

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.

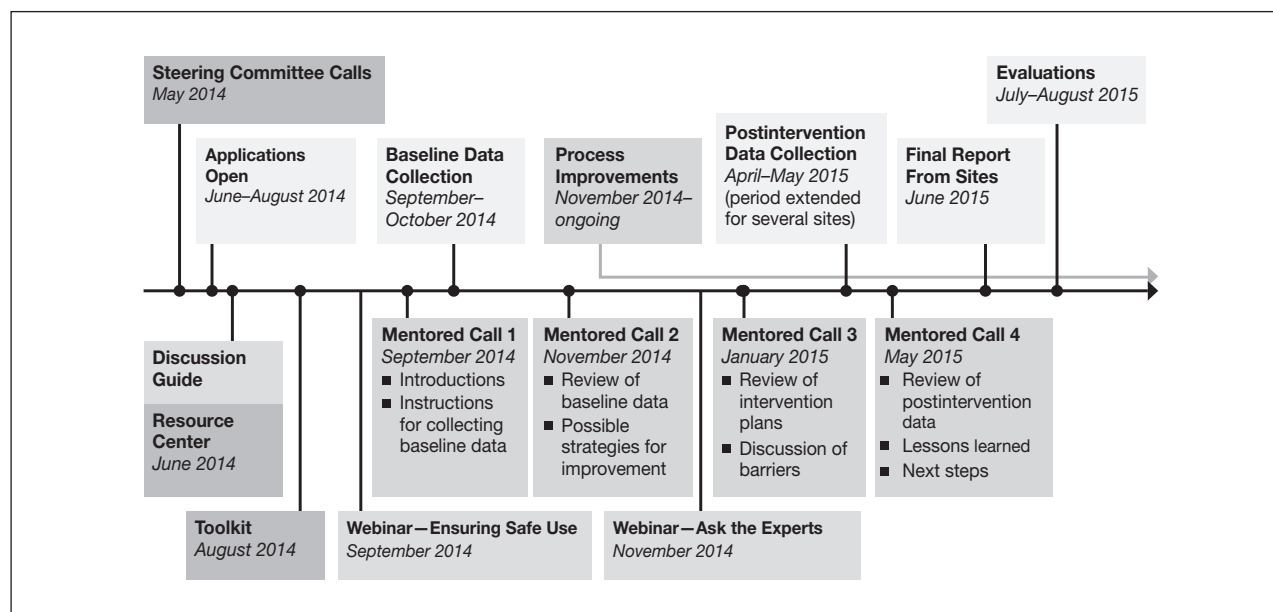
A nationwide call for applications for the MQIIP was made via e-mails to ASHP members, online advertisements on the ASHP website, and announcements in an ASHP e-newsletter. As part of the online application, applicants were required to name an interprofessional team of healthcare providers and managers, 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	5
Patient-specific storage areas for insulin pens	13	1	1	8	5	5
Required education and competency assessment for nurses addressing insulin pen safety and injection technique	8	6	6	6	2	2
Ongoing education for nurses about time-action profiles for different types of insulin	8	6	6	8	0	0
Insulin pen label with barcode for specific patient	7	7	4	1	9	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	8
Ongoing plan to conduct injection observations and pen audits to detect potential safety concerns	0	14	12	0	2	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 (%)		p
	Baseline	Postintervention	
1. Retrieves insulin pen device from hospital-approved patient-specific storage area	455/479 (95.0)	494/507 (97.4)	0.046
2. Expiration is documented on label	473/521 (90.8)	544/551 (98.7)	<0.001 ^a
3. Obtains replacement pen if expiration date is not documented or if expired ^b	34/69 (49.3)	25/28 (89.3)	<0.001 ^a
4. Displays use of proper hand hygiene before patient contact	466/525 (88.8)	524/539 (97.2)	<0.001 ^a
5. Performs patient identification (according to hospital policy)	497/530 (93.8)	532/547 (97.3)	0.007 ^a
6. Checks medication label	500/532 (94.0)	553/557 (99.3)	<0.001 ^a
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)	<0.001 ^a
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)	0.060
9. Swabs rubber stopper with alcohol swab	415/501 (82.8)	482/530 (90.9)	<0.001 ^a
10. Attaches new disposable needle onto the pen	520/522 (99.6)	551/551 (100)	0.236
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)	<0.001 ^a
12. Dials correct dose (e.g., based on patient-specific order)	532/537 (99.1)	561/561 (100)	0.028
13. Selects appropriate injection site (e.g., abdomen, back of arm, thigh)	528/534 (98.9)	558/559 (99.8)	0.064
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)	0.324
15. Lets go of skin fold and injects the entire dose of insulin	469/520 (90.2)	501/542 (92.4)	0.230
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)	0.039
17. Removes and discards needle in appropriate sharps container	508/512 (99.2)	559/559 (100)	0.052
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)	0.051

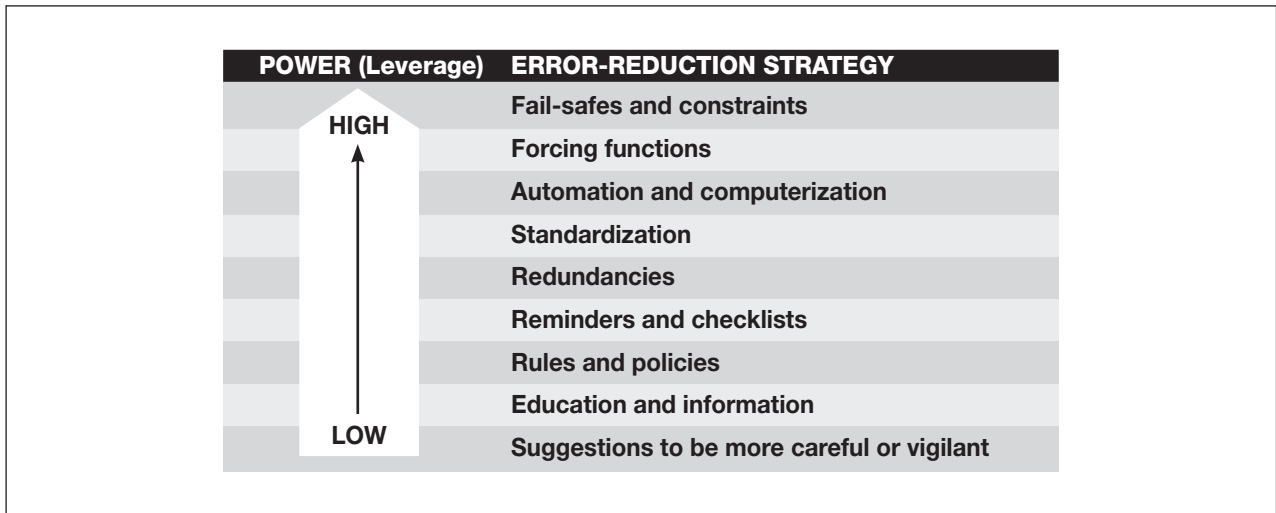
^aRepresents statistically significant change ($p \leq 0.01$).

^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 reinstated 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.oneopenonepatient.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.

Disclosures

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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