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May 8, 2008

Problem: A variety of insulin pen injectors (collectively called "pens") are currently available in the US. Intended primarily to facilitate easy and accurate patient self-administration of insulin, pens also can be found in many hospitals (30%, according to our recent survey comprising 1,369 respondents) to administer insulin to patients. Switching from insulin vials to pens is gaining popularity, as they offer several advantages over vials:

- Each pen is already labeled by the manufacturer with the product name and strength (whereas unit-based preparation of insulin from vials runs the risk of unlabeled syringes)
- Each pen will be individually labeled with the patient's name
- The pen provides the patient's insulin in a form ready for administration
- The pen lessens nursing time needed to prepare and administer insulin
- Insulin pens reduce medication waste that can occur when dispensing full insulin vials for each patient.

Despite these advantages, some hospitals that switched to insulin pens are reconsidering this decision while others have employed the technology successfully and safely. Although it is not our intention to discourage appropriate use of insulin pens in hospitals, below we describe common problems encountered with these devices in an effort to help those who plan to or are currently using insulin pens guard against failures that could be harmful to both patients and healthcare practitioners.

Needlestick injuries. Nurses have accidentally stuck a finger with a contaminated needle during pen delivery of insulin. Sometimes nurses pinch a thin patient's skin together when administering a subcutaneous injection. A needlestick may occur if the nurse does not maintain a 90 degree angle during the injection, as the needle may travel through the patient's skin and into the nurse's finger, which is holding the pinched skin. Along with misalignment of the angle of injection, visualization of the injection site during pen delivery of insulin can be poor, which has been reported as a contributing factor with this type of needlestick. Some insulin pen needles are not available with a needle guard, which presents another potential source of needlestick

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skin together, it can prevent exposure to a contaminated needle after the injection.

User technique errors. Nurses have reported seeing a "wet spot" on the skin after injection, which they thought was insulin. They were afraid that the patient had not received the full dose, particularly since they could not visualize the medication being delivered. In some cases, the "wet spots" left at the injection site turned out to be a very small amount of insulin residue left on the skin from priming the pen before injection. In other cases, the "wet spots" involved substantial amounts of insulin. The plungers/buttons of some pens are difficult to push down, making it easy to accidentally lift the needle out of the skin when delivering the insulin, thus leaving a "wet spot." Insulin can also leak out of the injection site if the needle is not left in for about 6 seconds after injecting the insulin-another source of a "wet spot."

To cite another example of technique errors, nurses (and patients) may not tip and roll insulin suspension (e.g., NPH, insulin mixtures) pens for proper mixing before use. This can result in large clumps of aggregated insulin flowing from the pen during the first injection, followed by subtherapeutic doses in subsequent injections.

Using pens like vials. The wide variety of pen designs makes it difficult for practitioners to become competent using all possible devices. When nurses are not sure how to use a pen or encounter problems when trying to use it, they sometimes solve the problem by withdrawing the insulin from the pen cartridge using a sterile needle and insulin syringe. In these cases, the pen cartridge is used as a multiple-dose vial for a single patient. In other cases, pen cartridges are used as floor stock for multiple patients, using a new sterile needle and insulin syringe for each puncture into the cartridge's membrane. Removal of insulin from the cartridge is not recommended by manufacturers unless an emergency exists and the pen is malfunctioning. Large air pockets or bubbles left behind in the cartridge after aspirating some of the insulin with a needle can result in dosing errors or subcutaneous injection of air if the pen is used to deliver a subsequent dose.

Using a pen for multiple patients. In a recent newsletter (March 27, 2008, Cross contamination with insulin pens), we described several cases of using an individual patient's insulin pen for another patient. Some nurses thought it was acceptable to put a new disposable needle on the pen that had been used for one patient, and use it to deliver a dose of insulin to another patient, much the same as a multiple-dose vial

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cartridge after injection while the needle is attached to the pen.

Dispensing and administration errors. Although mix-ups among insulin pens may not be more common than mix-ups among insulin vials, pens and vials are subject to similar risks given the look-alike packaging of each manufacturer's line of insulin products and similarities in product names. For example, we have received numerous reports of dispensing mix-ups between the **NOVOLOG MIX 70/30** (70% insulin aspart protamine suspension, 30% insulin aspart) **FlexPen** and the **NOVOLOG** (human insulin aspart) **FlexPen**. Similar mix-ups have happened to nurses and patients during drug administration. Administering a large dose of short-acting insulin, believing it is the long-acting insulin, can be fatal. (A new color differentiation system used by at least one manufacturer seems promising and will be the subject of a future report in this newsletter.)

Pen design flaws. The design of some pens can predispose users to error. For example, the **LANTUS** (insulin glargine) **OPTICLIK** and **APRIDRA** (insulin glulisine) pens are available with a digital display of dose information that can be easily misread if the pen is held upside down, as a left-handed person might do. For instance, a dose of 52 units looks like 25 units, and a dose of 12 units looks like 21 units, when the pen is oriented incorrectly. (A similar misreading of digital displays [165 read as 591] also has happened with a glucose meter when the device was held upside down.¹)

Safe Practice Recommendations

Potential problems with insulin pens are not insurmountable; the key to using these devices safely involves anticipating and reducing potential risks before implementation, and close monitoring during the first few months of implementation when unanticipated failures and workarounds are most likely to occur.

FMEA. Practitioners, including prescribers, pharmacists, nurses, and diabetes educators, should conduct a failure mode and effects analysis (FMEA) and implement identified risk reduction strategies to prevent critical failures before using any insulin pen in the hospital.

Formulary control. If possible, limit the variety of pens in the institution to promote staff education and ongoing competency with the devices.

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online for many of the insulin pens and should be readily available to pharmacists and nurses from the organization's Intranet. Staff should be given clear instructions about how to proceed if they encounter problems, with real-time help accessible at all times. One hospital pharmacist recently told us that after the initial phase of education, oneon-one trouble-shooting when problems were encountered was the key to successful implementation of insulin pens.

Guidelines. Written guidelines should be developed for each type of pen available in the hospital. The guidelines should be comprehensive and include very specific information about safety, including how to handle pens for patients in isolation, prohibitions regarding sharing pens or using them as multiple-dose vials, how to apply pharmacy labels to pens without obscuring important information, and other relevant safety guidelines. Technical information about how to give the injection should be provided, including needlestick precautions, keeping the needle under the skin for about 6 seconds after injection, and removing the needle immediately after injection to prevent entry of air or contaminants into the cartridge. Patient education materials should also be provided.

Although certainly not the only motivation for ensuring safe practices when using pens, compliance with The Joint Commission (TJC) standards should be considered. While TJC does not require organizations to use pens, facilities that use them may be cited for failing to comply with Infection Control standards (IC 3.10, EP.2) if pens are reused for multiple patients, and with Human Resources standards, for failing to validate staff competency with pens. As we mentioned in our November 30, 2006, newsletter article, *PEN injectors: Technology is not without imPENding risks*, we will continue to work to establish safe practice guidelines that can be employed in both the hospital and home setting to maximize safety when using pen technology to deliver medications.

Reference

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1. Steward D et al. An avoidable cause of false home glucose measurement. *Diabetes Care*. 2001;24:794.

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