Continuous Subcutaneous Insulin Infusion (CSII)

AADE White Paper

Issued June 6, 2014

Continuous subcutaneous insulin infusion (CSII), also known as insulin pump therapy, is in its fifth decade of use and continues to grow in popularity. In the United States, an estimated 30 to 40% of patients with type 1 diabetes and <1% of insulin-treated patients with type 2 diabetes use an insulin pump.[1] The most current data from 2010 indicate there are over 400,000 patients with type 1 diabetes now using an insulin pump.[2] Insulin pump therapy offers increased lifestyle flexibility and improved glucose control. The goal of this white paper is to outline the topics that should be covered by diabetes educators when teaching patients and families or significant others about insulin pump therapy. More detailed information can be obtained from resources in the reference list that follows.

Role of the Diabetes Educator

Diabetes educators play an integral role in helping patients achieve success in the use of insulin pump therapy, which can improve clinical outcomes and quality of life. They support patients as they consider, initiate, and learn how to use an insulin pump to manage their diabetes. Diabetes educators coordinate the plan of care between the prescriber, insulin pump manufacturer, and insulin pump trainer during pump initiation and ongoing management. They often serve as a resource for other healthcare professionals and community organizations that provide support for individuals who use insulin pumps, and to family members or significant others who support the person with diabetes. Training and experience, over and above that of being a Certified Diabetes Educator©, is necessary to be considered an expert in insulin pump therapy. Diabetes educators who wish to become insulin pump specialists must have advanced knowledge and training in the use of CSII, carbohydrate counting as it relates to CSII, and the evaluation and interpretation of self-care data. They must also obtain certification to provide training in the use of each specific brand and model of insulin pump with which they work. This is obtained through the individual insulin pump manufacturers.

Assessment for Insulin Pump Therapy

Careful assessment of the patient is essential to ensuring success with pump therapy. The diabetes educator must evaluate the physical and psychological readiness of each pump candidate to assume the responsibilities and challenges of pump therapy. There are a number

of clinical and lifestyle indicators and desired attributes that should be considered when performing a thorough assessment of whether a person is an appropriate candidate for insulin pump therapy. Some insurance providers and Medicare may require additional documentation, such as a history of diabetic ketoacidosis (DKA) or a specific fasting C-peptide level.[3]

Clinical Indications for Insulin Pump Use
▪ Inadequate glycemic control despite optimized multiple daily injection (MDI) therapy ▪ High glucose variability ▪ Elevated A1C ▪ Recurrent, severe, or unpredictable hypoglycemia ▪ Nocturnal hypoglycemia ▪ Hypoglycemia unawareness ▪ Recurrent hyperglycemia ▪ Dawn phenomenon ▪ Preconception planning ▪ Pregnancy ▪ Extreme insulin sensitivity ▪ Gastroparesis ▪ Early neuropathy or nephropathy ▪ Renal transplantation
Lifestyle Indications
▪ Erratic schedule ▪ Varied work shifts ▪ Frequent travel ▪ Desire for flexibility ▪ Inconvenience of multiple daily injections (MDI)
Desired* Attributes of a Pump Candidate (and/or parent(s) of pump candidate)
▪ Motivation to succeed, as pump therapy requires readiness, preparedness, and time investment before and during initiation. ▪ Realistic expectations of the capabilities of pump therapy. ▪ Demonstration of independent diabetes management and knowledge of the basics of diabetes education, including all topics listed in the *National Standards for Diabetes Self-Management Education and Support.* [4] ▪ Ability to problem-solve and use newly-acquired skills to manage diabetes. ▪ Ability to accept and deal with challenges that arise; check blood glucose a minimum of four times a day; keep detailed records of self-monitoring blood glucose (SMBG), dietary intake, insulin doses, and exercise; and stay in frequent contact with their healthcare provider. ▪ Intellectual capability to learn, practice, and understand insulin pump therapy parameters such as insulin-to-carbohydrate ratios (ICR), correction or sensitivity factors (CF), and the application of the parameters to determine appropriate insulin dosing in

response to nutritional intake, hypoglycemia, hyperglycemia, stress, exercise, and other personal parameters.
- Physical ability to view the pump screen and hear the alarms; dexterity to insert or charge the pump battery, fill and replace the insulin cartridge/reservoir in the pump; insert an infusion set; wear the pump; and perform the technical functions.[5]
- Emotional stability and adequate emotional support from family or significant others.
- Parents and caretakers have a thorough understanding of pump therapy and willingness to spend the time needed to work with their child and healthcare professionals, when applicable.
- Patience and willingness to work with healthcare provider during the time of pre-pump training and initiation, when appropriate basal rates, insulin-to-carbohydrate ratios, and correction (sensitivity) factors are being determined.
- Time to invest during the education process.
- Adequate insurance benefits or personal resources to afford the cost of the pump and necessary supplies.[5]

**Although these attributes are desired, they are not "requirements" for pump use. Diabetes educators are uniquely qualified to assist patients in overcoming limitations or deficits to achieve optimal outcomes.*

Regular assessments should be done to evaluate changes in a patient's clinical condition, motivation, abilities, and life circumstances that may necessitate the need to reconsider appropriateness of pump therapy. Considerations for discontinuing insulin pump use may include:

- lack of a willing spirit or motivation to monitor blood glucose per healthcare provider recommendations,
- lack of insurance or means to pay for insulin pump and pump supplies, and/or
- change in physical or mental capacity to manage an insulin pump.

Pump and Infusion Set Selection

Helping patients select the equipment that is best suited to their needs is integral to successful diabetes management. While all insulin pumps, infusion sets, and insertion devices have basic attributes in common, there are key differences that can impact suitability for a patient. Although insulin pumps may usually be returned within 30 days of purchase, it is uncommon for patients to do so. Once the 30-day period has passed, the user will not be eligible to "switch" or "upgrade" until the pump's warranty expires, which generally takes four years or more. Patients who are not exposed to or educated on their options may find themselves with a device that is ill-fitted to their needs. It is the responsibility of the diabetes educator to stay current with the various commercially available insulin pumps, infusion sets, and insertion devices, and equip the patient to make an informed and educated choice.

Pump Selection Criteria

When the decision has been made to initiate pump therapy, the starting point is verification of the patient's insurance or, if applicable, ability to self-pay. Most private health insurance plans allow their members to choose any type of insulin pump and infusion set. However, some public health and private plans will only pay for specific brands.

When a list of covered pump models is determined, the following qualities should be considered:

Device Qualities	**Consideration**
Insulin volume	Does the pump hold enough to last the patient 2-3 days?
Screen legibility	Can the patient read all on-screen text?
Alarm and alert recognition	Can the user hear or feel them?
Water-proof	Is it needed by the user?
Download capability	Is the software web-based? PC or Mac-compatible?
Ability to display continuous glucose monitor (CGM) data	Is it linked with CGM?
Interface with point-in-time blood glucose meters	Which brands of meters are compatible, and are they covered by the patient's insurance?
Remote control capabilities	Is it desirable/necessary by the user or caregiver?
Bolus calculation parameters	Are the dosage ranges, insulin-to-carbohydrate ratios, correction factors, and insulin-on-board features appropriate for the patient?
Infusion device compatibility	Which options are available?
Complexity of infusion site set changes	How many steps? How complex? How much dexterity?
Complexity of user programming	Is the menu layout simple? How many button presses are needed for basic programming?
Look and feel of the device	Size, weight, color, and wearing options (clips, cases) desirable for patient?
Special alerts and reminders	Are site change, missed bolus, and customizable reminders and alerts needed?
Tubing vs. "patch" style	Will tubing be a significant hindrance?
Customer support	What is the company's reputation and stability?

For unbiased and detailed comparisons of insulin pump features, consider referring your patients to third-party websites, such as www.diabetesnet.com, www.insulin-pumpers.org, and www.integrateddiabetes.com. Also, consider referrals to the various manufacturers for "test drives" of their top choices.

Infusion Set Selection

Just as certain insulin pumps are better suited to certain individuals, so are infusion sets and set insertion devices. Many pumps allow the user to choose from a variety of infusion set types, and some use proprietary sets that are only compatible with the manufacturer's pump. An initial assessment of body composition and the patient's lifestyle is necessary to determine the appropriate type of infusion set. [6]

Variables to consider when selecting an infusion set include Teflon® cannula versus metal needle, tubing and cannula or needle length, disconnect and insertion mechanisms, angle of insertion, adhesion and aesthetics. [7] If an infusion set is not specified when the insulin pump is ordered, a "default" infusion set will be sent. Use of a poorly matched infusion set can result in insulin malabsorption that can put the patient at risk for site infections or irritation, inconvenience or discomfort, and hyperglycemia that can lead to ketoacidosis.

Education

Pre-pump and on-going self-management education and skills training in the use of a pump should include correction of any misconceptions the patient may have regarding insulin pump therapy. The diabetes educator should conduct an assessment of the patient's knowledge of diabetes, knowledge deficits, and preferred learning style and then develop an individualized education plan. The patient's age or education level should not be considered a deciding factor in their ability to utilize pump therapy. At a minimum, the prospective pump user should have knowledge of the physiology of diabetes[4] and an understanding of the relationship between insulin and food, stress, exercise, and other factors that affect blood glucose. The foundation for advanced self-management with use of an insulin pump requires a thorough knowledge of diabetes management skills, including the ability to trouble-shoot and problem-solve, recognize and respond to glucose patterns, and demonstrate appropriate self-care behaviors. [5]

In most cases, it is ideal for MDI therapy to precede insulin pump therapy. The patient should also know how to count carbohydrates and calculate prandial insulin doses using their insulin-to-carbohydrate ratio(s) and correction (sensitivity) factor(s).

Pre-pump education is generally spread over the course of several weeks, with a minimum of three visits of 1–3 hours each. Some patients complete two to three 1-hour preparation sessions with a verbal exchange of information, whereas others need a structured learning environment and instruction that is spread over an extended period of time with practical or written evaluations to gauge their level of comprehension. A group class covering some of the pump education topics can be a time effective means for provision of the education. The educational plan for children should include their parents and caregivers. [5]

Pump education objectives should include:

- Establishment of goals
- Competence in carbohydrate counting

- Competence in calculation of insulin dosages with use of insulin-to-carbohydrate ratios
- Competence in calculating correction dosages with use of correction (sensitivity) factors
- Ability to manage hyperglycemia and hypoglycemia
- Ability to properly fill, if applicable, and insert cartridge/reservoir and insert and change infusion sets
- Ability to detect infusion set and site issues
- Ability to manage sick days, exercise, and travel; obtain supplies; and cope with lifestyle changes
- Ability to trouble-shoot and solve problems that may arise in use of their pump
- Ability to recognize the need for a back-up insulin regimen and how to safely switch back to injections
- Ability to determine how and where to wear the pump
- Ability to determine when and how to disconnect the pump

Pump Start

Insulin pump start-up education ("pump training") takes 2–4 hours and should nearly always be done in an outpatient setting, such as the prescriber/educator's office. Pump manufacturers employ or contract with healthcare professionals (RDs, RNs, and PharmDs) who are usually CDEs certified by the pump manufacturer as a certified pump trainer (CPT) to provide pump training services, following the prescribing physician's pump start orders.

The prescriber is responsible for providing or signing off on pump start orders to the diabetes educator or designated pump trainer providing the pump start-up training. These include:

- Starting basal rate(s)
- Insulin-to-carbohydrate ratio(s) (ICR)
- Target blood glucose level(s) [8,9]
- Correction (or sensitivity) factor(s) and instructions for use
- Duration of insulin action ("insulin on board" or "active insulin time")
- SMBG instructions
- Communication guidelines, i.e., who, when, and where the patient contacts for reporting SMBG results/asking for diabetes management assistance (educator/prescriber) and asking for technical assistance (pump manufacturer)

The educator should carefully set the pump start-up date, assuring that the patient's first few weeks of pump therapy are planned during "normal routine" days, avoiding situations or conditions that may adversely affect blood glucose levels or interfere with the establishment of basal rates. [5]

Start-up orders must be provided to the patient several days in advance and should include: 24-48 hour pre-pump adjustments in insulin injection therapy; self-monitoring blood glucose and dietary guidelines; a list of supplies to bring to the pump start-up appointment; and specific information regarding appointment time and location. [5]

The pump wearer must also learn the technical components of their pump, including how to: insert or charge the battery; fill and insert the insulin cartridge/reservoir; insert and change the infusion set and tubing (if applicable); input information for the pump to calculate appropriate insulin dosages; program basal rate changes; and review the pump history. Most manufacturers require that training on their pump is conducted by a healthcare provider certified by the manufacturer as a pump trainer ("CPT") for their company's pump. A pump start is best conducted at a time in the day and on the day(s) of the week when the managing healthcare professional is available for medical management following the pump initiation.

Specific instructions for follow-up and management during the first few weeks after pump start-up should include:

- Frequent SMBG, i.e. minimum of four to five times per day, i.e. 3:00 a.m., fasting, before each meal, and bedtime.
- Recording grams of carbohydrate consumed and specific food and beverage portions.
- Avoidance of alcohol, high-fat foods, and foods not usually consumed.
- Recording all bolus doses using the ICR for meals and snacks and any CF bolus doses given for hyperglycemia, or use the smart pump feature if pump downloading is to be done.
- Recording any unexpected or unusual events that could affect blood glucose levels, e.g., stress or illness, as well as the onset of menses.
- Instructions to call in, fax, or e-mail the information to the diabetes educator daily initially, then less frequently based on the results.
- Reminders to call the pump manufacturer's support service with questions or problems related to the technical functions of the pump if the questions cannot be answered by the diabetes educator.

A follow-up visit should occur within one week after start-up to review and observe an infusion set or pod site change and pump syringe/cartridge removal, fill, and insertion. The patient should return to the prescriber/educator 4–6 weeks after the pump start-up for a review of SMBG and insulin doses and inspection of infusion sites.

Ongoing Education and Management

The foundation for use of an insulin pump begins during the initial training session(s). Learning continues as insulin delivery is initiated and connections are made between prior knowledge and present experience. Because there are few, if any, life experiences that compare to the mechanical use or utility of an insulin pump, multiple learning sessions are often necessary to master basic skills. Experience in the use of long-acting insulin, insulin-to-carbohydrate ratio(s), and correction factor(s) must be expanded to promote understanding of how rapid-acting insulin works when delivered via an insulin pump. The use of CGM makes foundational learning even more imperative, as there is greater risk that the learner may "stack" insulin, over treat

hypoglycemia, or make inappropriate changes in pump settings in response to the continuous availability of glucose data. Safe practice requires that the learner understands the concept of active insulin, the use of advanced prandial delivery options, and effective management strategies during periods of activity, inactivity, stress, travel, or illness. (See Safe Practices in Use section.)

Teachable moments occur during the follow-up calls and visits for fine-tuning of basal and bolus settings. The educator should continually assess the patient's comprehension and continue with follow-up until the patient is able to demonstrate comfort and competence in the use of their pump and its features. The patient should be taught how to:

- properly insert and remove the specific type of infusion set used with emphasis on site rotation,
- adjust insulin delivery to accommodate physical activity, inactivity, sick days, and stress,
- safely untether (if appropriate) their infusion set tubing for special events,
- implement a backup plan in case of equipment failure,
- protect themselves and their pump, infusion set, and infusion site during certain physical activities and when undergoing some medical tests, such as a CAT scan, MRI, or X-ray,
- upload data for review by their healthcare team at regular intervals,
- prepare for and pack necessary supplies for travel within the United States as well as out of the country, and
- contact technical support and medical personnel when necessary.

The patient should expect to stay in daily contact with the diabetes educator during the first two to three days and at designated intervals in the weeks following the initiation of insulin pump therapy to report and review self-monitoring of blood glucose (SMBG) levels and titration of basal and bolus settings. Individual response to insulin delivery via an insulin pump can vary significantly from that of MDI. The educator must know how to make appropriate adjustments in basal and bolus settings during this time to prevent hypo- and/or hyperglycemia, and determine settings that match the patient's circadian rhythms and patterns of daily living.

Detailed attention should be given to infusion site management. Issues with site reactions, infusion set tolerance and compatibility, and site adherence should be assessed at the time of the first site change as well as during follow-up visits. The educator should never assume that the new or seasoned insulin pump wearer has achieved optimal mastery of skills. Every opportunity should be taken during office visits to evaluate the learner's current knowledge and build on their experience towards mastery of blood glucose management skills.

Safe Practices

Adverse events associated with insulin pump therapy are most often related to user error rather than pump malfunction.[10] Improper patient selection, inadequate education, and lack of ongoing support by clinicians who are knowledgeable of the benefits and limitations of insulin pumps are seen as contributing factors of the adverse events.[10]

Strategies to prevent and resolve insulin pump therapy challenges should be an education priority and include:

- **Self-monitoring of blood glucose (SMBG).** Monitoring frequency should be individualized but generally recommended at a minimum of 4-5 times daily to allow for early recognition of hypoglycemia or hyperglycemia and more often when initiating pump therapy and during periods of hyperglycemia and illness, and additionally, 2 hours after infusion site changes.[7, 11]

- **Infusion site selection and maintenance.** The infusion site should be changed every 2-3 days and monitored for inflammation, signs of infection, lipodystrophy or infusion site leakage.[7,11]

- **Troubleshooting and problem solving.** Teach causes of high and low blood glucose levels, including: catheter occlusion or dislodgement, insulin degradation if exposed to temperature extremes, battery failure, missed doses, over-correction of hyperglycemia, pump malfunction, incorrect pump programming of infusion rates or time settings. Teach patients how to identify these issues and how to take action to resolve them.[5, 7, 11, 12, 6]

- **Alerts and alarms.** Teach the benefits and limitations of using pump alarms and alerts. Although alarms can warn the wearer about problems such as catheter occlusion, low cartridge/reservoir volume, low battery, or other mechanical or software-related problems, these alarms may not always offer notification early enough to prevent hypoglycemia or hyperglycemia. Alerts can be set to remind users to monitor blood glucoses, change the infusion site, or change/charge the battery, but such alerts must be attended to in a timely way to prevent complications.[7, 11, 13]

- **Hyperglycemia management.** Teach the patient to maintain supplies, including extra blood glucose and ketone test strips in case of unanticipated hyperglycemia. A vial, or if appropriate, a pre-filled pump cartridge of rapid-acting insulin should be accessible to fill and replace the pump cartridge/reservoir. Rapid-acting insulin should be administered by syringe or pen in the presence of unresolved hyperglycemia and ketones.[11, 6]

Diabetes educators should facilitate safe use of insulin pumps through education about precautions and considerations during exercise, travel, and other special situations:

Exercise – Additional glucose monitoring should be encouraged before, during, and after exercise with plans for treatment to prevent hypoglycemia. Patients should also be taught to adjust basal settings (and/or bolus doses) to mitigate hypoglycemia risk as appropriate for the duration and intensity of activity.[7, 13]

Travel – Patients should be encouraged to carry monitoring and pump supplies (including insulin) in carry-on luggage when flying in case luggage is lost and to avoid extremes of temperature that are common in baggage compartments. Pumps should also be hand-checked rather than exposed to x-rays in airport security. [11 14] The pump wearer should check with the Transportation Security Administration (TSA) and their pump manufacturer for specific insulin pump travel guidelines.

School and day care settings – An individualized diabetes medical management plan needs to be developed for the child using an insulin pump. Appropriate training should be provided for school personnel who would assist with implementing the plan.[15]

Medical procedures – Patients should be made aware of pump manufacturers' recommendations for insulin pumps during procedures that involve radiation exposure (including x-rays) and magnetic resonance imaging (MRI). Pumps should be kept outside of the imaging room until testing is complete. If the pump is disconnected for an hour or more, alternative insulin treatment should be provided.[16,17, 18]

Hospitalization – Diabetes specialists and/or diabetes educators should develop policies that specify requirements of caring for those who maintain insulin pumps during hospitalization.[19,16,20,17,18]

Policy content should address the following:

1. Determinants of continuing (or discontinuing) pump use
2. Requirement of patient agreement
3. Strategies to address interruption in insulin pump infusion
4. Patient assessment requirements (i.e., competency to self-manage, site assessment)
5. Documentation requirements (i.e., assessments, self-administered doses)
6. Considerations for patients going to surgery and/or procedures involving radiation or magnetic fields

Acknowledgements:
Karen M. Bolderman, RD, LDN, CDE; Gary Scheiner, MS, CDE; Claire M. Blum, MS Ed, RN, CDE; Gwen Klinkner, MS, RN, APRN, BC-ADM, CDE; Janet Mertz, MS, RD, LD, CDE

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