively easy to program and use for properly trained patients; however, each of these pumps has different features that may make it better suited for one patient over another. Features common to all pumps include durability, safety mechanisms, and product support from the manufacturer. Features that vary include reservoir size, screen type/size, basal and bolus delivery increments, compatibility

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with SMBG meter(s)/continuous glucose monitoring (CGM) devices, specificity of bolus calculations, simplicity of programming, water-tightness, data downloading/uploading options and history reports. As a patient is connected to his or her pump almost all the time, how the pump looks and feels to wear may also be important to patients.<sup>12</sup> Understanding the features and capabilities of each pump helps the patient make an informed choice. Patients considering insulin pump therapy should consult their health insurance provider to discuss the level of reimbursement for CSII.

Characteristics to consider when selecting a pump include the complexity of the pump relative to the user's abilities, water resistance, whether the pump is attached to the patient directly to the skin or via tubing, whether or not the pump can communicate with a glucose monitor and/or sensor, and available diabetes data management software. All insulin pumps except the OmniPod (Insulet Corp., Bedford, MA), require the use of a separate infusion set, which consists of thin plastic tubing connected to a very thin stainless steel or flexible Teflon cannula inserted just under the skin at a 30–90-degree angle and a depth of 6–8 mm, and a plastic connector that joins the tubing to the cannula.<sup>13</sup> In addition, the cannula can be inserted manually or with the use of an insertion device. Short (average 23-inch) or long (average 43-inch) tubing can be used depending on patient preference. Patients may try several infusion set types before settling on which to use regularly.

### **Appropriate Candidates for Pump Therapy**

The panel agreed that patients should be considered for insulin pump therapy when intermittent insulin injections are not meeting

treatment goals and outcome measures are suboptimal, including, but not limited to:

- A1C >7.0-7.5%, accompanied by frequent severe hypoglycemia (<55 mg/dL)
- Hypoglycemic events requiring third-party assistance or interfering with work, school, or family obligations
- Frequent and unpredictable fluctuations in blood glucose levels
- Patient perception that diabetes management impedes the pursuit of personal or professional goals

Prospective pump users or their care givers must be able to change infusion sets, fill pump cartridges and program the pump, and must demonstrate willingness to collaborate with healthcare providers in achieving the goals of diabetes therapy.<sup>14</sup> In general, patients likely to succeed on insulin pump therapy will have had sufficient education and support while using other forms of insulin therapy so that they are already competent in assessing the nutritional value of meals and monitoring blood glucose levels frequently (minimum four times a day, preferably 6–8 times) and checking ketone levels when appropriate.<sup>15</sup> Insulin pump therapy is contraindicated in patients lacking the commitment or competence to perform basic diabetes self-management behaviors. Some studies have suggested that patients whose diabetes greatly disrupts their lifestyle do not benefit from use of pump therapy;<sup>16</sup> however, recent research has shown that such patients can see positive results from using a pump.<sup>17</sup>

Overall, there was a consensus among the panelists that, formal education and technological literacy notwithstanding, most patients have the capacity to start insulin pump therapy. A patient's functional ability, not his or her chronological age, should drive

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treatment decisions.<sup>18</sup> Adequate support can enable young children, adolescents and elderly patients to benefit from CSII. However, as the

panel noted, insurance copayments for pumps and supplies may be cost-prohibitive for some patients on low incomes.

# Principals and Practical Aspects of Pump Therapy

## Ongoing specialist support increases satisfaction with CSII, improving outcomes

To achieve treatment goals, insulin pump therapy should be prescribed and overseen in the long term by a specialist diabetes care team.<sup>12</sup> The panelists agreed that while prescribing an insulin pump is the domain of specialists, a prescribing physician need not be an endocrinologist. Familiarity and comfort with insulin pump therapy are the key characteristics of a qualified prescriber. For pump initiation and training, patients' interests are best served by a multidisciplinary team comprised of a physician and/or nurse practitioner, a certified diabetes educator and a dietitian.

## Choosing a Pump Model and Infusion Set

After a patient has been assessed as a suitable candidate for insulin pump therapy, he or she must select an insulin pump model and begin pump training. Understanding the features and capabilities of each pump helps the patient make an informed product choice. Characteristics to consider when selecting a pump include the complexity of the pump relative to the user's abilities, water resistance, whether the pump is attached to the patient directly to the skin or via through tubing, whether or not the pump can communicate with a glucose monitor

and/or sensor, and available diabetes data management software. Patients can become familiar with the different pumps by visiting manufacturers' websites and reading brochures. In addition, patients can be shown demonstrations of available pumps and interact with current "pumpers" so that they can assess the pumps' physical characteristics and ease of use. Patients should also be evaluated for the appropriateness for the different infusion sets. Considerations should include body fat composition, body placement options, and comfort of the set when worn.

Panelists' opinions diverged regarding the utility of saline trials in patients about to begin pump therapy. Patients' time commitments to diabetes management are typically extensive and a trial of the pump while still on MDI could add to the burden. On the other hand, a trial with saline can help a patient practice using the pump (pressing buttons, wearing the device) without running the risk of making a potentially serious treatment error. Patients who want to try wearing a pump before starting therapy, or those who seem anxious about the practicalities of being "connected," may benefit from being offered a saline trial.

## Initial Basal Rate and Bolus Ratio Calculation

Before starting therapy, the initial basal rate and bolus doses must be determined. The approximate total daily dose (TDD) of

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insulin that an adult type 1 diabetes patient requires can be calculated by multiplying the patient's current weight in kilograms (kg) by 0.7. Thus a 60-kg woman would require a TDD of insulin of about  $60 \times 0.7 = 42$  U. Adolescents may require more insulin, ~1 U/kg/day, whereas older patients (who are not more insulin sensitive, but who produce less endogenous glucose) may need only 0.5 U/kg/day.<sup>19</sup> In addition, if a patient is switching from MDI to insulin pump therapy, the initial TDD may be derived from MDI doses, but should be reduced by 10%<sup>20</sup> to 20% owing to pharmacokinetic differences between the modalities.

An appropriate basal rate keeps blood glucose levels stable overnight and when the patient has not eaten or bolused recently. In general, about 40-50% of the daily insulin requirement is given as basal insulin, though this ratio can vary significantly from patient to patient. The remaining 50-60% of daily insulin is delivered primarily as pre-meal boluses to compensate

for meals.<sup>21</sup> Correction doses to reduce glycemic excursions may also be delivered as pump boluses if the user is confident that the pump is delivering insulin correctly.

Once the initial flat basal rate has been established, the remainder of the insulin TDD may be divided into bolus doses, unless the pump user can carry over established bolus ratios from MDI. Patients using rapid-acting insulin should deliver the bolus about 15 minutes before the meal to avoid a postprandial glycemic spike. If the pump user has mild hypoglycemia (65–75 mg/dL) before the meal, he or she may prefer to bolus at the start of the meal. Pre-meal bolus doses are determined according to the preprandial blood glucose level, the estimated nutritional content of the meal (in particular, carbohydrates measured in grams), anticipated activity level after eating, and prior experience with insulin requirements for similar meals.<sup>22</sup>

## Priorities for Pump Users' Ongoing Diabetes Self-Management Education

Achieving the goals of CSII therapy requires diabetes self-management education regarding several topics specifically relevant to insulin pump use. The panel agreed that these topics include, but are not limited to:

- infusion site management
- fine-tuning basal rates and bolus ratios
- minimizing the risk of diabetic ketoacidosis
- exercising effectively with a pump

Additionally, patients using an insulin pump and their healthcare providers should discuss the role of record-keeping by the

patient in optimizing therapy. Although CSII discontinuation is rare, healthcare teams and patients benefit from understanding the conditions under which return to MDI may be more appropriate.

### Infusion Site Management

An immediate, practical difference between MDI and insulin pump therapy is the infusion set that connects the pump to the patient. Soft cannulas made of Teflon can remain in the subcutaneous tissue for up to 72 hours, but steel needles need to be changed every

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2 days.<sup>13</sup> During the summer months, in hot temperatures, the infusion set may need to be changed every two days, as sweat can affect the adhesive and encourage bacterial growth. The panel agreed that waiting more than 3 days to change the infusion set can increase the risk of infection and other complications.

### **Fine Tuning Basal Rates and Bolus Ratios**

The basal rate can be fine-tuned following careful assessment of fasting blood sugar using several readings, including a reading in the middle of night. Alternatively, continuous glucose monitoring can be used. If the glucose level remains steady overnight, then the basal rate is considered accurate. If the glucose level rises more than 30 mg/dL between readings, the basal rate should be increased at least 1 hour before the rise is observed. If the level decreases by more than 30 mg/dL, the rate should be reduced a minimum of 1 hour before the decline starts.<sup>23</sup> Once the overnight rate is established, the rate between waking and lunch can be evaluated by asking the patient to skip breakfast and test blood glucose level every 2 hours during the morning hours. Once the morning rate is established, the patient can skip other meals and again monitor blood glucose every 2 hours to determine basal rates during the day.

The process of fine-tuning boluses relies on the individual patient's correct insulin-to-carbohydrate (I:C) ratio(s) and insulin sensitivity factor (ISF). The correct I:C ratio – applied to accurate assessment of the nutritional content of a meal – should return a pump user's blood glucose value to a near pre-meal level 3-4 hours post-meal. Correction boluses are used to restore a patient's glucose level to his or her target range quickly if a hyperglycemic excursion is detected through SMBG or CGM 2-3 hours after the last meal bolus. Correction boluses may be given by

pump if the patient has used proper protocols to ascertain that glycemic excursion was not caused by pump malfunction, but rather by incorrect carbohydrate assessment at the previous meal or an infusion set issue that was resolved by changing the infusion set. The integrated bolus calculator in most marketed pumps can support users in programming meal and correction boluses to meet their needs. The bolus dose can be delivered all at once, in a "normal" bolus; the bolus can be given over a period time in a prolonged bolus; or the bolus can incorporate some insulin up-front with an initial normal bolus followed by extended delivery of the remaining bolus ("combination" bolus).<sup>21</sup>

### **Minimizing the Risk of Diabetic Ketoacidosis**

Hyperglycemia accompanied by ketones can lead to rapid dehydration so patients should be instructed to consume copious amounts of water or other carbohydrate-free fluids. The value of maintaining body fluid levels is a key element of patient education to prevent DKA in pump users. Pump or infusion set malfunction or failure can cause exogenous insulin deficiency, while inflammation, infection, or lipodystrophy at the infusion site may prevent proper delivery or absorption of insulin. Following cannula labeling by changing the infusion site every 72 hours minimizes the risk of skin infections and malabsorption. DKA may also result from insulin degradation, if insulin has been subjected to extremes of temperature.<sup>21</sup> The panel emphasized the importance of reminding patients to store insulin according to the manufacturer's labeling, as well as checking that rapid-acting insulin is clear, not crystallized or cloudy. Endogenous insulin resistance—which may arise from viral or bacterial infection, or severe stress—can also cause DKA.

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In pump users, glucose levels typically rise sharply within a few hours of insulin delivery being interrupted as pump therapy relies on continuous infusion of rapid-acting insulin instead of intermediate- or long-acting insulin preparations. To minimize the risk of DKA, patients should routinely check blood glucose levels a minimum of 4 times daily, optimally 6–8 times daily, in order to detect hyperglycemia early.<sup>24</sup> When DKA occurs, reducing glucose levels down to the patient’s target range must be the first priority. If the cause was a pump malfunction, the pump should be reconnected after the cause of the malfunction has been identified and addressed,<sup>25</sup> but the patient must revert to MDI if the problem cannot be corrected quickly.

A blood glucose level higher than 250 mg/dL and the presence of ketones in the blood (> 0.5 mmol/L) or urine (moderate or large) indicate an increased need for insulin. The patient should administer 0.1 U/kg (0.5 U/10 lb) body weight of rapid acting insulin with a pen or syringe. If blood glucose does not decrease within the hour, then an additional 0.1 U/kg (0.5 U/10 lb) can be used.<sup>26</sup> The patient should also increase intake of sugar-free fluids, at least 8 ounces every 30 minutes.

According to one panelist, patients must understand that “if blood glucose does not come down after a bolus, two at the most, this should be a signal to change the infusion site and to take insulin by a syringe or pen.” Another panelist commented that, when a pump occlusion has occurred, frequent SMBG is more reliable for preventing DKA than a pump malfunction alarm. A pump’s occlusion alarm may go off after the patient has entered DKA, depending on the patient’s insulin requirements and the pump’s occlusion detection sensitivity. In addition to insulin, patients should be advised to keep a glucagon

kit and urine ketone monitoring strips (or a blood ketone monitor and test strips) on hand, as well as a backup blood glucose monitor, pump batteries and syringes or an insulin injection pen.

### **Exercising effectively with a pump**

Insulin pump therapy is especially well suited to physically active patients as it allows flexibility and easy adjustment of basal and bolus insulin doses. In patients with DM, the risk of hypoglycemia during and in the hours following exercise is substantially increased because exercise enhances the body’s sensitivity to insulin.<sup>25</sup> Titrating the correct basal dose during exercise and hours later provides a clear benefit. Simply stopping the basal insulin during the workout can lead to hyperglycemia after the activity if the body enters a state of insulin deficiency. Effective dose adjustment strategies include reducing the bolus for the meal prior to exercise, consuming carbohydrate just before exercise, and/or lowering the basal rate starting 1-2 hours prior to exercise. If exercising in the afternoon, the patient can prevent delayed-onset hypoglycemia by lowering the basal dose 10-20% for the rest of the evening and overnight. Similar adjustments can be made for an irregular work schedule; for example, the basal insulin dose can be increased to compensate for the stress effect of staying awake overnight.<sup>21</sup>

### **Patient record-keeping aids therapy optimization**

The panel agreed that even with the more sophisticated electronic approaches now available, manual record keeping techniques such as a food and exercise diary still represent the gold standard. “It has been one of the paradoxes that old-fashioned manual logging has won out,” noted one panelist. Patients starting insulin pump therapy should

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be encouraged, at a minimum, to record blood glucose levels, boluses and basal rate adjustments. A food diary is also useful for assessing carbohydrate consumption and overall nutritional intake. If the food diary can be correlated to glucose levels, it can enable the patient and his or her healthcare team to detect and address behaviors and/or physiological phenomena impairing tight glucose control.

### **CSII Discontinuation is Rare**

As one panelist noted, patients do not discontinue pump use without a specific reason. According to the panel, the main reason for insulin pump discontinuation – estimated to occur in about 5% of users – is the patient simply tiring of pump use. Underlining the importance of patient selection for pump therapy, patients who could manage their diabetes successfully on MDI may decide that that they prefer MDI to CSII.

If a pump user's overall diabetes control deteriorates, the patient may be missing boluses for carbohydrate consumption; not correcting elevated blood glucose levels appropriately; or mismanaging hyperglycemia with ketones, leading to emergency treatment or hospitalization for diabetic ketoacidosis. In such cases, the healthcare team should work with the patient to develop appropriate problem-solving strategies and self-care behaviors before deciding whether to discontinue pump therapy.

Persistent infusion site problems or absorption issues affect a small number of patients. Another reason for discontinuation is when a patient's insurance changes: the co-pay required by a new insurer may be cost-prohibitive.

## **Future Directions for Insulin Pump Therapy**

Frequent SMBG remains the foundation of optimized insulin therapy, and CGM is gaining prominence in optimized CSII. This paradigm shift is occurring primarily because CGM can offer enhanced insight into glycemic patterns and variations. SMBG captures a patient's glucose level precisely at a moment in time, much like a photograph, while CGM can be compared to closed-circuit television. Measuring interstitial fluid (ISF) glucose levels with CGM may yield values not directly comparable with SMBG owing to lag time.<sup>27</sup> However, CGM can enable the patient and the healthcare team to make therapy adjustments to improve overall glycemic control.<sup>28</sup> CGM can offer benefits to both

pump users and patients on MDI, but pump users may find CGM particularly beneficial by using the data to support their diabetes management in real time.

CGM technology has improved significantly over the last decade, and research continues to develop its full potential. According to the panel, future advances in insulin pump therapy are likely to include closed-loop systems that can monitor glucose levels and dispense insulin automatically, in effect mimicking the physiology of the pancreas. This type of closed-loop system may be achieved with implantable sensors, but the technology is still under development. A

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true “closed-loop” or artificial pancreas does not appear to be imminent but research and development efforts are underway. Trials of CGM and pump systems sophisticated enough to control glucose levels overnight automatically, without patient intervention, may bear fruit within the next 10 years. Until approved by the FDA to replace SMBG, CGM devices should be used to complement SMBG, not as a substitute for SMBG.

### **Diabetes educators support pump users in achieving the goals of intensive therapy**

Diabetes educators and other healthcare workers provide essential ongoing education and training to diabetes patients on blood glucose monitoring, dietary evaluation, technical aspects of insulin pump therapy, sick-day management, management of hypoglycemia and hyperglycemia, and infusion site management.<sup>11</sup> The American Association of Diabetes Educators’ position statement on CSII outlines the integral role of diabetes educators in the management of patients on pumps.<sup>11</sup> Given the complexity of insulin pump therapy, diabetes educators are essential for providing ongoing education and training to patients. The panelists concurred that patients who succeed on insulin pump therapy are treated with a team approach to training, including the care of a diabetes educator.

During the first few weeks after insulin pump therapy initiation, the patient and main care provider for pump therapy – often a diabetes educator – should have daily contact. Blood glucose records can be faxed, e-mailed or telephoned to the diabetes educator at least weekly for the first month to six weeks of insulin pump therapy. The diabetes educator should advise a new pump user that his or

her glucose levels might be above target until correct basal rates are established. Patients should contact their diabetes educator immediately when they need pump or diabetes-related advice or support.

After the first month to six weeks following pump therapy initiation, the patient and diabetes educator may wish to communicate about pump-specific issues once a month and, eventually, according to the patient’s preference. During pump-specific appointments, the patient can be assessed to determine whether his or her therapy is meeting treatment goals agreed upon between the patient and care team at or since the start of therapy. In addition, any advances in technology or the need for a replacement device can be reviewed. Diabetes educators also provide support with respect to reinforcing certain aspects of using the pump, such as troubleshooting unexplained blood glucose fluctuations and specific scenarios, for example persistent high glucose levels.

In line with the American Association of Diabetes Educators’ position statement on patient education in CSII, the panel emphasized the role of the diabetes educator in achieving the goals of therapy. Patients develop the expertise to manage their diabetes successfully with an insulin pump through an ongoing program of education facilitated by a diabetes educator. As technology advances, insulin requiring patients and their healthcare providers must work together to take full advantage of potential benefits and rise to prospective challenges. Support from a healthcare team knowledgeable about insulin pump therapy, particularly a diabetes educator with the skill to maximize the benefits of pump therapy for an individual patient, is essential to improving outcomes in type 1 diabetes.

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