

# Continuous Subcutaneous Insulin Infusion (CSII) Without and With Sensor Integration

*Reviewed by the Professional Practice Committee*

*Updated March 2021*

Continuous subcutaneous insulin infusion (CSII), also known as insulin pump therapy, is in its fifth decade of use and continues to grow in popularity. More recently, there has been an integration of continuous glucose monitors (CGM) onto the pump screen and the creation of the first FDA approved insulin pump that responds to sensor data to adjust basal rates, suspend on low or impending low and give automatic correction bolus doses when glucose is approaching pre-determined targets. Automated insulin delivery systems are revolutionizing glucose management<sup>1,2</sup>. The current data indicate there are over 1 million people with diabetes on insulin pump therapy worldwide<sup>3</sup> and 350,000 to 515,000 in the United States<sup>4</sup>. Insulin pump therapy offers increased lifestyle flexibility and improved glucose management. The goal of this paper is to outline the topics that should be covered by diabetes care and education specialists when teaching people with diabetes (PWD) and their families or significant others. It focuses on insulin pump therapy and the importance of maintaining a high level of expertise in this subspecialty of diabetes education if choosing to include pump and sensor training in the individual specialist's practice.

## **Role of the Diabetes Care and Education Specialist**

Diabetes care and education specialists play an integral role in helping PWD achieve success in the use of insulin pump therapy, which has been demonstrated to improve clinical outcomes and quality of life.

### **Diabetes care and education specialists:**

- Support PWD as they consider, initiate and learn how to use an insulin pump to manage their diabetes.
- Coordinate the plan of care between the prescriber, insulin pump manufacturer and insulin pump trainer during pump initiation and ongoing management.
- Serve as a resource for other healthcare professionals and community organizations that provide support for individuals who use insulin pumps.
- Serve as a resource to family members or significant others who support the person with diabetes.
- Complete trainings and gain experience, over and above that of being a certified diabetes care & education specialist® (CDCES), to be considered an expert in insulin pump therapy (i.e. CPT).
- Obtain advanced knowledge and training in the use of CSII, carbohydrate counting as it relates to CSII, and the ability to evaluate and interpret data downloads to provide treatment recommendations.
- 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

Assessment of the PWD is important in ensuring success with pump therapy. The diabetes care and education specialist 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 private insurance providers and all government-based insurers require additional documentation, such as a specific fasting blood glucose and C-peptide levels or antibody results.<sup>5</sup>

#### Clinical Indications for Insulin Pump Use

- Persons with type 1 diabetes or type 2 diabetes requiring frequent multiple daily injections.
- Inadequate glycemic management despite optimized multiple daily injection 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.
- Potentially persons with needle phobia.

#### Lifestyle Indications

- Erratic schedule.
- Varied work shifts.
- Frequent travel.
- Desire for flexibility.
- Inconvenience of multiple daily injections.

#### 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*.<sup>6</sup>
- Ability to problem solve potential challenges with pump or infusion set malfunctions and how to maintain continuous insulin care in those circumstances.
- Ability to accept and deal with challenges that arise and check blood glucose levels consistently throughout the day or utilize a CGM. [7](#), [11](#)
- Capacity 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 adjustments in response to 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.<sup>5</sup>
- Emotional stability and adequate emotional support from family or significant others.
- Parents and caretakers must 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 their 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.
- Adequate insurance benefits or personal resources to afford the cost of the pump and necessary supplies.

*\*Although these attributes are desired, they are not "requirements" for pump use. Diabetes care and education specialists are uniquely qualified to assist individuals in overcoming limitations or deficits to achieve optimal outcomes.*

Regular assessments should be done to evaluate changes in a PWD'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 insurance or means to pay for an insulin pump and pump supplies.
- Change in physical or mental capacity to manage an insulin pump.
- Any suicidal ideation.

### **Pump and Infusion Set Selection**

Helping PWD 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 individual suitability. Although most insulin pumps may be returned within 30 days of purchase, it is uncommon for PWD 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 to five years. Individuals 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 care and education specialist to stay current with all the commercially available insulin pumps, integrated sensor options, infusion sets and insertion devices,

### Pump Selection Criteria

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

For unbiased and detailed comparisons of insulin pump features, consider referring individuals to third-party websites, such as [www.diabetesnet.com](http://www.diabetesnet.com), [www.insulin-pumpers.org](http://www.insulin-pumpers.org), and [www.integrateddiabetes.com](http://www.integrateddiabetes.com). Also, consider referrals to the various manufacturers for "test drives" of their top choices.

**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? Are basal rate increments small enough?
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 easy for the patient to download and review? Does the download data provide cloud technology to allow the provider to access the data?
Continuous glucose monitor (CGM) data	Is it linked with CGM?
Pump and CGM integration	Does the pump respond to sensor data by adjusting basal rate? Correctional insulin? Suspend prior to low?
Interface with point-in-time blood glucose meters	Does the meter communicate directly with the insulin pump?
Remote control capabilities	Is it desired/needed by the user or caregiver?
Infusion device compatibility	Which options are available? Are they suited to the needs of the patient?
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?

## 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 individual lifestyle is necessary to determine the appropriate type of infusion set. <sup>7</sup>

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. <sup>8</sup> 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 frustration and potential for discontinuation of insulin pump therapy.

## Education

Pre-pump and on-going self-management education in the use of a pump should include correction of any misconceptions the PWD may have regarding insulin pump therapy. The diabetes care and education specialist must conduct an assessment of the individual's knowledge of diabetes, knowledge deficits, and preferred learning style to develop an individualized education plan. The individual'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<sup>6</sup> 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 is best served with 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.<sup>9</sup>

Pre-pump education varies widely based on the incoming knowledge of the person with diabetes and or caregiver. Some individuals complete two to three 1-hour sessions with a verbal exchange of information. Others need a structured learning environment that is spread over an extended

period of time, with practical or written evaluations to gauge their level of comprehension. A group class covering pump education can be a time-effective means for provisions of education. The educational plan for children should include their parents and caregivers.<sup>9,10</sup>

### **Pump education objectives include:**

- Establishment of goals.
- Competence in carbohydrate counting.
- Full understanding of insulin to carbohydrate ratios.
- Full understanding of correction (sensitivity) factors.

### Ability to:

- Manage hyperglycemia and hypoglycemia.
- Properly fill and insert cartridge/reservoir and insert and change infusion sets.
- Detect infusion set and site issues.
- Manage sick days, exercise and travel.
- Obtain supplies.
- Trouble-shoot and solve problems that may arise in use of their pump.
- Recognize the need for a back-up insulin regimen and how to safely switch back to injections.
- Determine how and where to wear the pump.
- Determine when and how to disconnect the pump.

## Pump Start

Insulin pump start-up education ("pump training") takes 1-3 hours and should be done in an outpatient setting, such as the prescriber/specialist's office. Pump manufacturers employ or contract with healthcare professionals (RDs, RNs and PharmDs) who are usually CDCES certified by the pump manufacturer as a certified pump trainer (CPT). CPTs provide pump training services, following the prescribing physician's pump start orders. The American Association of Clinical Endocrinologists (AACE) consensus statement (2014) suggests there should be a more

structured program to start individual education and training in the United States, more closely aligned with extended education programs in other countries, such as France and the United Kingdom.

The prescriber is responsible for providing/signing off on pump start orders to the diabetes care and education specialist or designated pump trainer assigned to provide the pump start-up training.

**These include:**

- Starting basal rate(s).
- Insulin-to-carbohydrate ratio(s) (ICR).
- Target blood glucose level(s).<sup>10,11</sup>
- Correction (or sensitivity) factor(s) and instructions for use.
- Duration of insulin action (“insulin on board” or “active insulin time”).
- Self-monitoring of blood glucose (SMBG) instructions or utilization of a CGM device.
- Communication guidelines, i.e., who, when and where the patient contacts for reporting glucose results, asking for diabetes management assistance (specialist/prescriber) and asking for technical assistance (pump manufacturer/CDCES)
- Understand how to upload the device and provide data to the provider/CDCES.
- Determine who is available 24/7 to cover medical management questions that may arise.<sup>4</sup>

The specialist should carefully set the pump start-up date, assuring that the individual’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.<sup>9</sup>

**Start-up orders should be provided to the individual several days in advance and should include:**

- 24-48 hour pre-pump adjustments in insulin injection therapy.
- Glucose history either through meter or CGM data upload.

- A list of supplies to bring to the pump start-up appointment.
- Specific information regarding appointment time and location.<sup>9</sup>

**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.
- Review the pump history.

With advances in sensor-integrated insulin pumps, a thorough understanding of the automated systems and the potential to revert to manual mode is needed. Most manufacturers require that training on their pump is conducted by a healthcare provider certified by the manufacturer as a pump trainer (“CPT”). 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, 2 hours after meals and bedtime. All SMBG readings should be entered into the pump. Generally, CGM glucose data should also be entered into the system, however there is one system at this writing that auto inserts the glucose reading and incorporates the data into the delivery system without input from the user.
- Limiting alcohol and high-fat foods.
- Inputting all carbohydrate values.
- Recording any additional insulin or carbohydrate intake outside of the dosing within the insulin pump (correctional factors for blocked cannula, carbohydrates for



hypoglycemia) that would not otherwise be noted in the pump download.

- Recording any unexpected or unusual events that could affect blood glucose levels, e.g., stress or illness, unusual exercise routine as well as the onset of menses.
- Instructions to upload or e-mail the information to the diabetes care and education specialist as agreed upon, generally initially daily.
- Reminders to call the pump manufacturer's support service with questions or problems related to the technical functions of the pump if the diabetes care and education specialist is not available.

A follow-up visit should occur within one week after start-up. This allows for the opportunity to review and observe an infusion set or pod site change, remove pump syringe/cartridge, filling and insertion. The individual should be in contact with the prescriber or CDCES/CPT within 2-4 weeks after the pump start-up for a review of insulin pump download data including glucose, dosing, compliance with infusion site changes, alarms and any overriding of the automated system. Review of infusion set sights and options should also occur.

Non-programmable insulin patch pumps are also available. These systems have a fixed basal rate (different rates available) along with an option for bolus delivery. The dosing is not integrated into the pump but is at the discretion of the wearer. Data from these pumps is not downloadable at this time.

### 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. Twenty-four-hour coverage should be provided and may extend for months or years due to potential problems which can arise due to occlusions, pump malfunctions and illness. 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 and integrated systems makes foundational learning even more imperative. There is the potential for a greater risk that the learner may "stack" insulin, overtreat 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 specialist must continually assess the individual's comprehension and follow-up until the person is able to demonstrate comfort and competence in the use of their pump and its features. The PWD must 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, sensor and transmitter if applicable during certain physical activities and when undergoing some medical tests, such as a CAT scan, MRI, or X-ray, and airport scanning equipment.
- 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.
- Contact technical support and medical personnel when necessary.

The individual should expect to stay in daily contact with the diabetes care and education specialist during the first two to three days and at designated intervals during the weeks following the initiation of insulin pump therapy, to report and review glucose 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 specialist 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 person'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 and during follow-up visits. The specialist 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. Choosing the wrong pump candidate, 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.<sup>12</sup>

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

- **CGM and/or SMBG.** Some CGM/iCGM models can be used for dosing. Review the data frequently or self-monitor 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, illness and 2 hours after infusion site changes.<sup>7, 11</sup>
- **Infusion site selection and maintenance.** The infusion site must be changed every 2-3 days and monitored for inflammation, signs of infection, lipodystrophy or infusion site leakage.<sup>7,11</sup>
- **Troubleshooting and problem solving.** Potential 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 settings for date and time should be addressed. Teach patients how to identify these issues and how to take action to resolve them.<sup>12,13</sup>
- **Alerts and alarms.** Teach the benefits and limitations of using pump alarms and alerts. Although alarms can warn the wearer about 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 utilize SMBG, change the infusion site, change/charge the battery, missed bolus reminder, etc., but such alerts must be attended to in a timely way to prevent complications.<sup>7, 11,12</sup> Too many alarms can also result in alarm fatigue and individuals may be inclined to ignore them, missing some critical alarms.
- **Hyperglycemia management.** Teach the person to maintain supplies, including extra blood glucose test strips, ketone test strips and vials/syringes or insulin pens in case of unanticipated hyperglycemia, if pump failure occurs. Rapid-acting insulin should be administered by a syringe or pen in the presence of unresolved hyperglycemia and ketones.<sup>11,14,15</sup>

**Diabetes care and education specialists must 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. Individuals 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.<sup>7,16</sup> Several of the AID systems have a specific target for exercise which should be initiated 60-90 minutes prior to the activity when possible.
- **Travel.** Individuals 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 must also be hand-checked rather than exposed to x-rays in airport security.<sup>17,18</sup> The pump wearer should check with the Transportation Security Administration (TSA) and their pump manufacturer for specific insulin pump travel guidelines.
- **School and daycare settings.** An individualized diabetes medical management plan needs to be developed for the child with special instructions for management of the insulin pump at school. Appropriate training must be provided for school personnel who would assist with implementing and following the plan.<sup>16,19</sup> A 504 plan should also be written in conjunction with school personnel (school nurse, designated staff, principal etc.) to clearly delineate the role of the school in carrying out the medical management plan. The 504 plan is developed to ensure that a child who has a disability identified under the law and is attending an elementary or secondary educational institution receives accommodations that will ensure their academic success and access to the learning environment.
- **Medical procedures.** Individuals 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.<sup>20</sup>

- **Hospitalization.** Diabetes specialists and/or diabetes care and education specialists should develop policies that specify requirements of caring for those who maintain insulin pumps during hospitalization.<sup>20,21,22</sup> Post COVID-19, many hospitals have been incorporating CGM into caring for their patients. The future of this option is not known at this time.

#### Hospital insulin pump 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. Individual assessment requirements i.e., competency to self-manage, site assessment.
5. Documentation requirements i.e., assessments, self-administered doses.
6. Considerations for individuals going to surgery and/or procedures involving radiation or magnetic fields.

#### CGM integrated with insulin pumps

CGM provides invaluable information that is unattainable using finger stick blood glucose measurements. The ability to display rate of change, alarm the user with impending low blood glucose, and collect data every 5 minutes can help to inform, motivate and alert persons with diabetes to enhance management.

For further information on non-integrated sensors for persons on basal/bolus insulin, oral agents, or personal and professional CGM, the reader is referred to the ADCES practice document on CGM.<sup>24</sup>

**Sensor integrated pumps.** Technology is changing rapidly and several options are now available for reading sensor data on the pump

screen and responding to the data; Tandem X2 Basal IQ and Control IQ, Medtronic 670, 770G with Guardiansensor, non-FDA approved open source systems. These systems can alter basal rates and/or correctional insulin determined from sensor data and more systems are presently with the FDA for approval.

It is the role of the diabetes care and education specialist who works with PWD on multiple daily injections and/or an insulin pump to remain updated on the options. By providing PWD the knowledge of their availability in the marketplace, the individual can share in the decision making about tools that can be utilized to enhance their diabetes care, in addition to standard pump therapy.

Data supports the impact of sensor augmented pump therapy for A1C reduction in the Start 3 study.<sup>25</sup> In addition, most research suggests that even if A1C is not reduced, there is a reduction in hypoglycemia while retaining A1C, suggesting a reduction in glucose variability which is in itself a success.<sup>26</sup>

In a recent study on predictive hyperglycemia and hypoglycemia minimization, the predictive hyperglycemia and hypoglycemia systems optimized overnight glucose management and increased the time in range in children 6-14 years of age.<sup>27</sup>

Breton et. al.<sup>28</sup> reported improved glycemic management and a reduction in hypoglycemia during intensive winter cold and high-altitude activity with a closed-loop control system (the artificial pancreas), which is still in the research phase. This again demonstrates the value of sensor integrated insulin pump therapy. Tauschmann et al(29)

It is important for the specialist to be aware of options being utilized by individuals that are not FDA approved but are being used by over 2200 individuals worldwide such as Do It Yourself (DIY) and Night Scout.<sup>30</sup> This may be a particular challenge to the specialist in recognizing the concern over non-FDA approved devices and the individual's successful utilization of these systems. The role of the diabetes care and education specialist is more of acceptance and promoting safety, rather than education in regard to these devices at this time.

The most recent Standards of Medical Care in Diabetes – 2021 states the following: When prescribing CGM “robust diabetes education, training, and support are required for optimal CGM implementation and ongoing use”.<sup>33</sup> This is supported by the International Consensus on the use of CGM<sup>32</sup> which states “patient education should utilize standardized programs with the follow-up to improve adherence and facilitate appropriate use of data and diabetes therapies”. The sensor augmented insulin pumps are more complex than sensor add-on technology without augmentation and require more in-depth education to the pump trainer and PWD. Pump training will often occur over multiple days, with an initial visit for pump training, another visit for CGM training and a subsequent visit to go into auto mode.

**It is the role of the diabetes care and education specialist in sensor augmented insulin pump therapy to educate the PWD and caregivers on:**

- Options available for sensor added or integrated insulin pump therapy.
- Differentiating interstitial glucose and blood glucose results.
- Timing of sensor calibration if required and technique.
- Placement of the sensor for most accurate readings.
- Insertion of the sensor.
- Problem solving taping and securing the sensor.
- Skin care.
- Limitation to sensor readings.
- Appropriate use of the suspend feature.
- How to stay in or return to auto mode delivery in the 670 G Medtronic insulin pump (largely eliminated in the 770G).

The specialist should also be able to download data from the integrated insulin pump, review the information with the individual and make recommendations based on sensor data that can enhance glucose goals. They should have an ongoing relationship with the prescriber and communicate these changes. Education is ongoing

and pump upgrades as they become available should be reviewed and discussed as appropriate.

In addition, it is important for the diabetes care and education specialist to work with school nurses and support persons to enhance the understanding of sensor integrated pump therapy while children are at school. Employees may also want to integrate education within their workplace. Practical suggestions can be found in *Understanding Insulin Pumps, CGM and Artificial Pancreas*.<sup>33</sup> Sensors at this time are not approved for dosing in the hospital setting, but the specialist can (and should) be involved in creating hospital policy to allow sensor wear when appropriate and to augment POC data with sensor data in understanding individual BG variability during their hospital stay.<sup>34</sup>

It is important to note there has been some concern about the consistency of the accuracy of sensor data<sup>35</sup> which cannot be ignored.

Sensor integrated insulin pumps are becoming more common and will continue to improve over time with more options slated to come on the market in the near future. This may include dual hormone systems (glucagon and insulin) with sensor integration, implantable sensors and pumps and fully integrated sensor and pump systems (the artificial pancreas). And pumps that can be initiated with just the weight of the PWD, making it easier for primary care practices to initiate pump therapy.

The diabetes care and education specialist who chooses to work with individuals on sensor augmented insulin pumps must be aware of the options, keep up with the technology, understand the benefits and limitations, be able to download the technology and help direct the interpretation of the data.

### Summary

Diabetes care and education specialists with an in depth understanding of insulin pump options that are well trained in insulin pump therapy are a critical component to understanding and initiating pump therapy with PWD. The 2017 National Practice Survey<sup>36</sup> found that 88% of diabetes care and education specialists indicated that they had influence in insulin initiation and/or titration, medication adjustment, stress reduction, or the use of technology, including apps and diabetes devices. These influences included recommendations carried out in collaboration with other members of the care team and carried out independently. Diabetes care and education specialists play a continued role in helping individual's problem solve, overcome challenges with pump and sensor wear, and make decisions in case of illness and pump failure. In addition, specialists should be able to download, evaluate and interpret the data and make recommendations to enhance the diabetes management of the person who has chosen to utilize insulin pump or insulin pump integrated therapy.<sup>11,14,15</sup>

## References

1. Bergenstal R, Tamorlane W, Ahmann A et al. *Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes*. *N Engl J Med*. 2010;363:311-320.
2. Bally L, Hood T and Hovorka R. Closed-loop for type 1 diabetes-an introduction and appraisal for the generalist. *BMC Medicine*. 2-17:15:14. Accessed 8/26/2017/
3. Heinemann L, Fleming G, Petrie J et al. *Insulin Pump Risks and Benefits: A Clinical Appraisal of Pump Safety Standards, Adverse Event Reporting, and Research Needs A Joint Statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group*. *Diabetes Care* 2015;38:716–722.
4. Grunberger G, Abelson J, Bailey T, et al. (2014) *Consensus Statement by the American Association of Clinical Endocrinologists/American College of Endocrinology Insulin Pump Management Task Force*. *Endocrine Practice*: 2014;20(5) 463-489.
5. Decision Memo for Insulin Pump: C-Peptide Levels as a Criterion for Use (CAG-00092R) available: <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=109&>. Accessed 9/6/2017
6. Beck J, Greenwood D, Blanton L et al. *2017 National Standards for Diabetes Self-Management Education and Support*. <https://doi.org/10.2337/dci17-0025>. Accessed 9/9/2017.
7. Walsh J, Roberts R. *Pumping Insulin: Everything for Success on an Insulin Pump and CGM. 6th Edition*. Torrey Pines Press, 2016
8. McCrea, D. *A Primer on Insulin Pump Therapy for Health Care Providers*. *Nurs Clin N Am* 52 (2017) 553–564.
9. Bolderman K. “Pump Start-Up” in *Putting Your Patients on the Pump*. Alexandria VA: American Diabetes Association 2013.
10. Standards of Medical Care in Diabetes--2017. *Diabetes Care*. 2017;40 Suppl 1:S48-57.
11. Handelsman Y, Mechanick JI, Blonde L, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for developing a diabetes mellitus comprehensive care plan. *Endocr Pract*. 2011;17 Suppl 2:1-53.
12. Clayton-Jeter H. *Contributing Factors to Insulin Pump Errors in Children, Adolescents and Adults* Available: <http://www.fda.gov/forhealthprofessionals/articlesofinterest/ucm295562.htm>. Accessed February 13, 2014.
13. Aldasouqi S and Reed A. *Pitfalls of insulin pump clocks: technical glitches that may potentially affect medical care in patient with diabetes*. *J Diabetes Sci Technol* 2014;8(6):1215-1220.
14. Evert AB, *Insulin pump therapy troubleshooting for optimal performance*. *Empower*. 2015;7(4):23-24
15. Guilhem I, Leguerrier AM, Lecordier F, et al. *Technical risks with subcutaneous insulin infusion*. *Diabetes Metab*. 2006;32(3):279-284.
16. Maahs D, Horton L and Chase H. The use of insulin pumps in youth with type 1 diabetes. *Diabetes Technol Ther* 2010;12(suppl1):S59-65.
17. Cornish A, Chase HP. *Navigating airport security with an insulin pump and/or sensor*. *Diabetes Technol Ther*. 2012;14(11):984-985.
18. American Diabetes Association. Fact Sheet – *Air Travel and Diabetes* Available: <http://www.diabetes.org/living-with-diabetes/know-your-rights/discrimination/public-accommodations/air-travel-and-diabetes/what-can-i-bring-with-me.html?referrer=https://www.google.com/>. Accessed 9/10/2017
19. *Diabetes care in the school and day care setting*. *Diabetes Care*. 2014;37 Suppl 1:S91-96.
20. McCrea D. *Management of the hospitalized diabetes patient with an insulin pump*. *Crit Care Nurs Clin North Am*. 2013;25(1):111-121.
21. Boyle ME, Seifert KM, Beer KA, et al. *Guidelines for application of continuous subcutaneous insulin infusion (insulin pump) therapy in the perioperative period*. *J Diabetes Sci Technol*. 2012;6(1):184-190.
22. Buchko BL, Artz B, Dayhoff S, et al. *Improving care of patients with insulin pumps during hospitalization: translating the evidence*. *J Nurs Care Qual*. 2012;27(4):333-340.
23. Rodbard D. *Continuous Glucose Monitoring: A Review of Successes, Challenges and Opportunities*. *Diabetes Technol Ther*. 2016;18(Suppl2):S2-3-S2-13.
24. <https://www.diabeteseducator.org/practice/practice-documents/practice-papers>

25. Bergenstal RM<sup>1</sup>, Tamborlane WV, Ahmann A, et al STAR 3 Study Group. *Sensor-augmented pump therapy for A1C reduction (START 3) Study: results from the 6 month continuation phase. Diabetes Care.* 2011;34(11):2403-5.
26. Abraham MB<sup>1,2</sup>, Nicholas JA<sup>1,3</sup>, Smith GJ<sup>3</sup> et al; PLGM Study Group. *Reduction in Hypoglycemia With the Predictive Low-Glucose Management System: A Long-Term Randomized Controlled Trial in Adolescents With Type 1 Diabetes. Diabetes Care.* 2017;Nov 30. pii: dc171604. doi: 10.2337/dc17-1604. [Epub ahead of print]
27. Forlenza G, Raghinaru D, Cameron F, et al. *Predictive hyperglycemia and hypoglycemia minimization: In-home double-blind randomized controlled evaluation in children and young adolescents. Pediatric Diabetes.* 2017;1-9.
28. Breton M, Chernavvsky D, Forlenza G et al. *Closed-loop control during intense prolonged outdoor exercise in adolescents with type 1 diabetes: the artificial pancreas ski study. Diabetes Care.* 2017;40(12):1644-50. 12.
29. Tauschmann M, Thabit H, Bally L, et al. Closed-loop insulin delivery in suboptimally controlled type 1 diabetes: a multicentre 12-week randomised trial. *Lancet.* 2018;13:92.
30. OpenAPS.Outcomes. Downloaded 3/2/2021.
31. Standards of Medical Care in Diabetes-2021 *Diabetes Care.* 2021;44 Suppl 1:S89
32. Danne T, Nimri R, Battelino R et al. International consensus of use of continuous glucose monitoring. *Diabetes Care.* 2017;40(12):1631-1640.
33. Chase P and Messner L. *Understanding insulin pumps, continuous glucose monitors and the artificial pancreas* (3<sup>rd</sup> ed). 2016. Children's Diabetes Foundation at Denver, Colorado.
34. Wallia A, Umpierrez G, Rushakoff R et al. *Consensus statement on inpatient use of continuous glucose monitoring. J. Diabetes Sci Technol.* 2017;11(5);1036-1041.
35. Shapiro A. FDA approval of nonadjunctive use of continuous glucose monitors for insulin dosing: A potential risky decision. *JAMA.* 2017;318(16);1541-1542.
36. Rinker J, Dickinson J, Litchmanb M et al. *Diabetes Educator.* 2018;44(3):260-268.

### Acknowledgements

Carla Cox, PhD, RD, CDE, CPT; 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

Revisions in January 2018: Diana Isaacs, PharmD, BCPS, BC-ADM, CDE, Diane Battaglia, RN, CDE, Carla Cox, PhD, RD, CDE, CPT

Revisions in March 2021: Carla Cox, PhD, RDN, CDCES, CPT

### ADCES Representatives

1. Leslie Kolb, RN, BSN, MBA; Chief Science, Practice & Learning Officer, Association of Diabetes Care & Education Specialists
2. Joanne Rinker MS, RD, CDE, LDN, FAADE; Director of Practice and Content Development, Association of Diabetes Care & Education Specialists