The Current State of “Wrong Patient” Insulin Pen Injections

INTRODUCTION

Thousands of patients in the United States have received injections from potentially contaminated insulin pens, typically involving inappropriate or unrecognized sharing of a patient’s previously used insulin pen device. Analyst query of the Pennsylvania Patient Safety Reporting System (PA-PSRS) revealed similar event reports in Pennsylvania.

A variety of insulin pen devices are currently available in the United States. Insulin pen devices were originally developed to facilitate accurate and easy patient self-administration of insulin. The pen devices are designed to be used multiple times by a single patient, using a new needle with each injection; these devices are not to be used for more than one patient. Practitioners and patients may not recognize that biological contamination of the insulin solution contained in the pen is possible during regular use of the device.

Several studies found that regurgitation of biological material into the insulin cartridge can occur during administration, creating a risk of pathogen transmission if the pen device is used for more than one patient. Use of a new needle does not reduce this risk. Sonoki et al. detected hemoglobin in 4.1% of insulin cartridges tested. In a study of 120 patients, Le Floch et al. detected non-inert material, including squamous and other epithelial cells, in 58% of the insulin cartridges tested. In 2013, Herdman et al. conducted an analysis of newer models of insulin pens, introduced after those earlier studies, and found contamination in 5.6% of cartridges in used pens.

Since 2009, several cases of inappropriate sharing and wrong-patient use of insulin pen devices have been reported in the national media and literature (see Figure 1). These cases have involved thousands of patients and required large-scale efforts to notify patients and test patients for HIV and hepatitis. In each of these events, sharing or reuse of pens may have taken place over a period of years before the practice was identified.

METHODS

Pennsylvania Patient Safety Authority analysts searched for and reviewed insulin-related events that were reported through PA-PSRS from 2005 through 2014 to identify cases and contributing factors of wrong-patient errors and inappropriate sharing of insulin pens. Specifically, the “medication prescribed” and “medication administered” fields in medication error event reports were queried by the brand and nonproprietary names of the insulin products approved and on the market. This resulted in a data set with 23,159 reports. The initial query was not limited to the names of insulin pen devices, as facilities are not required to submit specific, official brand names or device information in medication product information fields.

The event descriptions contained in the resultant data set were then searched for the term “pen” as well as the names of the various approved insulin pen products to identify events involving the use of pen devices. The “medication prescribed” and “medication administered” fields were also examined to identify events involving pen devices when possible.

RESULTS

Analysts identified 82 reports of potential or actual wrong-patient errors with the use of insulin pen devices. Over half (n = 43) of the reports described actual administration events (e.g., a patient received a dose of insulin from another patient’s pen), 35.4% (n = 29) were close calls in which actual administration did not occur, and the remaining 12.2% (n = 10) did not indicate whether or not administration took place.
Nearly two-thirds (n = 54) of the 82 events, including roughly 67.4% (n = 29) of the 43 actual administration events, occurred during 2013 or 2014. Figure 2 illustrates the increasing trend in reported events.

Twenty-five different facilities in Pennsylvania reported events. The facilities ranged in size and facility type from critical access hospitals to large teaching facilities. Analysts also identified that events have occurred in all six regions of the commonwealth, as adopted by the Authority (see Figure 3).

Analysts were able to determine contributing factors when sufficient detail was provided in the event description. Improper or untimely disposal of a previous patient’s insulin pen upon patient discharge or transfer was cited in 12.2% (n = 10 of 82) of all reports and 16.3% (n = 7 of 43) of reports involving actual administration of insulin. Analysts were not able to determine if an actual administration took place in the other three reports.

Following is an example of an untimely disposal of a previous patient’s insulin pen contributing to a wrong patient error. Note that the details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

Previous patient was discharged from this room. This patient was admitted to the same room. Previous patient’s insulin pen was left in the medication server box. New patient was given correct dose of correct medication from the previous patient’s insulin pen. Event found upon pharmacy technician rounding on the medication server boxes after event occurred.

Mix-ups between roommates were cited in 6.1% (n = 5 of 82) of all the reports. Nearly 10% (n = 4 of 43) of the actual administration errors were associated with mix-ups between roommates, as shown in the following example.

The patient received insulin from roommate’s insulin pen. Physician notified. Lab work ordered. Both the patient and her family notified of incident. Consent obtained for blood work. Insulin pens handed to nurse placed in drawer. [Nurse] removed pens and scanned to administer without looking at labels.

Refer to the “Notes: Figure 1” section at the end of this article for the corresponding references.
Figure 2. Number of Wrong-Patient Events Involving Insulin Pen Devices Reported by Year to the Pennsylvania Patient Safety Authority, 2005 through 2014 (N = 82)

<table>
<thead>
<tr>
<th>YEAR</th>
<th>Reached patient—actual administration</th>
<th>Close call—no actual administration</th>
<th>Unknown*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>2</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>2013</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>2012</td>
<td>2</td>
<td>3</td>
<td>2</td>
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<tr>
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<tr>
<td>2005</td>
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</tr>
</tbody>
</table>

* The reports did not provide enough detail to determine if an actual wrong-patient administration occurred.

Figure 3. Pennsylvania Patient Safety Authority Wrong-Patient Insulin Pen Events by Region of the Commonwealth, 2005 through 2014 (N = 82)

Note: As with all reporting systems, the type and number of reports collected are dependent on the degree to which facility reporting is accurate and complete. The reporting cultures and patterns in each facility, and their interpretations of what occurrences are reportable, do lead to reporting variation.

Roughly 6% (n = 5 of 82) of all the reports also indicated that storage-related issues (e.g., insulin pens returned to wrong storage bin, insulin pens not stored in patient-specific bins) contributed to the events. All five events resulted in an actual wrong-patient insulin administration, including the following example.

*I gave the patient her Novolog® [insulin aspart (rDNA origin) injection].

After giving it, I realized that it was the Novolog pen from the patient in [room A]. The patient in [room A] had the patient in [room B]'s Novolog in her drawer and vice versa. Unknown if the patient in [room A] received insulin from wrong pen prior to discovery.

Other contributing factors included distractions (4.9%, n = 4 of 82), time pressures (4.9%, n = 4 of 82), wrong patient label on pen (1.2%, n = 1 of 82), and medication not available (1.2%, n = 1 of 82).

DISCUSSION

An increase in the number of reported potential or actual wrong-patient errors with the use of insulin pen devices occurred in 2013 and 2014 (see Figure 2). It is not known why this surge occurred. One possible explanation may be that staff awareness of the risks may have been elevated with the national media coverage and internal hospital staff education programs. Another possible explanation is that the use of insulin pens in hospitals may have risen, thereby increasing opportunities for close calls and events. However, it is likely that the actual incidence of potential and actual wrong-patient errors with insulin pen devices is higher, as many events may go unnoticed or unreported.

The national reports and Pennsylvania data illustrate that unsafe practices with the use of insulin pens place patients at risk of bloodborne pathogen transmission. It should be noted that while the level of biological contamination is
believed to occur in sufficient quantities to transmit bloodborne pathogens, to date, there is no clear evidence of pathogen transmission from pen sharing. However, it cannot be stated strongly enough that insulin pen sharing, whether intentional or not, could lead to this adverse outcome. In response to the nationally reported cases of insulin pen sharing, a number of national organizations and agencies, including the Centers for Medicare and Medicaid Services, Centers for Disease Control and Prevention, US Food and Drug Administration, Safe Injection Practices Coalition, American Society of Health-System Pharmacists Foundation, and Institute for Safe Medication Practices have published extensively on insulin pen safety and provided recommendations to prevent inadvertent exposure to bloodborne pathogens (see Figure 1). Recommendations have largely focused on education, labeling, policy creation, and monitoring, including the following:  

- Never use insulin pens for more than one person, even when the needle is changed. They are designed for use by a single patient only.
- Clearly label insulin pens with the person’s name or other identifying information to ensure that the correct pen is used exclusively on one individual. Take care to not cover essential product information (e.g., product name) or the dosing window.
- Hospitals and other facilities that use insulin pens and similar devices should have policies addressing safe use.
- Hospitals should have a program to ensure that staff are appropriately educated in advance of introducing these products and to actively monitor to ensure strict adherence to safe practices.
- If multipatient use is identified, promptly notify exposed individuals and offer appropriate follow-up, including bloodborne pathogen testing.

Unfortunately, hospitals may find it difficult to maintain effective ongoing education and monitoring because of staff turnover and other pressures. Breakdowns in these processes will enable hazardous conditions to persist because it only takes a few practitioners who are not aware of the risks of disease transmission to inadvertently expose patients to pathogens.

Current pen designs also provide challenges to applying patient-specific labels. In order to avoid affixing the label to the removable pen cap or covering critical drug information (e.g., drug name), pharmacy staff members must affix a flag label to the limited free space that exists on the pen body (see Figure 4). Faced with the risk of disease transmission, one multihospital system chose to move beyond the recommendations described above. They conducted detailed failure mode and effects analysis and employed safety best practices, in addition to ongoing education, to reduce the risk of wrong-patient insulin pen errors. Their strategies included the following:

- Standardize to use pen devices for only one type of insulin product, a rapid-acting insulin, and dispense other insulin products in vials or pharmacy-prepared syringes.
- Apply tamper-evident tape to help identify previously used pens.
- Cover the manufacture’s bar code on the pen with an orders-specific, bar-coded label to associate the specific pen with a specific patient.
- Implement highly visible alerts and hard stops in the bar-code system if the wrong patient’s identification band is scanned.
- Monitor bar-code administration records on a daily, weekly, and monthly basis to evaluate scanning compliance, identify close calls, and identify potential wrong-pen injections in which the nurse received a “wrong
“pen” alert but manually documented administration in the electronic medication administration record without scanning the correct pen. Despite these additional layers of safety, these hospitals identified seven instances in which a pen was reused on another patient during the first three months following implementation. In more than 400 events, the nurse picked the wrong patient’s insulin pen but the error was caught by the bedside bar-code scanning system prior to administering the dose. However, the facilities also identified that bar-code scanning did not occur in roughly 800 instances when insulin was administered with a pen device. Analysis of the contributing factors showed that most of the events were not due to knowledge deficits of the danger of sharing pens but were primarily associated with system issues, human error, and at-risk behaviors. Similar to what was found in the events reported to the Authority, untimely removal of pens from units upon patient 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; and other system and behavioral issues contributed to the wrong-patient events. Presented with continued vulnerabilities despite the implementation of the higher-leverage strategies mentioned above, the hospital system decided to discontinue the use of insulin pens and dispense the rapid-acting insulin in 3 mL vials.

**LIMITATIONS**

In-depth analysis by the Authority of wrong-patient events with the use of insulin pens occurring in Pennsylvania hospitals is limited by the information reported through PA-PSRS, including the event descriptions. Inconsistent use of product names and spellings confounds the identification of insulin-pen-related reports. As a result, additional wrong-patient events may have been reported but were not identified by the query and analysis.

**CONCLUSION**

Despite widespread media coverage, recommendations from various national organizations, and application of strategies considered best practices, wrong-patient insulin pen injections continue to occur, and patients continue to be vulnerable to the risk of wrong-patient errors and potential transmission of bloodborne pathogens with insulin pens. This has prompted some organizations to question whether to use pens, vials, or a combination of the two.

**NOTES**

7. Le Floch JP, Herbreteau C, Lange F, et al. Biological contamination of insulin pens and close examination of insulin-pen-related events. As a result, additional wrong-patient events may have been reported but were not identified by the query and analysis.


NOTES: FIGURE 1


4. Seely R. Dean Clinic says patients may have been exposed to hepatitis, HIV [online]. Wis State J 2011 Aug 13 [cited 2015 Apr 27]. http://host.madison.com/news/local/health_med_fit/dean-clinic-says-patients-may-have-been-exposed-to-hepatitis/article_5806e6b6-6d2611e0-8deb-0011c4c002e0.html


THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

The Pennsylvania Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (MCARE) Act. Consistent with Act 13, ECRI Institute, as contractor for the Authority, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the Pennsylvania Patient Safety Authority, see the Authority’s website at http://www.patientsafetyauthority.org.

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The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP’s efforts are built on a nonpunitive approach and systems-based solutions.