**Continuing Education Discussion Guide** 

# Promoting Safe Use of Insulin Pens IN THE HOSPITAL SETTING





Planned and coordinated by ASHP Advantage Supported by an educational grant from Novo Nordisk Inc.

## Promoting Safe Use of Insulin Pens IN THE HOSPITAL SETTING

This continuing pharmacy education discussion guide is part of an educational initiative designed to provide pharmacists with timely education and resources to facilitate the safe and appropriate use of insulin pens in the hospital setting.

For additional resources on this topic, visit www.onepenonepatient.org.

The estimated time to complete this activity is 60 minutes. This activity is provided free of charge and is available from June 30, 2014, to January 30, 2016.

### **Target Audience**

This continuing pharmacy education activity was planned to meet the needs of pharmacists, especially pharmacists, clinical specialists, pharmacy managers, leaders, and medication safety professionals who work in hospitals in which pen devices are used for subcutaneous administration of insulin for inpatients.

### **Reviewers and Disclosures**

The assistance of the planners and reviewers of this educational activity is gratefully acknowledged.

In accordance with the Accreditation Council for Continuing Medical Education's Standards for Commercial Support and the Accreditation Council for Pharmacy Education's Guidelines for Standards for Commercial Support, ASHP requires that all individuals involved in the development of activity content disclose their relevant financial relationships and that conflicts of interest be identified and resolved prior to delivery of the activity.

### Stuart T. Haines, Pharm.D., BCPS, BCACP, Planner

Professor and Vice Chair for Clinical Services University of Maryland School of Pharmacy Baltimore, Maryland

Dr. Haines declares that he has served as a consultant for Sanofi USA and has divested himself of this relationship. No relationships pertinent to this activity:

### Christine A. Lesch, Pharm.D., BCPS, *Planner*

Clinical Pharmacy Manager, Critical Care NewYork-Presbyterian Hospital Columbia University Medical Center New York, New York

### Mark F. Lutz, Pharm.D., CPPS, *Reviewer*

Drug Information Specialist Beaumont Hospital Royal Oak, Michigan

### Paul M. Szumita, Pharm.D., BCPS, *Reviewer*

Clinical Pharmacy Practice Manager Director, Critical Care Pharmacy Residency Brigham and Women's Hospital Boston, Massachusetts

#### Susan R. Dombrowski, M.S., B.S.Pharm., *Writer*

Carla J. Brink, M.S., B.S. Pharm., Staff

ASHP staff members have no relevant financial relationships to disclose.

### **Learning Objectives**

After participating in this knowledge-based educational activity, participants should be able to

- 1. State three authoritative resources that inform the safe and effective use of insulin in hospitals.
- 2. Compare and contrast pen delivery systems to traditional vial and syringe methods of delivering insulin.
- Identify strategies for proactively addressing potential patient safety issues related to the use of insulin pen delivery systems in hospitals.

### System Requirements

**Web Browser:** Microsoft Internet Explorer 8 or above, Mozilla Firefox, Apple Safari or Google Chrome.

**Note:** Please disable any "pop-up blocker" features.

**Software:** Adobe Acrobat Reader version 7 or above to view PDF files (If you do not have Acrobat Reader, you can download it for free from http://get.adobe.com/reader).

**Connection Speed:** Cable, DSL, or better of at least 300 kbps.

### **Executive Summary**

Hyperglycemia is common in the hospital setting, and inpatient hyperglycemia correlates with poor patient outcomes. Insulin therapy is the cornerstone of antihyperglycemic treatment in the hospital setting, but insulin is a high-alert drug associated with patient harm when used in error.

Compared with conventional vials and syringes, insulin pen delivery systems provide greater dosing accuracy, convenience, ease of use, and satisfaction among health care professionals and patients, with a lower risk for hypoglycemia in ambulatory care settings and lower health care utilization rates and costs. However, various prescribing, dispensing, and administration errors are associated with insulin pen use. The improper sharing of pens among hospitalized patients, which may expose patients to blood-borne pathogens, has been reported despite efforts to warn health care professionals about the danger.

An interprofessional approach is needed to ensure the safe use of insulin pen delivery systems in hospitals. Limiting availability of insulin pen products on the formulary; developing protocol-driven, evidence-based insulin pen orders; implementing policies and procedures and information technology solutions to promote safety; and educating staff and patients about appropriate pen use are among the proactive strategies for avoiding or minimizing harm from insulin pens in hospitals. The pharmacist can take an active role in leading interprofessional efforts to devise and implement these strategies.

### Introduction

Diabetes mellitus is a common condition that causes hyperglycemia and affects nearly 26 million Americans at an estimated annual cost of \$245 billion.<sup>1,2</sup> Hyperglycemia affects 38% of hospitalized patients, including 12% with no known history of diabetes.<sup>3</sup> Inpatient hyperglycemia may reflect the presence of previously undiagnosed diabetes or it may be transient due to the release of stress hormones (e.g., cortisol, epinephrine) during an acute illness.<sup>4,5</sup> Hyperglycemia has been linked to increased morbidity (e.g., wound infection) and mortality in hospitalized patients.<sup>4,6,7</sup> Prolonged hospital stays, increased likelihood of admission to an intensive care unit, and increased health care costs also are associated with inpatient hyperglycemia.<sup>4,6,7</sup>

Managing inpatient hyperglycemia can be challenging because of frequent changes in patient fluid, electrolyte, and nutritional status and the use of medications that cause hyperglycemia (e.g., corticosteroids).<sup>4,5</sup> Potential barriers to achieving glycemic control in the hospital setting include the following:

- Lack of communication among health care providers and poor coordination of blood glucose testing with antihyperglycemic drug therapy,<sup>4,5</sup>
- Inadequate education and knowledge or resistance to change among clinicians, (i.e., clinical inertia),<sup>5,8,9</sup>
- Fear of hypoglycemia from the treatment of hyperglycemia,<sup>5</sup> and
- Lack of integrated clinical information systems, staff time, and other resources.<sup>5,8</sup>

Insulin is preferred over other types of antihyperglycemic drug therapies for the management of hyperglycemia in the hospital setting.<sup>6</sup> Insulin is required for patients with type 1 diabetes. Authoritative guidelines and consensus statements from the Endocrine Society, American Association of Clinical Endocrinologists (AACE), American Diabetes Association (ADA), and American College of Endocrinology (ACE) advise against the use of noninsulin therapy for most hospitalized patients with type 2 disease.<sup>6,8-10</sup>

In the inpatient setting insulin usually is administered to critically ill patients by the intravenous (i.v.) route and non-critically ill patients by the subcutaneous (s.c.) route, with basal, nutritional (i.e., prandial), and correctional doses.<sup>9</sup> The prolonged use of sliding scale regular insulin alone is not recommended for the management of blood glucose concentrations in hospitalized patients because it is ineffective. <sup>6,8-10</sup> Safety concerns are a potential barrier to the use of insulin for the management of inpatient hyperglycemia. Insulin has been identified by the Institute for Safe Medication Practices (ISMP) as a high-alert medication associated with a risk for patient harm when used in error.<sup>11</sup> In 2013, an expert consensus panel convened by the ASHP Foundation identified 10 practical recommendations to enhance insulin-use safety throughout the medication-use process in hospitals (Table 1).<sup>12</sup>

A defined format should be used for insulin orders (i.e., pre-printed order sets or computerized prescriber order entry [CPOE] screens without "free text" options).<sup>13</sup> Other insulin safety measures include clear designation of insulin as a high-alert medication on labeling or packaging and in information systems (e.g., CPOE screens, electronic medication administration records) and storage locations (e.g., automated dispensing cabinet refrigerators). Standardized tall-man lettering can be useful throughout the medicationuse process (i.e., prescribing, storing, dispensing, and administering) for differentiating among insulin products with look-alike packaging or sound-alike names. Independent double checks may be used by pharmacists when dispensing insulin and nurses when administering the drug. Storage of insulin at the patient's bedside is discouraged. Observation by a health care professional of patient selfadministration of insulin if permitted in the hospital is advised to ensure that it is performed correctly.

Insulin pens are pen-shaped injector devices containing an insulin reservoir or cartridge (Figure 1).<sup>14</sup> The devices are intended for s.c. insulin administration by a health care professional or self-administration by a patient.<sup>14</sup> The pen may be disposable with a prefilled reservoir or reusable with a replaceable prefilled cartridge. Disposable pens contain multiple doses and are discarded when empty or when the maximum time recommended by the manufacturer after the first use has elapsed. A new needle should be used for each injection.

Insulin pens were introduced in the 1980s, became popular in the ambulatory care setting, and now are used for some inpatient s.c. injections in many hospitals.<sup>15</sup> Recent reports of pen sharing among hospitalized patients, which may expose the patient to blood-borne pathogens, highlights the need for evaluating the processes related to the use of insulin pens in hospitals and proactively addressing any potential safety risks.<sup>16-18</sup> This discussion guide presents the advantages and disadvantages of insulin pen use compared with conventional insulin vials and syringes in the inpatient

#### TABLE 1

#### ASHP Foundation Expert Consensus Panel Practical Recommendations for Enhancing Insulin-use Safety in Hospitals<sup>12</sup>

#### PRESCRIBING

- 1. Develop protocol-driven, evidence-based order sets.
- Eliminate routine administration of correction/ sliding scale insulin doses as a primary strategy to treat hyperglycemia.
- 3. Eliminate the use of "free text" insulin orders.

#### **STORING AND DISPENSING**

- 4. Store only U-100 concentration insulin and administration devices (e.g., syringes, pens) in patient care areas, store them securely, and keep them separate from other medications.
- 5. Develop standard concentrations for insulin infusions for use throughout institution.

#### **ADMINISTERING**

- 6. Limit preparation of all intravenous bolus insulin doses and infusions to the pharmacy department.
- Develop policies and procedures to ensure the safe use of insulin pens and disposable needle tips, including use of pens for only one individual.

#### **MONITORING**

8. Ensure that insulin use is linked directly to patient nutrition status.

#### **EVALUATING**

 Prospectively monitor rates of hypoglycemia and hyperglycemia, insulin use, and coordination of insulin administration, glucose testing, and nutrition delivery.

#### PLANNING

 Provide standardized education, including competency assessment, to all health care professionals responsible for insulin use.

How many of the practical recommendations for improving insulin-use safety in Table 1 have been implemented in your institution? What else could you do proactively to improve the safety of insulin use in your hospital? setting. Strategies for addressing potential patient safety issues related to the use of insulin pen delivery systems in hospitals are provided, as are authoritative sources of information about the safe and effective use of insulin in hospitals (Appendix A).

### **Advantages of Insulin Pens**

Improved dose accuracy, convenience, and ease of use are major advantages of insulin pens over conventional vials and syringes.<sup>19</sup> Insulin pens provide insulin in a ready-to-use form that expedites dose preparation and administration. Pens have an easy-to-read dial for selecting the dose with an audible click for each dosage increment, which reduces the risk of dose measurement error. In hospitals, one consideration in determining whether a double check by two nurses is required upon insulin administration may be the likelihood that the intended dose can be correctly measured for administration. Procedural differences in preparing doses with either insulin pens or vials and syringes may play a role in this consideration.

The use of insulin pens instead of vials and syringes results in time savings for pharmacy and nursing personnel.<sup>4,20</sup> Switching from vials and syringes to pens has been associated with greater satisfaction among nurses, physicians, and patients.<sup>4,21-23</sup>

Improved patient confidence and adherence are associated with insulin pen use.<sup>19,24</sup> The period of hospitalization of a patient who has never used insulin before may provide an opportunity to introduce insulin therapy and provide patient education. This may apply to patients with newly-diagnosed diabetes, those with known diabetes that was poorly controlled by oral antihyperglycemic therapy, and those with inpatient hyperglycemia requiring insulin therapy after discharge. By experiencing how insulin pens are used, these patients may be able to overcome the fear of and stigma associated with injections and gain confidence in the use of insulin during their hospitalization. Many patients prefer insulin pens because the short, thin needles used with them are less painful than the needles used with vials and syringes. Pens facilitate self-administration of insulin by patients with vision impairment or limited dexterity because of their ease of use. The pens do not need refrigeration after the first use and for the duration of the manufacturerspecified "use by" period, are portable, and can be used discreetly in public places.

#### FIGURE 1. Insulin pen.



*Source:* Centers for Disease Control and Prevention. Insulin pen brochure. www.oneandonlycampaign.org/content/print-materials (accessed 2014 May 22).

A lower risk of hypoglycemia has been associated with switching to or adding an insulin pen in ambulatory patients with type 2 diabetes.<sup>25</sup> Lower health care utilization rates and costs, including hypoglycemia-related costs, have been attributed to pen use.<sup>19,24,25</sup>

Switching from insulin vials and syringes to pens in the hospital setting has the potential to reduce waste, especially for patients with short stays at hospitals where 10-mL insulin vials are used.<sup>19,26</sup> However, the amount of waste and comparative costs of using insulin pens instead of vials and syringes depend on institution-specific circumstances (e.g., availability, contract prices, and volume discounts on 3-mL insulin vials).<sup>27</sup>

### **Disadvantages of Insulin Pens**

Various disadvantages and potential pitfalls can pose barriers to the use of insulin pens. The acquisition cost of insulin pens may be higher (or appear to be higher) than that for vials and syringes, although a higher acquisition cost may be offset by lower health care utilization rates and costs.<sup>4,19</sup> As outpatients, most patients incur a small incremental outof-pocket expense for the use of insulin pens instead of vials and syringes.<sup>19</sup> Some outpatients, however, lack insurance coverage for pens or have a higher copayment for pens than vials and syringes.<sup>22</sup>

The availability of insulin in pen form is limited; some insulin types (e.g., regular insulin) and mixtures are not available. Multiple pens and injections or the use of both pens and vials may be needed to accommodate the needs of an individual.

Numerous reports have been received in recent years of the reuse of insulin pens for multiple patients by health care professionals, thereby exposing patients to the risk of transmission of blood-borne infection.<sup>16-18</sup> These incidents occurred despite warnings from the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), ASHP, ISMP, and other authoritative groups about the danger of this practice.<sup>12,14,28,29</sup> Many of the health care professionals involved in these incidents were under the misperception that pen use for multiple patients is acceptable if the needle is changed.<sup>29</sup> However, patients are at risk for transmission of blood-borne pathogens from the sharing of insulin pens, regardless of whether the needle is changed. Regurgitation of blood and other biological material into insulin cartridges and reservoirs has been documented.<sup>30-32</sup> Although insulin cartridges and reservoirs contain antimicrobial agents (e.g., phenol, cresol), these agents are ineffective against viruses.<sup>32</sup> Transmission of human immunodeficiency virus, hepatitis B virus, and hepatitis C virus is possible when insulin pens are shared, although it has not yet been documented.<sup>28,33</sup> Because of the seriousness of infection with these viruses, CDC recommends that all patients injected using a pen that was previously used for another patient should be promptly notified about the risk and offered testing for blood-borne pathogens, regardless of whether the needle was changed between patients.<sup>14</sup> Notification of large numbers of patients has been required in the recently reported incidents.<sup>16-18</sup> CDC considers sharing of pens a "never event" because of the unacceptable risk.34

The use of an insulin pen as a multiple-dose vial, a practice sometimes followed by staff who prefer to make injections using conventional syringes, is problematic because it can introduce air into the cartridge or reservoir, leading to subsequent insulin under dosing or s.c. injection of air.<sup>35</sup> Transferring insulin from a pen to a conventional syringe could lead to error if the syringe is not promptly labeled to identify the contents.<sup>36</sup> Therefore, transfer of insulin from a pen to a syringe is not advised except in an emergency situation or when the pen malfunctions.<sup>37</sup>

ISMP has been a leader in collecting and analyzing error reports associated with insulin pens through its National Medication Errors Reporting Program. Some of the errors with insulin pens are similar to those associated with insulin vials and syringes. Confusion among insulin pen products from look-alike packaging or similarities among product names can lead to errors in prescribing, dispensing, and administering insulin.<sup>29</sup> Failure to "tip and roll" insulin suspensions (i.e., NPH) in pens prior to injection can result in dosing errors because of uneven dispersion of insulin in the suspension.<sup>29,37</sup>

Possible insulin pen administration technique errors include improper priming of the needle and failure to keep the needle under the skin long enough after injection, resulting in a "wet spot" on the skin due to failure to deliver the entire dose.<sup>29,37,38</sup> The needle should be promptly removed from the pen after injection; failure to do so can allow the entry of air and contaminants into the insulin cartridge or reservoir.<sup>29,37</sup>

Just as for any injection, needlestick injuries can occur among health care professionals using insulin pens.<sup>37</sup> Two types of needles are available for use with insulin pens. Some needles have covers that automatically deploy after injection, which circumvents the need for recapping the needle and eliminates the risk of needlestick injury. Other needles lack such covers. Lack of an automatic needle cover, failure to maintain a 90-degree angle with the skin surface during injection into a pinched skin fold, and poor visualization of the injection site may contribute to needlestick injuries.<sup>22,37</sup>

Most hospitals use needles with automatic covers. Insulin often becomes sequestered in the needle cover when the needle is primed and later deposited on the skin during injection, which may be misinterpreted by the nurse or patient as leakage from the injection site and delivery of a partial (i.e., inadequate) dose. Teaching patients preparing for hospital discharge to use insulin pens with these needles with covers is problematic because the needles often are not available for use in the outpatient setting.

### Strategies to Avoid or Minimize Harm from Insulin Pens

An interprofessional effort is needed to ensure the safe use of insulin in hospitals. Physicians (especially endocrinologists), nurses, pharmacists, dietitians, diabetes educators, and laboratory, information systems, infection control, and risk management staff should be involved.<sup>13</sup> Efforts to develop and implement strategies to promote safe insulin use should be coordinated through the pharmacy and therapeutics committee and various other institutional committees (e.g., infection control, safety, quality improvement). The pharmacist can assume a leadership role in spearheading these efforts. A culture of safety and a non-punitive approach to error detection and reporting are needed.<sup>13</sup>

Is there an interprofessional committee at your hospital with the responsibility for ensuring insulin-use safety? What disciplines are represented on the committee? Does the committee coordinate its efforts with those of the pharmacy and therapeutics committee and other institutional committees responsible for safety and quality improvement?

Because of the potential for misuse of insulin pens in hospitals, strategies for ensuring safe insulin use should address pens. According to the ASHP Foundation expert consensus panel, insulin pens can be used safely in hospitals if proper policies and procedures are established and staff education is provided.<sup>12</sup> The ASHP Foundation consensus panel further recommends that technology solutions need to be developed to ensure that insulin pens are not used for more than one patient. ISMP recommends transitioning away from routine inpatient use of insulin pens because of ongoing concerns about sharing of pens.<sup>39</sup> Partial or complete restrictions on insulin pen use have been used to reduce the risk for error in some hospitals.<sup>39,40</sup> In some settings, pens are used with only certain types of insulin (e.g., rapid-acting nutritional insulin). If a decision is made to restrict routine insulin pen use, exceptions may need to be allowed under certain circumstances (e.g., when preparing for discharge of a patient who will use a pen at home).<sup>12,39</sup>

Are insulin pens used in your hospital? If so, what proactive strategies have you established or could you implement to improve the safety of insulin pen use in your institution?

Guidelines and recommendations from authoritative groups to promote the safe use of insulin (e.g., the recommendations in Table 1) and pen delivery systems should be the cornerstone of institutional strategies to ensure the safe use of insulin pens. Insulin pen use is not addressed in guidelines or consensus statements from the Endocrine Society, AACE, ADA, or ACE, but pens are addressed in recommendations from the ASHP Foundation expert consensus panel, ISMP, CDC, FDA, and Centers for Medicare and Medicaid Services (CMS).<sup>12,14,28,37,41</sup> All of these groups recommend against the shared use of insulin pens.<sup>12,14,37,41</sup> The CMS recommendations have been incorporated into the agency survey process for infection control practices.<sup>41</sup> ISMP recommends conducting a failure-mode-and-effects analysis to identify risk-reduction strategies and implementation of these strategies before pens are used in the institution.<sup>29</sup> The analysis should address every step in the medication-use process from prescribing through dispensing, storage, and administration.

**Prescribing.** Strategies to improve the prescribing of insulin pens in hospitals include formulary review and control efforts.<sup>37</sup> Limiting the types of pens available for use in the institution can help avoid error due to confusion among products from look-alike packaging and similar product names.<sup>29</sup> Stocking pens with only a U-100 concentration (U-500 insulin pens are in development) can minimize dosing errors.<sup>12,42</sup>

Product selection considerations in prescribing insulin pens include both product-related and patient-related factors (Table 2). Product-related factors should be taken into consideration in formulary decisions about insulin pens. Compared with reusable pens, disposable pens are more convenient but they also cost more. The readability of numbers on the dose dial is particularly important. Most pens are designed to allow dose measurement in increments of 0.5 unit, 1 unit, or 2 units, and pens that allow small dose increments (i.e., 0.5 unit) may be useful for patients who need to fine tune their dosing. Metal pens are virtually unbreakable. Most plastic pens are less durable.

Some pens have special features, such as glucose meters and memory functions for automatically storing information about the date, time, and amount of recent doses. These features may facilitate patient self-management of blood glucose and optimize insulin therapy after hospital discharge, but they are seldom used in hospitals.

Insulin pens should be stored under refrigeration until the first use and at room temperature thereafter, with disposal after the maximum number of days recommended by manufacturer have elapsed (often 28 days). Storage requirements may be a consideration in selecting products to include in the formulary and dispense to a patient at the time of hospital discharge.

#### TABLE 2

#### Product Selection Considerations for Insulin Pens in Hospitals

#### **PRODUCT-RELATED FACTORS**

Reusable vs. disposable

Compatibility of reusable pen with available cartridges

Pen shape, color, and style

Strength and dexterity required to actuate pen

Readability of numbers on dose dial

Audibility of click when dial is turned to select a dose

Total volume in cartridge or reservoir (3 mL for most)

Maximum dose delivered

Smallest dose increment (0.5 units, 1 unit, or 2 units)

Durability

Special features

- Glucose meter
- Memory function

Storage requirements

**PATIENT-RELATED FACTORS**<sup>a</sup>

Needle phobia in children and other patients

Insulin needs

- Basal, nutritional, and correctional doses
- Small dose requirement
  - Pediatric patients
  - Adults with high insulin sensitivity
- Need for fine tuning of dosing in small dose increments (e.g., 0.5 units)

<sup>a</sup> Other patient-related factors that may be relevant for prescribing insulin pens for discharge include patient age (e.g., pediatric, geriatric), physical (vision, dexterity) and cognitive limitations, type of pen used previously at home, and insurance coverage and copayment or out-of-pocket cost.

The ASHP Foundation expert consensus panel recommends developing protocol-driven, evidence-based order sets for all insulin therapy and elimination of the use of "free text" insulin orders in electronic and paper medical records.<sup>12</sup> Insulin orders should include two patient identifiers (e.g., name and date of birth) and the insulin type, dose, route of administration, time of day or relationship to nutritional

#### FIGURE 2.

Example of an insulin pen "flag" label with patient identifiers.

Insulin, Susan G	5SB-5327
DOB - 11/22/1982	50612332001
insulin aspart injection	(NOVOLOG) 3 mL
Printed 6/12/14 1035	Expires:
RPh Tech	Lot:
Order # 236695447 PL	

intake, and blood glucose monitoring regimen.<sup>13</sup> The use of information technology solutions (e.g., computerized prescriber order entry with clinical decision support) is an important strategy for implementing these recommendations and reducing the risk of error in patients using insulin from pen delivery systems.

**Dispensing and storage.** Policies and procedures should be established for labeling insulin pens to reduce the risk for error. Labels should include the name of the patient or other identifying information (e.g., date of birth, medical record number). A "flag" label that does not obscure the name of the drug on the pen should be used (Figure 2).<sup>37</sup> This label should be affixed to the pen barrel, not the removable cap. A tamper-evident seal may be affixed perpendicular to the junction of the barrel and cap at the time of dispensing to indicate whether the pen has been used, which is helpful for avoiding waste of unused pens returned to the hospital pharmacy from patient care areas.<sup>20</sup> Designating insulin pens as high-alert medications and using tall-man lettering may be helpful for preventing errors.

Policies and procedures also should address the storage of insulin pens. Standardizing the locations for storing new, unused pens and cartridges can help prevent errors in retrieving the wrong type of insulin.<sup>43</sup> The storage of pens after use also should be addressed in policies and procedures; these pens should be stored in a patient-specific location (e.g., the patient-specific section of automated dispensing cabinets) but not at the bedside.<sup>13,20</sup> Policies and procedures should prohibit the storage and use of insulin pens brought from home. Administration. To promote proper insulin administration using pen delivery systems, policies and procedures that address the unique safety concerns associated with pens should be established in addition to general insulin safety measures (e.g., verification of insulin order appropriateness and the type and dose of insulin dispensed and selected for administration).<sup>20</sup> The use of pens only for specific individuals, not multiple patients, regardless of whether the needle is changed, should be explicitly stated in policies and procedures to be consistent with recommendations from the ASHP Foundation expert consensus panel, ISMP, FDA, CDC, and CMS.<sup>12,14,28,37,41</sup> Verification that the specific insulin pen used for injection is labeled for the individual should be part of these policies and procedures. The use of insulin pens as multiple-dose vials should be prohibited except in emergency situations or when the pen malfunctions because of the risk of introducing air into the cartridge or reservoir and subsequent under dosing and s.c. injection of air.<sup>35</sup> Other policies and procedures should address proper administration technique, including the need to

- Use needlestick injury precautions for pens without automatic needle covers;<sup>29</sup>
- Pinch a fold of skin at the injection site and hold the pen at a 90-degree angle to the skin surface during injection, except for children and very lean patients a 45-degree angle is permissible if using 8 mm (5/16 in) or 12.7 mm (1/2 in) length needle;<sup>37</sup>
- Keep the needle under the skin for 6 seconds after injection to ensure delivery of the entire dose;<sup>29</sup> and
- Promptly remove the needle after use to prevent air and contaminants from entering cartridge or reservoir.<sup>39</sup>

Information technology solutions (e.g., bedside barcodeassisted medication administration systems) can facilitate implementation of these policies and procedures for insulin administration using pen delivery systems.<sup>12</sup> Many information systems use barcode technology to ensure that the intended type of insulin is administered. Some systems have an advanced barcode functionality that also ensures that the specific insulin pen used is the one intended for the patient, which can help ensure that insulin pens are not shared among multiple patients (Figure 3).

The use of information systems can increase the likelihood of detecting and preventing errors in insulin pen use. For example, barcode medication administration reports can be generated that reveal errors suggesting the use of work arounds instead of the proper use of insulin pens.

#### FIGURE 3.

Example of an insulin pen "flag" label with patient identifiers, as well as a barcode that can be scanned to help verify that the product dispensed is for the intended patient.

Insulin, Susan G	5SB-5327
DOB - 11/22/1982	50612332001
insulin aspart injection	(NOVOLOG) 3 mL
Printed 6/12/14 1035	Expires:
RPh Tech	Lot:
Order # 236695447 PL   Warning! Confirm patient. Insulin pens   are for use in one patient only.	

**Staff education.** Insulin pen safety should be addressed during orientation and in repeated education programs for nursing, pharmacy, and other personnel involved with insulin use in the institution. Interprofessional involvement is vital to the success of education programs.<sup>43</sup>

Education is particularly important to prevent errors when converting from vials and syringes to pens in an institution because of the potential for confusion during the transition.<sup>20,43,44</sup> A stepwise approach with introduction of one device at a time has been successful in making a smooth transition from vials and syringes to pens.<sup>43</sup> The rationale for conversion should be explained to staff to promote acceptance and reduce work arounds.<sup>20</sup> The same holds true if converting from insulin pens to vials and syringes.

A variety of formats may be used for education, including inservice programs, printed handouts, online audiovisual clips, and demonstration kits with pens and needles.<sup>29,44</sup> Educational efforts should take a proactive approach to preventing common errors in the use of insulin pens. Reminders about safety issues associated with the prescribing, dispensing, storage, and administration of insulin using pens (e.g., computer screen savers, posters, and notes in the medication administration record with warnings about pen sharing) may be helpful. One-on-one troubleshooting by pharmacists may help resolve problems with nursing staff in the use of insulin pens.<sup>29</sup> Competency should be assessed to ensure that staff understand the proper use of insulin pens and any misconceptions have been dispelled. Feedback should be solicited from staff about the shortcomings of and ways to improve the educational programming as part of continuous quality improvement efforts.<sup>44</sup>

**Patient education.** At some hospitals, patients are discharged with plans to use insulin pens on an ambulatory basis. Patient education should be provided before discharge of these patients (see Appendix B with information for patients). The staff time required to provide patient education is no greater for insulin pens than for vials and syringes.<sup>21</sup>

Many patients lack the knowledge needed to use insulin pens, especially the proper priming of needles, need to keep the needle under the skin for a sufficient length of time after injection to ensure delivery of the entire dose, and storage of the pen in use.<sup>38</sup> Patient education can correct these knowledge deficits. Patients need to understand and demonstrate the ability to properly self-administer doses using pens and needles without automatic covers. Cartridges filled with saline are available for teaching purposes. These cartridges need to be stored separately from insulin cartridges to avoid mix ups. *Error management.* Errors involving insulin pens should be reported in accordance with institutional policies and procedures and to FDA's MedWatch Adverse Event Reporting program and ISMP. If the error is detected during a survey of a Medicare- or Medicaid-certified provider by an accrediting organization, the surveyor must report the breach of infection control to the state public health authority.<sup>45</sup>

Policies and procedures should be established for the notification of patients who may have been exposed to blood-borne pathogens due to the sharing of pens and to offer testing for blood-borne pathogens as recommended in a 2012 clinical reminder from CDC.<sup>14</sup> Institutional policies and procedures should be revised, corrective staff education should be provided, and other strategies should be implemented to prevent recurrence of the error as part of continuous quality improvement efforts.

### Conclusion

Insulin is a high-alert medication associated with patient harm when used in error. In the inpatient setting, insulin pens offer several advantages compared with conventional insulin vials and syringes, but proper use of pens is needed to prevent harm. An interprofessional effort led by pharmacists can be used to devise proactive strategies to ensure the safe and appropriate use of insulin pens for hospitalized patients.

- 1. Centers for Disease Control and Prevention. National diabetes fact sheet, 2011. www.cdc.gov/diabetes/pubs/pdf/ndfs\_2011. pdf (accessed 2014 May 22).
- American Diabetes Association. Economic costs of diabetes in the U.S. in 2012. *Diabetes Care.* 2013; 36:1033-46. http://care. diabetesjournals.org/content/36/4/1033.full.pdf+html (accessed 2014 May 22).
- Umpierrez GE, Isaacs SD, Bazargan N et al. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. *J Clin Endocrinol Metab.* 2002; 87:978-82. http://press.endocrine.org/doi/pdf/10.1210/jcem.87.3.8341 (accessed 2014 May 22).
- Davis EM, Foral PA, Dull RB, Smith AN. Review of insulin therapy and pen use in hospitalized patients. *Hosp Pharm.* 2013; 48:396-405.
- 5. Anger KE, Szumita PM. Barriers to glucose control in the intensive care unit. *Pharmacotherapy.* 2006; 26:214-28.
- Umpierrez GE, Hellman R, Korytkowski MT et al. Management of hyperglycemia in hospitalized patients in non-critical care setting: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2012; 97:16-38. http://jcem.endojournals. org/content/97/1/16.full.pdf+html (accessed 2014 May 22).
- 7. Bogun M, Inzucchi SE. Inpatient management of diabetes and hyperglycemia. *Clin Ther.* 2013; 35:724-33.
- ACE/ADA Task Force on Inpatient Diabetes. American College of Endocrinology and American Diabetes Association consensus statement on inpatient diabetes and glycemic control. *Diabetes Care*. 2006; 29:1955-62. http://care.diabetesjournals. org/content/29/8/1955.full.pdf+html (accessed 2014 May 22).
- Moghissi ES, Korytkowski MT, DiNardo M et al. American Association of Clinical Endocrinologists and American Diabetes Association consensus statement on inpatient glycemic control. *Diabetes Care*. 2009; 32:1119-31. www.ncbi.nlm.nih.gov/ pmc/articles/PMC2681039/pdf/zdc1119.pdf (accessed 2014 May 22).
- 10. American Diabetes Association. Standards of medical care in diabetes—2014. *Diabetes Care*. 2014; 37(Suppl 1):S14-80.
- Institute for Safe Medication Practices. ISMP's list of high-alert medications. 2012. www.ismp.org/tools/institutionalhighAlert. asp (accessed 2014 May 22).
- Cobaugh DJ, Maynard G, Cooper L et al. Enhancing insulin-use safety in hospitals: practical recommendations from an ASHP Foundation expert consensus panel. *Am J Health-Syst Pharm.* 2013; 70:1404-13.
- American Society of Health-System Pharmacists Section of Inpatient Care Practitioners, Hospital and Health-System Association of Pennsylvania. Professional practice recommendations for safe use of insulin in hospitals. 2004. www.ashp. org/s\_ashp/docs/files/Safe\_Use\_of\_Insulin.pdf (accessed 2014 May 22).

- Centers for Disease Control and Prevention. CDC clinical reminder: insulin pens must never be used for more than one person. January 5, 2012. www.cdc.gov/injectionsafety/PDF/ Clinical-Reminder-insulin-pen.pdf (accessed 2014 May 22).
- Reinke T. Though costly, insulin pens facilitate better adherence. *Manag Care*. 2013; 22:20-1. www.managedcaremag. com/linkout/2013/6/20 (accessed 2014 Jun 4).
- Anon. Possible HIV exposure at Buffalo VA hospital. USA Today. January 14, 2013. www.usatoday.com/story/news/ nation/2013/01/13/veterans-hospital-hiv/1831705/ (accessed 2014 May 22).
- Anon. Second N.Y. hospital warns of HIV infection risk from insulin pens. CBS News. January 24, 2013. www.cbsnews. com/news/second-ny-hospital-warns-of-hiv-infection-riskfrom-insulin-pens/ (accessed 2014 May 22).
- Anon. Thousands of Wisconsin clinic patients possibly exposed to HIV. August 30, 2011. www.newsytype.com/10766-wisconsininsulin-pens-hiv/ (accessed 2014 May 22).
- 19. Meece J. Effect of insulin pen devices on the management of diabetes mellitus. *Am J Health-Syst Pharm.* 2008; 65:1076-82.
- Pisupati R, Kornblit S, Sobel M, Cairoli M. A practical approach for conversion to insulin pens in a health system. *Hosp Pharm.* 2009; 44:871-3.
- Davis EM, Bebee A, Crawford L, Destache C. Nurse satisfaction using insulin pens in hospitalized patients. *Diabetes Educ.* 2009; 35:799-809.
- 22. Davis EM, Christensen CM, Nystrom KK et al. Patient satisfaction and costs associated with insulin administered by pen device or syringe during hospitalization. *Am J Health-Syst Pharm.* 2008; 65:1347-57.
- 23. Korytkowski M, Bell D, Jacobsen C et al. A multicenter, randomized, open-label, comparative, two-period crossover trial of preference, efficacy, and safety profiles of a prefilled, disposable pen and conventional vial/syringe for insulin injection in patients with type 1 or 2 diabetes mellitus. *Clin Ther.* 2003; 25:2836-48.
- Asche CV, Shane-McWhorter L, Raparla S. Health economics and compliance of vials/syringes versus pen devices: a review of the evidence. *Diabetes Technol Ther.* 2010; 12(Suppl 1):S101-8.
- Lee WC, Balu S, Cobden D et al. Medication adherence and the associated health-economic impact among patients with type 2 diabetes mellitus converting to insulin pen therapy: an analysis of third-party managed care claims data. *Clin Ther.* 2006; 28:1712-25.
- Ward LG, Aton SS. Impact of an interchange program to support use of insulin pens. *Am J Health-Syst Pharm.* 2011; 68:1349-52.

- Lee LJ, Smolen LJ, Klein TM et al. Budget impact analysis of insulin therapies and associated delivery systems. *Am J Health-Syst Pharm.* 2012; 69:958-65.
- 28. U.S. Food and Drug Administration. Information for healthcare professionals: risk of transmission of blood-borne pathogens from shared use of insulin pens. March 19, 2009. www.fda.gov/ DrugS/DrugSafety/PostmarketDrugSafetyInformationfor PatientsandProviders/DrugSafetyInformationforHeathcare Professionals/ucm133352.htm (accessed 2014 May 22).
- 29. Institute for Safe Medication Practices. Considering insulin pens for routine hospital use? Consider this...May 8, 2008. www.ismp.org/Newsletters/acutecare/articles/20080508.asp (accessed 2014 May 22).
- Le Floch JP, Herbreteau C, Lange G, Perlemuter L. Biologic material in needles and cartridges after insulin injection with a pen in diabetic patients. *Diabetes Care.* 1998; 21:1502-4.
- Herdman ML, Larck C, Schliesser SH, Jelic TM. Biological contamination of insulin pens in a hospital setting. *Am J Health-Syst Pharm.* 2013; 70:1244-8.
- Sonoki K, Yoshinari M, Iwase M et al. Regurgitation of blood into insulin cartridges in the pen-like injectors. *Diabetes Care*. 2001; 24:603-4.
- Hakre S, Upshaw-Combs DR, Sanders-Buell EE et al. An investigation of bloodborne pathogen transmission due to multipatient sharing of insulin pens. *Mil Med.* 2012; 177:930-8.
- Centers for Disease Control and Prevention. Be aware, don't share. One insulin pen, only one person (brochure). www.oneandonlycampaign.org/ (accessed 2014 May 22).
- Cohen MR. Pharmacists' role in ensuring safe and effective hospital use of insulin. *Am J Health-Syst Pharm.* 2010; 67(16 Suppl 8):S17-21.
- Grissinger M. Pen injector technology is not without 'impending' risks. *P & T.* 2010; 35:245, 266. www.ptcommunity.com/ ptjournal/fulltext/35/5/PTJ3505245.pdf (accessed 2014 May 22).

- Grissinger M. Avoiding problems with insulin pens in the hospital. *P & T.* 2011; 36:615-6. www.ncbi.nlm.nih.gov/pmc/articles/ PMC3278151/pdf/ptj3610615.pdf (accessed 2014 May 22).
- Mitchell VD, Porter K, Beatty SJ. Administration technique and storage of disposable insulin pens reported by patients with diabetes. *Diabetes Educ.* 2012; 38:651-8.
- Institute for Safe Medication Practices. Ongoing concern about insulin pen reuse shows hospitals need to consider transitioning away from them. February 7, 2013. www.ismp.org/newsletters/ acutecare/showarticle.aspx?id=41 (accessed 2014 May 22).
- U.S. Department of Veterans Affairs. Fact sheet for insulin pens. March 7, 2013. www.salisbury.va.gov/pressreleases/ Fact\_Sheet\_for\_Insulin\_Pens.asp (accessed 2014 May 22).
- 41. Centers for Medicare & Medicaid Services Director, Survey and Certification Group. Memorandum to state survey agency directors: use of insulin pens in health care facilities. May 18, 2012. www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/Surveyand-Cert-Letter-12-30.pdf (accessed 2015 May 22).
- Institute for Safe Medication Practices. 4,200 need testing after pen misuse. March 27, 2014. www.diabetesincontrol.com/ articles/diabetes-news/16181-ismp-4200-need-testing-afterpen-misuse (accessed 2014 May 22).
- 43. Greenwood B, Szumita PM, Pendergrass M. Conversion to insulin devices in the inpatient setting. *Am J Health-Syst Pharm.* 2008; 65:698-9.
- Sheldon KA, Seoane-Vazquez E, Szeinbach SL, Tubbs C. Using the plan-do-study-act model to convert to a new insulin delivery system. *Am J Health-Syst Pharm.* 2009; 66:1074-5.
- 45. Centers for Medicare and Medicaid Services Director, Survey and Certification Group. Memorandum to state survey agency directors: infection control breaches which warrant referral to public health authorities. May 30, 2014. www.cms.gov/ Medicare/Provider-Enrollment-and-Certification/Survey CertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-36.pdf (accessed 2014 Jun 23).

### Resources

American Society of Health-System Pharmacists "Strategies for Ensuring the Safe Use of Insulin Pens in the Hospital" initiative www.onepenonepatient.org

- Mentored Quality Improvement Activity for Insulin Pen Safety
- Web-based resource center and tool kit
- Live and archived webinar, "Ensuring the Safe Use of Insulin Pens in the Hospital: Role of the Pharmacist" (1 hour continuing pharmacy education)
- Live and archived webinar, "Ask the Experts: Use of Insulin Pen Delivery Systems in Hospitals" (1 hour continuing pharmacy education)

#### Centers for Disease Control and Prevention Safe Injection Practices Coalition

- One & Only campaign www.oneandonlycampaign.org
- Insulin pen posters and brochures for health care professionals and patients

#### Institute for Safe Medication Practices

- Insulin safety center www.consumermedsafety.org/tools-and-resources/insulin-safety-center
- Insulin pen safety webpage www.consumermedsafety.org/tools-and-resources/insulin-safety-center/ insulin-pen-safety

#### Joint Commission Center for Transforming Healthcare

- Safe and Effective Use of Insulin project details www.centerfortransforminghealthcare.org/projects/detail.aspx?Project=9
- Fact sheet about Safe and Effective Use of Insulin project www.centerfortransforminghealthcare.org/assets/4/6/CTH\_Insulin\_Fact\_ Sheet.pdf

## Information for discharge counseling of patients about insulin pen use

- Store your insulin pen (and cartridge refills if you have a refillable pen) in the refrigerator until the first time you use it, then store the pen at room temperature. Write down the date you first use your pen and use it for no longer than directed in the instructions that came with the pen.
- Read and follow the instructions that came with your pen about assembly, priming the needle (the "air shot" or "safety test"), use, and disposal.
- Use your insulin pen exactly as directed. Do not change your dose without consulting your health care provider.
- Follow your health care provider's instructions for testing your blood sugar and changing your dose if your dietary intake or physical activity changes or you have an illness that prevents eating.
- Do not share your insulin pen with another person because it could be contaminated with viruses that can be passed to another person.
- When you are in the hospital, do not allow anyone to inject you using an insulin pen that is not clearly labeled with your name or other personal identifying information (e.g., date of birth, medical record number).
- Choose an area (e.g., stomach, thigh) and use a new site in that area for each injection at least an inch away from the last site until you run out of space, then choose a new area.
- Pinch a skin fold and hold the pen at a 90-degree angle with the skin surface when injecting your insulin. For children and very lean patients, a 45-degree angle is permissible if using a short needle (8 mm [5/16 in] or 12.7 mm [1/2 in] length).
- Promptly remove the needle after each injection. Always use a new needle for each injection to reduce the risk of infection and blocked needles.
- Ask your health care provider what to do if signs of low blood sugar occur (e.g., dizziness, shaking, hunger, sweating, fast heartbeat, blurred vision, unconsciousness). He or she will probably tell you to drink a sugary beverage, eat a sugary food or candy, or take a glucose (sugar) tablet.
- When you have your insulin pen prescription refilled, make sure that you receive the correct type of insulin.
- Ask your pharmacist if you have any questions about your insulin pen.

### **To Receive Continuing Pharmacy Education Credit**

Once you have read the discussion guide (an assessment test is provided here as a study aid only), click on the link below to take the online assessment test (minimum score 70%) and complete your evaluation. Continuing pharmacy education (CPE) credit will be reported directly to CPE Monitor. Per ACPE, CPE credit must be claimed no later than 60 days from the date of a live activity or completion of a home study activity.



The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity provides 1 hour (0.1 CEU, no partial credit) of continuing pharmacy education credit (ACPE activity # 0204-0000-14-483-H05-P).

Take Test & Process CE

### Assessment Test Study Aid

This assessment test is provided as a study aid only. Follow the instructions above to complete this assessment test and the evaluation online to obtain CPE credit for this activity.

- 1. Which of the following resources provides 10 practical recommendations to enhance insulin-use safety throughout the medication-use process in hospitals?
  - a. 2006 American College of Endocrinology and American Diabetes Association consensus statement
  - b. 2009 American Association of Clinical Endocrinologists and American Diabetes Association consensus statement
  - c. 2012 Endocrine Society clinical practice guideline
  - d. 2013 ASHP Foundation expert consensus panel report
- 2. Which of the following is a major advantage of insulin pens over traditional vials and syringes?
  - a. Less waste
  - b. Less confusion from look-alike packaging and sound-alike names
  - c. Lower cost
  - d. Greater dosing accuracy

- 3. Which of the following statements best describes the amount of waste related to the use of insulin pen delivery systems compared with the use of insulin in 10-mL vials and syringes?
  - a. Potential to reduce waste, especially for patients with a short length of stay
  - b. Potential to reduce waste, especially for patients with a long length of stay
  - c. Uniformly reduces waste and associated insulin costs
  - d. No effect on waste
- 4. Which of the following institutional policies for the sharing of insulin pens among multiple patients is most appropriate?
  - a. It should not be allowed, even if the needle is changed
  - b. It should not be allowed unless the needle is changed
  - c. It should be allowed only if the pen is being used during the manufacturer-specified "use-by" period
  - d. It should be allowed only if the pen contains antimicrobial agents (e.g., phenol, cresol)

- 5. Which of the following organizations has been a leader in collecting and analyzing error reports involving insulin pens?
  - a. American Society of Health-System Pharmacists
  - b. Centers for Disease Control and Prevention
  - c. Institute for Safe Medication Practices
  - d. The Joint Commission
- 6. Which of the following is a potential disadvantage of using needles with automatic covers with insulin pens in the hospital setting?
  - a. Risk for needlestick injury when changing the needle
  - b. Misinterpretation of insulin from priming and then deposited on the skin during injection as a partial dose
  - c. Delivery of a partial (i.e., inadequate) dose
  - d. Obstructed view that inhibits ability to maintain the recommended angle with the skin surface during injection into a pinched skin fold
- 7. Which of the following is an information technology solution to increase the use of protocol-driven, evidence-based orders for insulin therapy in hospitals?
  - a. Pens with memory functions
  - b. Barcode-assisted medication administration systems
  - c. Electronic health records linked with the clinical laboratory
  - d. Computerized prescriber order entry
- 8. Which of the following statements about labeling of insulin pens dispensed for inpatient use is correct?
  - a. A flag label with the patient's identity should be affixed to the barrel of the pen
  - b. A tamper-evident seal should be affixed to the barrel of the pen
  - c. An auxiliary high-alert label should be affixed to the cap of the pen
  - d. A label with tall-man lettering for the type of insulin should be affixed to the cap of the pen

- 9. Which of the following is the preferred location for storage of an insulin pen that is in use by a patient in the hospital?
  - a. At the patient's bedside
  - b. Among high-alert medications in floor stock
  - c. In a patient-specific section of an automated dispensing cabinet
  - d. In a refrigerator
- 10. Which of the following statements about the administration technique that should be used for insulin pens is correct?
  - a. Promptly withdraw the needle from the skin after injection and remove the needle from the pen
  - Promptly withdraw the needle from the skin after injection and recap the needle for use with the next dose
  - c. Keep the needle under the skin for 6 seconds after injection and promptly remove the needle from the pen after withdrawing the needle from the skin
  - d. Keep the needle under the skin for 6 seconds after injection and promptly recap the needle after withdrawing it from the skin for use with the next dose
- 11. Which of the following resources includes a specific recommendation to offer testing for blood-borne pathogens as part of follow up after sharing of insulin pens among multiple patients?
  - a. 2009 U.S. Food and Drug Administration safety alert
  - b. 2012 Centers for Disease Control and Prevention clinical reminder
  - c. 2012 Endocrine Society clinical practice guideline
  - d. 2013 ASHP Foundation expert consensus panel report

CONTACT ASHP ADVANTAGE FOR ASSISTANCE COPYRIGHT 2014 TRADEMARK PRIVACY POLICY