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.

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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 needlestick 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 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.

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.

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

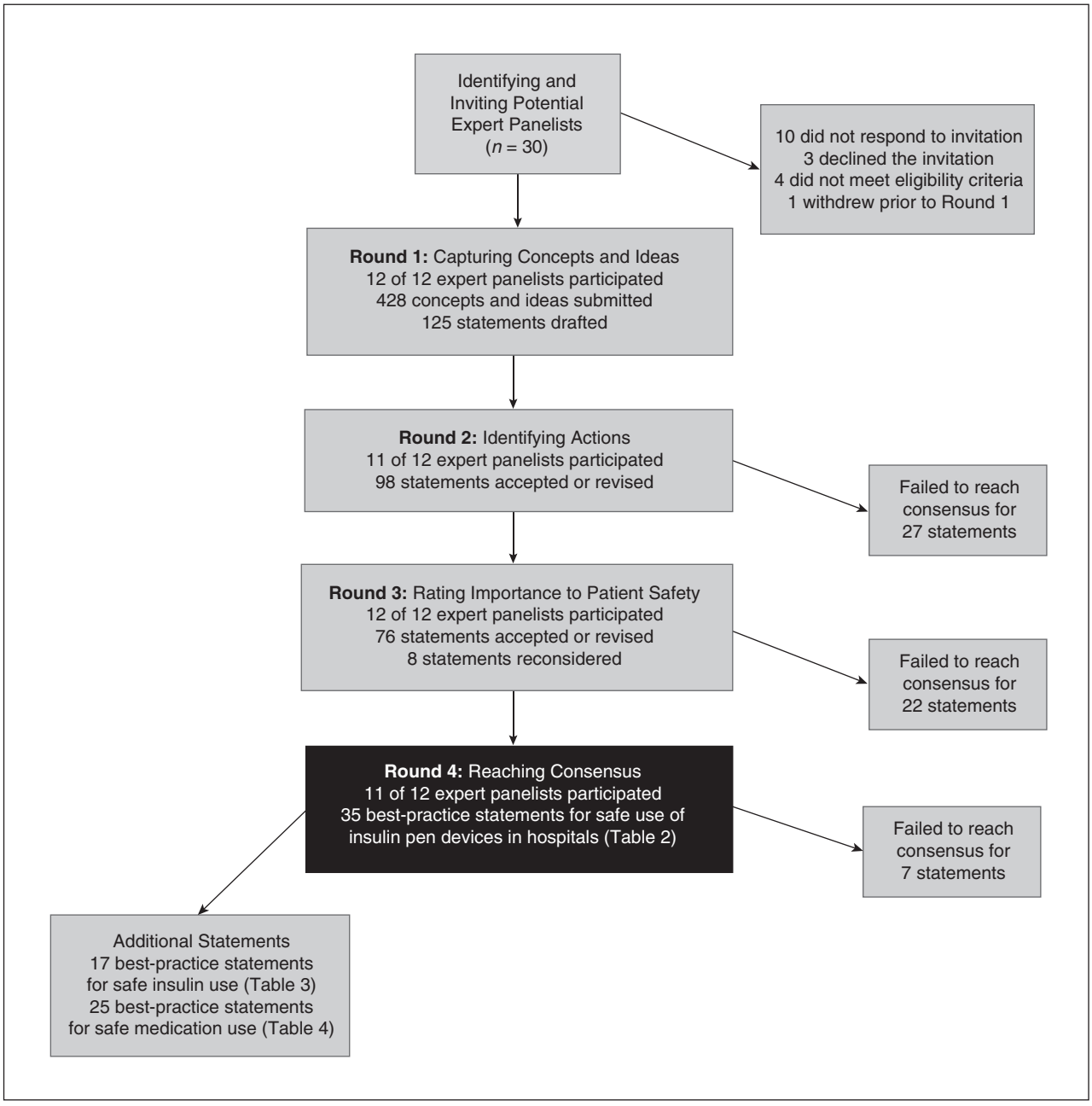
Characteristics of expert panelists. A total of 30 potential panelists were contacted: 10 did not respond to our e-mail invitation, 3 declined to participate, 4 did not meet the eligibility criteria, and 13 agreed to participate (Figure 1). One panelist who initially accepted our invitation did not participate 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 . . .
Ordering and Documenting	
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"
Labeling and Dispensing	
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
Storing	
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
Administering	
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: • 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
Policies and Procedures	
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 • 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)
Monitoring, Planning, and Evaluating	
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

[a]CDC = 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 interprofessional 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 . . .
Ordering	
1	Require the use of order sets when prescribing insulin
2	Create order sets for insulin that have the following components: • 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
Labeling and Dispensing	
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
Administering	
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
Monitoring	
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
Policies and Procedures	
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): • 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: • 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

[a]An 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 insulin 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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