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SUPPLEMENT

Best practices in ensuring the safe use of insulin pens
in the hospital

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Best practices in ensuring the safe use of insulin pens in the hospital: Introduction

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Hyperglycemia is common in hospitalized patients, and insulin is the preferred antihyperglycemic treatment in the inpatient setting.^{1,2} Insulin is a high-alert medication associated with a significant risk for patient harm when used incorrectly or inappropriately.³ Numerous reports have described the reuse of insulin pens on multiple patients by health-care professionals, potentially exposing patients to blood-borne diseases.⁴⁻⁶ Safety concerns associated with U-500 insulin pens have also been raised, underscoring the need for a systematic approach to ensure the safe and effective use of insulin and insulin pen devices.⁷

Although guidance has been published for the safe use of insulin in the inpatient setting,⁸ best practices specifically addressing the safe use of pen devices have not been established. The first article in this supplement provides specific recommendations to improve the safe use of insulin pen devices in hospitals and health systems. These best practices were developed by an expert panel using a Delphi consensus development process managed through the Center for Innovative Phar-

macy Solutions at the University of Maryland School of Pharmacy. The 12-member interprofessional expert panel of nurses, pharmacists, and physicians with extensive knowledge of insulin therapy and patient safety principles identified 35 best practices that should be implemented by hospitals and health systems that elect to use insulin pen devices. Recommended practices for the safe use of insulin were also identified.

In a separate but related endeavor, ASHP embarked on an educational initiative aimed at ensuring the safe use of insulin pens in hospitals. Intended for institutions that used insulin pen devices for administering insulin to inpatients, components of this initiative included Web-based resources and several continuing-education activities. In 2014, hospitals and health systems were invited by ASHP to apply for the MENTORED QUALITY IMPROVEMENT IMPACT PROGRAMSM (MQIIP) on Ensuring Insulin Pen Safety in Hospitals. Fourteen hospitals were selected to participate, and pharmacists with expertise in insulin pen use and systems improvement provided constructive feedback, advice, and support to the interprofessional teams at these institutions over nine months. Three of the four articles in this supplement focus on the initiative's mentored quality-improvement program—the methods used to collect safety data on insulin pen use, the opportunities for improvement identified, the changes implemented, and the improvements realized—as well as the perspectives of the team leaders from two participating sites. The tools developed to identify potential problems in the medication-use process and assess the impact of

quality-improvement efforts related to insulin pens are available online at the One Pen One Patient website (www.onepenonepatient.org) and as supplementary material linked to the full text of the article by Lutz et al. (www.ajhp.org). The articles by Rosenberg and Botsford provide insights regarding the real-world challenges that interprofessional teams face as they address insulin pen safety issues at their institutions. Although each institution will face unique challenges and barriers to improving insulin pen safety, the lessons learned and shared by Rosenberg and Botsford are universal.

Many of the strategies implemented to improve insulin pen safety at the hospitals participating in the MQIIP are consistent with the recommended best practices by the expert panel. The tools, approaches, and recommended practices outlined in this supplement are suitable for use by any health system seeking to ensure the safe use of insulin pens.

Disclosures

The educational initiative, Strategies for Ensuring the Safe Use of Insulin Pens in the Hospital, and this supplement were supported by educational grants from Novo Nordisk Inc. Dr. Haines received an honorarium for participating in the initiative and preparing this article. The supplement authors and planners have declared no potential conflicts of interest.

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Best practices for safe use of insulin pen devices in hospitals: Recommendations from an expert panel Delphi consensus process

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Purpose. A Delphi consensus development process was used to identify best practices for the safe use of insulin pen devices in hospitals.

Methods. A panel of healthcare professionals with experience in patient safety activities and development of insulin-use guidelines was selected. In round 1 of a 4-round Delphi process, panelists were asked to identify key concepts and practices relating to safe use of insulin pen devices in hospitals. In round 2, panelists indicated their level of agreement with draft practice statements reflecting input received in round 1; statements with strong support were refined based on panelist suggestions. In round 3, the modified draft statements were rated for potential impact on patient safety. In round 4, panelists selected a final list of statements to recommend as best practices.

Results. A 12-member interprofessional panel consisting of nurses, pharmacists, and physicians participated in the Delphi process. In round 1, panelists submitted more than 450 statements describing safe practices for insulin pen use. Based on that input, 125 draft practice statements were developed; among 98 statements receiving panelist support in round 2, 76 were judged in round 3 to be critical to patient safety or likely to have a positive impact on patient safety. In round 4, panelists unanimously affirmed a final list of 35 best-practice statements for the safe use of insulin pens in hospitals.

Conclusion. A Delphi consensus development process yielded a list of recommended best practices to help ensure the safe use of insulin pen devices in hospitals and health systems.

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Hyperglycemia is common among hospitalized patients, including patients with and without a known diagnosis of diabetes mellitus.^{1,2} Moreover, hyperglycemia is associated with increased morbidity and mortality, so there has been increased emphasis on treating hyperglycemia in hospitals.² Guidelines for the management of hyperglycemia in hospitalized patients recommend insulin therapy as the standard of care for most patients.³⁻⁵ Therefore, insulin use in hospitals is very common.

A growing number of insulin products and delivery devices are

available for use in the inpatient setting; most patients receive insulin therapy by the intravenous or subcutaneous route of administration.⁶ Subcutaneously administered insulin can be withdrawn from a vial and administered using an insulin syringe. Alternatively, the dose can be measured and administered using an insulin pen device. In the outpatient setting, the use of insulin pen devices by patients has been shown to improve ease of use, convenience, and adherence.⁷ Similarly, the use of these devices has some potential advantages in the hospital setting.

In one study, nurses felt that it was easier to teach patients to measure and self-administer insulin doses using pens instead of vials and syringes.⁸ In addition, nurses believed that insulin pen use lowered the risks of dosing error and inadvertent needle-stick injury and reduced the amount of time needed to prepare and administer an insulin dose. In another study, a majority of nurses felt that insulin pen devices were more convenient and easier to use than vials and syringes.⁹ Not only do nurses prefer using insulin pens over vials and syringes; patient satisfaction is also higher.¹⁰ Using insulin pen devices instead of vials and syringes in hospitals may also reduce waste and decrease costs. One study projected a cost savings of \$36 per patient per hospital stay with insulin pen use.¹⁰ In a 214-bed hospital that converted from insulin vials and syringes to pen devices, a total cost savings of \$60,000 was realized during a six-month postimplementation period.¹¹

Despite the potential advantages of insulin pen devices, there are potential risks. Regardless of the delivery method used, insulin is designated as a high-alert medication by the Institute for Safe Medication Practices (ISMP).¹² Medication errors involving insulin are frequent, can occur at any stage of the medication-use process, and have the potential to cause serious harm.¹³ In one study, nearly two thirds of the observed errors related to insulin use occurred during administration, 17% occurred during prescribing, and 10% occurred during dispensing.¹³ The most common errors were wrong dose, omitted or delayed dose, and wrong insulin product.

Insulin pens are associated with a unique risk. The insulin pen cartridges can become contaminated, and transmission of blood-borne pathogens could occur if a pen is used in multiple patients, even if the needle is changed.^{14,15} Insulin pens are approved for use only by a single patient, but reports of pen reuse in

KEY POINTS

- An interprofessional panel of experts established a list of best-practice recommendations that hospitals should adopt to ensure the safe use of insulin and insulin pen devices.
- These recommendations include specific actions that should be implemented throughout the medication-use process to mitigate the potential reuse of pen devices in more than one patient.
- Ensuring the safe use of insulin pen devices in hospitals requires collecting, evaluating, and using data to create interventions that have impact.

multiple patients have been published.^{16,17} These reports are alarming because the patients involved were potentially exposed to blood-borne pathogens. The incidents of pen sharing involved 2114 patients at a federal hospital in Texas (reported in 2009), 1915 patients at a community hospital in New York (reported in 2013), 716 patients at a federal facility in New York (reported in 2014), and 3149 patients at a community hospital in Connecticut (reported in 2014).¹⁷ These incidents prompted several organizations, including ISMP, the Food and Drug Administration, and the Centers for Disease Control and Prevention (CDC), to issue advisories about the dangers of this practice.¹⁸⁻²⁰ CDC and the Safe Injection Practices Coalition also launched the One and Only Campaign to promote safe insulin pen use by both healthcare professionals and patients.²¹ This educational effort centers around the principle of “one patient, one pen.”

Although guidance has been published to promote the safe use of

insulin in the inpatient setting, best practices specifically addressing the safe use of insulin pen devices have not been established.²² We sought to develop a list of best practices for the safe use of insulin pen devices in hospitals by engaging an interprofessional panel of experts and using a rigorous consensus development process.

Methods

The Delphi technique was used to identify best practices and articulate a list of statements describing specific actions that hospitals should implement to ensure the safe use of insulin pen devices. The Delphi technique is a structured consensus development process commonly used when there is a lack of empirical data on the subject of inquiry.²³ During this process, the opinions of expert panelists who have extensive knowledge and experience regarding the subject are collected and considered. The process typically is conducted by deploying several rounds of questionnaires either by mail or online.²⁴ After each round, controlled feedback is provided to the panelists. Unlike focus group meetings, which are conducted face-to-face, the Delphi method is conducted asynchronously, and panel members are unaware of the identity of other panelists. Therefore, panel members are not swayed by the opinions of panelists who are more assertive or perceived to have greater expertise. Thus, each panelist has an equal opportunity to contribute to and shape the consensus of the group.^{25,26} To obtain a comprehensive understanding of the subject, qualitative open-ended questions are often asked during the first round. The collected data are subsequently analyzed and summarized by the researchers.²⁵ After each round, a summary of the findings is distributed to the participants, new questions are posed, and additional information is collected. The goal is to achieve consensus.²⁴

In our study, each panelist was required to have the following qualifications: (1) membership in a healthcare profession (e.g., nursing, pharmacy, medicine), (2) involvement in patient safety activities, such as (but not limited to) serving on a patient safety committee, as a patient safety officer, or in a safety organization within the past three years, and (3) experience developing insulin-use guidelines or providing input into such guidelines. A panel size of 12–15 members was targeted. An initial list of potential panelists was developed by (1) conducting a PubMed search to identify authors with published works related to insulin use and patient safety and (2) reviewing reports published by professional organizations (e.g., American Society of Health-System Pharmacists [ASHP], Society of Hospital Medicine) regarding the safe use of insulin to identify the authors, reviewers, and participants. Invitations to participate were extended sequentially to multiple groups of nurses, pharmacists, and physicians to ensure that at least three individuals from each healthcare profession were represented on the expert panel and diverse perspectives were considered during the consensus development process. In addition, the investigators made conscious efforts

to invite experts from diverse geographic regions and institutions (e.g., academic health science centers, community hospitals) to participate. Potential expert panelists believed to meet the inclusion criteria were contacted via e-mail and invited to participate in the study. Invitations were extended until the targeted number of panelists had agreed to participate.

The study protocol (HP-00065923) was reviewed by the University of Maryland, Baltimore, institutional review board (IRB). The study was determined to be category 2 research, which is exempt from further IRB review under Department of Health and Human Services regulations.²⁷

At the beginning of each Delphi round, an e-mail with an electronic link to the survey instrument was sent to each panelist. To maximize the response rate, two reminder e-mails were sent to panelists who had not yet responded five days and one day before the deadline for each round. A total of four rounds were planned. Panelists were offered a modest honorarium as an incentive to participate in all four rounds. Although the research team was aware of the identity of the participants and their responses, panel members were unaware of who served on the panel and their responses. SurveyMonkey

(SurveyMonkey Inc., Palo Alto, CA) was used to collect responses from panel members.

Delphi round 1: Capturing concepts and ideas. During the first round of the Delphi process, panelists were asked in an open-ended manner to provide “concepts, ideas, and thoughts” related to the safe use of insulin pen devices during each step of the medication-use process. For the purposes of our study, the medication-use process was divided into eight discrete steps (Table 1). The panelists were cautioned against limiting their responses to only “the best,” “most effective,” or “highest-value” actions that could be taken to ensure the safe use of insulin pen devices. The panelists also were asked to consider their responses to each question over several days. There was no limit to the length of the responses. In addition, panelists were asked seven general questions intended to characterize their professional experience and institutional affiliations. Responses from the first round of the Delphi process were aggregated and grouped by the investigators into common themes. Action-oriented statements related to each of the steps in the medication-use process were drafted using words from the panelists’ responses. Each state-

Table 1. Discrete Steps in Medication-Use Process

Step	Description
1: Prescribing	The act of determining what medication would be the most appropriate in the patient-specific circumstances and within the situational context
2: Communicating the order	The act of transmitting and transcribing the medication order to those who will act on this information (e.g., nurse, pharmacist, patient, respiratory therapist)
3: Product preparation and labeling	The act of selecting the product to be dispensed, preparing it for use, and ensuring that it is properly labeled
4: Storing	The act of placing the medication in a location for future use
5: Administering	The act of giving a medication to (or the taking of a medication by) a patient
6: Monitoring	The act of collecting data about the intended and unintended effects produced by medication use (or misuse)
7: Evaluating	The act of judging the meaning, value, and credibility of medication-use (or misuse) data
8: Planning	The act of using data to design future action(s) for improved medication use

ment began, “To ensure the safe use of insulin pen devices, hospitals and health systems should . . .”

Delphi round 2: Identifying actions. During the second round of the Delphi process, the panel was provided with the list of statements crafted by the investigators based on the responses from the first round. The panelists were asked to indicate whether they agreed with the statement as written, agreed with the statement in principle but would like to see changes (if so, panelists were asked to recommend specific changes), or disagreed with the statement. At the conclusion of the second round, the percentage of panelists selecting each response option was calculated. The investigators removed statements for which consensus was not achieved and modified other statements based on panelist suggestions. Only those statements with which more than 75% of panelists indicated some level of agreement were included in round 3 of the Delphi process.

Delphi round 3: Rating importance to patient safety. In the third round of the Delphi process, panelists were presented with a set of modified statements and instructed to rate the relative importance of each action in terms of improving the safe use of insulin pens in hospitals. The panelists were asked to rate each statement based on the following 4-point patient safety impact scale: 1 = this action is unlikely to impact patient safety, 2 = this action might have a slight positive impact on patient safety, 3 = this action will have a positive impact on patient safety, and 4 = this action is critical to patient safety. The panelists were also asked whether the action was unique and specific to the safe use of insulin pen devices or a “general medication safety measure” that would improve the use of most medications. At the conclusion of the third round, the investigators calculated the number and percentage of responses for each statement that panelists rated at 3 or

4 on the patient safety impact scale. Those statements rated by more than 75% of panelists as either 3 or 4 were included in round 4 of the Delphi process. Statements were then classified as (1) unique and specific to insulin pen devices, (2) specific to insulin use (regardless of delivery system), or (3) general medication safety measures. Eight statements that were rated by a large number of panelists as critical to patient safety but were one vote short of the specified number for achieving consensus in round 3 were included in round 4 for reconsideration by the panel.

Delphi round 4: Reaching consensus. During the fourth and final round of the Delphi process, respondents were provided with the statements on which consensus was reached in round 3, with the statements classified as (1) actions specific to insulin pen safety, (2) actions specific to insulin safety (regardless of delivery system), or (3) actions to improve general medication safety. Panelists were asked to affirm that the statements represented “best practices that can be feasibly implemented at most hospitals.” In addition, panelists were given the opportunity to reclassify any statement. Lastly, panelists were given a final opportunity to reconsider the eight statements on which consensus was not achieved in round 3. Panelists were asked to decide if each statement described a “best practice” and therefore should be included in the best-practice list or, alternatively, did not describe a best practice (or described a practice unlikely to improve patient safety) and therefore should not appear on the best-practice list.

Results

Characteristics of expert panelists. A total of 30 potential panelists were contacted: 10 did not respond to our e-mail invitation, 3 declined to participate, 4 did not meet the eligibility criteria, and 13 agreed to participate (Figure 1). One panelist who initially accepted our

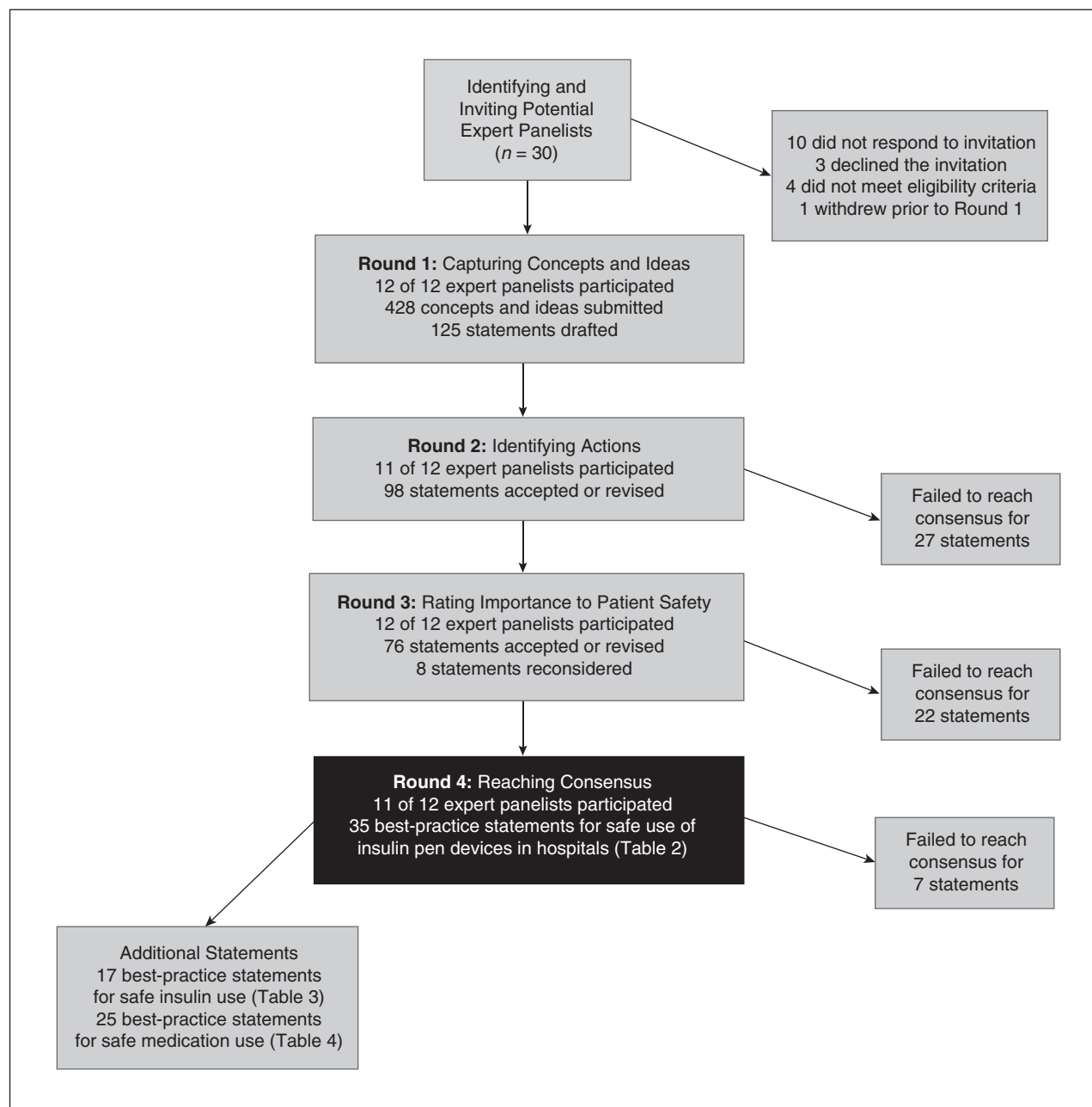
invitation did not participate in the first round and withdrew from the study. Panelists’ names, credentials, titles, and institutional affiliations are listed in the appendix. Four nurses, five pharmacists, and three physicians participated. On average, panelists had been licensed as healthcare professionals for 19.4 years (median, 15 years; range, 4–47 years) and had been engaged in formal and structured patient safety activities for 11.3 years (median, 11 years; range, 3–26 years). Four of the 12 panelists reported that they served currently or in the recent past as a patient safety officer.

Delphi round 1: Capturing concepts and ideas. During the first round, all 12 panelists completed the open-ended questionnaire. Panelists submitted 428 statements regarding the safe use of insulin pen devices. For each of the eight steps in the medication-use process (Table 1), at least 36 statements were submitted. After reviewing panelist responses, the investigators grouped items into themes and created a total of 125 statements for the panelists to consider in round 2. Fourteen statements related to the prescribing step, 8 related to communicating the order, 27 addressed preparing and labeling the product, 13 related to storage, 26 focused on administering insulin, and 32 related to monitoring, evaluating, and planning. Five additional statements that addressed multiple steps or did not directly address any of the medication-use steps were also drafted.

Delphi round 2: Identifying actions. Eleven of 12 panelists (92%) participated in the second round. There was a high level of agreement with 98 of the 125 statements drafted in round 1. Twenty-three modified statements and 75 unmodified statements were included in round 3.

Delphi round 3: Rating importance to patient safety. During the third round, all 12 panelists responded to the questionnaire. Seventy-six of the 98 statements evaluated were

Figure 1. Delphi consensus process used to develop best-practice statements on the safe use of insulin pen devices in hospitals and health systems.



each rated by more than 75% of the panelists as describing practices that were critical to patient safety or would have a positive impact on patient safety. Of these 76 statements, 34 statements were believed by the panelists to be specific and unique to insulin pen devices. Several panelists

indicated that some of the remaining 42 statements were specific to insulin use, as opposed to describing general medication safety measures. Eight statements on which consensus was not achieved but which were considered critical to patient safety by at least 5 respondents were included

in round 4 for reconsideration by the panelists.

Delphi round 4: Reaching consensus. Eleven of 12 panelists (92%) participated in the fourth round. Consensus was affirmed by all 11 respondents for 34 best-practice statements on the safe use of insulin pen

devices in hospitals (Table 2). There was a high level of agreement (10 of 11 respondents) on 17 best-practice statements on insulin use in hospitals and health systems (Table 3). Consensus was affirmed, with 9 of 11 respondents indicating agreement with 25 best-practice statements related to general medication safety measures (Table 4). Of the 8 statements for which consensus was not achieved in round 3 that were included in round 4, consensus was reached (9 of 11 respondents) for 1 statement, which was added to the list of best practices for the safe use of insulin pen devices, bringing the total number of best-practice statements to 35 (Table 2).

Discussion

The expert panel reached consensus on a set of actions that should be implemented to ensure the safe use of insulin pen devices (Table 2). The expert panel represented a diverse group of healthcare professionals (nurses, pharmacists, and physicians) from a variety of institutions (appendix). The panelists had many years of experience, and each contributed a unique perspective in developing a robust set of best-practice statements. The panel also recommended 17 actions that hospitals should implement to ensure the safe use of insulin regardless of the delivery system (Table 3). Finally, 25 actions were recommended to improve general medication safety (Table 4). The best-practice statements articulated in this report are specific actions that can be feasibly implemented by most hospitals and health systems.

The best-practice statements in this report were developed using a robust consensus development method. The Delphi technique is a widely accepted consensus development process. The blinding of participants to the identity of other panel members minimized the likelihood that any one individual dominated the process by force of will, charisma,

position, experience, or perceived hierarchy.²⁸ The four rounds of the Delphi process were conducted in a timely manner, and confidentiality was maintained through the use of electronic communication. All statements were developed using the words of the expert panelists, and consensus among more than 75% of panelists was required for a statement to be considered a best practice. The Delphi method was conducted with an appropriate amount of time (approximately three weeks) between iterative rounds to allow sufficient feedback while keeping panelists engaged in the process. The use of technology (the online survey application and e-mail invitations and reminders) facilitated communication. The high participation, response, and retention rates of the expert panel indicate that the participants were committed, motivated, and dedicated to developing best practices for insulin pen devices in hospitals. Through the use of multiple iterations, the progressive nature of the Delphi technique allowed the panelists to shape their opinions over time, improving the usefulness and precision of the statements while simultaneously building consensus.²⁸

The panelist recommendations align with and expand on previous recommendations from an expert panel convened by the ASHP Research and Education Foundation in 2012 to address the safe use of insulin in hospitals.²² Given the high incidence of medication errors related to insulin use, including the reuse of insulin pens for multiple patients, reductions in errors will only occur through a multifaceted approach. The recommendations of the ASHP Foundation-convened panel included forming an interprofessional committee with expertise in diabetes management to develop and review policies and procedures related to ordering, labeling, dispensing, storing, and administering insulin.

The participants in our study emphasized that all documents related to ordering, dispensing, labeling, and administering insulin using a pen device should clearly indicate that the product is an insulin pen, that the product is for individual patient use only, and that a new needle is required for each use. Moreover, our panel strongly agreed that computerized prescriber-order-entry (CPOE) systems should clearly display the word “pen” in the product description.

With regard to labeling and dispensing an insulin pen device, a key best practice recommended by the expert panel is the inclusion of a patient- and product-specific barcode on the pharmacy label. The label should instruct the health professional to confirm patient identity prior to administration and use the pen only in one patient. The pharmacy label should be attached to the barrel (not the cap) of the insulin pen device. Moreover, the manufacturer's label, with the product name and lot number, should be visible. Once a label has been attached, tamper-evident tape should be applied perpendicular to the junction of the cap and barrel. Pharmacy staff should then sequentially scan the manufacturer's barcode and the barcode on the patient-specific pharmacy label to confirm that the correct pen product is dispensed to the correct patient. The panel felt strongly that insulin pens that are not labeled by the pharmacy should not be available on a patient care unit (e.g., as part of floor stock), nor should a label be affixed to a plastic bag in which the pen device might be dispensed.

The recommendations to store insulin pen devices only in patient-specific locations (automated dispensing cabinet bins or other containers) and immediately return the pen to the location after each use would, if implemented, reduce the likelihood that pens are used as floor stock or for the wrong patient. In addition, the panel recommended that pen needles should

Table 2. Best Practices for Safe Use of Insulin Pen Devices in Hospitals and Health Systems^a

Item No.	Statement: To ensure the safe use of insulin pen devices, hospitals and health systems should . . .
<i>Ordering and Documenting</i>	
1	Indicate on all documents/labels/electronic records that product is an “insulin pen”
2	Indicate on all documents/labels/electronic records that product is “for individual patient use only”
3	Clearly display the word “pen” in the computerized prescriber-order-entry product description
4	Indicate on all documents/labels/electronic records that product requires “a new needle for each use”
<i>Labeling and Dispensing</i>	
5	Include a barcode that is both patient-specific and product-specific on the pharmacy label
6	Ensure that the pharmacy label is affixed only to the barrel of the pen (not the cap)
7	Indicate on the pharmacy label, “Warning! Confirm patient. Insulin pens are for use in one patient only.”
8	Ensure that the pharmacy label does not obstruct the product name or lot number on the manufacturer’s label
9	Prohibit unlabeled patient-specific insulin pens on unit (i.e., floor stock)
10	Apply tamper-evident tape to the pen device perpendicular to the junction of the cap and barrel
11	Require pharmacy staff to sequentially scan manufacturer’s barcode and patient-specific pharmacy label to confirm correct pen product is being dispensed
12	Ensure that each and every pen device has a patient-specific pharmacy label affixed to it
13	Prohibit labeling a plastic bag in which the labeled pen device is dispensed
<i>Storing</i>	
14	Ensure that insulin pen devices are stored in a patient-specific location (e.g., bin, drawer, pocket)
15	Ensure that insulin pen devices are immediately returned to the patient-specific location after each use
16	Ensure that pen needles are stored along with the pen device in patient-specific location or easily accessible location
17	Ensure that a sufficient supply of insulin pen needles is available on the unit
<i>Administering</i>	
18	At the time of barcode scanning, provide a prominent warning to the health professional if there is a mismatch between the patient’s identification wristband and the patient-specific (insulin pen) pharmacy label: <ul style="list-style-type: none"> • Warning: Do not administer” • “Mismatched patient” or “Incorrect patient” • Suggested steps to correct the error
19	Indicate on the medication administration record, “Warning! Confirm patient. Insulin pens are for use in one patient only.”
20	Ensure that pens are cleaned prior to and after each use
21	Ensure that health professionals use the appropriate administration technique for insulin pens
22	Ensure that health professionals prime the insulin pen prior to administration
23	Ensure that health professionals hold the pen device against the skin for at least 5 seconds after injection is given
24	Use safety pen needles
25	Ensure that health professionals remove the pen needle from the pen device after medication administration
26	Prohibit the withdrawal of insulin from the pen cartridge using a syringe and needle
<i>Policies and Procedures</i>	
27	Have hospitalwide policies and procedures for administration of insulin using insulin pen devices

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Table 2. Best Practices for Safe Use of Insulin Pen Devices in Hospitals and Health Systems^a

Item No.	Statement: To ensure the safe use of insulin pen devices, hospitals and health systems should . . .
28	Have a systematic and standardized process for educating health professional staff regarding <ul style="list-style-type: none"> • Insulin pen use for all new nurse hires • Appropriate insulin pen injection technique • One patient, one pen (per CDC and SIPC campaign)
29	Require all health professionals to pass a competency assessment for insulin pens (at the time of hire and periodically thereafter)
<i>Monitoring, Planning, and Evaluating</i>	
30	Regularly monitor/observe insulin pen use, including dispensing procedures, storage areas, and medication administration
31	Use a detailed checklist to perform direct observations of injection technique
32	Develop a system to prompt the proper disposal of insulin pens when the order is discontinued
33	Pilot test an order-specific and patient-specific barcode medication administration system to ensure that insulin pens are used in the intended patients prior to hospitalwide implementation
34	Conduct a failure mode effects analysis for insulin pen use
35	Review barcode medication administration scanning reports to ensure appropriate insulin pen use and detect inappropriate use

^aCDC = Centers for Disease Control and Prevention, SIPC = Safe Injection Practices Coalition.

be stored along with the pen device or in another easily accessible location so that a sufficient supply of pen needles is readily available. Having easy access would ensure that insulin is given in a timely manner and clinicians would resist the temptation to take needles from another patient's supply.

As with insulin vials, there is a risk that insulin pen devices can be used for the wrong patient; thus, the provision of prominent alerts to the healthcare professional during the barcode scanning process is a critical safety feature. If there is a mismatch between the patient's identification wristband and the patient-specific pharmacy label on the pen, an alert—for example, "Warning: Do Not Administer," "Mismatched Patient," or "Incorrect Patient"—should be triggered. Critically examining "near misses" is another best practice.

When administering insulin using pen devices, healthcare professionals should ensure that they use the appropriate administration technique to prevent infection and ensure the

delivery of the correct dose. Recommended steps include

1. Cleaning the pen device prior to and after each use,
2. Attaching a new safety pen needle to the pen device prior to use,
3. Priming the pen prior to use,
4. Holding the pen device against the skin for at least five seconds after the injection is given, and
5. Removing the pen needle from the device after each use.

Withdrawal of insulin from the pen cartridge using a syringe and needle should be prohibited.

Adopting hospitalwide policies and procedures for the safe use of insulin pen devices is another best practice. These policies and procedures should include a system to prompt the proper disposal of insulin pens when the order is discontinued. All healthcare professionals should successfully complete a competency assessment for safe insulin pen use at the time of hiring and periodically thereafter. An interprofes-

sional team should be established, and creating a standardized process for educating staff about insulin pen use, including appropriate insulin pen injection technique, should be among its goals. The CDC and Safe Injection Practices Coalition One and Only campaign might be part of this educational process.²¹

Prior to an institutionwide rollout of new policies and procedures for insulin pen devices, clinicians should pilot test a system of order- and patient-specific barcoding to ensure that pens are used in the intended patient and a root-cause analysis is conducted for all potential errors. In addition, a failure mode effects analysis (FMEA) should be conducted prior to widespread adoption of insulin pens in a hospital. This FMEA will facilitate the identification of potential problems by examining the effects of all potential failures and providing opportunities to make recommendations to eliminate or reduce failures and mitigate the risks. In addition, it is important to monitor actual performance by directly observing the dispensing,

Table 3. Best Practices for the Safe Use of Insulin in Hospitals and Health Systems

Item No.	Statement: To ensure the safe use of insulin, hospitals and health systems should . . .
<i>Ordering</i>	
1	Require the use of order sets when prescribing insulin
2	Create order sets for insulin that have the following components: <ul style="list-style-type: none"> • Algorithm for initial dose • Algorithm for correctional dose • Timing of administration • Blood glucose monitoring timing and frequency • Hypoglycemia management • Circumstances under which basal insulin can be withheld • Circumstances under which prandial insulin can be adjusted or withheld
3	Clearly display the units per mL in the computerized prescriber-order-entry product description
4	With the exception of the dose, not allow prescribers to “free text” an insulin pen order
<i>Labeling and Dispensing</i>	
5	Not print the dose on the pharmacy label, because the dose may change during the patient’s stay
6	Store pharmacy stock of insulin (including pens) in clearly labeled individual locations (e.g., carousels) that differentiate each insulin pen by type
<i>Administering</i>	
7	Have date, time, and last (actionable ^a) blood glucose measurement visible in the electronic medication administration record
8	Have policies and procedures regarding insulin administration times, including how to coordinate the administration of insulin at meal times
9	Use an electronic medication administration record that automatically records the administration event when triggered by barcode scan and then prompts the nurse to enter the number of units administered and the site of administration
<i>Monitoring</i>	
10	Ensure that all patients receiving insulin have their blood glucose checked, at a minimum, three times daily before meals or every 6 hours depending on eating status
11	For patients using rapid-acting insulin, have health professionals monitor the patient’s nutritional intake
<i>Policies and Procedures</i>	
12	Have one set of policies and procedures for monitoring patients who are receiving insulin regardless of drug delivery system
13	Appoint a hyperglycemia control committee (consisting of physicians, endocrinologists, hospitalists, nurses, advanced nurse practitioners, pharmacists, physician assistants, dietitians, certified diabetes educators, information technologists, and patients): <ul style="list-style-type: none"> • That regularly monitors the use of insulin/insulin pens and provides feedback to the health professional staff • To develop standardized order sets
14	Have a systematic and standardized process for educating health professional staff regarding: <ul style="list-style-type: none"> • The time–action profile of insulins on formulary • The management of hypoglycemia • The timing of blood glucose monitoring
15	Review blood glucose readings less than 40 mg/dL
16	Review the use of dextrose 50% injection, oral glucose, and other measures to reverse hypoglycemia
17	Review interventions ordered for the management of hypoglycemia

^aAn actionable blood glucose reading is one that has been obtained within an appropriate time window prior to insulin administration. For rapid- or short-acting insulin, a 30-minute time window is appropriate. If the blood glucose measurement was obtained more than 30 minutes prior to insulin administration, it should be repeated.

Table 4. General Best-Practice Statements to Ensure Safe Use of Medications in Hospitals and Health Systems

Item No.	Statement
1	Limit the formulary of available options that can be prescribed
2	Permit pharmacists to automatically convert medication orders to the authorized formulary option(s)
3	Require the use of computerized prescriber order entry
4	Develop a system of communication during patient transfers explicitly indicating that the medication order is to be continued (or discontinued)
5	Automatically alert prescribers of potential therapeutic duplications
6	Use pharmacy labels that when removed from the product leave evidence that the patient-specific label has been removed (i.e., tamper-evident labels)
7	Ensure that all medications are labeled only by pharmacy staff
8	Require pharmacy staff to sequentially scan the manufacturer's barcode and patient-specific pharmacy label to confirm that the correct product is being dispensed
9	Ensure that all information on the pharmacy label is visible and easily read (e.g., font is sufficiently large, label folding does not impair readability)
10	Have clear policies and procedures for the uniform storage of medications throughout the institution
11	Do not store medication in a patient's room, unless it is in a secured, locked area (e.g., medication box or drawer)
12	Ensure that medications are stored in such a location that allows nursing staff to administer doses in a timely manner
13	Ensure that all medications are stored in a secure location
14	Prohibit storage of a patient's home medications in the patient care area, unless there is an active order to use the patient's home supply
15	(If the patient is willing and able) have the patient verify his/her name and have the health professional state the name of the medication prior to administration so that the patient can serve as a double check
16	Scan the patient's identification wristband and the patient-specific pharmacy label immediately prior to administration
17	Have a "red rule" (a rule that should not be broken) that requires barcode scanning prior to medication administration
18	Ensure that health professionals are following the "six rights of medication administration"
19	Require immediate review of dosing errors
20	Create methods to collect clinical outcome data and routinely determine if quality-improvement measures are necessary
21	Encourage health professionals to report concerns, near misses, and medication errors through a secure, nonpunitive, anonymous system
22	Perform root-cause analysis of near misses, medication errors, and problems discovered during audits
23	Mandate an institutional committee review of all adverse events and medication errors
24	Perform drug-use evaluations
25	Review published research data to determine medication safety concerns and effective interventions

storage, and administration of insulin in pens using detailed checklists. Direct observation is critical to ongoing quality-improvement efforts. Reviewing barcode-assisted medication administration scanning reports for insulin pens is also important to identify and address potential problems.

Several of the expert panel recommendations constitute best practices for ensuring the safe use of insulin in hospitals but are not specific to insulin pen devices (Table 3). Although some of these recommendations have been made previously,²² recommendations unique to our expert panel include documenting the insu-

lin concentration (in units per milliliter) in the CPOE product description. This recommendation is particularly important because new concentrated insulin pens (e.g., U-200, U-300, U-500) recently became available and are widely used.

The panel strongly believed that the dose of insulin should not be

printed on the pharmacy label because of the high likelihood of frequent changes during a patient's hospital stay. When insulin—including insulin pen devices—is stored in the pharmacy, each insulin type should be placed in a separate, clearly labeled location such as a carousel with separate compartments.

To reduce insulin administration errors, the panel recommended displaying the date, time, and results of the last actionable blood glucose measurement in the electronic medication administration record (eMAR) prior to administration of a dose. This strategy would prevent the nurse from administering an insulin dose to a patient who is hypoglycemic and prompt a correctional insulin dose for a patient who is hyperglycemic. An actionable blood glucose measurement is one that is within a prespecified range at an appropriate time interval prior to the insulin dose. The expert panel reiterated the need for policies and procedures that provide guidance regarding the coordination of insulin administration at mealtimes. Ideally, an eMAR that automatically records the event when triggered by the barcode scan and prompts the nurse to enter the number of units administered and the site of administration should be used.

Monitoring is essential in any quality-assurance process. All patients receiving insulin should have their blood glucose concentration checked a minimum of three times daily before meals or every six hours, depending on nutritional intake. Healthcare professionals should review each patient's nutritional status and the last actionable blood glucose measurement prior to injecting a rapid- or short-acting insulin. Consistent with previous best-practice recommendations, our expert panel recommended creation of a hyperglycemia control committee consisting of healthcare practitioners (physicians, endocrinologists, hospitalists, nurses, advanced nurse practitioners, pharmacists, physician

assistants, dietitians, certified diabetes educators, and information technologists) and patients to monitor the use of insulin and insulin pens and provide feedback to the health professional staff.²² This hyperglycemia control committee should also be responsible for developing and maintaining standardized order sets for insulin use.

Although the Delphi consensus development process is considered rigorous for reaching consensus about best practices when empirical data are lacking, the technique is not without uncertainties. A lack of standards for selecting the expert panel, determining the optimal panel size and response rate, and defining consensus are possible shortcomings of the use of the Delphi process.^{25,26,28} Although standards for selecting panelists are not available, individuals who are invited to participate in a Delphi consensus panel should be perceived to be knowledgeable, experienced, and credible by the intended audience.^{26,28} Our panelists included directors of pharmacy operations, clinical pharmacists, frontline nurses, nursing managers, hospitalists, endocrinologists, and safety officers with extensive training and knowledge of insulin use and experience with patient safety initiatives (appendix).

Most studies employing the Delphi technique have between 15 and 20 expert panelists.^{28,29} A panel size of 10–15 is considered adequate if the members have similar knowledge and experience.²³ Our goal was to have 12–15 participants on our panel, with at least 11 members participating in each round. A minimum response rate of 70%, which was attained in all four rounds of our study, has been recommended to uphold the rigor of the Delphi method.³⁰ We employed several follow-up strategies and provided a modest honorarium to foster a high response rate. Panelists were motivated to participate due to their interest in the subject and the study outcomes. Although we attempted to convene an

interprofessional panel with strong experience and high credibility, we acknowledge that many other experienced and well-informed individuals with different yet equally worthy insights, sentiments, and opinions were not invited to participate or included in the process.

To date, there are no empirically validated standards for what constitutes consensus. Several methods of establishing whether a consensus has been achieved have been described.^{25,26,28} In most Delphi studies, the investigators prospectively establish a specific threshold percentage for agreement among the panelists, typically ranging from 51% to 100%.²⁵ Alternatively, the investigators can examine the consistency of responses across the rounds of the Delphi process.²⁶ In our study, consensus was reached when there was agreement among more than 75% of the panelists.

Conclusion

The 35 best-practice recommendations for the use of insulin pen devices in hospitals and health systems made by the expert panelists in this study are actionable and feasible. Hospitals and health systems can translate these recommendations into practice, professional healthcare organizations can disseminate and endorse them, and consumer groups can use them in quality assessments. Follow-up research is needed to evaluate the impact of these recommendations on patient safety.

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Disclosures

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Appendix—Expert panelists

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Facilitating the safe use of insulin pens in hospitals through a mentored quality-improvement program



Supplementary material is available with the full text of this article at www.ajhp.org.

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Purpose. Results of the MENTORED QUALITY IMPROVEMENT IMPACT PROGRAMSM (MQIIP) on Ensuring Insulin Pen Safety in Hospitals, which was part of an ASHP educational initiative aimed at ensuring the safe use of insulin pens in hospitals, are described.

Methods. During this ASHP initiative, which also included continuing-education activities and Web-based resources, distance mentoring by pharmacists with expertise in the safe use of insulin pens was provided to interprofessional teams at 14 hospitals between September 2014 and May 2015. The results of baseline assessments of nursing staff knowledge of insulin pen use, insulin pen storage and labeling audits, and insulin pen injection observations conducted in September and October 2014 were the basis for insulin pen quality-improvement plans. Postintervention data were collected in April and May 2015.

Results. Compared with the baseline period, significant improvements in nurses' knowledge of insulin pen use, insulin pen labeling and storage, and insulin pen administration were observed in the postintervention period despite the relatively short time frame for implementation of quality-improvement plans. Program participants are committed to sustaining and building on improvements achieved during the program. The outcome measures described in this report could be adapted by other health systems to identify opportunities to improve the safety of insulin pen use.

Conclusion. Focused attention on insulin pen safety through an interprofessional team approach during the MQIIP enabled participating sites to detect potential safety issues based on collected data, develop targeted process changes, document improvements, and identify areas requiring further intervention. A sustained organizational commitment is required to ensure the safe use of insulin pen devices in hospitals.

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Hyperglycemia affects 38% of hospitalized patients, including 12% with no known history of diabetes mellitus.¹ 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.^{2,3} Hyperglycemia has been linked to increased morbidity (e.g., wound infection) and mortality in hospitalized patients.^{2,4,5} Prolonged hospital stays,

increased likelihood of admission to an intensive care unit, and increased healthcare costs also are associated with inpatient hyperglycemia.^{2,4,5}

Insulin is preferred over other types of antihyperglycemic medications for the management of hyperglycemia in the hospital setting with or without the diagnosis of diabetes mellitus.⁴ Authoritative guidelines and consensus statements from the Endocrine Society, American Association of Clinical Endocrinologists,

American Diabetes Association, and American College of Endocrinology advise against the use of noninsulin therapy for most hospitalized patients with type 2 diabetes.^{4,6-8} Insulin is required for patients with type 1 diabetes.

In the inpatient setting, insulin administration via the intravenous route is recommended for critically ill patients and via the subcutaneous route for the noncritically ill, with basal, nutritional (i.e., prandial), and correctional doses.⁷ Insulin may be administered subcutaneously using either an insulin syringe and vial or a pen injector device. Insulin pens were introduced in the 1980s, became popular in the ambulatory care setting, and now are commonly used in many hospitals.⁹ Insulin pens have several perceived advantages compared with traditional vials and syringes in inpatient and outpatient settings, including improved dose accuracy, satisfaction with and preference by both patients and healthcare providers, convenience and ease of administration, and, in some scenarios, less cost and waste.^{2,10-14}

As important and effective as insulin is in the inpatient management of hyperglycemia, insulin has been identified by the Institute for Safe Medication Practices (ISMP) as a high-alert medication associated with risk for patient harm.¹⁵ Although the risk for patient harm with inpatient use of insulin provided as an intravenous infusion or subcutaneous injection using traditional vials and syringes has long been recognized, the use of insulin pens in the inpatient setting has been associated with numerous recent reports of improper use and patient safety concerns. Reports have included technique-related concerns such as improper priming, failure to “tip and roll” suspensions, use of the pen as a multiple-dose vial, incorrect injection method, misinterpretation of fluid on the skin after an injection as delivery of a partial dose, needle-

KEY POINTS

- Safe and appropriate use of insulin pens in the hospital setting requires pens to be dedicated for use in a single patient only and correct administration technique.
- Direct observations and standardized data collection of insulin pen knowledge, storage and labeling, and injection technique provide valuable information for assessing the safety and appropriateness of insulin pen use.
- Interprofessional team efforts to evaluate and devise strategies to improve insulin pen use have the potential to improve patient safety.

stick injury, and the potential for blood-borne pathogen transmission if insulin pens are used intentionally or inadvertently in more than one patient.^{11,16-29}

In response to reports of insulin pen misuse in more than one patient, the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) issued communications intended to notify healthcare professionals and the public about the potential for transmission of hepatitis B and C viruses, HIV, and other blood-borne pathogens, with recommendations for mitigating the risk of misuse.^{30,31} An expert consensus panel convened by the ASHP Research and Education Foundation identified 10 practical recommendations to enhance insulin-use safety throughout the medication-use process in hospitals.³² This document recommended the development of policies and procedures to ensure the safe use of insulin pens and disposable needle tips, including the use of pens

for only one individual, and recognized that technology solutions are needed to ensure that insulin pens are not used for more than one patient. These recommendations were recently expanded, and a list of best practices for safe insulin pen use based on the consensus of an expert panel has been published.³³

ISMP has issued numerous newsletters describing the perceived benefits of and potential safety concerns associated with inpatient insulin pen use, consistently urging health systems to ensure that safety measures are established and clinical staff education is provided.^{16,34-38} Citing ongoing reports of misuse despite clinical staff education and system safety measure implementation, ISMP has suggested that the most effective strategy to mitigate patient risk due to insulin pen sharing would be for hospitals to transition away from the routine inpatient use of insulin pens.^{39,40} More recently, insulin pen formulations for insulin regular U-500 and other concentrated insulins have been approved by FDA. For these insulins, the availability of pen formulations mitigates unique safety concerns related to correct dose measurement in both the ambulatory care and inpatient environments, though recent FDA approval of a U-500 syringe to replace the use of tuberculin and U-100 insulin syringes will also help mitigate safety concerns related to correct dose measurement of U-500 insulin regular from multiple-dose vials.⁴¹⁻⁴³ For hospitals that may be transitioning away from routine inpatient use of insulin pens, ISMP provided a review of potential safety concerns with the use of insulin vials and syringes, as well as safe-use recommendations to reduce the risk of errors.⁴⁴

ASHP Advantage conducted a multifaceted quality-improvement initiative, Strategies for Ensuring the Safe Use of Insulin Pens in the Hospital, to provide practitioners with the information needed to advocate for best practices in the use of insulin pens

in the hospital setting. Designed for practitioners who work in hospitals that use insulin pens to administer insulin to inpatients, the initiative provided education and practical tools and strategies to facilitate the safe and appropriate use of insulin pens in the hospital setting using a team-based approach. One component of the initiative was a quality-improvement program for insulin pen safety that included distance mentoring for health professionals at selected hospitals. This article describes and reports the results of the MENTORED QUALITY IMPROVEMENT IMPACT PROGRAMSM (MQIIP) on Ensuring Insulin Pen Safety in Hospitals.

Methods

In 2014, a four-member steering committee of experts in insulin safety and outcomes measurement was convened to design and provide guidance on the development of a multifaceted quality-improvement initiative. Appendix A lists the components of this initiative. The Beaumont Research Institute institutional review board determined that, as designed, the MQIIP was not considered human subject research.^{45,46}

Components of the MQIIP included participation in two webinars regarding insulin pen safety and a series of four mentored telephone calls that included Web-based screen sharing, the collection of baseline and postintervention data for three outcome measures, and the implementation of process improvements after the review of baseline data (Figure 1). Distance mentoring of participating interprofessional teams was provided by pharmacists with expertise in glycemic control and medication safety and experience in using pen devices for insulin delivery within their hospitals. There was no charge for participating in the MQIIP or any other components of the initiative.

Resources for insulin pen safety were developed by the steering committee and made available on a

website for the multifaceted quality-improvement impact initiative (www.onepenonepatient.org) for use by the public, as well as sites selected to participate in the MQIIP to support development of improvements in insulin pen safety. The website includes links to primary literature and other key information and recommendations from FDA, CDC, and ISMP related to the appropriate use of insulin pens. A toolkit was also created, including sample policies and procedures, assessment tools, newsletters, an interactive video tool, and other educational resources related to safe practices for the use of insulin pens in hospitals. Some of these materials were designed to allow for customization for use within a health system. Procedural information and data collection forms for the three outcome measures to be used by selected sites participating in the MQIIP were also provided.

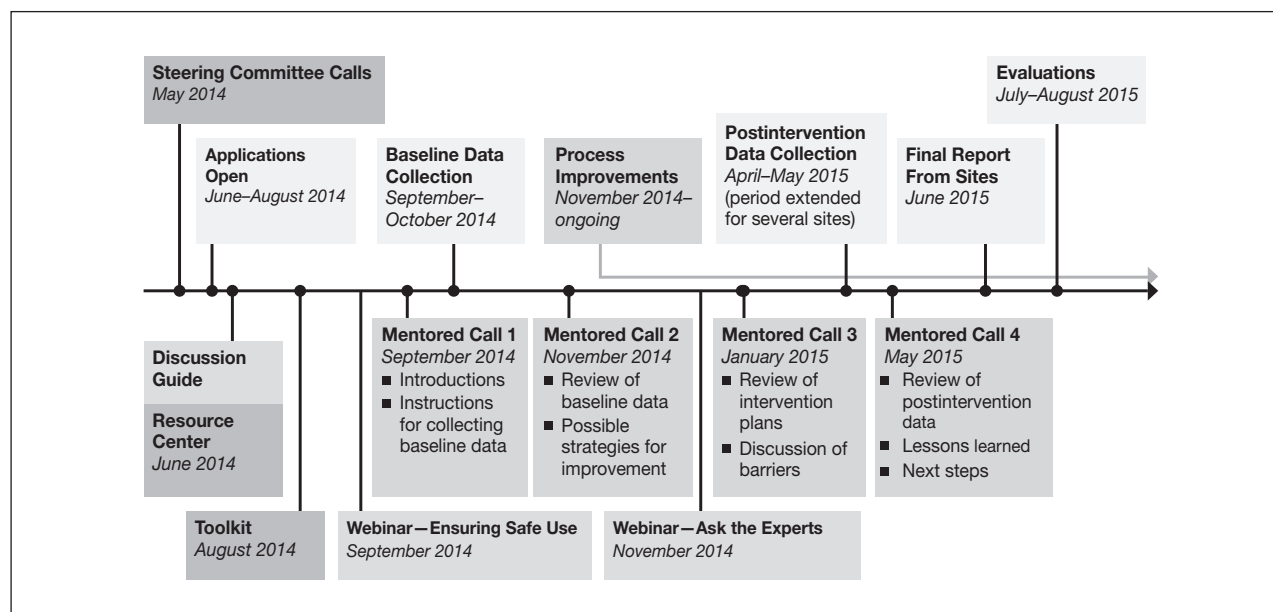
A nationwide call for applications for the MQIIP was made via e-mails to ASHP members, online advertisements on the ASHP website, and announcements in an ASHP e-newsletter. As part of the online application, applicants were required to name an interprofessional team of healthcare providers and managers, such as physicians, pharmacists, and nurses. A total of 21 completed applications were received. From the resulting pool of applicants, 15 hospital sites were selected to participate based on the steering committee's assessment of key selection criteria. These criteria included evidence that the site had a supportive administrative climate to make practice changes, a team with an appropriate mix of individuals in key positions, adequate personnel and technology resources to collect observational data and distribute an online questionnaire to inpatient nursing staff, and the potential to benefit from participation based on current insulin pen use. Team leaders from each site were notified of their selection to participate in the program.

Three pharmacists from the steering committee served as mentors for selected hospital sites, with five hospitals assigned to each mentor. The assigned ratio of one mentor to five sites was chosen to allow for meaningful interactions throughout the MQIIP. Before the first formal meeting between mentors and teams, team members were encouraged to attend a live continuing-education webinar (or participate in an archived version made available shortly thereafter) that provided background information on ensuring the safe and appropriate use of insulin and insulin pens in the hospital setting.

Outcome measures and data collection methods. The outcome measures and methods selected for the program included a survey of nursing staff knowledge about insulin pens using an online questionnaire, insulin pen storage and labeling audits, and insulin pen injection observations. (The nurse questionnaire and data collection forms are available as supplementary material with the full text of this article at www.ajhp.org and at www.onepenonepatient.org/toolkit.) The goal was to determine whether clinicians who are engaged in the medication-use process successfully safeguard patients by properly labeling and storing insulin pens, use the pens in accordance with manufacturer-recommended injection techniques, and adopt strategies to limit the use of each pen to only one patient. For these outcome measures, uniform processes were established and data were collected in a systematic manner during the baseline and postintervention periods.

Nurse questionnaire. A brief online questionnaire designed to assess nursing staff knowledge about insulin pens was developed. In addition to collecting general demographic information about roles and responsibilities related to medication use, the questionnaire addressed declarative and procedural knowledge of in-

Figure 1. Flow diagram of MENTORED QUALITY IMPROVEMENT IMPACT PROGRAMSM on Ensuring Insulin Pen Safety in Hospitals.



insulin pharmacokinetic profiles, clinical situations associated with a high risk of hypoglycemia, the perceived benefits and risks of insulin pen use in hospitals, the proper use of insulin pens in accordance with manufacturer recommendations, and the storage of insulin pens in appropriate locations. During this assessment, nurses were asked to watch three videos that simulated a health professional administering insulin to a patient using a pen device. Respondents were asked to identify steps in the medication administration process that were performed incorrectly. The questionnaire was customized to reflect the most commonly used rapid-acting and basal insulins at each hospital site. The questionnaire also asked about potentially unsafe medication-use practices that had been witnessed in the preceding three months.

During both the baseline and postintervention periods, each participating hospital received an Internet hyperlink from ASHP Advantage to the questionnaire created in and hosted by Qualtrics online survey

software (Qualtrics LLC, Provo, UT). Sites were responsible for distributing the questionnaire to all inpatient nursing personnel. During both survey periods, ASHP Advantage provided weekly updates regarding the number of respondents to encourage survey participation. The questionnaire data were compiled by ASHP Advantage, and a site-specific report was provided to each participating team and mentor.

Insulin pen storage and labeling audit. The storage and labeling of insulin pen devices were audited at the participating sites during the baseline and postintervention periods. Sites were asked to make at least 60 total observations (20 or more from each of three different patient care units where insulin pen devices were commonly used) during each observation period using the provided data collection form. If needed to reach the total of at least 20 observations on each patient care unit, audits could be repeated on multiple days but could not be repeated on the same unit on the same day.

Participants were asked to find all insulin pens on the audited units, regardless of whether there was an active order, including pens without an appropriate label. Detailed procedural instructions for conducting the audit were provided to each team and summarized briefly on the data collection form.

Auditors from participating interprofessional teams, including any team leader-trained auditors, were instructed to obtain a report from the pharmacy department with the names of all patients on the patient care unit who had an active order for an insulin pen. In addition to looking in the hospital-approved insulin pen storage locations on each unit, auditors were encouraged to ask nursing staff for assistance in locating a pen if it was not found in the usual hospital-approved storage location. An example of an appropriate storage location would be a patient-specific location, not comingled with medications for other patients. If a patient had an active order and the insulin pen could not be located, “not found” was recorded in the stor-

age per hospital policy column on the data collection form. Auditors were encouraged to check elsewhere on the patient care units, such as mobile medication carts, drawers and cabinets in patient rooms (with unit nurse assistance, where appropriate), nursing stations, and medication storage rooms, to determine if leftover or expired insulin pens were stored in unapproved locations.

For this audit, a pen was considered properly labeled if three conditions were met: (1) the pen was labeled with a patient-specific identifier, (2) the label was attached to the pen barrel, and (3) the expiration date was clearly stated on the label. If a pen was found unlabeled, the designation “unknown” was used for the patient’s initials on the audit form.

Insulin pen injection observations. The administration of insulin to patients using insulin pen devices was directly observed at the participating sites during both the baseline and postintervention periods. The insulin pen injection observation form used to record findings was an 18-step checklist developed by the steering committee. The checklist included storage and labeling procedures, hand hygiene requirements, insulin pen preparation steps, and administration instructions in accordance with the FDA-approved product labeling. If a step was performed as described and in the appropriate sequence, “yes” was documented (meaning it was observed) on the checklist. If a step was not performed as described or performed at a clearly incorrect time during the sequence, “no” was marked. Because there is some flexibility in the sequence in which steps may be performed appropriately, the observer exercised judgment. If an observer did not witness the nurse performing one or more steps because the observation began after the nurse had started to prepare the insulin for use or the observation was terminated before all steps were completed, “not observed” was documented on the

form. Observers recorded “not applicable (n/a)” for any step that was not relevant under the circumstances (e.g., the pen is not expired, so no replacement is needed).

Sites were asked to observe at least 45 injections (15 or more from three different patient care units where insulin pens were commonly used) during each observation period. Sites were instructed that the observations must be made from three different patient care areas during prespecified time frames when insulin administration is most common (e.g., before breakfast, before lunch, before dinner, and at bedtime) and that the number of observations in each patient care area and during each time frame should be similar. Sites were asked to make at least 8 observations during each mealtime time frame, with no minimum for the bedtime time frame. Sites were instructed to conduct observations in the same three patient care areas during the baseline and postintervention periods, with reasonably similar distributions of times and numbers of observations.

Instructions were provided to the observers to ensure a uniform approach when interacting with the nursing staff and conducting observations on patient care units. Observers were instructed to obtain permission from the nurse manager and to explain that “medication administration procedures” were being audited for quality purposes. Observers were advised not to tell the nurse manager that insulin pen use was being audited. Observers obtained a report from the pharmacy department with the names of all patients on the patient care unit who had an active order for an insulin pen. Observers then determined which patients were likely to have an insulin dose administered during the observation time frame (e.g., if the audit was being conducted at bedtime, observers identified which patient orders included a bedtime dose). Upon identification of the nursing staff responsible for

administering insulin to identified patients, observers asked to observe him or her administering medications, once again in the context of an audit of “medication administration procedures” without specific mention of insulin pen use.

Audit results for the insulin pen storage and labeling and the injection observations were entered by participating institutions into an online data management tool developed by ASHP Advantage. Each site could generate a hospital-specific report with results from the baseline and postintervention periods.

Mentored calls and process improvement plans. Between September 2014 and May 2015, team leaders and members, and at some sites pharmacy students and residents, participated in a series of four mentored telephone calls. The mentored calls were scheduled at critical times to support progress during and after completion of the MQIIP (Figure 1). The calls were conducted using a Web-based tool that allowed real-time sharing of the presenter’s computer screen, and all lines were unmuted to allow participants to ask questions and share ideas. The objectives of the first mentored call included welcoming teams to the program, learning about each site’s experiences with inpatient use of insulin pens and motivation for participation in the program, and reviewing the overall planned program structure. Because the baseline data collection period began shortly after the first mentored call, the outcome measures and data collection tools and methodologies were also reviewed in detail.

Upon completion of the baseline data collection period for the three outcome measures, the second of four mentored calls occurred during the first week of November 2014. Individual hospital teams were encouraged to review and become familiar with their site-specific baseline data in advance of the second mentored call. The goal of this second call was

for each mentor and their five participating sites to collectively discuss potential insulin pen safety risks based on baseline data and devise strategies to address the risks. Each hospital team would then be responsible for incorporating these strategies into the development of site-specific insulin pen process improvement plans by early January 2015.

At the beginning of the second mentored call, mentors established that the call format would be interactive, with open and honest discussion of baseline data in a “judgment-free zone.” Although aggregate findings rather than site-specific results were discussed by mentors during the call, team members were encouraged to (and did) share their experiences, including both positive and negative ones and those of the greatest value and interest. In addressing individual safety risks and areas identified as opportunities for improvement, both mentors and team members described their experiences and the effectiveness of various strategies for reducing risk.

Resources on the initiative website supporting the identification, development, and implementation of insulin pen process improvement strategies were reviewed during the second

mentored call. Strategies included those intended to prevent sharing of insulin pens by more than one patient in hospitals, as well as those intended to monitor administration to confirm insulin pen injections in the correct patient. Team members were also strongly encouraged to take advantage of the continuing-education activities that were developed as part of the initiative.

A third mentored call took place in mid-January 2015 to answer questions and discuss any challenges in implementing process improvement plans. The upcoming postintervention data collection period (April 1–May 1, 2015) was also discussed.

The fourth and final mentored call occurred in mid-May 2015. During this call, participating teams provided a recap of their site-specific action plans and items implemented from those plans. Based on the comparison of site-specific postintervention and baseline data and other experiences, teams shared lessons learned and discussed ideas for how to sustain and build on insulin pen safety efforts, as well as address remaining challenges. Mentors outlined instructions for the preparation and submission of a brief report summarizing site-specific involvement

in the MQIIP. Each team submitted a final report that provided an overview of process improvements implemented, selected results, lessons learned, and anticipated next steps in ongoing efforts to maintain and further improve the safety of inpatient insulin pen use. After final reports were submitted, team leaders were asked to complete an online evaluation of the MQIIP in July 2015.

Data analysis. Data were aggregated from all participating sites. Results for the baseline period were compared with the postintervention period using the chi-square test, with a priori levels of significance of 0.05 for the insulin pen storage and labeling audit and of 0.01 for the nurse knowledge and assessment survey and insulin pen injection observations, which contained multiple outcome measures, to avoid Type I statistical errors.⁴⁷

Results

A total of 15 sites were selected for inclusion in the MQIIP. There was no systematic method of assigning sites to mentors, although 5 sites with the same electronic medical record system were assigned to a mentor familiar with that system. Fourteen sites successfully completed all program components (Appendix B). One hospital team withdrew from the program after the baseline data collection period but before action plan implementation because of a decision by the health system to use insulin vials and syringes instead of pens, aligning with other hospitals within the health system. Demographic and outcomes data included in this report are from the 14 sites that completed the program.

The type and size of participating hospitals varied, and all but 1 site was part of a larger health system (Table 1). All sites had a pharmacist as the team leader, with nurses and pharmacists included on all 14 teams and comprising the majority of team members. Three teams included a

Table 1. Characteristics of Participating Hospitals (*n* = 14)

Characteristic	Number of Hospitals (%)
Hospital type	
Community hospital (nonteaching)	6 (43)
Academic health science center	4 (29)
Community teaching hospital	4 (29)
Number of inpatient beds	
<100	3 (21)
100–249	3 (21)
250–499	4 (29)
≥500	4 (29)
Affiliated with health system	
Yes	13 (93)
No	1 (7)

physician. The median team size was 6 members. On average, the team leader and 2.5 other team members participated in the mentored calls. The insulins most commonly available on formulary in pen form for inpatient use were insulin detemir, insulin aspart, and insulin glargine.

A summary of implemented insulin pen process improvement strategies was provided by each site in its final report and was made available on the initiative's website. Collectively, implemented insulin pen-use improvement strategies included the following actions: enhancing barcode scanning capabilities, establishing clinician double checks and computerized alerts, implementing policies and procedures for pen storage and labeling and insulin administration, and providing staff education and information (see box). After completion of the mentored program, each site team leader completed an online evaluation of the mentored program that captured information about selected insulin pen practices that were in place before and after participation in the mentored program (Table 2).

Outcome measures. The results and statistical analysis for each of the three outcome measures are outlined in Tables 3–5.

Nurse questionnaire. A total of 1539 nurse respondents completed the questionnaire (827 in the baseline period and 712 in the postintervention period, representing participation rates of 10.2% and 8.8%, respectively). Respondent characteristics were similar in the baseline and postintervention periods, with 92% reporting they were staff nurses responsible for direct patient care and 87% working 32 or more hours per week in each period. In the baseline and postintervention periods, respondents most commonly reported working the day shift (7 a.m.–7 p.m.; 53% and 52%, respectively), followed by the night shift (7 p.m.–7 a.m.; 40% and 36%, respectively). Significant changes in responses that reflected

Examples of Implemented Strategies for Improved Use of Insulin Pens

Implementing electronic health record-supported enhancements for insulin administration

- Barcode system enhancements to verify that insulin pen is for correct patient
- Electronic prompt for required double check by second nurse at time of administration
- On-screen alert for nurse to verify correct pen for patient

Establishing or revising policies and procedures

- Pen labeling
 - Patient-specific identifiers on label
 - Tamper-evident tape on pen barrel and cap
 - Beyond-use date on label
 - Label covered and secured to pen barrel with clear tape
- Pen storage on patient care units
 - Patient-specific storage location
 - Use of patient transfer and discharge reports to ensure that pens stored on units (and other medications) are removed promptly

Providing staff training, education, and information

- Inservice programs ("one on one," small groups, shift-change huddles, continuing-education presentations)
- Newsletters
- Online education modules
- Information posted on patient care units and/or hospital intranet (addressing appropriate insulin pen use, insulin time-action profiles)
- Competency and skills validations (i.e., upon hiring and annually)

improved knowledge of insulin and insulin pen use were seen in 5 of 14 items (Table 3). The greatest knowledge or skill gap perceived by nurse respondents included the time-action profiles of insulin products (i.e., time to onset, time to peak, and duration of each insulin product) and timing of injections.

Insulin pen storage and labeling audit. The storage and labeling of a total of 3468 insulin pens were evaluated (1876 in the baseline period and 1592 in the postintervention period). Observations recorded by audit personnel that represented unsafe storage practices included pens remaining in storage despite the patient no longer being on the patient care unit; storage of multiple patients' pens together in a nurse's pocket, on a counter, or in a storage bin; and the presence of multiple pens of the same insulin product labeled for the same patient. Observations of unsafe product labeling practices included pens with missing patient-specific labels, labels with missing or incor-

rect beyond-use date information, and labels that had been affixed to the removable pen cap rather than the barrel. Significant improvements were documented in three of the five measured outcomes after action plan implementation (Table 4). A reduction in the number of pens found on the patient care unit without an active order was also observed, but the difference was not significant ($p = 0.080$). The percentage of unlabeled pens identified on patient care units was significantly higher in the postintervention period compared with the baseline period (5.7% versus 3.9%, respectively; $p = 0.018$).

Observations of insulin pen injections. The process of insulin administration using a pen device was observed during more than 500 unique administrations in both the baseline and postintervention periods. There were numerical improvements in the postintervention period compared with the baseline period in every step of the process, with significant improvements documented in 8 of the

Table 2. Summary of Selected Insulin Pen Practices Before and After Participation in Mentored Program (*n* = 14)

Practice	Number of Hospitals				
	Before Mentored Program		During or After Mentored Program		
	Yes	No	Implemented New	Improved Existing	No Change
Policies and procedures addressing the safe and effective use of insulin pens in hospital	7	7	6	3	5
Patient-specific storage areas for insulin pens	13	1	1	8	5
Required education and competency assessment for nurses addressing insulin pen safety and injection technique	8	6	6	6	2
Ongoing education for nurses about time-action profiles for different types of insulin	8	6	6	8	0
Insulin pen label with barcode for specific patient	7	7	4	1	9
Ongoing plan to monitor barcode medication administration scanning reports to identify and address incidents that may indicate inappropriate pen use	7	7	3	3	8
Ongoing plan to conduct injection observations and pen audits to detect potential safety concerns	0	14	12	0	2

18 medication administration steps (Table 5).

Discussion

Process improvement plans.

Although all participating teams measured the same quality metrics, had the same access to pen safety resources and mentors, and shared the goal of improved safety of inpatient insulin pen use, the process improvement plans were unique to each institution. Conducting staff knowledge assessments and performing direct observations enabled each institution to identify the areas in need of greatest improvement.

Process improvement plans were created by analyzing baseline data and considering environmental factors (i.e., the type and number of insulin products provided in pen form, current policies and procedures for labeling and storage, information technology support for making changes to the electronic health record system, and resource and time constraints). Key themes for the most beneficial aspects of the MQIIP emerged from evaluations completed after conclusion of the program. These themes included the value of performing direct observations to identify practices in need of improvement and exchanging ideas among practitioners from different institutions and mentors during mentored calls.

Patient safety and error reduction strategies are not all equally beneficial; some types of actions may be more effective than others. ISMP has described a “rank order” of error-reduction strategies that lead to lasting system changes for improving safe medication use (Figure 2).⁴⁸ The highest ranked strategies are those that are most effective because they impact the overall care delivery system in which individuals operate. The lowest ranked and least effective strategies are rules, policies, and education that rely entirely on human vigilance and memory. Strategies employed by teams involved in the

Table 3. Assessment of Nursing Staff Knowledge of Insulin Pen Use

Survey Item (Correct Response)	Number of Respondents (%)		p
	Baseline (n = 827)	Postintervention (n = 712)	
Case-based questions about use of insulin			
Period of risk for hypoglycemia from long-acting basal insulin (selected best response)	30 (3.6)	85 (11.9)	<0.001 ^a
Identify the patient at greatest risk of developing hypoglycemia (selected best response)	502 (60.7)	450 (63.2)	0.318
Statements about use of insulin pen devices			
Pen devices should be primed prior to each and every use (true)	759 (91.8)	680 (95.5)	0.004 ^a
Pen device should be held against skin for 5–6 seconds after injection (true)	744 (89.9)	664 (92.3)	0.022
A drop of fluid after the injection indicates part of the dose has leaked (false)	449 (54.3)	449 (63.0)	0.010 ^a
Routine use of pen devices reduces the risk of infection transmission (false)	348 (42.1)	313 (44.0)	0.576
Pen devices lead to more dosing errors than vials + syringes (false)	804 (97.2)	699 (98.2)	0.313
Accurate identification of incorrect step performance in video			
Video 1: what step was not performed correctly? (best response: preparing device and needle for attachment)	406 (54.3)	419 (63.5)	<0.001 ^a
Video 2: what step was not performed correctly? (best response: priming pen device)	645 (86.6)	583 (88.9)	0.222
Video 3: what step was not performed correctly? (best response: administering insulin dose)	408 (55.0)	416 (63.6)	0.001 ^a
Affirmative response to witnessing item in past 3 months			
A pen device used on more than one patient	21 (2.5)	6 (0.8)	0.011
A pen device without a patient-specific label attached to it	95 (11.5)	99 (13.9)	0.166
A pen device stored in an unapproved location	157 (19.0)	162 (22.7)	0.020
Insulin withdrawn from an insulin pen cartridge with a syringe	28 (3.4)	20 (2.8)	0.662

^aRepresents statistically significant change ($p \leq 0.01$).

Table 4. Audit Findings of Insulin Pen Storage and Labeling Practices

Finding	Number of Pens Audited (%)		p
	Baseline (n = 1876)	Postintervention (n = 1592)	
Pens on unit not labeled	74 (3.9)	91 (5.7)	0.018 ^a
Pens on unit with no active order	136 (7.2)	91 (5.7)	0.080
Pens on unit not stored per hospital policy	244 (13.0)	150 (9.4)	0.020 ^a
Pens on unit not labeled properly	330 (17.6)	126 (7.9)	<0.001 ^a
Pens on unit labeled and stored properly	1324 (70.6)	1290 (81.0)	<0.001 ^a

^aRepresents statistically significant change ($p \leq 0.05$).

MQIIP included those from a variety of categories defined by ISMP.

Updated insulin pen policies and procedures as well as staff education about appropriate insulin pen use were the most common interventions made by participating hospitals in the MQIIP. Although these interventions alone are relatively low in error-prevention effectiveness, they help create a unified organizational understanding of expectations for safe practices and are necessary components of a comprehensive safety strategy.

Insulin pen labeling and storage practices in an inpatient environment play a key role in ensuring that insulin pens are used in only one (the intended) patient. Most participating sites implemented error-reduction strategies that improved pen labeling, storage, or both. Pen labeling and storage interventions directly impact the environment in which the nursing staff practice. The success of labeling and storage changes relies on nurse adherence to institutional policies and procedures for storage of insulin pens as well as verification of the patient and device before medication administration.

Reminders and redundancies were also implemented at participating hospitals to promote insulin pen safety. These included a computerized reminder to verify use of the correct pen and an electronic prompt requiring documentation by

a second nurse verifying the correct insulin, dose, and use of the proper pen for the specific patient. Although both interventions should occur during the administration of each insulin dose, they may not eliminate all errors because they often rely on humans to visually verify the dose, pen, and patient.

Some institutions implemented patient- and order-specific barcode scanning during the MQIIP to help ensure appropriate pen use. A primary example of a forcing function, this bedside barcode scanning verifies that the pen chosen for administration is linked to and used only for that specific patient. An electronic alert is generated for the nurse if there is a mismatch between the patient identification wristband and the patient-specific insulin pen label. The value of this strategy is that it is a targeted hard-stop function during the medication administration process that can intercept errors that would otherwise reach the patient. With patient- and order-specific barcode implementation, it becomes possible to monitor barcode medication scanning reports to confirm appropriate and inappropriate insulin pen administration practices, including near misses and possible injections using a wrong patient's pen.⁴⁹

Outcome measures. Although the ideal outcome when assessing insulin pen safety is a measurable

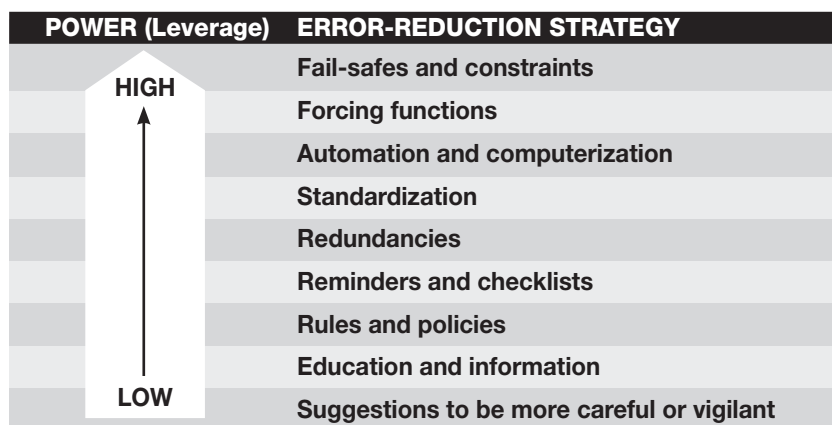
reduction in adverse effects related to improper use (e.g., hypoglycemia, blood-borne infections), it was not feasible to measure these outcomes through the MQIIP. The results for the three outcome measures collected during the program indicate that participation led to substantial improvements in the overall safety of inpatient insulin pen use. The nurse knowledge assessment demonstrated modest but significant improvements in many areas of knowledge about safe and correct insulin pen use. Compared with the baseline period, more nurses in the postintervention period knew that a pen device must be primed before each use and that the needle needs to be held in the skin for at least five seconds after the injection is given to ensure delivery of the entire dose. After participating in the program, more nurses were able to identify the steps during the insulin pen dose preparation and administration processes that were incorrectly performed. Although it is encouraging that fewer nurses reported observing a pen device used in more than one patient in the postintervention period compared with the baseline period (0.8% versus 2.5%, respectively), lack of improvement in some areas (e.g., a belief that routine insulin pen device use reduces infection transmission risk) indicates that knowledge deficits remain. Sustained gains in knowledge from educational initia-

Table 5. Steps Performed Correctly During Observed Insulin Pen Injections

Step	Fraction of Observations Performed Correctly (%)	
	Baseline	Postintervention
1. Retrieves insulin pen device from hospital-approved patient-specific storage area	455/479 (95.0)	494/507 (97.4)
2. Expiration is documented on label	473/521 (90.8)	544/551 (98.7)
3. Obtains replacement pen if expiration date is not documented or if expired ^b	34/69 (49.3)	25/28 (89.3)
4. Displays use of proper hand hygiene before patient contact	466/525 (88.8)	524/539 (97.2)
5. Performs patient identification (according to hospital policy)	497/530 (93.8)	532/547 (97.3)
6. Checks medication label	500/532 (94.0)	553/557 (99.3)
7. Scans the patient's identification band and the insulin pen barcode (prospectively, before administration) (when applicable) ^b	511/526 (97.1)	544/548 (99.3)
8. Mixes insulin by gently tilting pen device back and forth 8–10 times or rolling in palm of hands (isophane [NPH] insulin only) ^b	39/46 (84.8)	41/42 (97.6)
9. Swabs rubber stopper with alcohol swab	415/501 (82.8)	482/530 (90.9)
10. Attaches new disposable needle onto the pen	520/522 (99.6)	551/551 (100)
11. Primes pen before injection (e.g., dials 2 units on the dose selector; points needle up so that bubbles are forced to top, and firmly presses plunger until drop of insulin appears; repeat if needed until drop of insulin appears; if no drop appears after 6 attempts, changes pen device)	423/502 (84.3)	515/543 (94.8)
12. Dials correct dose (e.g., based on patient-specific order)	532/537 (99.1)	561/561 (100)
13. Selects appropriate injection site (e.g., abdomen, back of arm, thigh)	528/534 (98.9)	558/559 (99.8)
14. Pinches fold of skin ^c at the injection site, holds pen at 90° angle ^d to skin, and inserts pen needle all the way into the skin	498/527 (94.5)	526/549 (95.8)
15. Lets go of skin fold and injects the entire dose of insulin	469/520 (90.2)	501/542 (92.4)
16. Keeps plunger pressed and holds against the skin for at least 5 seconds after injection is given	470/525 (89.5)	515/553 (93.1)
17. Removes and discards needle in appropriate sharps container	508/512 (99.2)	559/559 (100)
18. Returns pen device to hospital-approved patient-specific storage area in a timely manner (e.g., within 15 minutes of injection or before giving medications to another patient)	440/470 (93.6)	503/520 (96.7)

^aRepresents statistically significant change ($p \leq 0.01$).^bNot applicable included as option.^cFor 31-gauge, 5-mm (3/16-in) needle, it is not necessary to pinch a skin fold.^dFor children or very lean patients, a 45° angle is permissible if 8-mm (5/16-in) or 12.7-mm (1/2-in) needle is used.

Figure 2. Rank order of error-reduction strategies. Adapted, with permission, from the Institute for Safe Medication Practices.⁴⁸



tives rely on an individual's ability to remember what was learned. Staff turnover is continual, and new staff must receive education. Accordingly, insulin pen education should be provided not only at the time of hiring but updated and repeated periodically to maintain knowledge gains.

While the response rate for the nurse knowledge assessment was not as robust in the postintervention period as in the baseline period (8.8% versus 10.2%, respectively), the response rate during both periods is respectable for this kind of survey. The typical response rate for an e-mail survey ranges from 5% to 15% and depends on the number of reminders and subject matter. Several participating hospital teams indicated that the timing of the postintervention questionnaire was close in proximity with other staff education and internal e-mail surveys.

Substantial improvements were observed in pen labeling during the MQIIP. Although a significant improvement was observed in the percentage of pens stored in the appropriate hospital-approved location on patient care units, the primary driver of the observed improvement

in pen labeling was a nearly 10% reduction in the incidence of pens not labeled properly (Table 4). Not all observed changes were favorable. The percentage of pens found on units with no label affixed was higher in the postintervention period compared with the baseline period. Failure to use a tape overlay on the label to affix it to the pen might have contributed to this finding. As part of one site's process improvement plan to begin using "smudge-proof" labels, the practice of applying a tape overlay to the label was discontinued. During the subsequent postintervention pen labeling audits, missing labels were more frequently observed and attributed to this practice. Hence, the practice of taping labels to the pen barrel was reinstituted at that site.

Although a significant improvement was observed in 8 of 18 steps in the medication-administration process using insulin pens (Table 5), factors contributing to a lack of significant improvement in some steps are noteworthy. The performance rate at baseline for 3 steps (steps 10, 13, and 17) was very high (98.9% or higher), leaving little room for improvement, and the postintervention perfor-

mance rates did not significantly differ from baseline. Although step 8 (mixing of isophane [NPH] insulin) was performed more often in the postintervention period, the increase was not statistically significant, most likely due to the small sample size (46 observations during the baseline period and 42 in the postintervention period).

The first three steps in the witnessed insulin pen injections represent steps related to labeling and storage. These steps were included in the insulin pen injection observations because the steering committee considered them part of the medication-use process, as medication administration traditionally begins with the retrieval of the pen device from a storage location. Thus, these data captured additional information regarding insulin pen labeling and storage.

Although the gains in performance rates observed for some medication administration steps (e.g., step 5: positive patient identification) may seem small and inconsequential, it is important to consider the high frequency of insulin administration and the large number of doses that are positively impacted by

small incremental changes in a large health system.

The results of the MQIIP are impressive given the relatively short time frame—less than six months—within which changes in insulin pen use practices were implemented. Many of the planned process improvements had not yet been implemented before the postintervention data collection period due to time constraints. There was a high level of commitment among study participants to sustain and build on improvements achieved during this initiative. All 14 sites plan to implement additional system changes and process improvements that were not feasible within the study time frame. Most sites have plans for ongoing monitoring of insulin pen use, either by periodically repeating outcome measure data collection using the methods described in this report or by implementing barcode scanning to identify incidents that may indicate inappropriate insulin pen use.

Although this MQIIP has concluded, the outcome measures described in this report and other resources at www.onepenonepatient.org remain available for use by interprofessional teams at other hospitals. These resources can be adapted and used to identify opportunities to improve the medication-use process involving insulin pens. The findings from institution-specific audits should be used as the basis for quality-improvement initiatives.

Conclusion

Focused attention on insulin pen safety through an interprofessional team approach during the MQIIP enabled participating sites to detect potential safety issues based on collected data, develop targeted process changes, document improvements, and identify areas requiring further intervention. A sustained organizational commitment is required to ensure the safe use of insulin pen devices in hospitals.

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Appendix A—Components of the Strategies for Ensuring the Safe Use of Insulin Pens in the Hospital initiative

Web-based resources

(www.onopenonepatient.org)

- Resource center
- Toolkit

Continuing-education programs

- Discussion guide: "Promoting Safe Use of Insulin Pens in the Hospital Setting"
- Live and archived webinar: "Ensuring the Safe Use of Insulin Pens in the Hospital: Role of the Pharmacist"
- Live and archived webinar: "Ask the Experts: Safe Use of Insulin Pens in Hospitals"

MENTORED QUALITY IMPROVEMENT IMPACT PROGRAMSM

- 10-month quality-improvement impact program using distance mentoring for 15 hospitals that use insulin pens

**Appendix B—Institutions
Participating in the 2014–
2015 MENTORED QUALITY
IMPROVEMENT IMPACT
PROGRAMSM on Ensuring
Insulin Pen Safety in the
Hospital**

Ashtabula County Medical Center,
Ashtabula, Ohio

Community Medical Center, Missoula,
Montana

CVPH Medical Center, Plattsburgh, New
York

Goryeb Children's Hospital, Morristown,
New Jersey

Indiana University Health Ball Memorial
Hospital, Muncie, Indiana

Kosair Children's Hospital, Louisville,
Kentucky

Magee Rehabilitation Hospital, Philadel-
phia, Pennsylvania

Mercy Hospital of Joplin, Joplin, Missouri

Munson Medical Center, Traverse City,
Michigan

Ochsner Medical Center, New Orleans,
Louisiana

Our Lady of Fatima Hospital, North
Providence, Rhode Island

ProMedica Bay Park Hospital, Oregon,
Ohio

St. Joseph's/Candler Health System,
Savannah, Georgia

UF Health, Shands Hospital, Gainesville,
Florida

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

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FL.

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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Safety concerns surrounding the use of insulin, a known high-alert medication, remain a focus of hospitals throughout the country.^{1,2} 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, sound-alike 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.³⁻⁷ 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-

ulin 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 PROGRAMSM (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 mix-ups (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 patient-specific 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 tech-

nician 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 high-alert 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 patient-specific 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 blood-borne 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 blood-borne 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 medical-surgical units, which were the pa-

tient 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 best-practice 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.¹ 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*, vancomycin-resistant *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 problem-solving 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. Medica-

tions 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 time-consuming 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.¹⁰ 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-

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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Building on a safety culture with transparency by participating in a mentored quality-improvement program for insulin pen safety

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Purpose. The experience at a medium-sized regional medical center participating in the ASHP MENTORED QUALITY IMPROVEMENT IMPACT PROGRAMSM (MQIIP) on Insulin Pen Safety in Hospitals is described.

Summary. With the support of top hospital leaders, Munson Medical Center (MMC) applied in June 2014 to participate in the MQIIP to complement its ongoing risk assessment related to the use of pen devices for insulin administration. Nurse knowledge deficits, problems with insulin pen storage and labeling, and improper insulin injection practices identified in baseline assessments for the MQIIP were the basis for process improvements, including new policies and procedures, an electronic alert and education for nurses, and individualized communication with pharmacy and nursing personnel about insulin pen safety. The experiences of other hospitals helped us identify solutions to safety issues and formulate communication strategies for improving insulin pen safety in our hospital. Awareness of the importance of insulin pen safety increased in all staff. Implementing these process improvements during the five-month intervention period resulted in increases in nurse knowledge and improvements in insulin pen storage, labeling, and injection practices, although problems persisted. Additional plans have been made to further enhance the safety of insulin use at MMC.

Conclusion. The ASHP MQIIP on Insulin Pen Safety in Hospitals provided a structured and supportive approach to identifying and addressing insulin pen safety issues at MMC. The insight gained through participation enabled us to devise strategies to communicate with staff about safety issues and improve the safety of insulin pen use in the institution.

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Munson Medical Center (MMC) is a 391-bed, nonprofit hospital that serves as a regional referral center and is the only level II trauma center in northern Michigan. MMC is the largest of nine Munson Healthcare System hospitals in the region. A magnet-designated hospital since 2006, MMC is nationally recognized for its superior quality of care and operational performance. The Cerner PowerChart electronic health record (EHR) and barcode medication administration with CareMobile software are used at MMC.

In 2009, the hospital switched from using traditional vials and sy-

ringes for insulin administration to insulin pens. Potential cost savings, greater convenience, enhanced patient teaching, and perceived improvements in safety and accuracy were factors involved in the decision to switch.¹⁻⁴ Formulary insulin products include insulin aspart (NovoLog Flexpen, Novo Nordisk, Denmark) and insulin glargine (Lantus Solostar pen, sanofi-aventis, Bridgewater, NJ), which constitute the majority of insulin use at MMC.

In early 2014, staff at MMC began reevaluating the decision to switch from insulin vials and syringes to pens because of ongoing concerns

of the Institute for Safe Medication Practices related to insulin pen safety in hospitals and the risk for blood-borne pathogen transmission from sharing of insulin pens between patients.⁵ As part of a formal risk assessment, we queried our nurses using an online questionnaire, and 16 nurses (5.8% of 276 respondents) responded affirmatively to the question, “Have you ever observed the same insulin pen being used on more than one patient?” We also looked at hospital data related to nurse needlestick injuries during insulin administration and found a 50% reduction in the five-year period after the switch from insulin vials and syringes to pens compared with the previous five-year period. In early 2015, in the midst of our evaluation of insulin pen safety, an incident was reported through our electronic system involving inadvertent pen sharing between two patients that required notification and blood-borne pathogen testing for both patients. Fortunately, both patients tested negative for human immunodeficiency virus and hepatitis B and C viruses, and no long-term harm was anticipated. To date, there have been no known cases of blood-borne pathogen transmission at health systems despite thousands of patient exposures due to sharing of insulin pens.⁵

Our formal risk assessment was ongoing when we learned in June 2014 of the call for applications for the ASHP MENTORED QUALITY IMPROVEMENT IMPACT PROGRAMSM (MQIIP) on Insulin Pen Safety in Hospitals, which was part of the multifaceted quality-improvement initiative, Strategies for Ensuring the Safe Use of Insulin Pens in the Hospital.⁶ Because creating a safety culture with transparency is paramount at MMC, our top hospital leaders were engaged and concerned with our insulin pen use processes. These leaders encouraged us to apply for the MQIIP to complement our ongoing risk assessment.

KEY POINTS

- Participation in a mentored quality-improvement program showed that hospitals grapple with similar safety issues surrounding insulin pen use, such as use in more than one patient, improper administration technique, and suboptimal storage and labeling.
- The program’s structured format provided an opportunity to implement strategies that were vetted among the leader and participants and generally led to enhanced safety of insulin pen use and storage.
- After implementation of safety strategies, a small number of nurses continued to report observing insulin pen use on more than one patient, which underscore the need for continuous efforts to ensure insulin pen safety.

Baseline data

The medication safety pharmacist served as the team leader in the MQIIP as well as in the formal risk assessment. Team members involved in both the mentored program and the formal risk assessment included the physician chair of the pharmacy and therapeutics (P&T) committee and several pharmacists, pharmacy residents, and nurses, including frontline nurses, nurse educators, and nursing leaders. As described by Lutz et al.,⁶ data were collected for three outcome measures as part of the mentored program using a nurse questionnaire to assess insulin pen knowledge, insulin pen storage and labeling audits, and insulin pen injection observations.

Nurse questionnaire. Results of the baseline nurse questionnaire completed by approximately 200

nurses suggested that knowledge of insulin pharmacokinetics, including the time to onset, peak, and duration of activity, was suboptimal. For two questions related to a case study assessing pharmacokinetic knowledge, only 4% and 55% answered the questions correctly. Additionally, 81% of respondents identified this as the greatest knowledge or skill gap in the safe use of subcutaneous insulin. Eight nurses responded affirmatively to the question “In the past 3 months, have you seen or witnessed an insulin pen device used on more than one patient?” with about twice that number observing an insulin pen device stored in an “unapproved” location (e.g., the patient’s bedside, nursing station drawer). In addition, six nurses observed pens without patient-specific labels, and three nurses observed insulin withdrawn from an insulin pen cartridge using a syringe (i.e., use of the pen as a multiple-dose vial). Free-text comments from nurses about insulin pen safety echoed these findings, as well as concerns about insulin orders within the EHR that were confusing.

Labeling and storage audit. The audit results were similar for the three nursing units studied, which included a postoperative open heart surgery unit, medical cardiology unit, and medical/surgical floor. In general, the audit revealed that safe practices were followed for insulin pen labeling and storage, with high rates of adherence ($\geq 90\%$) to proper practices for all aspects of labeling and storage. However, missing expiration dates, labels that obscured the manufacturer’s barcode, smudged labels, and multiple pens of the same type of insulin labeled for a specific patient were detected in the audit. In one instance, insulin pens had been swapped (i.e., misplaced) in the individual patient medication storage bins for two patients, which was subsequently addressed as a possible blood-borne pathogen exposure for both patients.

Insulin injection observations.

The most concerning finding from insulin injection observations during the baseline period was that nurses checked the patient-specific label on the pen only 68% of the time, reflecting a lack of knowledge that scanning the manufacturer's barcode on the pen does not verify the patient identity. Many nurses did not appreciate the need to check the beyond-use date on the pharmacy label affixed to the pen, and these labels were often smudged and difficult to read. Other findings from insulin injection observations included use of an improper scanning sequence (i.e., scanning the patient barcode on his or her wrist identification band after instead of before medication administration) and failure to keep the plunger pressed and pen held against the skin for at least five seconds after injecting the dose. Whenever violations to standard, safe medication practice were observed, such as improper scanning sequence, the observers completed online occurrence reports to ensure follow up by unit leadership.

To complement information gleaned from the storage and labeling audit, while observing the insulin injections

we observed inconsistency in the storage of insulin when patients were in contact isolation. In some cases, the pen was stored on the windowsill in the room or in the patient medication storage bin with the individual's other medications.

In interacting with the nursing staff when observing insulin injections, it was challenging for us to maintain the premise that we were observing medication administration in general rather than insulin administration specifically. At most of the times when insulin doses were scheduled, no other medications were administered. The nursing staff had heard about the hospitalwide focus on insulin pen safety. Nevertheless, this difficulty did not seem to negate the benefit derived from making direct observations.

Process improvements

Many nursing- and pharmacy-related opportunities for improvement in safe insulin pen use were identified through the MQIP, as well as from hospital incident reports and observations collected as part of the formal risk assessment (see box). We began by creating specific policies and procedures for insulin pen

formulary selection, labeling, dispensing, administration, storage, and disposal that were approved by the nurse practice and P&T committees. The tool kit and resource center that were components of the ASHP quality-improvement initiative for ensuring the safe use of insulin pens in the hospital provided a comprehensive starting point for creating our institution-specific policies.⁷

The pharmacy processes for handling insulin pens were standardized and included ensuring that tamper-evident tape is affixed to each pen when a new box is opened, placing smudge-proof tape over the patient-specific label on pens, and placing an appropriate beyond-use date on the pen label. We installed a magnetic white board on the wall next to the dispensing counter with a list of drugs and drug classes, including insulin, with different beyond-use dates. On a daily basis, the midnight pharmacy technician affixes a magnet to the white board with the updated beyond-use date for each of these drugs and drug classes. This procedure facilitates labeling of insulin pens and other medications with the proper beyond-use date by pharmacy technicians and pharmacists at the time of dispensing.

The next and most challenging issue to overcome was the lack of an electronic solution at the point of care that would help ensure that a specific insulin pen is used only for the patient for whom it is intended. This type of functionality would provide a more robust—albeit not fool-proof—safety net for ensuring that a pen is not used for more than one patient.⁸ We learned through mentored calls that other hospitals using different EHR systems had achieved this goal. However, the EHR system used at our hospital currently does not have this capability, although requests for this functionality enhancement have been submitted to the vendor by MMC and other hospitals across the nation over the last several years.

Opportunities for Improving Safe Use of Insulin Pens Identified at Munson Medical Center

Nursing Opportunities

- Absence of policies and procedures for insulin pen administration and storage, including storage for patients with contact isolation precautions
- False belief that barcode scanning of the insulin pen identifies the patient
- Lack of understanding of pharmacy-specific expiration date for insulin pens
- Inadequate knowledge about insulin pharmacokinetics
- Improper barcode scanning sequence for insulin pen use
- Lack of timely insulin availability and potential for "borrowing" pens to meet needs of patient

Pharmacy Opportunities

- Inconsistent location of labels on insulin pen
- Smudged labels on insulin pens
- Inconsistent beyond-use date assignment and placement on labels for insulin pens
- Inconsistent process for handling medications, including insulin pens, left in patient care areas after patient discharge
- Information regarding pens previously dispensed not readily available to pharmacist during order verification, leading to oversupply or delay in dispensing
- Absence of process for discharging patient home with insulin pen

As an alternative to address the shortcomings of our EHR, we developed an electronic alert that is activated by the scanning of any insulin pen. The alert reads, “!!One Pen One Patient!! Verify PATIENT name on label!” We were concerned about the possibility of alert fatigue if the alert was activated for every insulin pen administration, so our alert is activated only once in a 24-hour period for each individual nurse, regardless of the patient or type of insulin involved. We incorporated the alert into our EHR system within the timeframe of the MQIIP so that when we performed postintervention insulin administration observations we were able to ask nurses about the effectiveness of the alert.

Education played a large role in our process improvements for insulin pen use. We developed a “badge buddy” card for nurses that contains basic pharmacokinetic information on the most commonly used insulin products on one side and tips from our hypoglycemia protocol on the other side (Figure 1). The pharmacy department provided funding for the badge buddies, and all nurses now have this information readily available during insulin pen use. In addition, pharmacokinetic information was added to the primary description of each type of insulin that is now included in the medication administration record section of the EHR.

Next, we began efforts to promote insulin pen safety through individualized meetings with each nurse, pharmacist, and pharmacy technician by using standardized script-driven communication, a method used by highly reliable organizations and referred to as “rounding to influence.”⁹ We developed slightly different scripts for nursing and pharmacy staff and trained a small number of nurse educators and pharmacists to use these scripts when meeting with each staff member (appendix). The conversation begins with a discussion of our core value of keep-

ing our patients and employees safe from harm and moves into safety concerns related to current insulin pen data, including the results of the recent nurse questionnaire. This format provides an opportunity to share information with frontline staff who may not have been aware of the safety issues. Problem-solving solutions (“can do’s”) and concerns about and perceived barriers to committing to our requested safe practice behaviors are addressed. We end the conversation by asking for a commitment to specific safety behaviors.

In addition, a nursing newsletter highlighting the results of baseline data collection and planned im-

provement strategies as part of the MQIIP was distributed throughout the hospital.

Last, we developed a mandatory online education module for nurses about insulin pen safety. The completion rate was 70% at the time of postintervention data collection.


Postintervention results

Overall, we noted improvement in all three areas assessed. For the insulin injection observations, the greatest improvement was seen in the rate of adherence to the practice “checks medication label,” which increased from 68% to 100%. Several nurses appreciated the new barcode scanning


Figure 1. “Badge buddy” card that attaches to the name badge for all nurses at Munson Medical Center and displays insulin pharmacokinetic information on one side (top) and the hospital’s hypoglycemia protocol on the other side (bottom).

NAME OF INSULIN	ONSET	PEAK	DURATION
Rapid acting			
Insulin aspart (Novolog)	15–20 min	1–3 hr	3–5 hr
Insulin glulisine (Apidra)	15–30 min	1.6–2.8 hr	3–4 hr
Insulin lispro (Humalog)	15–30 min	0.5–3 hr	≤ 5 hr
Short acting			
Regular (Novolin R/Humulin R)	30 min	2.5–5 hr	4–12 hr
Intermediate acting			
NPH (Novolin N/Humulin N)	1–2 hr	4–12 hr	14–24 hr
Long acting			
Insulin glargine (Lantus)	3–4 hr	None	24 hr
Insulin detemir (Levemir)	3–4 hr	3–9 hr	6–23 hr

Reference: Lexicomp 2014



HYPOGLYCEMIA PROTOCOL POLICY # 070.015	
Blood glucose result	Less than 70 mg/dL, give one carb Less than 50 mg/dL, give two carbs
Ability to swallow?	Yes, give oral carbs No or NPO, give IV D50 or glucagon (if no IV access)
Examples of ONE carb choices	Glucose gel 8 oz. milk 1 package graham crackers 3 packages saltines 1 slice bread 1 container jello
Recheck blood glucose	15 minutes
Order meal	If no meal in 30 minutes order tray. Call #57080 or supply meal from unit pantry.
Documentation requirements	Write a focus note about what occurred



alert, which reminded them to verify the patient name on the insulin pen label. In performing insulin injection observations, we found duplicate insulin pens in patient medication bins on several occasions (this was also noted during the storage and labeling audit), suggesting problems with the medication dispensing and distribution processes.

Insulin pen storage and labeling practices improved in the time that elapsed between the baseline and postintervention audits, with a rate of adherence to proper practices increasing from 90% to 96%. In the postintervention audit, pens were consistently labeled for a specific patient, with clear tape covering the label so that it was not smudged and was easy to read. The label was placed consistently on the pen barrel with a handwritten 28-day beyond-use date in accordance with hospital policies.

The response rate to the nurse questionnaire for the baseline and postintervention periods was similar (approximately 15% of nurses in both periods), with similar demographic data, such as number of years worked, shift worked, and type of position. In general, the insulin pharmacokinetic questions continued to pose a challenge for the nurses in the postintervention period. The greatest improvement in nurse knowledge was seen using the false statement, "A drop of fluid indicates that a portion of the dose has leaked from the site," with 48% and 77% correctly identifying the statement as false at the baseline and postintervention assessment, respectively.

The finding of greatest concern was that four nurses responded "yes" in the postintervention period to the question, "Have you witnessed an insulin pen used on more than one patient in the past 3 months?" Equally concerning was the number of nurses who responded affirmatively to the question, "Have you witnessed an insulin pen without a patient-specific label?," which increased from 6 nurses in the baseline

period to 14 nurses in the postintervention period. Substantially more nurses observed insulin pens stored in unapproved areas in the postintervention period compared with the baseline period (31 and 18, respectively), and withdrawal of insulin from a pen cartridge using a syringe was reported by four nurses in the postintervention period.

Implications

Participation in the MQIIP provided a strategy for examining multiple facets of insulin pen use within our institution. We discovered that problems with insulin pens were more widespread than we had anticipated, but our baseline data were consistent with those at other hospitals participating in the program.⁶ In addition, the improvements observed in a relatively short period were comparable to (if not greater) than those at most other participating hospitals.

Several responses to the nurse questionnaire were less favorable in the postintervention period than in the baseline period. This change could be attributed to greater awareness of pen safety issues in the postintervention period, leading to increased detection and the appearance of worsening practices. Pen sharing among patients, whether intentional because of a knowledge deficit or unintentional because of system issues, remains our greatest concern. We also learned that gaining access to rapid-acting insulin in a timely manner from the pharmacy continues to present a challenge and may contribute to unsafe insulin pen practices. We are exploring the possibility of having multiple-dose vials of a rapid-acting insulin available in automated dispensing cabinets (ADCs) for nurses to use while awaiting delivery of insulin pens dispensed by pharmacy. We also are considering a trial of insulin pens stocked in ADCs. Our biggest concern with this practice is relying on nurses to consistently label pens with the patient name. Last, we have not ruled out switching from

pens to vials and syringes for insulin administration and will continue to evaluate risks, benefits, and cost considerations moving forward.

To address nurses' concern about insulin orders within the EHR that are confusing, our clinical informatics and provider groups are examining options for changing internal policies to allow modifying an existing insulin order if the dosage changes rather than requiring a new insulin order.

Our participation in the MQIIP highlighted a problem with the handling of insulin pens and other medications left in patient care areas after patient discharge. On several occasions we found an insulin pen for a discharged patient among medications for current patients in medication storage areas. This problem is addressed in script-driven communication with nursing staff, emphasizing the need to return all medications, including insulin pens, to the pharmacy after patient discharge and with pharmacy technicians emphasizing the need to be vigilant about looking for stray pens during daily medication cart exchanges. In addition, we are considering a process change that would streamline return of patients' discharged medications by pharmacy staff rather than nursing staff. This has the potential to improve safety by timely removal of excess medications from nursing units and to re-use short-dated products. Our pharmacy operations group is currently tasked to review this topic.

Finally, we have submitted a request to our information systems department to create an electronic alert for pharmacists during insulin pen order verification if an insulin pen was dispensed previously for the patient. This alert should reduce the dispensing of duplicate pens for an individual.

We found that participation in the MQIIP was very beneficial. We were held accountable to ASHP and other participants in the program as well as at MMC. The timeline and

format helped keep us on track while we juggled our busy schedules and demands on our time. We took some solace in knowing that other hospitals were struggling with similar issues and working alongside us to improve insulin pen safety. Their experiences and challenges helped us identify solutions to insulin pen safety issues and formulate communication strategies for improving insulin pen safety in our hospital. Awareness of the importance of insulin pen safety increased in all staff, including pharmacy technicians, nurses, pharmacists, and hospital leaders.

Conclusion

The ASHP MQIP on Insulin Pen Safety in Hospitals provided a structured and supportive approach to identifying and addressing insulin pen safety issues at MMC. The insight gained through participation enabled us to devise strategies to communicate with staff about safety issues and improve the safety of insulin pen use in the institution.

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- patients to blood-borne pathogens while in our hospital?
- Many of these involved pens of discharged patients and occurred in many units of the hospital.
 - In addition, the recent insulin nurse questionnaire revealed that 8 out of approximately 200 nurses answered *yes* to the question, "In the past three months, have you witnessed or seen an insulin pen device used on more than one patient?"
- ### Can Do's
- What can you tell me about safe insulin administration practices? Remember: One pen, one patient!
 - Pens with the wrong patient label or no patient label should *never* be used to give insulin.
 - Barcode scanning of the pen *does not* ensure that the correct patient's pen is at hand; it only identifies the correct drug. *Only reading the patient name* on the label will identify the correct pen.
 - When patients are discharged, all meds including insulin should be sent back to pharmacy (unless in isolation).
 - Use the following points only for pharmacy staff.
 - Labeling and dispensing should be done per the new insulin pen policy, covering the label with dispensing tape to prevent smudging, 28-day beyond-use date handwritten in lower right corner, and tamper-evident tape intact.
 - All insulin should be handled as urgent with expeditious processing and delivery to unit to avoid the need for nurses to "borrow" another pen.
 - During cart exchange *every* med tray must be exchanged and all insulin pen labels should be verified for the correct patient drawer. If it is not the correct patient, the unit manager, charge nurse, or patient's nurse should be notified immediately. Complete a VOICE report or notify medication safety pharmacist.
- ### Concerns
- What are the issues you see daily that make it difficult to follow those expectations?
 - Encourage reporting of any problems that you may think of or that develop.
- ### Commitment
- I need you to do something for our patients.^b
 - I need you to change your practice and to carefully check the pa-

Appendix—Rounding to influence script used at Munson Medical Center

Greeting

- Hello. I'm rounding on everyone today. Do you have a few minutes for a brief conversation about insulin pen safety?

Core Value

- Keeping our patients safe from harm is one of the most important things we do every day!
 - Did you know that over the past four months, there have been 14 "wrong patient" VOICE^a reports related to unsafe insulin pen use or storage potentially exposing

tient label for the patient's name and the medication beyond-use date every time you administer insulin.

- I need you to change your practice and to carefully label the pen in a standard manner as outlined in the new insulin pen policy.
- I need you to share the information about the pens and the patient labels with two of your colleagues and let me know what you find out.
- I need you to report any instances of these issues that you see using the VOICE system.
- I need you to be vigilant during cart exchange and check every insulin pen for the correct patient.
- Can you do that for me?

Closing

- Thank you for being a part of our team and for committing to keeping our patients safe!

^aVOICE (RL Solutions, Toronto, Ontario) is the online occurrence monitoring system used at Munson Medical Center.

^bRequests should be chosen based on the health professional (i.e., nursing or pharmacy staff).

Best Practices in Ensuring the Safe Use of Insulin Pens in the Hospital

ACPE Activity Number 0204-0000-16-458-H05-P

Knowledge-based activity

Qualifies for 2.5 hours (0.25 CEU) of continuing pharmacy education, no partial credit

Target Audience

This continuing pharmacy education activity was planned to meet the needs of pharmacists in hospitals, health systems, and ambulatory care clinics in which pen devices are used for subcutaneous administration of insulin for inpatients.

Learning objectives

After studying these articles, the reader should be able to

1. Discuss the strengths and weaknesses of the Delphi process for consensus development.
2. Describe best practices for the safe use of insulin pen devices in hospitals and health systems identified by an expert panel using the Delphi consensus development process.
3. Develop a plan for evaluating processes related to the use of insulin pen devices in hospitals and health systems.
4. Discuss strategies that have been used to ensure insulin pen safety in hospitals and health systems.

Self-assessment questions

For each question there is only one best answer.

1. Which of the following is a characteristic of the Delphi method used by Haines et al. to develop best practices for the safe use of insulin pen devices in hospitals and health systems?
 - a. Transparency about the identity of other panelists to provide accountability.
 - b. Blinding of participants to the identity of other panelists to minimize undue influence.
 - c. An evidence basis with grading of the strength of recommendations.
 - d. A consensus of opinion weighted based on experience and expertise.
2. Which of the following is a possible shortcoming of the Delphi method used by Haines et al. to develop best practices for the safe use of insulin pen devices in hospitals and health systems?
 - a. Long time investment.
 - b. Subjective definition of consensus.
 - c. Limited applicability to real world practice.
 - d. Lack of interprofessional input.
3. Which of the following is among the best practices identified by Haines et al. specifically for the safe use of insulin pen devices in hospitals and health systems?
 - a. Limit the formulary of available options that can be prescribed.
 - b. Require the use of computerized prescriber order entry.
 - c. Mandate an institutional committee review of all adverse events and medication errors.
 - d. Ensure that health professionals use the appropriate administration technique.
4. Which of the following practices is consistent with the best practices for the safe use of insulin pen devices in hospitals and health systems developed by Haines et al.?
 - a. Attach the pharmacy label to the cap of the insulin pen device.
 - b. Affix the pharmacy label to the bag in which the insulin pen is dispensed.
 - c. Include the insulin dose on the pharmacy label.
 - d. Include a patient- and product-specific barcode on the pharmacy label.
5. Which of the following is a perceived advantage of insulin pens over traditional vials and syringes?
 - a. Lower risk of misuse and patient harm.
 - b. Improved dose accuracy.
 - c. Improved administration technique.
 - d. Lower risk of transmission of infection.
6. Which of the following is the least feasible outcome measure to use in assessing the effect of interventions to improve the safe use of insulin pens in a hospital?
 - a. Percentage of insulin pens stored in patient-specific location.
 - b. Percentage of insulin pens with expiration date (that is not expired) documented on label.
 - c. Incidence of blood-borne infections attributable to inappropriate pen use.
 - d. Number of nurses who have witnessed an insulin pen device used on more than one patient.

The following two questions refer to ABC Hospital, where pen devices are used for subcutaneous administration of insulin. The hospital's hyperglycemia control committee

together with the medication safety team is evaluating its processes related to the use of insulin pens in the hospital.

7. Which of the following would be the most appropriate method of identifying potential safety concerns related to insulin administration?
 - a. Direct observation.
 - b. Medication administration record audit.
 - c. Review of error reports.
 - d. Nurse survey.
8. Which of the following would be the most appropriate method of identifying potential safety concerns related to insulin pen labeling and storage?
 - a. Direct observation.
 - b. Audit of patient care unit.
 - c. Review of error reports.
 - d. Nurse survey.
9. According to the nurse questionnaire results reported in the MENTORED QUALITY IMPROVEMENT IMPACT PROGRAMsm (MQIIP), which of the following is the greatest self-identified knowledge or skill gap of nurses related to insulin use?
 - a. Risk factors for hypoglycemia.
 - b. Proper insulin pen injection technique.
 - c. Time-action profiles of insulin products.
 - d. Proper labeling of insulin pens.
10. As described by Lutz et al., which of the following is a high-reliability strategy that would likely be most effective in creating lasting system changes for ensuring the safe use of insulin pens in hospitals and health systems?
 - a. Competency and skills validations for new nurse hires and then annually.
 - b. Use of clear tape to cover and secure label to insulin pen barrel.
 - c. Use of patient transfer and discharge reports to ensure prompt removal of pens stored on units.
 - d. Barcode system enhancements to verify insulin pen is for correct patient.
11. Which of the following is a best practice for dispensing of insulin pens that was adopted at UF Health while participating in the MQIIP?
 - a. Use of tamper-evident tape applied perpendicularly across the barrel-cap junction on the pen.
 - b. Use of tamper-evident tape wrapped around the barrel-cap junction on the pen.
 - c. Use of tamper-evident tape applied to the barrel, not the cap, of the pen.
 - d. Discontinuation of the use of tamper-evident tape because it is ineffective.
12. According to Rosenberg, which of the following was a feasible approach for conducting insulin injection observations within a hospital or health system as part of the MQIIP for insulin pen safety?
 - a. Train one team member to ensure consistency.
 - b. Train a group of team members, diabetes resource nurses, and students.
 - c. Ask for staff volunteers with an interest in research and train as needed.
 - d. Hire and train a temporary part-time pharmacist.
13. As reported by Rosenberg, which of the following strategies was used to provide secure insulin pen storage and reduce the likelihood of transmission of pathogens on pens with surface contamination from patients with contact isolation precautions to other patient care areas?
 - a. Store the pen in a clear plastic lockable box mounted on the wall in the patient room.
 - b. Store the pen in a patient-specific storage bin in an automated dispensing cabinet.
 - c. Store the pen in a locked, secured supply cart in the hallway near the patient's room.
 - d. Store the pen at the patient's bedside.
14. Which of the following options best describes the teams assembled by Rosenberg and Botsford and reflects a best practice related to policies and procedures for the safe use of insulin in hospitals and health systems?
 - a. Interprofessional team with active participation of hospital leaders that regularly provides feedback to the health professional staff.
 - b. Interprofessional team that reports annually to hospital leadership.
 - c. Subcommittee of the glycemic control committee that reports as needed to the medical staff.
 - d. Medication safety officer who consults with pharmacy and nursing leadership and writes a monthly newsletter column.
15. Which of the following is a possible disadvantage of using direct observation of insulin pen injections by nurses as part of a hospital's quality-improvement initiative to ensure insulin pen safety?
 - a. Extensive training needed for individuals doing observations.
 - b. Difficulty in obtaining patient consent before observation.
 - c. Nurse awareness that medication administration procedures are under observation.
 - d. Large time commitment to conduct multiple observations of each nurse.

16. Which of the following best describes the “rounding to influence” strategy used by Botsford and colleagues to facilitate change in health professionals involved in insulin pen use in their hospital?
- Distribution of a newsletter.
 - Creation of a mandatory online education module.
 - Standardized script-driven communication.
 - Grand round seminars.

AJHP Continuing Education

Activity Title: Best Practices in Ensuring the Safe Use of Insulin Pens in the Hospital

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