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ISMP

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

Managing hospitalized patients with ambulatory pumps—Part 2

Guidelines for the use of insulin pumps during hospitalization

The availability of lightweight ambulatory infusion pumps in the early 1980s made infusion therapy possible in settings outside the hospital, including in the home. This mode of delivery may be used to administer medications, blood factors, nutrition, or hydrating solutions via the intravenous (IV), subcutaneous, epidural/intrathecal, percutaneous, intrawound, intrahepatic, or other parenteral routes. Their use is expected to grow at an annual rate of about 9% over the next few years.[1] This means that, by now, many healthcare practitioners in hospitals have likely encountered patients presenting for treatment with an ambulatory pump. Thus, hospitals need to determine whether to allow patients to continue to use and self-manage their medications using the ambulatory pump, or to remove the pump upon admission and deliver the medications using an alternative method.

One year ago, we published the results of a survey we conducted to learn about practices and concerns associated with patients who arrive at the hospital with an external ambulatory pump.[2] Overall, the results exposed a high degree of variability in assessing and managing these patients in the hospital, with many aspects of patient safety overlooked. We also found that a large number of respondents did not know whether certain policies, procedures, guidelines, or practices were in place in their hospitals to safeguard patients with an ambulatory pump.

If a therapeutically equivalent (alternative) medication pump is currently available in the organization (e.g., an IV infusion pump), the patient's own ambulatory pump might be reasonably replaced with a hospital pump during hospitalization to continue the delivery of an important medication (e.g., epoprostenol). However, for some ambulatory infusion pumps, the hospital may have no compatible pump replacement. Furthermore, there may be a clinical benefit to allow certain hospitalized patients to self-manage their medication via their ambulatory pump. One example is a subcutaneous insulin pump, which is used by more than a half million patients with type 1 or type 2 diabetes in the US.[3-7]

Insulin pumps

In a 2014 consensus statement, the American Association of Clinical Endocrinologists and the American College of Endocrinology encouraged hospitalized patients and their admitting physicians not to discontinue an insulin pump, but rather to consult the specialist responsible for the patient's insulin pump management if the patient cannot manage his or her own pump.[5] The American Diabetes Association[7] and ECRI Institute[8-10] make similar recommendations, both encouraging the continued use of an insulin pump during hospitalization after a screening process demonstrates the patient's or family member's physical and mental ability to use the pump. Furthermore, these patients or family members have often been extensively educated in diabetes self-management and have invested considerable time in mastering the insulin pump technology, and thus, are often eager to continue using the pump during hospitalization.[11-14]

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SAFETY wires

Tamper evident ring on eye ointment cap can fall into eye. A hospital reported a problem with **LUBRIFRESH P.M.** ointment 3.5 g tubes. This product is used by the organization's anesthesia department as eye lubrication during surgeries. The anesthetists will separate the plastic ointment cap from the plastic tamper evident neck ring (also called a collar or band) and then invert the tube tip towards the patient's eye after the patient is asleep and lying horizontally on the operating room table. Unfortunately, once the seal is broken, the neck ring separates from the cap (**Figure 1**) and falls from the tube, past the uncapped tip, and into the patient's eye. This problem has been tested with several different tubes, and all of the neck rings exhibited this condition. There have been no known injuries.

Figure 1. A tube of Lubrifresh P.M.

This is similar to a situation that the US Food and Drug Administration (FDA) reported earlier this year with eye drop bottles (www.fda.gov/Drugs/DrugSafety/ucm490693.htm). A loose safety seal or ring presents a safety risk as it may cause eye injuries. In fact, with eye drop bottles, FDA said the agency had received reports of six adverse events associated with the loose safety seals that had fallen into eyes.

The LubriFresh P.M. manufacturer, Major Pharmaceuticals, told us that the company has redesigned the product

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> **Insulin pumps**—continued from page 1

There are nearly a dozen different insulin pumps available in the US today, all featuring complex technology. The pumps rarely have standard components, making it difficult for hospital staff to gain familiarity with all the available pumps.[6] Thus, the potential for errors is high, the most dangerous of which is an insulin overdose leading to clinically significant hypoglycemia. In fact, 30% of the respondents to our 2015 survey reported such errors, some stating they were "too frequent" to list (previously unpublished data). Even allowing very capable patients to manage their own insulin pump can be risky. For example, errors have been reported to ISMP in which a patient self-administered a bolus dose of insulin via an insulin pump without telling the nurse, and the nurse administered the same dose via an injection.

Insulin pump use during hospitalization

Safely managing hospitalized patients who present for treatment with an insulin pump requires extensive planning, widespread clinician education, clearly defined approaches to communication, and a commitment to attend to the myriad details associated with caring for these patients. Because insulin pumps are likely to be the most frequently encountered external ambulatory pump when patients present to hospitals and have been recommended for continued use during hospitalization, the remainder of this article focuses on guidelines for establishing policies and procedures related to the use of external insulin pumps during hospitalization. The guidelines provide suggestions for developing policies, procedures, and associated documents that meet the dual goals of allowing patients the flexibility to continue using their insulin pump during hospitalization while ensuring their safety.[6,12] If you have comments about the guidelines or would like to recommend any additions, we would love to hear from you (ismpinfo@ismp.org)!

The guidelines appear on pages 3-7 and are followed by the references.

Healthcare consumers are watching!

A consumer (also a nurse) reported that an unlabeled syringe was observed at a dermatologist's office during her son's appointment for a wart removal. The unlabeled syringe was on a table with a piece of paper under it. Her son asked if the injection was for him, and the nurse replied, "No, that's for a different type of procedure." On another occasion, the consumer noticed an unlabeled syringe of what looked like propofol in an oral surgeon's treatment room, but it clearly was not needed for her procedure, which did not require sedation.

Then, more recently, another consumer took her mother to a neurologist for a nerve block to treat head and neck pain. A nurse holding two unlabeled syringes and a sheet of paper in her hand ushered them into a treatment area. They remained in the room for about 30 minutes, along with the 2 unlabeled syringes, until a physician assistant (PA) arrived in the treatment room. The consumer reported her concern about the unsecured and unlabeled syringes, suggesting several adverse scenarios that could happen as a result.

First, a patient might try to divert or tamper with the unknown medications in the syringes, or even self-administer the contents of one or both syringes; furthermore, a nurse could put the syringes of unknown medications into the wrong treatment room, where a PA or physician could assume the syringes contained the anticipated medications and inject the unknown medications without confirmation. While the consumer spoke up and did everything possible to address the risk she observed, she probably ruffled some feathers in the office for bringing this to the PA's attention. However, soon after, the neurologist came into the room, proceeded to freshly prepare the needed medications, and assured the consumer that he would address the risk. Kudos to the consumer for speaking up! The proper labeling of prepared syringes of medications is absolutely critical to safety.

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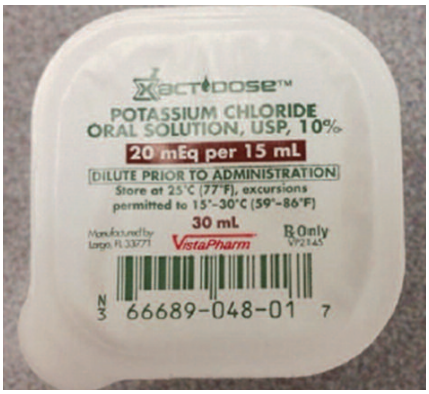
cap so the neck ring stays attached to the cap when it is removed. Distribution of the redesigned product has already begun, according to the manufacturer. Major was not one of the companies associated with the FDA announcement about eye drop bottles earlier this year.

Misleading VistaPharm label. We again received a report about VistaPharm's potassium chloride oral solution 10%. The unit dose cups indicate they hold 20 mEq in 15 mL. Elsewhere on the label it indicates that the volume in the cup is actually 30 mL, which is 40 mEq (see **photo** below). Several patients received overdoses, although none were injured. The label is misleading and potentially dangerous. We contacted VistaPharm in March to request a label change that shows the exact quantity in the container (40 mEq per 30 mL). Although this has been done, products with older labeling are still in circulation. Please check your supplies to make sure that these poorly labeled cups are not available.



2016-2017 ISMP *Fellows*

ISMP welcomes **Staley Lawes, PharmD, BCPS**, the **2016-2017 ISMP Safe Medication Management Fellow**, supported in part by Baxter, Novartis Pharmaceuticals, and Fresenius Kabi; **Maximilian Straka, PharmD**, the **2016-2017 FDA/ISMP Safe Medication Management Fellow;** and **Celeste Karpow, PharmD**, also a **2016-2017 FDA/ISMP Safe Medication Management Fellow**. Staley will spend an entire year at ISMP, and Max and Celeste will rotate halfway through the year by spending 6 months at FDA and 6 months at ISMP.

Guidelines for the Safe Management of Patients with an External Subcutaneous Insulin Pump During Hospitalization

Please note: These guidelines were compiled and vetted by ISMP after reviewing current policies and procedures that have been honed through experience in several large and small US hospitals, a review of the professional literature,[1-17] the results of the 2015 ISMP survey on this topic,[2] and analysis of reports of errors related to insulin pumps submitted to ISMP or published in the literature. Examples of some of the recommended documents mentioned in the guidelines (e.g., patient consent/agreement, insulin pump order set, patient bedside worksheet/log) are provided in several of the references[6,11,12,14-17] listed at the end of the guidelines.

I. Initial Assessment Process

Admission Assessment

1) As part of an initial patient admission assessment, nurses should be prompted to specifically ask all patients if they are using an insulin pump.

2) If the patient is using an external insulin pump, the nurse conducting the initial patient assessment should notify the patient's admitting physician. This should set into motion a process to determine whether or not the pump can remain in place and be managed by the patient or a responsible adult representative during hospitalization.

Patient Selection Criteria

3) A standard process should be used to determine if the patient is an appropriate candidate to manage his or her own insulin infusion (per prescriber orders) via the insulin pump during hospitalization. Consideration should be given to the following elements when developing patient selection criteria:

   a. The patient, or a knowledgeable, responsible adult representative of the patient, may be an appropriate candidate if he or she is alert, physically capable, able to properly work the pump functions, and willing to manage the pump during hospitalization. If an adult representative will be managing the pump, he or she must be on site and immediately available 24 hours/day, 7 days/week.

   b. At a minimum, the patient or the responsible representative should be assessed for awareness of hypoglycemia symptoms; the ability to calculate and deliver bolus doses; the ability to change the basal rate, set a temporary rate, or suspend insulin delivery; and glucose control prior to hospitalization when using the pump.

   c. Contraindications to self-management of the pump during hospitalization may include:

      i. Altered state of consciousness, including prescribed medications that could alter consciousness
      ii. Lack of orientation to person, place, or time
      iii. Any physical, cognitive, or behavioral problem that would preclude self-management
      iv. Presence of diabetic ketoacidosis or hyperosmolar hyperglycemia
      v. Critical illness (e.g., sepsis), trauma, or a condition that warrants IV administration of insulin (e.g., to counteract the glycemic effects of high-dose steroids used for transplant rejection)
      vi. Suicidal ideation
      vii. The patient or responsible representative is unwilling or unable to provide essential information about the pump and insulin doses (see guideline # 9)
      viii. The patient or responsible representative is unwilling or unable to sign a consent/agreement that delineates self-management responsibilities (see guideline # 13)
      ix. The patient or responsible representative cannot provide needed pump supplies during the hospitalization (see guideline # 15)

4) An initial determination by the admitting physician to allow the patient (or representative) to manage his or her own insulin via the pump should be verified (within 12 hours) by an endocrinologist, inpatient diabetes management service, or a physician with documented training in insulin pump management (see guideline # 19) to ensure the patient has sufficient knowledge to manage his or her pump and make dose adjustments per prescriber orders during hospitalization (as opposed to knowing only enough to get by under normal circumstances at home). Verification is not required if the admitting physician is an endocrinologist, a member of an inpatient diabetes management service, or has documented training in insulin pump management.

II. Next Steps for a Patient Who Does Not Meet Criteria for Self-Management

Discontinuation of the Insulin Pump

5) The insulin pump should be discontinued and alternative insulin orders should be obtained for patients who exhibit the following:

   a. The patient or representative exhibits any of the contraindications listed above during an initial assessment upon admission or during ongoing assessments of the patient to identify potential changes.

   b. The patient has had two consecutive blood glucose values greater than a hospital-defined limit (e.g., 250 mg/dL) that have not decreased

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with insulin administration, have not been corrected by insulin pump setting changes as ordered by the prescriber, and have not been reduced by changes in the insertion site or tubing.

c. The patient's representative is not available on site and/or does not respond to a call/text while on site within a timeframe determined by the hospital.

d. The insulin pump malfunctions and cannot be remedied within 1 hour (see guideline # 37).

e. The insulin pump is temporarily halted for longer than 1 hour (see guideline # 39).

6) Guidelines should be provided for prescribers converting insulin pump therapy to subcutaneous injections or intravenous infusions if the insulin pump must be discontinued. These guidelines should include a process to help determine the patient's current total daily dose of insulin via the insulin pump, including the patient's typical nutritional bolus and correction bolus doses.

7) The hospital should specify how to disconnect an insulin pump, how to label it, and whether to store it or send it home with a responsible family member.

8) Any decision to reinstate the insulin pump should be based on the same criteria noted in guidelines # 3 and 4.

III. Next Steps for a Patient Who Meets Criteria for Self-Management

Insulin Pump Information

9) The patient or responsible representative should assist the nurse in interrogating the insulin pump's settings and documenting information about the pump and insulin therapy so that it can be placed in the patient's health record to provide the following information to the healthcare team:

a. Insulin pump model and manufacturer
b. Customer support number(s)
c. Name and concentration of the insulin currently used in the insulin pump
d. Name and phone number of the patient's insulin pump educator (if known)
e. Type of infusion set/inserter
f. Name and phone number of a person who can help with pump use in case of emergency
g. Insulin basal rate(s) upon admission
h. Nutritional bolus doses based on carbohydrate ratio or other specific information about nutritional bolus doses
i. Correction bolus doses for elevated glucose levels (e.g., correction scale, sensitivity factor [amount of insulin for each increment over target glucose])

Functionality Verification

10) If the insulin pump uses wireless technology, there should be a process in place to ensure that it will work in areas of the hospital where the patient may visit before allowing its use during hospitalization.

11) The biomedical engineering department should be contacted if any problems were encountered when testing the wireless technology or during pump interrogation (see guideline # 9) to determine if the pump should be inspected further to verify functionality.

Baseline Blood Glucose

12) The patient's blood glucose value should be obtained upon admission to serve as a baseline.

Patient Consent/Agreement

13) The patient or responsible representative should sign an agreement/consent delineating the patient's or representative's responsibilities and clarifying the conditions that could lead to insulin pump discontinuation. Examples are provided below:

a. Responsibilities
   i. Use of a hospital-supplied glucometer for glucose testing upon which dosing is based (see guidelines # 32 and 33)
   ii. Use of hospital-supplied insulin for refills (see guideline # 35)
   iii. Make changes in basal rates only if prescribed by the physician
   iv. Change the tubing and rotate the site every 72 hours and as needed (see guideline # 34)
   v. Provide own insulin pump supplies (except insulin) (see guideline # 15)
   vi. Document on a worksheet/log and show nurses all insulin bolus doses and changes in basal rates (see guidelines # 43 and 45)
   vii. Report symptoms of hyper- and hypoglycemia (see guideline # 27)
   viii. Report insulin pump problems and error/alert messages (see guideline # 37)

b. Conditions that could lead to disconnecting the insulin pump
   i. Physician's orders

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ii. Changes in the patient's abilities, judgment, or medical condition (see guideline # 3)
iii. Certain procedures (see guidelines # 38 and 41)
iv. Unavailability of the patient's representative (see guideline # 5)
v. Other reasons deemed necessary by the medical staff

14) If the patient or representative is unable or unwilling to sign the agreement/consent, the insulin pump should be discontinued and disconnected from the patient. If the patient or representative is unable or unwilling to sign the agreement/consent and refuses to discontinue the insulin pump, the patient's physician and risk management should be notified immediately.

Patient Provision of Supplies

15) Patients should provide their own pump supplies (except insulin when a refill is necessary), and have at least a 5- to 7-day supply, to start, of reservoirs/syringes/cartridges for the insulin, infusion sets and tubing, and a set of extra batteries.

IV. Inpatient Management of the Patient Who is Self-Managing the Insulin Pump

Orders for Insulin Pumps

16) The hospital pharmacy and therapeutics committee (or a similar committee) should specify the insulin product(s) that are available for insulin pump refills.

17) Order sets should be established and used when prescribing patient self-management of insulin via the patient's insulin pump. At a minimum, the following orders/order types should be included in all order sets:

a. An order to leave the insulin pump in place and allow the patient (or representative) to self-manage the insulin pump and insulin doses based on prescriber orders
b. Basal rate(s) settings
c. Algorithms for nutritional bolus doses and correction bolus doses
d. Target blood glucose range
e. Frequency of blood glucose monitoring
f. An order to allow the patient or representative to assist with site and tubing changes
g. When to temporarily halt the insulin pump as indicated for certain procedures (see guidelines # 38-42)
h. An order to implement a standard hypoglycemia treatment protocol as needed (see guideline # 28)
i. An order to notify the prescriber if the patient experiences poor glycemic control, becomes unable or unwilling to manage the pump or document all doses on the worksheet/log, is or will be made NPO, requires pump discontinuation, or the pump is halted for more than 1 hour

Consultations

18) The outpatient healthcare provider responsible for the patient's ambulatory insulin infusion pump should be contacted upon the patient's arrival in the hospital for input as needed.

19) A consult should be completed within 12 hours of inpatient hospital admission by an endocrinologist, inpatient diabetes management service, or a physician with documented training in insulin pump management. The consultant should assess and verify the appropriateness of the insulin pump settings, and ask the patient or responsible representative to demonstrate his or her competency with using the insulin pump. The consultant must either agree with the appropriateness of continuing insulin therapy via the insulin pump or recommend discontinuation. The consultant should document either decision in the patient's medical record.

20) A consult with a diabetes educator should be initiated on inpatient admission to evaluate the patient's knowledge of insulin pump management and provide education and support if necessary. If the diabetes educator identifies gaps in the patient's (or responsible representative's) knowledge that might adversely impact self-management of the pump during hospitalization and that cannot be remedied via education, discontinuation of the pump should be recommended to the admitting physician.

21) A consult with a nutrition specialist should be initiated on inpatient admission to reinforce the patient's or representative's carbohydrate counting skills.

Staff Competency and Education

22) An in-house expert or outside consultant who is knowledgeable about most insulin pumps should be readily available to healthcare practitioners for questions or concerns.

23) A process should be in place to facilitate education of healthcare practitioners about the basic components of insulin pumps, the models most likely to be encountered based on the hospital's past experiences, and interrogating the pumps' settings.

24) The hospital should maintain easily accessible resources about insulin pumps being used in the community, including at a minimum, the manufacturers' clinical services contact numbers for troubleshooting (often available on the back of pumps), and pump menu maps (available from pump companies) that show where certain information in the pumps can be found.

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25) A process should be in place to ensure that clinical staff know how to turn the insulin pump off in case of an emergency.

Ongoing Patient Assessment

26) Nurses should evaluate the patient's (or representative's) continued appropriateness for self-management of the insulin pump at least once per shift and report any changes to the physician.

27) Practitioners should review with patients using an insulin pump or their representatives the signs and symptoms of hyper- and hypoglycemia. Patients and representatives should be instructed to report any signs to the nurse, including hyperglycemia nonresponsive to bolus doses.

28) The hospital's hypoglycemia protocol policy should be followed for patients with insulin pumps who experience clinically significant hypoglycemic events.

29) Nurses should assess the insulin pump insertion site for signs of bleeding, leakage, irritation, infection, and/or discomfort at least once per shift, and if present, instruct the patient to change the insertion site (see guideline # 34).

30) Nurses should specifically verify with the patient that there have been no insulin pump alarms indicating pump suspension or malfunction at least every shift.

31) If a nurse finds that the patient's insulin pump tubing is kinked, disconnected, or loose, the patient is instructed to remedy the problem if possible or report its continuance to a nurse if unresolved.

Blood Glucose Monitoring

32) Blood glucose monitoring should be conducted by the patient or representative with a hospital-provided glucometer in the presence of a nurse or trained staff designee, and the results should be recorded by a nurse or designee in the patient's medical record.

33) Any blood glucose values used as the basis for bolus insulin doses or prescribed changes in the basal rate should be obtained from the hospital-provided glucometer and witnessed by a nurse or designee.

Patient Management of Insertion Site, Tubing, Refills, and Insulin Pump Problems

34) The patient should rotate the catheter site and change the infusion set using aseptic technique in the presence of a nurse at least every 72 hours. More frequent catheter site changes may be needed if the site is red, swollen, itchy, leaking, bleeding, or uncomfortable, if a delivery alarm occurs that is not caused by a tubing problem, or if the patient experiences two consecutive blood glucose readings greater than a hospital-defined limit (e.g., 250 mg/dL) that are not responsive to insulin administration and insulin pump setting changes.

35) Patients or representatives should refill the insulin pump reservoir/cartridges/syringes using insulin dispensed for the patient by the hospital pharmacy only.

36) Nurses should verify the insulin (preferably via barcode scanning against the insulin refill order on the medication administration record) prior to refill and before the insulin pump is restarted.

37) The patient or representative should report to a nurse all error or alert messages issued by the pump and refer to the manufacturer's guidelines or contact the clinical support telephone line directly if the insulin pump requires troubleshooting. If the issue is not resolved in 1 hour, an alternative insulin should be prescribed and the pump discontinued.

Temporarily Halting the Insulin Pump

38) An insulin pump should not be exposed to electromagnetic fields or ionizing radiation and should be temporarily removed by the patient or responsible representative prior to any procedure that may cause such exposure (e.g., MRI, CT scan, PET scan, intravenous pyelogram, mammogram, x-ray, nuclear medicine studies, radiation therapy) and reconnected immediately after the procedure is completed. Signage is recommended in radiology suites instructing patients to inform the technician if they are wearing an insulin pump.

39) If the insulin pump is removed for longer than 1 hour, the prescriber should be contacted for alternative insulin delivery. If the disruption is anticipated to last longer than 1 hour, the prescribed alternative insulin should be administered 30 minutes prior to pump removal.

40) Patients should be allowed to disconnect their insulin pumps temporarily (under 1 hour) to shower.

41) For patients receiving general anesthesia or sedation for a procedure, the physician overseeing the anesthesia/sedation plan should evaluate the patient before the procedure to determine the appropriateness of continuing the insulin pump during the procedure. If discontinuation is recommended, patients should be started on an alternative source of insulin once the pump has been removed.

42) Before resuming the pump, any alternative insulin administered while the pump was halted or removed should be taken into consideration when deciding on the basal rate to avoid hypoglycemia, or the pump should be resumed only after the alternative insulin is expected to be cleared.

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Documentation of Therapy and Monitoring Results

43) Patients or responsible representatives should be provided with a documentation worksheet/log to keep at the bedside to record all basal rates, carbohydrate counts and nutritional doses, correction doses, glucose monitoring results, site changes, and other related clinical data.

44) Nurses should monitor the patient's documentation record at least once per shift and contact the prescriber if there is a problem with patient compliance with the required documentation.

45) Patients or the responsible representative should communicate all insulin self-administered through the pump to a nurse at the time of administration.

46) Nurses should document all basal and bolus doses of insulin on the patient's medication administration record in the patient's health record.

47) Nurses should document the type of insulin pump, catheter site assessments, site rotations, tubing changes, refills, and ongoing patient assessments and education in a designated area of the patient's health record.

Discharge Education

48) Prior to discharge with an insulin pump, a diabetes educator should evaluate the patient to ensure he or she knows how to fully use the insulin pump and the importance of regular follow-up with the physician managing their pump. The patient should also know where to find the resources to resolve any issues that might arise with pump use after their discharge.

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