American Association of Diabetes Educators

# INSULIN PUMP THERAPY:

## Best practices in choosing and using infusion devices

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## Best practices in choosing and using infusion devices

A panel of experts convened in Chicago in May 2011 to discuss best practices in the management of infusion devices for continuous subcutaneous insulin infusion (CSII), also called insulin pump therapy. The panel discussion focused on infusion set selection, set usage, patient training/education, troubleshooting, special populations and the role of the diabetes educator in achieving successful outcomes with insulin pump therapy. The importance of individual assessment was a key theme of the discussion. The following is a summary of the panel dialogue.

# Executive summary

### CHOOSING INFUSION DEVICES

- Infusion set selection should take into account both the attributes of the infusion device and a range of patient factors. Infusion set attributes include the mechanics of insertion, aesthetics, as well as adhesive, cannula/needle and tubing. Patient factors relevant to infusion set selection include a patient's age, immune system function, body characteristics, activities, personal preferences, and his or her history of diabetic ketoacidosis.

### USING INFUSION DEVICES

- Replacing infusion devices according to their approved labeling is important for enabling good outcomes for patients using insulin pump therapy. Improved glycemic control may be achieved with more frequent infusion device changes.
- Patients should change the insulin, the reservoir/cartridge, tubing and infusion site with each infusion site change. Patients should follow manufacturers' recommendations regarding cannula fill amounts when performing infusion set changes. Patients should fill each pump cartridge/reservoir with the approximate amount of insulin they will require until the next planned set change, plus the amount required to prime the tubing and the cannula.

### SELECTING INFUSION SITES

- Appropriate infusion site selection and rotation is crucial for achieving successful outcomes with insulin pump therapy. Infusion site rotation reduces the risk of lipodystrophy and scar tissue development with insulin pump therapy
- In addition to good basic hygiene practices, insulin pump users may benefit from solutions or wipes intended to increase the adhesion of the infusion set to the skin and the use of underbandages to support the infusion set and increase adhesion.

### BEST PRACTICES IN PATIENT TRAINING

- Hands-on training is essential at initiation of pump therapy, when there are concerns about glycemic control, and when patients change types of infusion sets. In the course of training, clinicians should address patients' and family members' psychological concerns regarding the change from injection therapy to wearing a pump. Healthcare providers should confirm patients' and caregivers' understanding of infusion site management and device usage during initial training and in follow-up care.
- Patients should be taught comprehensive troubleshooting and problem-solving techniques for handling unexplained high glucose levels to reduce the risk of diabetic ketoacidosis associated with infusion device failure, insulin spoilage or unplanned pump disconnection.
- Patients should be taught to recognize infusion site infections so they can seek appropriate medical attention as required.

### THE ROLE OF THE DIABETES EDUCATOR

- The diabetes educator plays a central role in infusion device and site selection and management, providing patient education, and increasing awareness about infusion site issues among healthcare providers



# Introduction

Insulin pump therapy is considered the "gold standard" of care for insulin-requiring diabetes.[1-4] In addition to clinical benefits in terms of glucose control, insulin pumps can improve the quality of life for patients with type 1 and type 2 diabetes.[5-7] After thirty years of research and development involving insulin pump therapy, a vast body of clinical literature articulates the indications for use of insulin pump therapy and associated patient selection criteria. However, there is a relative lack of literature regarding the subcutaneous insulin infusion devices ("infusion sets") that deliver insulin from the pump into the body. Healthcare providers and patients alike face challenges to optimal diabetes control arising from poorly selected and/or managed infusion devices.[8-10] Diabetes educators can play an important role in achieving patient outcomes with insulin pump therapy.[11] By utilizing and sharing best practices in infusion device selection and management, diabetes educators can empower other healthcare providers and patients alike to optimize infusion set selection and use.

# Choosing infusion devices

The panel agreed that the optimal insulin infusion set varies by individual and is a critical factor in the success of insulin pump therapy. Infusion set selection should take into account both the attributes of the infusion device and a range of patient factors. Infusion set attributes include the mechanics of insertion, aesthetics, as well as adhesive, cannula/needle and tubing. Patient factors relevant to infusion set selection include a patient's age, immune system function, body characteristics, activities, personal preferences and his or her history of diabetic ketoacidosis. Key characteristics of commonly used infusion devices currently marketed in the United States are listed in Tables 1 and 2.

***Table 1.*** Plastic cannula infusion sets

| CANNULA MATERIAL | INFUSION SET NAME | INSERTION ANGLE (90° OR 30-45°) | CANNULA LENGTH | CANNULA GAUGE | CONNECTION COMPATABILITY | TUBING LENGTHS | DISCONNECTION TECHNIQUE | INSERTION AID DEVICE |
|---|---|---|---|---|---|---|---|---|
| Plastic | Silhouette (Medtronic Diabetes), Comfort (Unomedical/ Animas), Tender (Roche-Accu-Chek) | 30 – 45° | 13 mm ("Mini" or "Short"); 17 mm | 27 gauge intro needle, 25 gauge cannula | Silhouette: Medtronic Paradigm or Luer lock<br>Comfort, Tender: Luer lock | Silhouette: 23in., 43in.<br>Comfort: 23in., 31in., 43in.<br>Tender: 24in., 31in., 43in. | Sideways-pull at site | Silhouette: separate Sil-Serter device |
| | Inset 30 (Animas) | 30° | 13 mm | 27 gauge intro needle, 25 gauge cannula | Luer lock | 23in.<br>43in. | Sideways-pull at site | Built-in |
| | Quick-set (Medtronic Diabetes) | 90° | 6 mm<br>9 mm | 27 gauge intro needle, 25 gauge cannula | Medtronic Paradigm or Luer lock | 23in.<br>43in. | Twist-and-lift-off at site | Separate Quick-serter® device |
| | Ultraflex (Roche Accu-Chek) | 90° | 8 mm<br>10 mm | 27 gauge intro needle, 25 gauge cannula | Luer lock | 24in.<br>31in.<br>43in. | Sideways-pull at site | Separate Link Assist insertion device |
| | Mio (Medtronic Diabetes) | 90° | 6 mm<br>9 mm | ---- | Medtronic Paradigm | 18in.<br>23in.<br>32in. | Sideways-pull at site | Built-in |
| | Inset (Animas) | 90° | 6 mm<br>9 mm | ---- | Luer lock | 23in.<br>43in. | Sideways-pull at site | Built-in |
| | Orbit 90 (ICU Medical) | 90° | 6 mm<br>9 mm | 26 gauge cannula | Luer lock | 24in.<br>31in.<br>42in. | Twist-and-lift-off at site | Compatible with Medtronic Quick-serter® |
| | Cleo 90 (Smiths Medical) | 90° | 6 mm<br>9 mm | 28 gauge intro needle, 25 gauge cannula | Luer lock | 24in.<br>31in.<br>43in. | Twist-and-lift-off at site | Built-in |
| | Sof-set Micro Ultimate QR® (Medtronic Diabetes) | 90° | 6 mm (Micro)<br>9 mm | 27 gauge intro needle, 25 gauge cannula | Medtronic Paradigm or Luer lock | 23in.<br>43in. | Twist-and-pull short tail | Separate Medtronic Sof-serter® device |

*Adapted from Diabetesnet.com "Infusion set comparison"*
*available at http://www.diabetesnet.com/diabetes-technology/infusion-sets. Last accessed September 14, 2011.*

*Table 2.* Steel needle infusion sets

| CANNULA MATERIAL | INFUSION SET NAME | INSERTION ANGLE (90° OR 30-45°) | CANNULA LENGTH | CANNULA GAUGE | CONNECTION COMPATABILITY | TUBING LENGTHS | DISCONNECTION TECHNIQUE |
|---|---|---|---|---|---|---|---|
| Steel | Polyfin QR® (Medtronic Diabetes) | 30 – 45° | ----- | 28 gauge needle | Medtronic Paradigm | 24in.<br>42in. | Twist-and-pull short tail |
| | Sure-T® (Medtronic Diabetes) | 90° | 6 mm<br>8 mm<br>10 mm | 29 gauge needle | Medtronic Paradigm | 18in.<br>23in.<br>32in. | Sideways-pull secondary location |
| | Contact Detach (Unomedical) | 90° | 6 mm<br>8 mm<br>10 mm | 29 gauge needle | Luer lock | 24in.<br>31in.<br>43in. | Sideways-pull secondary location |
| | Rapid D Link (Roche Accu-Chek) | 90° | 6 mm<br>8 mm<br>10 mm | 28 gauge needle | Luer lock | 24in.<br>31in.<br>43in. | Twist-and-pull short tail |
| | Orbit Micro (ICU Medical) | 90° | 5.5 mm<br>8 mm | 31 gauge needle | Luer lock | 18in.<br>24in.<br>30in.<br>42in. | Twist-and-lift-off at site |

*Adapted from Diabetesnet.com "Infusion set comparison" available at http://www.diabetesnet.com/diabetes-technology/infusion-sets. Last accessed September 14, 2011.*



## CANNULA OPTIONS: STEEL NEEDLE OR PLASTIC CANNULA?

Steel needle infusion sets are favored for patients who have reactions to plastic cannulae, and those who are fit and active with a history of bent cannulae. The panel agreed that steel needle sets can also benefit patients who have frequent kinks in plastic cannulae. As they do not insert a cannula, steel needles are relatively small. Insertion is similar to taking an injection. For that reason, steel needle sets can be appropriate for patients who prefer smaller needles. Steel needle infusion sets are typically very easy to teach patients to use and for patients to insert. Patients, parents or caregivers who are hesitant about infusion site changes may prefer steel sets because there is no insertion device and no introducer needle to withdraw after device insertion.

## ANGLE OF INSERTION

Infusion sets are designed to be inserted at a 90° or a 30-45° angle to the surface of the skin. The panel discussed the potential advantages and disadvantages of each style of set for different types of patients.

Dexterous lean or muscular patients and those with lipohypertrophy can benefit from a 30-45° angled set. Patients with a higher risk of the set being pulled out, including active children and athletes as well as pregnant women (near the end of the second trimester or in the third trimester, when abdominal tissue is stretched taut) may benefit from these infusion sets as well. The angle of insertion and the fact that 30-45° angled cannulae are longer than 90° cannulae may reduce the risk of a cannula being dislodged. These sets have less impact from movement so may be associated with less risk of dislodged or bent cannulae for very active patients.

Angled sets may also be advantageous for patients with recurrent site infections. Patients should change the cannula at the first sign of redness around the infusion site. The clear window in the adhesive tape of an angled set allows patients to see any redness developing around the cannula, thus potentially reducing the risk of a site infection. Some patients may have to stretch to see the window, or may not always be able to see it depending on the specific position (body part, direction of insertion, adhesives) of the infusion set.

The panel discussed the benefits of 90º insertion angle sets for patients with poor dexterity, patients preferring arm or hard-to-reach infusion sites (i.e., the buttocks, where two-handed insertion may be impractical), needlephobic patients (who may use insertion devices that hide the needle) and those who need simplicity in set insertion. 90° insertion angle sets may also be easier for children learning to insert their own sets to use. However, the panel observed that 90° plastic cannula sets may be more susceptible to kinking under the skin than 30-45° angled sets.

## CANNULA LENGTH

The panel discussed indications for using insulin pump infusion devices with either shorter or length cannulae. The panel agreed that shorter-length cannulae (6 mm for 90° sets, 13 mm for 30-45° angled infusion sets) are appropriate for most patients.

Members of the panel acknowledged the conventional wisdom of patients with a high BMI requiring a longer cannula, but cautioned that rigorous clinical research has not been carried out.[12] The panel also considered the volume of insulin being delivered via the set, and the risks of seepage or poor absorption in insulin-resistant patients. For patients requiring large boluses (≥25 units) for meals, a longer cannula may be necessary to ensure that the insulin is delivered successfully into the subcutaneous tissue.[13] The panel also explored the implications of high basal rates (≥2.5 units per hour) for cannula selection and agreed that patients with such basal rates may benefit from a longer cannula.

Beyond patients with a high BMI, the panel agreed that a longer cannula may be useful for patients who have experienced difficulty with a shorter cannula working its way out of the skin or patients who develop lipohypertrophy. However, the panel considered that longer length plastic cannulae may have a higher risk of kinking in the subcutaneous tissue than shorter plastic cannulae.

## TUBING LENGTH

### *Shorter*

The panel agreed that tubing length is very much a matter of patient preference, but it is probably appropriate to recommend shorter length (typically 23 inches) tubing initially to most patients. Shorter tubing is generally less likely to get tangled or caught on everyday items like doorknobs than longer tubing. For pediatric patients, shorter tubing is more proportional to body size. Pump alarms may be easier to hear if the pump is on a shorter length of tubing and thus closer to the patient's body at all times. Furthermore, there is less tubing that may be exposed to heat, cold and sunlight compared to longer tubing.

### *Longer*

Patients for whom longer tubing (typically 43 inches) is appropriate include those who prefer to wear the pump far from the infusion insertion location. For example, a patient may prefer to insert an infusion set in the abdomen and place the pump inside his or her sock or next to the calf, with the tubing running down the inside of the pant leg. Patients who prefer to insert an infusion set in the arm and wear the pump in a pants pocket or on a belt may run their tubing up the sleeve and down the inside of a shirt. Patients who usually wear the pump on the waistband of a pair of pants may find longer tubing convenient because they can sit down to use the toilet without having to remove the pump from their clothes. Additionally, longer tubing allows patients to choose whether to wear the pump in the right or left pants pocket, regardless of the side of the body where the set is inserted.

Patients using the continuous glucose monitoring (CGM) capability of a sensor-augmented insulin pump system should be advised that the choice of tubing length should take into account the fact that the pump should stay in close proximity to the transmitter for optimal CGM data transmission. Patients with a strong preference for longer tubing may be advised to sleep with the pump on top of the bed covers to avoid pump alarms being muffled within the bed; however, they should be made aware that distance between the transmitter and pump increases the possibility that CGM data transmission may be impaired.

### *Safety loops*

For patients using a set that disconnects along the tubing and leaves a short tail, making a safety loop with an adhesive bandage or piece of tape positioned over the tubing near the cannula can help decrease cannula motility. Controlling cannula motility can reduce the risk of dislodging or bending the cannula.

### *Manual or device-assisted assisted insertion*

The panel discussed reasons for choosing to insert an infusion set manually or using a mechanical insertion device ("insertion aid").

### *Manual insertion*

Patients with an aversion to the noise of a mechanical insertion device, or those who feel a need to control the process, speed, or precise angle of insertion are likely to prefer to insert sets manually.

### *Mechanical insertion devices*

Needlephobic patients and those with dexterity problems may prefer to use a mechanical insertion aid. Patients with low vision, or those inserting sets in areas that are harder to reach such as the back of the arm, lower back or buttocks may particularly benefit from an infusion set with a built-in insertion device.

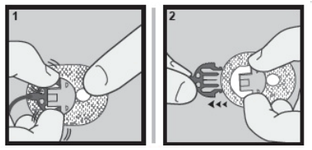
The panel noted that insertion aids make replacing the infusion set much easier for many patients. However, some patients become reliant on the insertion device to change an infusion set and may place themselves at undue risk of DKA by postponing an infusion set change until they have access to an inserter device, despite rising blood glucose levels indicative of poor insulin absorption. All patients should be taught to insert an infusion set manually in case the insertion device is not available, unless their preferred infusion set has a built-in disposable insertion device.

## DISCONNECTION MECHANISM

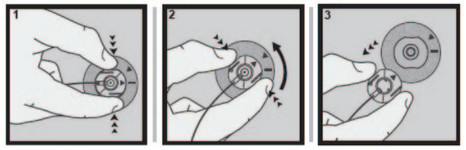
The panel considered three common types of infusion set-tubing disconnection mechanisms used for insulin pump therapy: twist-and-lift-off, sideways pull, and secondary location, illustrated in Figure 1.

***Figure 1.*** Common disconnection mechanisms

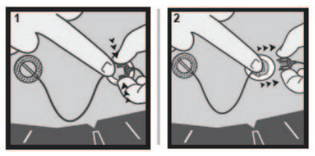
A: Sideways-pull




B: Twist-and-lift-off




C: Secondary location




*Quick-set®, Sihouette®, and Sure-T® images courtesy of the Diabetes business unit of Medtronic, Inc.*

The panel agreed that the twist-and-lift-off sets are usually the easiest to disconnect, with the potential drawback of being difficult to re-connect without third-party assistance, if, for example, the set is inserted into the lower back and a mirror is unavailable. Additionally, sets with twist-and-lift-off disconnection mechanisms may be more prone to kinked cannulae due to physical movement at the insertion site due to connecting and disconnecting.

The discernable "click" on reconnecting a set with sideways-pull mechanism offers reassurance to patients, including suitable patients whose vision is impaired. However, the panel saw a possible drawback of sideways-pull disconnection mechanism: less dexterous patients may lack the grip strength or coordination to squeeze the connector at the end of the tubing to disengage it from the infusion set housing.

The panel agreed that sets with a secondary location for disconnection may offer an advantage in terms of ability to reach additional potential infusion sites (i.e., the upper buttocks) and keeping the connection point accessible. Additionally, having the second site for disconnection offers some protection from pulling on the insertion site. Inserting an infusion device with a secondary disconnection location involves a two-stage process of cannula insertion and secondary location site adhesion. Thus, secondary disconnection location sets may have significant drawbacks for patients who prefer to have only one adhesive patch attached to their bodies. Image-conscious or very active individuals may prefer a set that has a less conspicuous profile when disconnected. Less dexterous patients may lack the grip strength to disengage the end of the tubing from the infusion set housing. Patients should be cautioned that wearing a set with a secondary-location disconnection mechanism in a hot tub or exposing it to heat, sunlight, and temperature extremes can cause spoilage of the insulin remaining in the tubing between the cannula and the disconnection location.

## ADDITIONAL CRITERIA FOR INFUSION DEVICE SELECTION

### *Safety features*

Sets with safety features to prevent accidental needlesticks following cannula insertion may be particularly suitable for children who may have to perform an infusion set change at school and for patients who are unable to insert their own infusion sets and require third-party assistance. The panel agreed that protection from accidental needlesticks is a priority for many patients, not only children.

### *Patient dexterity*

Patients with limited vision or dexterity may struggle to connect the sideways-pull and secondary disconnection devices.

### *Device aesthetics*

Pediatric, adolescent and some adult patients may value the option of an infusion set available in colors to suit their preference. Additionally, patients can customize certain infusion sets with commercially available decorative patches.

### *Convenience versus environmental impact*

For some patients, having all constituent parts of an infusion set (single-use insertion device, infusion set and tubing) packaged together for each set change (as with the Inset or Mio) offers a high degree of convenience. Meanwhile, some patients express concern about the environmental impact of the amount of waste generated by replacing an infusion set of that type.

The panel's recommendations regarding device factors to consider in selecting an infusion set are summarized in Table 3.

***Table 3.*** Device factors in infusion device selection

**DEVICE FACTORS**

| CANNULA | TUBING | ERGONOMICS/AESTHETICS |
|---|---|---|
| Steel vs Plastic | Safety loop/patch (e.g. Sure-T) | Adhesion strength |
| Angled (30-45°) vs straight (90°) insertion | Compatibility with pump cartridge/reservoir | Skin compatibility |
| Length (mm) | Length (cm/inches) | Assenbly and disconnection mechanism |
| Diameter | Risk of snagging/pulling out (patient lifestyle-related) | Protection from accidental needlesticks |
| Visibility after insertion | ----- | Color |

### *Insulin pump manufacturers*

The panel agreed that insulin pump manufacturers have a significant influence on patients' initial infusion set, with healthcare providers often paying more attention to the choice of pump than the choice of infusion set. The panel observed that insulin pump company representatives routinely offer training on the use of the insulin pump, but do not usually discuss infusion set options with patients in the context of pump training. The panel called for an increase in the amount of training on infusion sets offered to both patients and clinical staff by insulin pump company representatives. The panel placed importance on both patients and health care providers being aware of available infusion set options to facilitate productive conversations about set choices and drive a change of set type when required.

The panel also recommended that insulin pump companies include instructions regarding the use of a number of compatible infusion sets in their user manuals. Providing instructions and illustrations for only one type of infusion set when numerous options exist may contribute to errors in patient practice. Furthermore, emphasizing one set type above others undermines awareness of the different options available. Including a checklist of infusion device choices on the pump prescription or certificate of medical need could enhance healthcare providers' capacity to match infusion devices to individual patients.

### *Healthcare providers*

The panel agreed that a pre-pump assessment consultation with the patient, including a discussion of historical injection site issues, infection risk status and current activities is helpful for determining the optimal infusion set. This assessment should include an examination of potential insertion sites to check for the presence of lipoatrophy, lipohypertrophy or changes to the skin (e.g., scars or striae). Any such areas of damaged tissue should not be used for infusion. Diabetes care teams should inform patients that many infusion set options are available. Patients should be asked on a regular basis if they are experiencing any issues with insertion or use of infusion sets. Furthermore, infusion set practices should be evaluated when patients experience problems with glycemic variability and DKA.

Healthcare providers should discuss infusion set options with patients when they express concerns about their current infusion sets or have frequent infusion set problems. Children or physically active adults may need to order two different types of sets for use during different types of activities or in different environmental conditions. Patients switching to a different infusion set after their initial pump training should be offered formal training to ensure correct use of the new type of infusion set.

The panel's recommendations regarding patient factors to consider in selecting an infusion set are summarized in Table 4.

***Table 4.*** Patient factors in infusion device selection

**PATIENT FACTORS**

| PATIENT AGE | BODY CHARACTERISTICS | IMMUNE SYSTEM FUNCTION | PSYCHOLOGICAL | PATIENT ACTIVITIES | OTHER |
|---|---|---|---|---|---|
| Newborn | Leanness/ little subcutaneous fat | Neonates | Needlephobia | Outdoor activities | DKA history/ risk threshold |
| Child | Lipodystrophy | Immunocompromised | Need to see insulin or needle entering the body | Sports | Literacy (for training) |
| Adult | Scar tissue/risk of occlusion | Chemotherapy | — | — | — |
| Elderly | Preganacy<br>Hairiness<br>Excessive perspiration | Steroid treatment<br>Infection history/risk<br>Allergies to Teflon/adhesive | — | — | — |

# Choosing infusion devices – summary of recommendations

### STEEL NEEDLE INFUSION SETS

- Patients who have reactions to plastic cannulae, or those who are fit and active with a history of bent cannulae
- Patients or parents and caregivers who are hesitant about complex infusion site changes
- During pregnancy, to minimize the risk of ketosis because of bent/obstructed plastic cannulae

### 30-45° ANGLED SETS:

- Dexterous lean or muscular patients and those with lipohypertrophy
- Patients with a higher risk of the set being pulled out, including active children and athletes
- Pregnant women (near the end of the second trimester or in the third trimester, when abdominal tissue is stretched taut)
- Patients with recurrent site infections – patients can see any redness developing around the cannula

### 90° INSERTION ANGLE SETS

- Patients with poor dexterity
- Patients preferring arm or hard-to-reach infusion sites
- Needlephobic patients and those who need simplicity in set insertion
- Children learning to insert their own sets

### SHORTER-LENGTH CANNULAE

(6 mm for 90° sets, 13 mm for 30-45° angled infusion sets)

- Appropriate for most patients

### LONGER-LENGTH CANNULAE

- Patients with a high BMI
- Patients requiring large boluses (≥25 units) for meals or high (≥2.5 units per hour) basal rates
- Patients who have experienced difficulty with a shorter cannula working its way out of the skin
- Patients who develop lipohypertrophy

### SHORTER (TYPICALLY 23 INCHES) TUBING

- Initial recommendation for most patients
- Pediatric patients
- Patients using the continuous glucose monitoring feature on their pump

### LONGER (TYPICALLY 43 INCHES) TUBING

- Patients who prefer to wear the pump far from the infusion insertion location

### MANUAL SET INSERTION

- Patients with an aversion to the noise of a mechanical insertion device
- Patients who feel a need to control the process, speed, or precise angle of insertion
- All patients should be taught to insert an infusion set manually in the event that the insertion device is not available

### MECHANICAL INSERTION DEVICES

- Needlephobic patients and those with dexterity problems
- Patients with low vision, or those inserting sets in areas that are harder to reach

### TWIST-AND-LIFT-OFF DISCONNECTION MECHANISM

- Usually the easiest to disconnect but may be difficult to re-connect depending on location of cannula insertion
- May be more prone to kinked cannulae than other set types

### SIDEWAYS-PULL DISCONNECTION MECHANISM

- Discernable "click" may reassure patients, including suitable patients whose vision is impaired, when they reconnect the tubing to the infusion set
- Less dexterous patients may lack the grip strength or coordination to use this properly

### SECONDARY DISCONNECTION LOCATION

- Patients who want to reach additional potential infusion sites while keeping the disconnection point accessible
- May have drawbacks for patients who prefer to have only one adhesive patch attached to their bodies
- Less dexterous patients may lack the grip strength to disengage the end of the tubing from the infusion set housing
- Unsuitable for wear in a hot tub or in temperature extremes

### SAFETY FEATURES

- Sets with features to prevent accidental needlesticks following cannula insertion may be particularly suitable for children who require third-party assistance

### PRE-PUMP ASSESSMENT CONSULTATION

- Discuss historical injection site issues, infection risk status and current activities
- Examine insertion sites to assess for the presence of lipodystrophy, hypertrophy or changes to this skin (e.g., scars or striae) that should be avoided.
- Inform their patients that many infusion set options are available

### FOLLOW-UP CARE

- Ask patients on a regular basis if they are experiencing any issues with insertion or use of infusion sets
- Evaluate infusion set practices when patients experience problems with glycemic variability and DKA
- Discuss infusion set options with patients when they express concerns about their current infusion sets or have frequent infusion set problems
- Offer formal training to patients switching to a different infusion set after their initial pump training to ensure correct use of the new type of infusion set
- Children or physically active adults may need to order two different types of sets for use during different types of activities or in different environmental conditions

# Using infusion devices

## FREQUENCY OF INFUSION DEVICE REPLACEMENT AND GLYCEMIC CONTROL

The panel discussed the results of a survey regarding the frequency with which patients/caregivers replace insulin infusion devices, conducted at the 2010 Children With Diabetes Conference (June 29 – July 4, 2010, Orlando, Florida). The results of the survey and the correlated mean blood glucose values of patients are shown in Table 5.

***Table 5.*** Correlation between days of infusion set wear and mean blood glucose values. *(Self-reported, not correlated to carbohydrates consumed or activity level).*

| % PATIENTS | DAYS SET USED | AVERAGE BLOOD GLUCOSE |
|---|---|---|
| 1% | 1 | n/a |
| 20% | 2 | 122 mg/dL |
| 67% | 3 | 143 mg/dL |
| 9% | 4 | 154 mg/dL |
| 3% | 5+ | 163 mg/dL |

Bearing in mind the association between prolonged infusion set wear and higher mean blood glucose levels, the panel agreed that replacing infusion devices according to their approved labeling is important for enabling good outcomes for patients using insulin pump therapy. However, the panel recognized that improved glycemic control may be achieved with more frequent infusion device changes, and encouraged changes every 48 hours (or more often) where feasible. This recommendation applies to both plastic and steel needle infusion devices.

The panel recommended that healthcare providers check the priming history on patients' insulin pumps to determine the frequency with which individual patients replace their infusion devices. Patients may self-report infusion set replacement frequency in line with product labeling but their actual behavior may differ. In most cases, pump downloading software will report these data.

Healthcare providers should also assess patterns in glycemic control related to infusion site changes. If there appears to be a consistent pattern of deterioration of glycemic control prior to the end of the labeled set wear period, the patient should be advised to change his or her infusion set more frequently. Additionally, more frequent infusion set changes may be beneficial for pregnant patients and those at risk for infection.

The panel concluded that, while replacing the cannula more frequently than recommended in product labeling may increase the cost of therapy, the benefits in terms of a patient's glucose control justify it – particularly when glucose control regularly deteriorates on the third day of infusion device use – or as an initial practice for patients at high risk of infection.

The panel also considered the importance of communication around recommended cannula change frequency when patients switch from plastic to steel cannulae, or vice-versa. Steel needle sets are labeled for use up to 48 hours; however, the panel was aware of widespread use of steel needle sets for longer than 48 hours. The panel recommended that further research be conducted on the appropriate duration of cannula use for steel needles because frequent cannula changes can be traumatic and costly for some patients.

The panel concurred that the most important factor in determining infusion set replacement frequency is whether the patient's glucose levels are sufficiently controlled. In line with the principle "when in doubt, take it out," patients should be instructed to replace the insulin in the reservoir/cartridge, the reservoir/cartridge itself, the tubing and the insertion site if their diabetes control deteriorates, if ketones develop or when a high blood glucose level does not respond to a correction bolus. The panel also suggested that because insulin in the pump can be exposed to agitation, temperature extremes and sunlight, most patients should change the insulin, the reservoir/cartridge, tubing and infusion site with each infusion site change.

## ISSUES WITH EXTENDED INFUSION DEVICE WEAR

Poor insulin absorption was discussed as a common problem among patients extending the use of their infusion devices beyond the period of time specified in the product labeling. According to the panel's clinical experience, more frequent infusion set replacement can ameliorate poor absorption in many cases. Additionally, patients may "stack" insulin boluses when poor absorption leads to delayed onset of insulin action following the first dose. "Stacking" boluses places patients at risk of severe hypoglycemia if all the bolused insulin is absorbed at once[14], and patients should be educated about this risk.

### *Filling (priming) the cannula*

The panel discussed the correct amounts of insulin for filling (priming) the cannula after insertion. Using too little insulin to fill the cannula can result in hyperglycemia and using too much can result in hypoglycemia. Manufacturers' recommendations regarding cannula fill amounts are presented in Table 6.

***Table 6.*** Recommended cannula fill amounts

| CANNULA TYPE | FILL AMOUNT (U) |
|---|---|
| Steel | 0.0 |
| 6 mm plastic | 0.3 |
| 8 mm plastic | 0.4 |
| 9 mm plastic | 0.5 |
| 10 mm plastic | 0.6 |
| 13 mm plastic | 0.7 |
| 17 mm plastic | 0.7 |

Additionally, the panel recommended that patients be informed that replacing a cannula before a planned bolus (i.e., before a meal) may help assess quickly whether or not the infusion set is working and may help maintain glycemic control over the next several hours. Patients should monitor their blood glucose levels in the hours following infusion set changes to assess the performance of the new infusion set.[15] For this reason, patients should ideally perform infusion set changes at times of day when it is feasible to check their blood glucose levels within 2-3 hours rather than late at night.

### *Filling the cartridge/reservoir*

The panel recommended that, in order to minimize insulin waste, patients should be instructed to fill each pump cartridge/reservoir with the approximate amount of insulin they will require until the next planned set change, plus the amount required to prime the tubing and the cannula (approximately 12 units for 23" tubing and 21 units for 43" tubing). A patient's average daily insulin requirements can be calculated based on the total daily dose history in the pump's memory.

### *Effects of insulin on infusion device performance and site quality*

The panel concluded that most variations in insulin performance across patients are linked to individual differences in absorption, insulin allergy and potentially antibodies. The panel agreed that all available rapid-acting insulin analogues perform well when delivered via subcutaneous infusion devices no apparent infusion site management liabilities with diluted insulin.

The panel acknowledged that in addition to U-100 insulin, some patients deliver different insulin concentrations and other medications via insulin infusion pumps. Further research on the use of these products should be performed before recommendations on these matters can be made.

## REASONS FOR TEMPORARY INSULIN PUMP DISCONNECTION

The panel acknowledged that situations ranging from daily hygiene to leisure activities and medical interventions can require patients to disconnect from the pump temporarily, for lengths of time from less than an hour up to several hours (Table 7).

***Table 7.*** Common reasons for pump disconnection

- **Shower**
- **Sports**
- **Beach activities**
- **Water parks**
- **Hot tubs**
- **Sauna**
- **Whirlpool**
- **Heavy exerecise**
- **Intimacy**
- **Formalwear**
- **Imaging in hospital** (CT, MRI)

## MANAGING TEMPORARY INSULIN PUMP DISCONNECTION

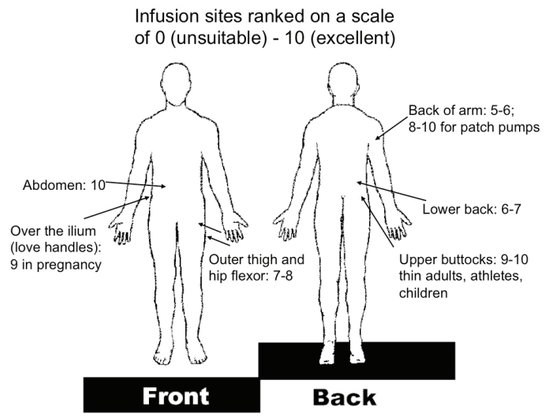
Patients' basal rates and insulin sensitivity can be important factors in determining the appropriate course of action for pump disconnection. All patients should be trained to check their blood glucose levels before, during and after the period of disconnection. In most cases, patients planning to disconnect the pump for up to 60 minutes should deliver a bolus prior to disconnection in order to replace the basal insulin that they will not receive while disconnected. Patients planning to disconnect the pump for more than 60 minutes should plan to bolus prior to disconnection, then reconnect hourly to replace missed basal insulin (or a portion thereof when exercise is taking place).

Patients who take pre-emptive boluses to replace missed basal insulin may be at risk of hyperglycemia several hours later if those boluses are included in insulin-on-board (active insulin) calculations. The panel recommended using the pump's "fill cannula" priming feature when delivering pre-emptive boluses, since cannula primes are not included in the pump's insulin-on-board calculations or daily delivery history.

## SELECTING INFUSION SITES

The panel discussed the suitability of different body parts with adequate fat as subcutaneous infusion sites, summarized in Figure 2. The panel endorsed the general preference for utilizing the abdomen, as is common in clinical practice. Sites on the front of the body, the abdomen or the front of the thigh are most suitable for visually or dexterity challenged patients because they are easier to see and reach. Additionally, patients using continuous glucose monitoring (CGM) need to consider the placement of their CGM sensor in relation to their insulin pump infusion set. The labeling for most CGM devices specifies a minimum distance between the CGM sensor and an infusion site, which should be observed.

***Figure 2.*** Infusion sites ranked on a scale of 0 (unsuitable) – 10 (excellent)






### *Infusion site rotation*

The panel discussed principles and tactics for appropriate infusion site rotation among patients using insulin pump therapy. Patients may believe they are choosing a new infusion site when they alternate from the right to left sides of the body, but they may in fact be inserting a new cannula in a recently used site that is still healing. This behavior can put patients at greater risk of lipodystrophy and scar tissue development, eventually reducing the number of available infusion sites and compromising diabetes control.[16] Appropriate infusion site rotation is therefore a crucial behavior for successful outcomes with insulin pump therapy.

### *How far away from the "old" infusion site is a "new" site?*

The panel acknowledged the lack of data to support specific infusion site rotation strategies but recommended that a new 30-45º insertion angle cannula (e.g. Comfort/Silhouette/Tender) should be inserted adjacent to but a minimum of 2 inches away from the previous cannula site and a new 90º insertion angle cannula should inserted adjacent to but at least 1 inch away from the previous cannula site. Patients should be taught to keep the old infusion set on the body until after completing an infusion set change so the old site can serve as a reference point for the recommended distance between the old and new infusion sites.

To encourage patients to use the maximum surface area recommended for insulin infusion, the panel recommended that patients be taught to visualize the abdomen (or buttocks, or thigh, according to patient preference) on a grid. If a patient inserts an infusion set in the upper part of the recommended area of the abdomen at the beginning of a given month, he or she selects a new site adjacent to the old one with each successive cannula change, and then moves down to the middle of row, and eventually crosses to the other side, followed by a bottom row, and repeats the process. This strategy can facilitate increased healing of previous infusion sites compared to patients simply alternating from the right to the left side of the umbilicus.

For patients who prefer sites with less surface area than the abdomen, such as the upper buttocks or the back of the arms, the panel recommended a site rotation schedule incorporating different body parts from site change to site change. For example, if a patient had an infusion set in the back of the right arm at the beginning of a month, his or her next infusion site might be the right upper buttock, followed by the left upper buttock and then the back of the left arm, then a different area of the back of the right arm from the first site.

The panel emphasized the importance of teaching patients to avoid placing infusion sets in areas of scar tissue, including stretch marks, and areas of lipohypertrophy or lipoatrophy, which are associated with poorer insulin absorption compared to undamaged tissue. Furthermore, patients should be instructed to avoid inserting the infusion device into muscle tissue as muscular insertion is associated with site irritation and can affect insulin absorption.

### *Skin preparation*

The panel discussed several aspects of skin preparation, including cleansing, antiperspirant use and precautions for patients with recurrent site infections (i.e., history of cellulitis or staph) or compromised immunity. The panel's recommendations for skin preparation prior to infusion device replacement are summarized in Table 8.

***Table 8.*** Skin preparation: best practices in hygiene

**GENERAL**

- Thoroughly scrub hands and nails
- Wipe the new infusion site with an alcohol swab, clean area with soap and water or take a shower
- Allow skin to air dry

**SPECIAL PRECAUTIONS**

- History of cellulitis, infection, staph, compromised immunity
- Betadine, Hibiclens, Phisohex (dab upon removal)

The panel also discussed the use of solutions or wipes intended to increase the adhesion of the infusion set to the skin and the use of underbandages to support the infusion set and increase adhesion. The panel's recommendations are summarized in Table 9.

***Table 9.*** Recommended products to increase adhesion and underbandage options

**RECOMMENDED PRODUCTS TO INCREASE ADHESION**

- Mastisol (Delasco)
  - Allow 15-30 minutes to dry prior to infusion set insertion
  - Odor may be an issue
- Benzoin (generic)
- Skin-Tac (Torbot)

**RECOMMENDED UNDERBANDAGE OPTIONS**

- Hypafix (Smith & Nephew)
- Opsite Flexifix (Smith & Nephew)
- IV 3000 (Smith & Nephew)
- Tegaderm (3M)
- Hy-Tape (Hy-Tape International)

Note: To prevent occlusions, adhesives or underbandages should be applied *around*, but not directly on, the area of skin where the cannula will be inserted.

The panel also discussed the use of Hypercare (aluminum chloride hexahydrate [topical]), a prescription-only antiperspirant spray, prior to infusion set insertion for patients whose excessive perspiration weakens the infusion set adhesive. The panel commented on the association between the use of underarm antiperspirants containing aluminum chloride and breast cancer, but agreed that some patients may benefit from the use of small amounts of aluminum chloride to keep their infusion sets intact.

***Pinching an inch before device insertion***

Moving to the practicalities of cannula insertion, the panel discussed whether to pinch up the skin and fat prior to inserting a cannula. With a manually inserted set, it may be necessary to pinch up to create enough resistance for the needle to pierce the surface of the skin. Spring-powered insertion devices, on the other hand, quickly drive the needle through the skin without the need to pinch up. The panel's recommendations regarding skin manipulation are summarized in Table 10.

The panel considered that pinching the skin to insert a cannula into a neonate or an infant requires care not to isolate a skin fold. The panel recommended against obese patients pinching up the skin prior to cannula insertion; stretching the skin taut may be more appropriate to ensure successful cannula insertion in this population. Some patients benefit psychologically from the distraction of pinching up the skin prior to cannula insertion even if it is not strictly necessary.

***Table 10.*** Panel recommendations regarding skin manipulation prior to infusion set insertion

| PINCH | NO PINCH/NO STRETCH | STRETCH |
|---|---|---|
| Lean person | Short cannula | Obese person |
| Angled set | Device-aided insertion | — |
| For distraction | — | — |
| Manula cannula insertion | — | — |



# Using infusion devices – summary of recommendations

**FREQUENCY OF INFUSION DEVICE REPLACEMENT**

- Change the infusion set every 48 hours where feasible. This recommendation applies to both plastic and steel needle infusion devices
- Check the priming history on patients' insulin pumps to determine the frequency with which individual patients replace their infusion devices
- Assess patterns in glycemic control related to infusion site changes to determine whether a patient needs to change his or her infusion set more frequently
- Frequent infusion set changes may be particularly beneficial for pregnant patients and those at risk for infection
- Patients should replace the insulin in the reservoir/cartridge, the reservoir/cartridge itself, the tubing and the insertion site with every routine set change and if their diabetes control deteriorates, if ketones develop or when a high blood glucose level does not respond to a correction bolus

**FILLING (PRIMING) THE CANNULA**

- Patients should follow manufacturers' recommendations regarding cannula fill amounts *(see Table 6)*
- Patients should monitor their blood glucose levels in the hours following infusion set changes to assess the performance of the new infusion set

**FILLING THE CARTRIDGE/RESERVOIR**

- Patients should fill each pump cartridge/reservoir with the approximate amount of insulin they will require until the next planned set change, plus the amount required to prime the tubing and the cannula (approximately 12 units for 23" tubing and 21 units for 43" tubing)

**TEMPORARY PUMP DISCONNECTION**

- Patients disconnecting for <60 minutes should deliver a bolus prior to disconnection in order to replace the basal insulin that they will not receive during the period of disconnection
- Patients disconnecting for >60 minutes should bolus prior to disconnection and then reconnect hourly to replace missed basal insulin (or a portion thereof when exercise is taking place)
- Patients should use the pump's "fill cannula" priming feature when delivering pre-emptive boluses to cover a period of disconnection

**BEST PRACTICES IN PATIENT TRAINING**

The panel's recommendations regarding best practices in patient training are summarized below.

- Hands-on training is essential at initiation of pump therapy, when there are concerns about glycemic control, and when patients change types of infusion sets
- As part of the training, patients should be observed successfully replacing the disposable infusion system
- To allow the patient to gain familiarity with the pump and infusion device, the panel endorsed a trial period with saline rather than insulin in the pump with special populations (i.e., patients with vision problems, dexterity difficulties or very low literacy; those with a history of DKA related to medication adherence; or those who will require the assistance of multiple caregivers to manage)
- In initial training, acknowledge and discuss patients' and family members' psychological concerns regarding the change from injection therapy to wearing a pump, which may include
  - Fear of the unknown
  - Anxiety about being attached to the pump
- Teach the principles of pump therapy with reference to what patients or caregivers already know
  - For example, compare the basal rate to long-acting insulin and the bolus to a mealtime or correction injection of rapid-acting insulin

- Encourage patients to watch the training video or instructions on the pump company's website, including instructions regarding infusion device usage, prior to the hands-on training appointment
- Encourage patients to learn the button-pressing sequences and screens of the pump in advance of wearing the device
- Discuss subcutaneous infusion devices before or after other training topics, depending on the patient's level of anxiety or interest in infusion sets
  - Simply wearing a cannula (without a saline trial in progress) or a dummy patch pump prior to formal pump training may increase patients' comfort with a subcutaneous infusion device

## TIME AND TOPICS FOR INFUSION DEVICE TRAINING

The panel explored the amount of time necessary to train patients on infusion set usage. The panel agreed that 30 minutes to 1 hour is a reasonable length of time for most patients beginning insulin pump therapy. For experienced patients switching infusion set types, 15-30 minutes is sufficient training time in most cases.

The panel compiled a checklist of infusion device topics to be covered during initial pump training *(Table 11)*.



*Table 11.* Sample insulin pump initiation training checklist

| **TOPICS** ( ☒ when covered) | **NOTES** |
|---|---|
| **INSULIN STABILITY**<br>□ Temperature range<br>□ Expiration dates | |
| **RESERVOIR/CARTRIDGE**<br>□ Filling technique<br>□ Removing air bubbles | |
| **PRIMING**<br>□ Priming tubing<br>□ Cannula fill amounts (as applicable) | |
| **INFUSION SITES**<br>□ Site assessment and selection<br>□ Hygiene/skin preparation | |
| **INFUSION SET OPTIONS**<br>□ Angled (30-45°) sets<br>□ Straight (90°) sets<br>□ Manual insertion<br>□ Insertion aids<br>□ Available tubing lengths<br>□ Aesthetics (as applicable) | |
| **SET INSERTION TECHNIQUE**<br>□ With insertion aid (as applicable)<br>□ Manual (as applicable)<br>□ Provide patient with take-home checklist/diagrams re infusion set replacement | |
| **SITE CHANGE FREQUENCY**<br>□ Labeled period of use for device<br>□ Infusion site rotation plan<br>□ Individual factors (e.g., infection risk) | |
| **INFUSION SET ADHESION**<br>□ Pre-application products<br>□ Under/overbandage options | |
| **WHAT TO DO WITH TUBING**<br>□ Tubing length considerations<br>□ Threading/accommodating tubing under clothing<br>□ Safety loops (if applicable) | |
| **DISCONNECTION PROCEDURES**<br>□ Replacing missed basal insulin<br>□ Keeping the pump out of direct sunlight/away from sand | |
| **SHARPS DISPOSAL**<br>□ What to do with used introducer needles/steel needle sets | |
| **HOW TO REORDER DISPOSABLE SUPPLIES**<br>□ Contacting the pump company or distributor<br>□ Part/re-order numbers<br>□ Quantities to order | |
| **TROUBLESHOOTING PRINCIPLES** (SEE TABLE 14) | |
| **BACKUP PLAN IN CASE OF PUMP FAILURE**<br>□ Intermediate/long-acting insulin dosing<br>□ Keeping insulin pens or syringes on hand | |

The panel explored the use of training tools to improve communication regarding infusion site management and device us. Such tools can provide both children and adults with valuable play therapy and practice to improve their technique. Injection practice pads are useful for training patients on infusion set insertion technique as well as injection practice. A human volunteer, e.g. a parent or a spouse, or the healthcare provider personally, could wear a strap-on injection practice pad to help make the practice more realistic. Additionally, clear jelly filled injection practice pads can help patients understand how a cannula sits in the subcutaneous tissue.

The panel concurred that teaching tools representing healthy tissue and damaged tissue (lipodystrophy, scarring, etc.) would be highly valuable in patient education and called upon diabetes care companies to consider developing such tools.

### *Confirming patients' and caregivers' understanding of infusion site management and device usage*

The panel discussed methods for confirming patients' and caregivers' understanding of infusion site management and device usage following training. Post-tests, role-playing, problem-solving exercises and game-show format quizzes are all useful and should be utilized as appropriate. All adult family members who care for a child using a pump, not just one parent, should be observed independently replacing the disposable infusion system in the course of the family's pump training.

In addition to intervening when patients complain of infusion site or set management problems, diabetes educators should routinely inspect infusion sites and ask patients and caregivers how they are doing with infusion sites and devices at diabetes education appointments. Educators should also plan to review infusion sites and devices in depth during one appointment per year. In addition to informing patients and caregivers of new developments in therapy, an annual infusion device management review provides a chance for educators to assess patients' infusion sites and address any related issues.

The panel considered that inpatient care might provide an opportunity to check the appropriateness of a patient's infusion set. In particular, healthcare providers may wish to evaluate pediatric, pregnant and immuno-compromised inpatients whose glycemic control is sub-optimal in the hospital. The hospital-based diabetes care team can switch the patient's infusion set to one that may be more appropriate based on the patient's history and a physical evaluation. On discharge, the hospital-based diabetes team should communicate its recommendation to change the patient's infusion set type to the patient's usual diabetes care provider for follow-up.

## TROUBLESHOOTING AND PROBLEM-SOLVING

### *Managing the risk of diabetic ketoacidosis (DKA)*

Patients on insulin pump therapy can develop DKA within hours after infusion device failure, insulin spoilage, or unplanned disconnection due to the short duration of action of rapid acting insulin. Patients should be informed not to surrender the insulin pump without alternative insulin administration (insulin drip or basal-bolus injections) should they be admitted to the hospital. The panel discussed the importance of teaching patients strategies for preventing DKA. The panel's recommendations for preventing DKA are summarized in Table 13.

*Table 13.* Preventing DKA

| CLINICAL OBJECTIVE | CONSIDERATIONS | SPECIFIC ACTION(S) |
|---|---|---|
| **Preventing diabetic ketoacidosis (DKA)** | Does the patient have an unexplained elevated blood glucose level? | 1 Advise patient to check blood ketones if possible, urine ketones if not possible to check blood ketones (≥ 0.6 mmol/L or rising)<br>2 Instruct patient to inject supplementary bolus via syringe and enter the data into the pump (disconnect pump from infusion site, deliver equivalent bolus)<br>3 Advise the patient to replace the infusion set and tubing, and use a new insulin vial to fill a new cartridge/reservoir<br>4 Advise the patient to drink water to prevent dehydration |
| | Is the patient vomiting or showing other symptoms of DKA? | Advise the patient to go to the emergency room immediately (call 911 if breathless or very ill) |
| | Is the patient's blood glucose meter accurate? | 1 Confirm that the patient's blood glucose meter test strips are in-date and the meter is coded correctly (as applicable)<br>2 Advise the patient to wash and dry his or her hands and re-test<br>3 Advise the patient to follow the manufacturer's instructions regarding glucose control testing as applicable<br>4 Instruct patient to contact manufacturer and replace meter if it is malfunctioning |

### *Common problems with infusion sites or devices*

The panel discussed troubleshooting and drew up a list of problems that may arise in the course of insulin pump therapy, and courses of action for problems that may be solved quickly upon intervention, shown in Table 14.

***Table 14.*** Troubleshooting

| CLINICAL OBJECTIVE | CONSIDERATIONS | SPECIFIC ACTION(S) |
|---|---|---|
| **Identifying the cause(s) of high blood glucose levels** | Did the patient's infusion set fall out? | 1 Discuss with the patient the potential use of adhesion aids, underbandages or overbandages to increase adhesion<br>2 Consider whether using another body part could result in better adhesion<br>3 Check whether the patient is replacing the infusion set approximately every 72 hours in accordance with labeling |
| — | Is insulin leaking from the pump or infusion set? | Advise the patient to check for the smell of insulin around his or her infusion site and the connection between the reservoir/cartridge and tubing; if insulin is detected, change the infusion set and cartridge/reservoir |
| — | Is the insulin in the pump spoiled? | Advise the patient to fill a new cartridge/reservoir from a new insulin vial when replacing the infusion set. Review proper storage conditions for insulin at home and away from home |
| — | Is the correct (rapid-acting) insulin in the pump? | Advise the patient fill a new cartridge/reservoir from a new rapid-acting insulin vial when replacing the infusion set |
| — | Is the time on the insulin pump's clock correct? | Advise the patient to confirm the time on the pump's clock, specifically in terms of am/pm, to ensure that basal insulin is delivered appropriately |
| — | Is there air or an insulin leak in the system? | Check the patient's cartridge/reservoir filling and set replacement technique |
| — | Is there an occlusion (clog) in the cannula? | If occlusions are frequent, consider use of a steel needle infusion device and/or changing to a different rapid-acting insulin analog. If these do not resolve the problem, advise the patient to contact the pump manufacturer regarding a replacement pump |
| — | Is the pump primed? | Review the patient's cartridge/reservoir filling technique and priming practices |
| — | Has a basal rate been accidentally deleted from the pump? | Ask the patient to review basal rates programmed into the pump against written records |
| — | Did the patient forget to deliver a meal bolus? | Ask the patient to check his or her bolus history to confirm bolus delivery or non-delivery |
| — | Did the patient accurately count the carbohydrates in his or her last meal and deliver an appropriate bolus? | Review carbohydrate counting principles and insulin : carbohydrate ratios |
| — | Is the patient experiencing erratic insulin absorption?<br>Does the patient have lipodystrophy? | 1. Review the patient's choice of cannula type, infusion sites and duration of infusion set use<br>2. Advise the patient to avoid inserting cannulae in areas of lipodystrophy<br>3. Assess the patient's infusion sites at each visit |
| — | Does the patient have a concurrent illness or is he/she on steroid treatment? | Review sick day management practices with the patient, including temporarily increasing basal rates |
| — | Is the patient extending the use of the infusion set or insulin reservoir/cartridge beyond the labeled time? | Discuss with the patient whether he/she is experiencing anxiety around infusion set changes or cannula insertions or health insurance coverage/reimbursement problems |



***Other variables in glycemic control to consider include:***

- Exercising of muscles near infusion site
- Exposure to high temperatures, as heat may cause vasodilation and increased insulin action, potentially resulting in hypoglycemia
- The presence of insulin antibodies, which can cause malabsorption or erratic insulin action. If the patient tests positive for insulin antibodies, changing the insulin may resolve the issue.[17]

### *Identifying infusion site infections*

The panel discussed strategies for managing skin and tissue problems arising from subcutaneous infusion. Patients should be taught to watch for erythema, itching, edema, warmth, pus and blistering at the infusion site. Patients presenting with an infusion site infection should be treated with antibiotics, and lancing/draining in cases of abscess.

### *Managing lipodystrophy*

The panel discussed best practices in managing lipodystrophy. Patients should be taught to palpate infusion sites to determine tissue health. If the subcutaneous tissue feels hard or lumpy, patients should avoid using the site for the next three months, and then reassess the area.

### *Blood in the cannula*

The panel also discussed the best advice to give to patients when they see blood in the cannula or tubing, or bleed profusely on inserting a cannula. Persistent blood in the cannula (if visible) or tubing necessitates infusion set replacement because blood is taking the place of insulin in the system and may contribute to clogging. If a patient bleeds profusely on cannula insertion, he or she should remove the cannula and re-attempt the set insertion with a new infusion set at a different site.

## WHEN SHOULD INSULIN PUMP THERAPY BE DISCONTINUED?

The panel noted that a very small number of patients overall discontinue pump therapy, but the reasons for discontinuation merited discussion. In the panel's experience, infusion site issues are a common cause of discontinuation of pump therapy.

In some instances, patients who began insulin pump therapy under another provider before being seen in their current practices had been poorly selected for insulin pump therapy. In other instances, patients may have been appropriate candidates for pump therapy but may have received inadequate education or training and lacked the skills for success with an insulin pump. In such cases, the panel recommended returning to multiple daily injection (MDI) therapy until proper education can be provided. Patients with inadequate training and skills may be able to resume pump therapy after appropriate education.

## THE ROLE OF THE DIABETES EDUCATOR

Diabetes is a complex chronic disease. The quality of diabetes control is related to both the skills of diabetes educators and the self-management skills that educators impart to patients.[11]

Diabetes educators can take the lead in the selection and use of appropriate insulin infusion devices for patients using insulin pump therapy. Educators can initiate conversations with patients and caregivers regarding device factors and patient factors that can affect the success of pump therapy and perform infusion site assessment and management. The relationship between patient and diabetes educator can help increase patients' adherence to best practices in infusion site and device management, which may enhance treatment effectiveness.

Diabetes educators are also ideally positioned to increase awareness of infusion site and device management issues outside of the clinic. For example, diabetes educators assisting at children's diabetes camps may have the opportunity to evaluate infusion set choice and site rotation practices among campers struggling with infusion sites or diabetes control overall and can communicate their recommendations to the child's family. Diabetes educators can also make recommendations regarding infusion device and site management in inpatient care.

# Conclusions

The success of insulin pump therapy depends heavily on the consistency of insulin absorption on a day-to-day basis and over the long term. Infusion set devices are crucial to the delivery of insulin via an insulin pump. Appropriate infusion device selection and management are therefore cornerstones of insulin pump therapy.

Insulin pump manufacturers have a role to play in improving education and communication strategies so that patients can make informed choices regarding infusion devices. Third-party payers can help raise the standard of patient education regarding infusion devices and sites by linking coverage for pump therapy to structured education, including teaching on infusion sets, as well as providing coverage for a variety of devices in quantities necessary for optimal glycemic control.

The diabetes educator plays a central role in infusion device and site selection and management, providing patient education, and increasing awareness about infusion site issues among healthcare providers. The lack of clinical literature regarding subcutaneous insulin infusion management may present a barrier to broad application of best practices in infusion device selection and site management. However, diabetes educators' clinical expertise with regard to infusion device management can help maximize outcomes in insulin pump therapy.



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