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

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

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

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

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

In 2009, the hospital switched from using traditional vials and syringes for insulin administration to insulin pens. Potential cost savings, greater convenience, enhanced patient teaching, and perceived improvements in safety and accuracy were factors involved in the decision to switch.[1-4] Formulary insulin products include insulin aspart (NovoLog Flexpen, Novo Nordisk, Denmark) and insulin glargine (Lantus Solostar pen, sanofi-aventis, Bridgewater, NJ), which constitute the majority of insulin use at MMC.

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

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

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

KEY POINTS

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

Baseline data

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

Nurse questionnaire. Results of the baseline nurse questionnaire completed by approximately 200 nurses suggested that knowledge of insulin pharmacokinetics, including the time to onset, peak, and duration of activity, was suboptimal. For two questions related to a case study assessing pharmacokinetic knowledge, only 4% and 55% answered the questions correctly. Additionally, 81% of respondents identified this as the greatest knowledge or skill gap in the safe use of subcutaneous insulin. Eight nurses responded affirmatively to the question "In the past 3 months, have you seen or witnessed an insulin pen device used on more than one patient?," with about twice that number observing an insulin pen device stored in an "unapproved" location (e.g., the patient's bedside, nursing station drawer). In addition, six nurses observed pens without patient-specific labels, and three nurses observed insulin withdrawn from an insulin pen cartridge using a syringe (i.e., use of the pen as a multiple-dose vial). Free-text comments from nurses about insulin pen safety echoed these findings, as well as concerns about insulin orders within the EHR that were confusing.

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

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

To complement information gleaned from the storage and labeling audit, while observing the insulin injections we observed inconsistency in the storage of insulin when patients were in contact isolation. In some cases, the pen was stored on the windowsill in the room or in the patient medication storage bin with the individual's other medications.

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

Process improvements

Many nursing- and pharmacy-related opportunities for improvement in safe insulin pen use were identified through the MQIIP, as well as from hospital incident reports and observations collected as part of the formal risk assessment (see box). We began by creating specific policies and procedures for insulin pen formulary selection, labeling, dispensing, administration, storage, and disposal that were approved by the nurse practice and P&T committees. The tool kit and resource center that were components of the ASHP quality-improvement initiative for ensuring the safe use of insulin pens in the hospital provided a comprehensive starting point for creating our institution-specific policies.[7]

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

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

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

Nursing Opportunities

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

Pharmacy Opportunities

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

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

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

Next, we began efforts to promote insulin pen safety through individualized meetings with each nurse, pharmacist, and pharmacy technician by using standardized script-driven communication, a method used by highly reliable organizations and referred to as "rounding to influence."[9] We developed slightly different scripts for nursing and pharmacy staff and trained a small number of nurse educators and pharmacists to use these scripts when meeting with each staff member (appendix). The conversation begins with a discussion of our core value of keeping our patients and employees safe from harm and moves into safety concerns related to current insulin pen data, including the results of the recent nurse questionnaire. This format provides an opportunity to share information with frontline staff who may not have been aware of the safety issues. Problem-solving solutions ("can do's") and concerns about and perceived barriers to committing to our requested safe practice behaviors are addressed. We end the conversation by asking for a commitment to specific safety behaviors.

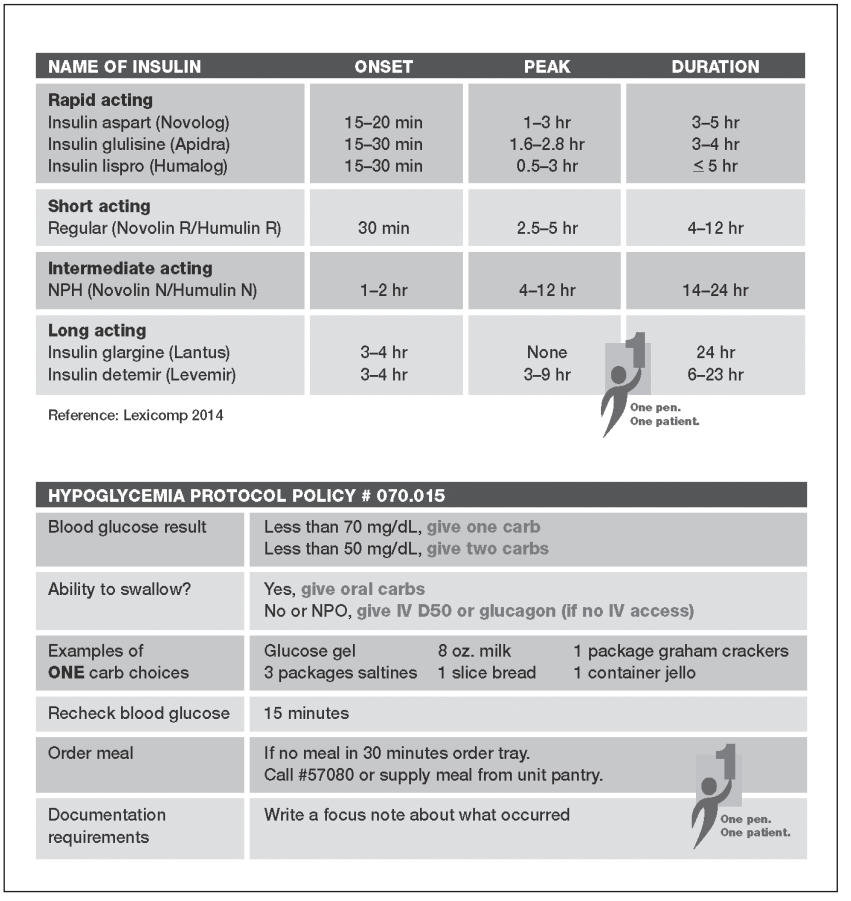
In addition, a nursing newsletter highlighting the results of baseline data collection and planned improvement strategies as part of the MQIIP was distributed throughout the hospital.

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

Postintervention results

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

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



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

Reference: Lexicomp 2014

One pen. One patient.

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

One pen. One patient.

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

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

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

The finding of greatest concern was that four nurses responded "yes" in the postintervention period to the question, "Have you witnessed an insulin pen used on more than one patient in the past 3 months?" Equally concerning was the number of nurses who responded affirmatively to the question, "Have you witnessed an insulin pen without a patient-specific label?," which increased from 6 nurses in the baseline period to 14 nurses in the postintervention period. Substantially more nurses observed insulin pens stored in unapproved areas in the postintervention period compared with the baseline period (31 and 18, respectively), and withdrawal of insulin from a pen cartridge using a syringe was reported by four nurses in the postintervention period.

Implications

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

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

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

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

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

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

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

Conclusion

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

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Appendix—Rounding to influence script used at Munson Medical Center

Greeting

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

Core Value

- Keeping our patients safe from harm is one of the most important things we do every day!
  - Did you know that over the past four months, there have been 14 "wrong patient" VOICE[a] reports related to unsafe insulin pen use or storage potentially exposing patients to blood-borne pathogens while in our hospital?
  - Many of these involved pens of discharged patients and occurred in *many* units of the hospital.
  - In addition, the recent insulin nurse questionnaire revealed that 8 out of approximately 200 nurses answered *yes* to the question, "In the past three months, have you witnessed or seen an insulin pen device used on more than one patient?"

Can Do's

- What can you tell me about safe insulin administration practices? Remember: One pen, one patient!
  - Pens with the wrong patient label or no patient label should *never* be used to give insulin.
  - Barcode scanning of the pen *does not* ensure that the correct patient's pen is at hand; it only identifies the correct drug. *Only reading the patient name* on the label will identify the correct pen.
  - When patients are discharged, all meds including insulin should be sent back to pharmacy (unless in isolation).
- Use the following points only for pharmacy staff.
  - Labeling and dispensing should be done per the new insulin pen policy, covering the label with dispensing tape to prevent smudging, 28-day beyond-use date handwritten in lower right corner, and tamper-evident tape intact.
  - All insulin should be handled as urgent with expeditious processing and delivery to unit to avoid the need for nurses to "borrow" another pen.
  - During cart exchange *every* med tray must be exchanged and all insulin pen labels should be verified for the correct patient drawer. If it is not the correct patient, the unit manager, charge nurse, or patient's nurse should be notified immediately. Complete a VOICE report or notify medication safety pharmacist.

Concerns

- What are the issues you see daily that make it difficult to follow those expectations?
  - Encourage reporting of any problems that you may think of or that develop.

Commitment

- I need you to do something for our patients.[b]
  - I need you to change your practice and to carefully check the pa-

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

Closing

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

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[a]VOICE (RL Solutions, Toronto, Ontario) is the online occurrence monitoring system used at Munson Medical Center.

[b]Requests should be chosen based on the health professional (i.e., nursing or pharmacy staff).