**Institute for Safe Medication Practices (accessed 3/30/2020)**

***Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors***

September 7, 2017

**Conduct an FMEA.** Prior to introducing any technology, it is always a good strategy to perform a failure mode and effects analysis (FMEA) to identify potential risk points, and to plan interventions prior to technology implementation based on high potential severity and probability scores, and low detectability scores. Be sure to include representation from all pharmacy personnel who may be using the WFMS, including technicians. Conducting the FMEA prior to implementation of WFMS also allows a comparison of the current compounding process to the ideal process using the technology to identify and communicate anticipated improvements.

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**A Crack in Our Best Armor: “Wrong Patient” Insulin Pen Injections Alarmingly Frequent Even with Barcode Scanning**

**October 23, 2014**

Last month, ISMP learned about some rather alarming data associated with what could be called best practices for proper insulin pen use in a multihospital system. The best practices employed by these hospitals to prevent the sharing of insulin pens between multiple patients included one-on-one staff education regarding the safe use of insulin pens, implementation of barcode scanning of both the patient barcode and the patient- and order-specific barcode on the insulin pen, an electronic medication administration record (eMAR) at the bedside, and an effective monitoring system. Despite these high-level strategies to prevent the sharing of insulin pens, errors still occurred for reasons beyond a knowledge deficit or mistaken belief that changing the needle is sufficient to prevent cross-contamination when sharing pens. Further, the frequency of “wrong patient’s pen” alerts at the bedside that were detected, and administration avoided, with patient- and order-specific barcode scanning gives us great pause when we think about what this means for thousands of US hospitals that are ill-equipped to implement the same best practices and monitor their effectiveness. Fortunately, the hospitals involved are anxious to share what they have learned with the healthcare community at large.

Background: Insulin Pen Safety

Insulin pens are designed to be used multiple times for a single patient using a new needle with each injection. Pens should never be used for more than one patient. Regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of pathogen transmission if the pen is used for more than one person, even if a new needle is used. Older studies have found squamous, epithelial, and red blood cells; hemoglobin; and macrophages in up to 58% of insulin cartridges in used pens.1,2 With newer models of insulin pens introduced since then, a 2013 study found 5.6% of contaminated cartridges in used pens.3 While the level of biologic contamination is believed to occur in quantities enough to transmit bloodborne pathogens, to date, there is no clear evidence of pathogen transmission from pen sharing.4

Yet, it can’t be stated enough that pen sharing could lead to such an adverse outcome.1-4

In our March 27, 2008 newsletter,5 we first warned facilities that we had received reports of insulin pen sharing between patients. In one report, a nurse told us that colleagues at her hospital often borrowed a pen from another patient, put on a new needle, and administered a dose to the second patient using the same pen, rather than wait for the patient’s pen to be dispensed from the pharmacy. Evidently, the nurses failed to recognize the possibility of biologic contamination of the insulin solution, even if aspiration does not occur prior to injection.

Since then, ISMP and others have chronicled large-scale, potential exposures to bloodborne pathogens caused by using insulin pens for multiple patients after changing the needle, including:6-10

* 2,114 patients at a Texas Army medical center in 2009
* 2,345 patients at a Wisconsin clinic in 2011
* 716 patients at a New York Veterans Affairs medical center in 2013
* 1,915 patients at a New York general hospital in 2013
* 3,149 patients at a Connecticut hospital in 2014

In 2009, in response to reports of improper use of insulin pens in hospitals, the US Food and Drug Administration (FDA) issued an alert for healthcare professionals to remind them that insulin pens are meant for single patient use only and are not to be shared between patients.11 FDA worked with ISMP to produce a Patient Safety News video that discussed how contamination could occur.12 FDA also began working with the Centers for Disease Control and Prevention (CDC) and other professional organizations to address infection control issues with insulin pens.

In our October 21, 2010 newsletter, we again mentioned the ongoing safety issue with insulin pens, noting that special precautions are required before implementation in hospitals.13 In our January 12, 2012 newsletter, we published a Hazard Alert about continuing events related to sharing insulin pens.14 At that time, we urged hospitals to dispense insulin pens assigned to individual patients only and to label the pens accordingly. We also re-emphasized that safety could only be assured through timely education and ongoing monitoring. If education and continuous monitoring could not be accomplished, we suggested that hospitals may need to examine their practices to determine if patients would be safer by dispensing insulin vials or prefilled syringes. We also called for manufacturers to prominently label pens with a statement such as, “Warning! For Single Patient Use ONLY.” Many manufacturers have yet to implement this important strategy despite the seriousness and scope of this ongoing problem.

In our May 31, 2012 newsletter, we reported that the Centers for Medicare & Medicaid Services (CMS) was citing hospitals if surveyors identified the sharing of insulin pens between patients.15  That year, CDC issued a Clinical Reminder stressing that insulin pens must never be used for more than one person,16 and the Safe Injection Practices Coalition (SIPC) began a campaign to promote, “Be Aware, Don’t Share. One Insulin Pen, Only One Person.”17 Also in 2012, an expert panel convened by the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation concluded that pens could be used safely in hospitals if proper procedures, policies, and staff education are in place.18

In our February 7, 2013 newsletter,19 ISMP again warned healthcare providers about ongoing issues with the reuse of insulin pens for multiple patients. This time, we suggested that the risk associated with pen reuse is best mitigated by removing insulin pens from use in inpatient settings. Also in 2013, the 2012 ASHP Foundation consensus recommendations were published along with a call for rigorous evaluations to assess the impact of these recommendations.18 It is with this objective in mind that the aforementioned multihospital system has agreed to share their findings with others in confidence.

Multihospital Insulin Pen Use

In 2008, several hospitals within a multihospital system began using pens for various types of insulin. In 2013, when ISMP suggested that hospitals consider transitioning away from insulin pens, the multihospital system convened an interdisciplinary team to evaluate the issue. The team conducted a detailed failure mode and effects analysis (FMEA) associated with using one patient’s pen for another patient. In the areas of greatest risk, the system identified safety measures and best practices that, once implemented, the system believed would allow for proper use of insulin pens. Thus, the team recommended continued use of the pens once the best practices were in place. These best practices included:

**Standardized use.** A decision was made to use insulin pens for just one insulin type (rapid-acting) to reduce the risk of pharmacy application of a barcode to the wrong pen—an error that would not be picked up by the barcode system if the barcode was scanned. Other types of insulin were dispensed from the pharmacy in vials (e.g., intermediate-acting insulins) or pharmacy-prepared, patient-specific syringes (e.g., basal insulins).

**Tamper-evident tape on each pen.** Tamper-evident tape was applied perpendicular to the pen cap/barrel junction to help prevent accidental reuse if a pen was returned to the pharmacy for credit.

**Order-specific, barcoded label.** A computer-generated, order-specific, barcoded label was applied to the barrel like a flag on each pen. The label included the patient’s name and tied the specific insulin pen to the specific patient. The label covered the manufacturer’s barcode to prevent accidental scanning but left uncovered the name of the insulin and the manufacturer’s lot number and expiration date.

**Labeling of pen only.** The labeled pens were dispensed to patient-specific medication bins in automated dispensing cabinets (ADCs) in unlabeled baggies. This prevented the risk of placing the pen for one patient into a baggie labeled for another patient.

**Barcode system alerts.** If a nurse scanned the label of an incorrect patient-specific insulin pen, a highly visible alert notified the nurse that the drug was not a valid order for the patient. This was a hard stop that did not allow the nurse to document administration of the dose on the eMAR unless the correct pen was obtained and scanned or if the barcode scanning workflow was abandoned to manually document administration of the insulin.

**Procedure just a click away.** The eMAR (and order entry) screens included an insulin pen safety hyperlink that users could click if they had questions, along with a reminder to use insulin pens for one patient.

**Initial and ongoing education.** Insulin pen procedures and the problems associated with sharing pens were included in an initial wave of education for nurses, and the topic appeared in system-wide newsletters, staff in-services, online educational modules, and departmental meetings.

**Ongoing monitoring.** The multihospital system began monitoring immediately after implementing the best practices. Daily, weekly, and monthly barcode medication administration reports were monitored to evaluate overall nurse compliance with scanning the patient and insulin pen, to identify close calls where the wrong pen was at the bedside but not used to administer an injection, and to identify wrong pen injections where the nurse received a “wrong pen” alert but proceeded with administration and manual eMAR documentation without scanning the correct pen.

Monitoring Best Practices

**Month 1.** Monitoring during the first month showed several instances in which a pen was reused for another patient. In one event, the nurse scanned the pen and received a warning that it was not a valid order for the patient. She mentally confirmed the insulin order but could not find a pen labeled for that patient. So she withdrew a dose from the cartridge of another patient’s pen using an insulin syringe, administered the dose, and manually documented it. The nurse knew she could not use the same pen for more than one patient. But she mistakenly believed it was acceptable to administer a dose taken from the cartridge of another patient’s pen, believing it could be used like a multiple-dose insulin vial.

In another event, after scanning the pen and receiving an alert that the drug was not a valid order, the nurse mentally confirmed that the pen contained rapid-acting insulin as listed on the eMAR. Not understanding the alert, she administered a dose of the insulin to the patient using the scanned pen and then manually documented administration. The nurse had been carrying two insulin pens in her pocket and inadvertently used the wrong patient’s pen to deliver the dose. Unfortunately, the patient whose pen was used in error tested positive for active hepatitis C. To date, seroconversion has not been detected in the patient who received the dose.

Another error involved a new nurse who received an alert when scanning an insulin pen. The nurse had found two pens in the patient’s medication supplies. She asked another nurse about the alert. Looking at both pens, the nurses saw that they were identical products and noticed that both listed the correct location (unit, room #) of the patient. Neither nurse noticed that a different patient’s name was on the pen that was scanned, likely due to confirmation bias. The pen used to administer the insulin dose had been dispensed for the prior patient in the room and had not been removed from the patient’s locked storage drawer in the room after discharge.

It is important to note that, particularly with the latter two errors, the events did not happen because nurses thought it was acceptable to use another patient’s pen after just changing the needle. Instead, the nurses thought they had the correct patient’s pen and then mistakenly used it to administer a dose.

After these errors, the pharmacy began enlarging the patient’s name and highlighting it in yellow on the pen label. Additional barcodes were added to the “flag” so they were visible on both sides of the folded label, and the manufacturer’s barcode was blacked out and covered by the patient-specific labeling to be sure only the pharmacy label was scanned. Managers were asked to individually coach each clinician who may administer insulin about the correct use of insulin pens, and a flyer was created as a loose script for the coaching sessions. Within a few weeks, 99% of all nurses had received the one-on-one coaching about safe insulin pen use.

**Month 2.** During the second month, several more errors happened. Two events again happened when a previous patient’s insulin pen was left in the locked storage drawer in the room after discharge. In these cases, the tamper-resistant tape was still intact because the pen had not been used for the prior patient. Although no potential cross-contamination occurred, the wrong patients’ pens were used despite issuance of an alert that the wrong pen was in hand, and before the correct pen could be dispensed for the newly admitted patients.

**Month 3.** In the third month, errors continued despite all efforts to prevent them. During dispensing, pens were accidentally placed in the wrong patient’s medication bin in the ADC. During administration, pens were accidentally obtained from a roommate’s proximal medication bin in the ADC or returned to the wrong bin after use. Analysis of the events detected by the barcode monitoring system alone during the first 3 months showed that the contributing factors were not related to a knowledge deficit about the dangers of sharing pens. Instead, they were almost exclusively caused by system issues, at-risk behaviors, and human error associated with inadvertently administering an insulin dose to one patient from another patient’s pen. Mixing up pens carried in pockets; keeping pens in locked drawers in patients’ rooms where they may not be removed in a timely fashion upon discontinuation; untimely removal of pens from units upon discharge or transfer; accidentally retrieving the wrong patient’s pen from a proximal medication bin; dispensing the pen to the wrong patient bin; putting the pen back into the wrong patient bin after use; alert fatigue; and other system and behavioral issues were resulting in inadvertent use of the wrong patient’s pen.

**Tipping point.** Looking at the data collected over a 3-month period, the multihospital system found that the aggregate data alone could lead to overconfidence in barcode scanning to detect errors because the overall percentages of correct use were high. For example:

The overall frequency of scanning the patient, the pen, or both was well over 99% for close to 80,000 insulin pen doses administered. While these percentages seem laudable, even the high rate of compliance meant that barcode scanning **did not occur** during 800 patient encounters in which insulin administration via a pen occurred over 3 months. Thus, mistakes for up to 800 patients could not be confirmed or ruled out.

The rate of close calls that were averted at the bedside due to barcode scanning was less than 1% for close to 80,000 insulin pen administrations during the 3 months. But, again, more than 400 times in 3 months, nurses had picked up the wrong patient’s insulin pen and, without the barcode scanning system, might have used it to administer a dose. These results shed light on the frequency of wrong pen injections that may be occurring in hospitals that have not implemented barcode scanning. While some may view these data as proof of how robust the barcode scanning system is, we believe it is no less alarming than if the hospitals had detected 400 cases of potential wrong site/wrong patient surgery during “time outs” over 3 months!

The rate of using the wrong patient’s insulin pen when administering a dose to another patient was less than 0.1%. However, this still meant that 7 patients received an insulin dose using another patient’s insulin pen over 3 months.

Conclusion

Despite laudable compliance with the best armor available to prevent “wrong patient” pen use, this multihospital system decided, after 3 months of data, to dispense 3 mL vials of rapid-acting insulin instead of insulin pens. For now, the hospital system is not convinced that the benefits of using insulin pens in hospitals (e.g., accurate dosing) outweigh the risks—even if every nurse knows that pens should not be shared, and best practices are implemented, including order-specific barcode scanning with compliance rates above 99% and a hard stop if the wrong pen is scanned.

For ISMP, this multihospital system’s experiences have pulled back the curtain to view a crack in the armor of patient- and order-specific barcode scanning and its ability to ensure correct pen use. Even with this and other strategies considered best practices, hospitals are still vulnerable to pen sharing. While we can’t call for an all-out moratorium on using insulin pens in hospitals, we still lean toward their use only under special circumstances, such as the use of pens that may become available for concentrated U-200, U-300, and U-500 insulin.

We urge hospitals to consider the findings from the multihospital system when determining the safest way to dispense and administer insulin to inpatients. Of course, there are also risks associated with using insulin vials that can lead to errors,20 and we can’t ignore the current reality that other bloodborne diseases may bring new meaning to risks associated with reuse of pens or misuse of vials. Thus, we know decisions regarding pen vs. vial use may not be clear-cut for all hospitals. ISMP will continue to bring information to readers as it becomes available to help hospitals make the most informed decisions possible.

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