Participation in a mentored quality-improvement program for insulin pen safety: Opportunity to augment internal evaluation and share with peers

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**Purpose.** UF Health's participation in a mentored quality-improvement impact program for health professionals as part of an ASHP initiative— "Strategies for Ensuring the Safe Use of Insulin Pens in the Hospital"—is described.

**Summary.** ASHP invited hospitals to participate in its initiative at a time when UF Health was evaluating the risks and benefits of insulin pen use due to external reports of safety concerns and making a commitment to continue insulin pen use and optimize safeguards. Improvement opportunities in insulin pen best practices and staff education on insulin pen preparation and injection technique were identified and implemented. The storage of insulin pens for patients with contact isolation precautions was identified as a problem in certain patient care areas, and a practical solution was devised. Other process improvements included implementation of barcode medication administration, with scanning of insulin pens designated for specific patients to avoid inadvertent and intentional sharing of pens among multiple patients. Mentored calls with teams at other hospitals conducted as part of the program provided the opportunity to share experiences and solutions to improve insulin pen use.

**Conclusion.** Participating with a knowledgeable mentor and other hospital teams struggling with the same issues and concerns related to safe insulin pen use facilitated problem solving. Discussing challenges and sharing ideas for solutions to safety concerns with other hospitals identified new process enhancements, which have the potential to improve the safety of insulin pen use at UF Health.

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Cafety concerns surrounding the Ouse of insulin, a known highalert medication, remain a focus of hospitals throughout the country.<sup>1,2</sup> Complexities of patient care are magnified when designing systems to ensure safe use of medications, such as insulin, in large hospitals. Insulin pens were introduced at UF Health approximately 10 years ago and were thought to improve safety by decreasing the opportunity for large insulin dosing errors and helping to decrease look-alike, soundalike medication errors compared with the use of vials and syringes. Ad-

ditionally, inpatient insulin pen use facilitated patient education by bedside nurses and diabetes educators because most outpatients use pens.

Safety concerns related to inpatient pen use have mounted in recent years, especially the risk of blood-borne pathogen transmission if used in more than one patient.<sup>3-7</sup> These concerns caused UF Health to engage in a comprehensive analysis and consider moving away from using insulin pens in the hospital. UF Health concluded that substantial but different safety concerns are associated with insulin pens and in-

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sulin provided in vials and syringes. The clinical consequences and potential benefits and harms of using one delivery system versus another are difficult to compare. UF Health elected to continue using insulin pens in the hospital but wanted to ensure that all possible safety systems were in place to prevent insulin pen sharing. The ASHP MENTORED QUALITY IMPROVEMENT IMPACT PROGRAM<sup>SM</sup> (MQIIP) on Ensuring Insulin Pen Safety in Hospitals was announced during the time of ongoing conversations at UF Health about this safety issue.1 Participation in this program was an excellent opportunity to ensure that all best practices were in place for safe insulin pen use in the hospital.

## Insulin pen use at UF Health

UF Health, Shands Hospital is an 875-bed, academic medical center located in Gainesville, Florida. The hospital is a level 1 trauma center with six adult intensive care units (ICUs), four pediatric ICUs, and 41 operating rooms. The hospital is also a primary teaching site for the University of Florida Health Sciences Colleges of Medicine, Nursing, Pharmacy, Health-Related Professions, and Dentistry.

The hospital is made up of two buildings: a more contemporary building that opened in November 2011 and the original building that opened in 1958. These infrastructure differences became important in the audits, observations, and action plan during the MQIIP.

In 2003, the UF Health pharmacy and therapeutics committee recommended adding insulin pens to the formulary because use of pens was thought to enhance the safety of inpatient insulin use. The frequency of errors related to insulin product selection and dose measurement was thought to be lower with the use of insulin pens compared with vials and syringes. At a time before barcode medication administration was implemented, care was taken dur-

## **KEY POINTS**

- A safe process for storage and disposal of insulin pens upon discharge for patients on contact isolation may present challenges when medications are stored securely in an automated dispensing cabinet used by the entire patient care unit. One possible solution for in-room secure storage was identified.
- A standardized, insulin administration observation process helped to identify areas for improvement.
- Collaboration with other hospitals and a mentor with a defined timeline helped drive process improvement.

ing formulary management to select insulin pen products that looked as different as possible from other pens to minimize risk for product mixups (e.g., rapid-acting insulin versus long-acting insulin).

All insulin products were dispensed by the pharmacy department to the patient care units with a patientspecific label affixed to the container, except for vials of regular insulin that are stored in locked, refrigerated medication boxes on patient care units for the emergent treatment of hyperkalemia. With this exception, insulin products were stored only in patient care areas after a provider entered an order into the hospital's electronic order entry system.

Upon order review and pharmacist verification, a patient-specific label was printed and affixed to the insulin pen's barrel (or vial for regular insulin) along with a separate sticker indicating the assigned beyond-use date [28 days after dispensing]). After pharmacist verification of insulin product selection, labeling, and beyond-use date, a pharmacy technician delivered the medication to patient-specific storage bins in an automated dispensing cabinet (ADC) on the patient care unit. If more than one type of insulin was ordered for a patient (e.g., both a basal and prandial insulin), they were stored in separate bins designated for that patient. This practice minimized insulin product selection mix-ups for patients receiving multiple types of insulin.

Insulin is a high-alert medication at the hospital. Expectations for storage, dispensing, and administration are defined in UF Health's highalert medication policies, look-alike, sound-alike medication policies, and nursing medication administration policies. Key elements of safe insulin use in these three policies include the following:

- Requirement for dual verification of the five medication rights (right patient, right drug, right dose, right route, and right time) by nurses upon administration
- Restrictions on the storage and use of concentrated insulin (U-500).
- Look-alike, sound-alike caution labeling on all insulin storage bins and locations

The hospital began implementing barcode medication administration in 2014. Prior to participation in the MQIIP, pharmacy-generated labels were designed to include a patientspecific barcode, which was affixed to the barrel of insulin pens dispensed from the pharmacy. Patient-specific barcodes ensure that the correct pen is used to administer doses to the patient and to help avoid using the same pen for more than one patient. If a patient's identification wristband is scanned followed by the scanning of a pen that was not dispensed for that patient, the nurse receives a wrong patient alert. Extensive discussion occurred concerning the decision to require nurses to scan a patient-specific barcode (to intercept "wrong patient's pen" errors) or the manufacturer's barcode (to intercept "wrong insulin" errors) at the bedside. Concerns were weighed regarding the accidental sharing of patients' insulin pens with that of potential pharmacy dispensing errors, such as when an electronic health record (EHR)–generated label is attached to the wrong type of insulin pen (e.g., an insulin glargine label is placed on an insulin aspart pen). A decision was made to direct barcode medication administration scanning to the patient-specific barcode rather than to the manufacturer barcode.

Nurses received specific education about blood glucose management, insulin use, and insulin pen safety during new employee education by the hospital's inpatient diabetes educator. Nurses also were required to complete an annual knowledge assessment, including items related to insulin pen safety, through the hospital's online learning system. Each patient care unit identified registered nurses who received additional training and worked closely with the diabetes educator through the hospital's diabetes self-management program. These nurses earned the title of "diabetes resource nurse" and served as a local, patient care unit expert on insulin administration and blood glucose management.

#### Insulin pen safety concerns

In a February 2013 alert, the Institute for Safe Medication Practices (ISMP) described several large-scale potential patient exposures to bloodborne pathogens when insulin pens were shared among patients in the hospital setting.8 Although ISMP had previously published warnings about this risk, the group recommended that hospitals consider moving away from the use of insulin pens for inpatients. This recommendation spurred the UF Health medication safety committee to initiate a comprehensive evaluation of the risks and benefits of continued inpatient insulin pen use.

An interprofessional task force was convened by the UF Health

medication safety committee to evaluate insulin pen safety. The task force included pharmacists, nurses, endocrinologists, a diabetes educator, an infection control professional, and hospital leadership representatives. In August 2013, during the course of this group's discussions, an expert consensus panel convened by the ASHP Research and Education Foundation published practical recommendations for insulin-use safety in hospitals.9 This document provided additional guidance and recommendations for consideration by the task force. According to the expert consensus panel, insulin pens can be used safely in hospitals, but robust systems must be in place to prevent inadvertent or intentional sharing of insulin pens between patients. After much deliberation, the task force reached a consensus that the benefits of continuing to use insulin pens outweighed the risks. The task force considered the main benefits of using pens instead of vials and syringes to be an anecdotal decrease in insulin dosing errors; the elimination of barriers to patient education by using the insulin delivery devices that most patients use on an outpatient basis; and the decreased risk for occupational needlestick injuries in nurses administering insulin. The task force also considered that although a risk for exposure to bloodborne pathogens is associated with sharing of insulin pens among multiple patients, actual transmission of blood-borne infection has not been demonstrated in reported cases of pen sharing.3-7 In contrast, serious insulin overdoses occurred in the hospital before the introduction of insulin pens, and this risk remained more than a theoretical concern. Although task force members concluded that risks associated with inpatient insulin use are substantial with pens as well as with vials and syringes, they were unable to conclude that moving away from insulin pen use would ultimately reduce these risks.

Upon deciding to continue using insulin pens, UF Health was motivated to ensure that all possible system safeguards were in place to optimize patient safety. In exploring additional safety measures, the UF Health medication safety committee recommended that the institution apply to participate in ASHP's MQIIP on Ensuring Insulin Pen Safety in Hospitals.

#### **Immediate benefit**

In participating in the MQIIP, UF Health's goal was to share experiences and challenges with other organizations and insulin safety experts and to learn about additional safeguards that could be implemented. UF Health established a project team-composed of three pharmacists, three nurses, and the inpatient diabetes educator-and obtained the support of the nurse managers and clinical leaders on the three patient care units where audits and observations for the program were conducted. The medication safety pharmacist served as the team leader. Leadership support was obtained from the chief quality officer and the directors of the departments of pharmacy and nursing and the diabetes self-management program.

The team learned from participating in the introductory continuing education webinar that although they were following best practices in applying tamper-evident tape (i.e., seals) to insulin pens at the time of dispensing from the pharmacy, they were not applying the tape correctly. Tamper-evident tape should be applied perpendicular to the junction between the pen cap and barrel. The team had been wrapping the tape around the barrel-cap junction, which increased the possibility that the tape would not break when removing the pen cap and prevent detection that a pen had been used.

In planning the baseline data collection period of the project, the team selected three adult medicalsurgical units, which were the patient care areas with the highest use of insulin pens in the hospital. These units were chosen to help ensure that the team would be able to make the required number of insulin pen administration observations during the one-month, data collection period. All three of these patient care areas were located in the hospital's older building.

Performing the insulin pen audits and administration observations required resources and coordination among team members, but the observations were not overly burdensome. Insulin administration observations were performed by project team members, two nurses assigned to special projects through the department of nursing, diabetes resource nurses on the observation patient care units, and advanced pharmacy practice experience pharmacy students. All observers were trained in the use of the data collection tool and methods for observing insulin administration to minimize the likelihood of observation bias. These observers coordinated observation days and insulin administration times so that an even distribution of observations across administration times and patient care units could be obtained. The team leader communicated weekly with team members during the data collection period to keep track of progress and the distribution of observations among units and times. Data collection sheets were reviewed by the team leader regularly.

During the baseline data collection period, the team identified several areas for improvement and education. Although the majority of the insulin pen administrations were performed according to the 18 bestpractice checklist items, the team noted opportunities for improvement in several areas: swabbing the pen's rubber stopper with alcohol before attaching the needle; priming the needle with 2 units of insulin; and holding the needle in the skin for at least five seconds after injection.<sup>1</sup> These items were addressed during annual nurse orientation and education.

# Challenges in insulin pen storage

The area in greatest need of improvement was the storage of insulin pens. The patient care units chosen for observations were located in the older of two contiguous hospital buildings. After pharmacy technicians delivered and stored insulin pens in patient-specific bins in the ADC on the patient care unit, a nurse accessed an insulin pen by logging into the ADC, selected the patient's name, and then selected the insulin based on the medication administration record. The ADC then guided the nurse with a flashing light to the correct bin that contained only that patient's insulin pen. The nurse removed the pen, administered the insulin, and then returned the pen to the patient-specific bin in the ADC. This process was used throughout the hospital.

The insulin pen delivery and storage process worked well for all patients with the exception of those with contact isolation precautions to prevent the transmission of pathogens, such as methicillin-resistant Staphylococcus aureus, vancomycinresistant Enterococcus, and Clostridium difficile. For these patients, proper storage of medications in multiple-dose containers-such as insulin pens, inhalers, and tubes of topical medications-is a challenge. These medication containers must be stored in a secure location, but they also must be handled in a way that does not allow surface contamination and transmission of the pathogen to locations outside of the patient room.

During the baseline observation period, the process for storage of insulin pens for contact isolation patients involved removal of the insulin pen by the nurse from the ADC and placing it with any other multiple-dose medication containers in a plastic bag with a computer-generated patient label. The bag was stored in a locked supply cart's drawer in the hallway near the patient's room. The supply cart drawer was large and might have contained bags of multiple-dose medication containers labeled for other patients. When it was time to administer the insulin, the nurse removed the pen from the bag; took it into the patient room after donning proper gowning and gloving; administered the insulin; brought the pen back outside the room; placed it in the patient's bag; and then stored the bag in the supply cart.

The complex process used for patients with contact isolation precautions in the older UF Health hospital building was not necessary for patients in the newer building because patient rooms in the newer building contained a lockable cabinet inside the patient room. Multiple-dose medication containers for any contact isolation patients in the newer building were stored inside the lockable cabinet located inside the patient room. When patients were discharged, a reliable process was in place for the nurse to remove and dispose of all medications from the cabinet, thus allowing environmental services personnel to clean the cabinet along with the rest of the room.

Although the process for storing insulin pens for contact isolation patients in the older hospital building where the MQIIP audits and observations took place was not ideal, baseline observations helped to quantify problems related to the storage process. Insulin pens for contact isolation patients who had been discharged were found in the supply carts days after the patients had been discharged. This situation occurred because these pens were stored in a location that was not part of the medication delivery, disposal, or patient discharge processes. Staff members often forgot that insulin pens were stored in the supply carts and needed to be removed and disposed of when patients were discharged from the hospital. The practice of storing insulin pens for multiple patients in a single, large drawer in the supply cart raised concerns about the potential for mix-ups, despite the use of patient-specific labels on the medication bags. Lastly, the team occasionally found insulin pens for patients without contact isolation precautions in the supply carts instead of the ADC, which was due to greater proximity to patient rooms and ease of use of the supply carts.

Following the baseline data collection period, the team shared its findings with other hospital teams and the mentor during the second of four mentored calls. The team found the conversation with others valuable for learning about problemsolving approaches that proved successful in other hospitals, and the team shared some solutions with other teams. In particular, the team learned that other hospitals had the same challenges with medication storage in older hospital buildings. Lastly, it was motivating for the team to talk with colleagues from other hospitals across the country, and it served as a valuable source of peer support.

### **Process improvement**

Three central issues were noted during the baseline data collection period. The first two were the need to swab the stopper on the insulin pen before attaching the needle and correct priming of the insulin pen. These two observations led to stronger emphasis on these steps of the insulin pen injection process during required nurse training. The third and largest issue was recognition of the need for a better process to store multiple-dose medication containers for patients in contact isolation. This had been a concern of nursing and pharmacy leadership before participation in the MQIIP, but the audits showed how often problems with storage of bulk medication containers for contact isolation patients occurred and highlighted the importance of finding a solution. Medications and packaging brought to the patient bedside and then back out of the patient room for storage in a central medication storage area, such as an ADC, present a problem when patients are infected or colonized with organisms that require contact isolation. Concern for cross contamination of other surfaces outside of the patient room dictates minimizing medication packaging going in and out of the patient room. Although insulin pens were the focus of this project, problems with the storage of other bulk medications for contact isolation patients-such as inhalers, creams and ointments, and eye drops-were also better understood.

A small task force of pharmacists, nurses, and a pharmacy technician was formed to investigate possible solutions to the medication storage problem in the older building. This group identified clear plastic lockable boxes mounted to the wall in all patient rooms as the best solution. The use of these boxes for storage of insulin pens eliminated the need for storage outside the patient room and the risk of transmission of pathogens from medication containers with surface contamination to other patient care areas. In the newer building, it was feasible to establish a reliable process that ensured thorough cleaning of any cabinets or boxes in the room by environmental services personnel after patient discharge. The use of a clear box made it easy for staff members to see whether medications remained after patient discharge and needed to be removed and disposed of to allow for thorough cleaning of the box.

Selecting, purchasing, installing, and providing staff education about the clear lockable boxes was a timeconsuming process that was not completed before the postintervention data collection period of the MQIIP. However, improvement in the storage of insulin pens was found to be consistent with UF Health's policies and procedures at the time (e.g., fewer pens were found for discharged patients and patients without contact isolation precautions in the supply carts). This improvement probably was the result of intensive staff education efforts by the department of nursing and frequent auditing of medication storage practices by a pharmacy team member as part of the continuous internal auditing of compliance with Joint Commission medication management standards.

By the time of preparation of this article, the clear lockable boxes had been installed in patient rooms in the older building, and compliance was achieved in policies and procedures for storage of insulin pens in these boxes. UF Health continued to provide extensive staff education surrounding the issue of safe insulin pen use. Posters designed by the Centers for Disease Control and Prevention and Safe Injection Practices Coalition as part of their One and Only Campaign were displayed prominently in staff work areas on all patient care units to raise awareness of safe injection practices, including the need to avoid sharing insulin pens.<sup>10</sup> The hospital fully implemented barcode medication administration in all patient care units, including the ones where audits and observations took place for the MQIIP. The routine generation of barcode scanning reports allows for identification of cases where barcode scanning has detected a wrong pen scan. Following a wrong pen scan alert, a correct pen scan of the patient-specific barcode indicates that the correct patient's pen was used, whereas subsequent administration documentation without an additional scan may indicate that an incorrect pen was used. To date, the hospital has not identified any cases in which a patient appears to have received an injection with the wrong insulin pen since implementation of barcode scanning and other systemwide safety enhancements.

If a case is identified in which an insulin pen may have been shared among multiple patients, the hospital has established policies and proce-

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dures to notify the clinical risk management department and the patient care area leadership immediately to begin a thorough investigation of the incident. The infection control and prevention department, physician, and patient would be promptly notified and testing for blood-borne pathogens would be offered to the patient. Finally, a root-cause analysis of the event would be performed to determine causes and possible solutions, findings would be shared with the hospital community, and then plans would be made to implement process changes as appropriate.

#### **Future plans**

UF Health's future plans include continuation of all educational efforts for nursing and pharmacy staff on insulin pen safety. This topic now receives greater emphasis in the new nurse, pharmacist, and pharmacy technician orientation in addition to the ongoing education and annual competency assessments. The routine monitoring of insulin pen-related, barcode-scanning reports will continue, and report enhancements are being made to make it easier to identify potential wrong pen insulin administration incidents that warrant closer review. Lastly, UF Health continues to explore feasibility of workflow changes to the pharmacy dispensing process and is evaluating the concept of scanning the manufacturer barcode first to verify the correct insulin product selection. This is followed by covering the manufacturer barcode with the EHR-generated label that contains the order-specific barcode to be scanned by nurses at the bedside (that intercepts "wrong patient's pen" errors).

## Conclusion

Participating with a knowledgeable mentor and other hospital teams struggling with the same issues and concerns related to safe insulin pen use facilitated problem solving. Discussing challenges and sharing ideas for solutions to safety concerns with other hospitals identified new process enhancements, which have the potential to improve the safety of insulin pen use at UF Health.

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