Improving Patient Safety in the Treatment of Diabetes: Opportunities for Pharmacy
Autumn Stewart-Lynch, PharmD, BCACP, CTTS

Today’s Speaker
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Potential Conflicts of Interest
The speaker’s spouse is an employee of Pfizer, Inc.

Learning Objectives
At the conclusion of this program, participants will be able to:
1. Describe the impact of medication errors and unsafe medication use encountered in the treatment of diabetes.
2. Identify examples of medication errors and patient safety problems that arise with the use of insulin and oral diabetes treatments.
3. Apply strategies utilized in the practice of pharmacy to prevent patient harm related to the treatment of diabetes.
According to the CDC, what is the most common cause of ED visits among adults with diabetes?

A. Hyperglycemia  
B. Hypoglycemia  
C. Needle-stick injuries  
D. Falls

Insulin-related hypoglycemia and errors leading to emergency department visits are most frequently caused by which precipitating factor?

A. Intentional use of additional insulin doses  
B. Inappropriate timing of insulin and meals  
C. Unintentional use of wrong amount of insulin  
D. Accidental use of wrong insulin product

A physician writes for “Novolog 70/30® 20 units with breakfast and dinner”.  The order is correctly entered into the pharmacy’s dispensing software but the patient is dispensed Novolog®.  Which one of the following strategies could have prevented this error from reaching the patient?

A. Store insulin products in the refrigerator arranged by manufacturer  
B. Double check timing of insulin doses with meals  
C. Require insulin orders to be entered and dispensed by RPh only  
D. Employ a mandatory, independent double check at critical steps
Knowledge Pre-Assessment

A patient reports higher than normal blood glucose readings since switching to an insulin pen. The insulin product and dose are unchanged. Which one of the following is an error in administration that could result in this observation?

A. Rotating injection sites
B. Using a syringe to draw insulin from pen device
C. Removing the needle from skin too quickly
D. Priming the pen device before each use

Diabetes Statistics: National

2015 CDC estimates
- 30.3 million (9.4%) Americans have diabetes
  - 7.2 million (23.8%) are undiagnosed
  - About 1 in 4 adults over the age of 65 have diabetes

Diabetes Statistics: PA

2015 CDC estimates
- 8.8% of adults living in PA are diagnosed with Diabetes
  - Fayette County
    - CDC “Diabetes Belt”
  - Clearfield County
    - Adults with diabetes >10%
Medication Use in Diabetes

### Treatment of diabetes among people aged 18 years or older with diagnosed diabetes, United States, 2010–2012

<table>
<thead>
<tr>
<th>Medication Type</th>
<th>Number of Adults Using Diabetes Medication (in millions)</th>
<th>Percentage Using Diabetes Medication (unweighted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin only</td>
<td>1.2</td>
<td>14.0</td>
</tr>
<tr>
<td>Both insulin and oral medication</td>
<td>5.1</td>
<td>14.7</td>
</tr>
<tr>
<td>Oral medication only</td>
<td>11.5</td>
<td>14.6</td>
</tr>
<tr>
<td>Neither insulin nor medication</td>
<td>7.0</td>
<td>14.4</td>
</tr>
</tbody>
</table>

*Data are subject to total number of adults with diagnosed diabetes because of the different data sources and methods used to estimate the number of adults with diabetes.


“To err is human…”

The National Coordinating Council for Medication Error and Prevention (NCCMERP) defines the term “medication error” as:

... any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems including: prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

http://www.nccmerp.org/about-medication-errors

ISMP List of High-Alert Medications

**Community/Ambulatory Healthcare**
- Insulin
- Metformin
- Oral hypoglycemics
  - Sulfonylureas (glibizide, glimepiride, glyburide)
- Repaglinide

**Acute Care Settings**
- Insulin, subcutaneous and IV
- Oral hypoglycemics
- Insulin U500

http://www.ismp.org
What examples have you seen in practice?

Emergency Department Visits

Table 5. Number and rate of emergency department visits among adults aged 18 years with diagnosed diabetes, United States, 2014

<table>
<thead>
<tr>
<th>Case of emergency department visit</th>
<th>No. in thousands</th>
<th>Crude rate per 1,000 persons with diabetes (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic ketoacidosis</td>
<td>211</td>
<td>18.5 (16.4-20.6)</td>
</tr>
<tr>
<td>Hypoglycemic</td>
<td>245</td>
<td>21.2 (19.4-23.1)</td>
</tr>
<tr>
<td>Hypoglycemic crisis</td>
<td>25</td>
<td>0.3 (0.0-1.2)</td>
</tr>
<tr>
<td>95% confidence interval</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Research

Original Investigation | LESS IS MORE

National Estimates of Insulin-Related Hypoglycemia and Errors Leading to Emergency Department Visits and Hospitalizations

Andrew C. Geller, MD, Nadine Shehata, PharmD, MPH, Maribeth C. Lawrance, MPH, Scott R. Kegler, PhD, Kelly N. Wenderoth, MPH, Gina J. Aya, PharmD, CDSS, Daniel L. Burdron, MD, MPH

A look at the numbers...

Between 2007 and 2011

- 97,648 emergency department (ED) visits for insulin-related hypoglycemia and errors (IHEs) occurred annually. IHEs account for 9.2% of ED visits for all adverse drug events (ADEs)
  - 1 of every 8 ED visits for ADEs among the very elderly (>80 years)
  - 53.3% IHEs occurred at home
  - 95.4% related to clinical presentation of hypoglycemia


Precipitating Factors

<table>
<thead>
<tr>
<th>Precipitating Factors</th>
<th>Annual National Estimate, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meal-related Misadventure</td>
<td>45.9 (38.2-53.6)</td>
</tr>
<tr>
<td>Unintentionally took wrong insulin product</td>
<td>22.1 (17.2-26.9)</td>
</tr>
<tr>
<td>Unintentionally took wrong dose/confused units</td>
<td>12.2 (9.2-15.2)</td>
</tr>
<tr>
<td>Intentionally took &quot;additional&quot; dose</td>
<td>6 (4.7-7.6)</td>
</tr>
<tr>
<td>Pump-related misadventure</td>
<td>1.5 (0.7-2.2)</td>
</tr>
<tr>
<td>Other misadventure</td>
<td>13.4 (10.4-16.4)</td>
</tr>
</tbody>
</table>


Case examples

- 51 year old male, per spouse she injected him with 50 units of NovoLog instead of 50 units of Lantus, blood glucose 33 at time of arrival.

- 62 year old male given 40 units of regular insulin instead of 4, finger stick blood glucose 47.

- Unrestrained 19 year old female driver hit tree and brick wall. Blood glucose was 24. Took insulin 2 hours ago, but no time to eat.

How many units of Lantus is this patient to receive?

Pennsylvania Patient Safety Authority: Prescribing Errors

- Insulin was 3rd most common drug class involved in serious prescribing errors
- Insulin accounted for 16.5% of all serious errors caused by Wrong dose/Overdose
  - Illegible handwriting
  - Error-prone abbreviations (e.g., “u” for units) and trailing zeros
  - Confusing the product concentration (i.e., 100 units/mL) with the dose
  - U-500 insulin
- Example: Home med list included Humalog® 75/25 Mix; physician inadvertently ordered Humalog® resulting in symptomatic hypoglycemia

Wrong Drug Errors

Figure 1. Examples of Insulin Products Reported to PA-PSRS as “Wrong Drug” Errors.

- Humalog – Humulin R
- Humulin N – Humulin R
- Humulin R – Humulin 70/30
- Humalog 70/30 – Humalog 75/25
- Humalog 75/25 – Humalog
- Lente Insulin – Lantus
- Novolog – Novolog Mix 70/30
- Novolog Mix 70/30 – Humulin 70/30
- Novolin 70/30 – Novolog Mix 70/30
ISMP Confused Drug Names

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Confused Drug Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actos</td>
<td>Actonel</td>
</tr>
<tr>
<td>Amaryl</td>
<td>Reminyl</td>
</tr>
<tr>
<td>Apiolex</td>
<td>Spiriva</td>
</tr>
<tr>
<td>Avandia</td>
<td>Coumadin, Prandin</td>
</tr>
<tr>
<td>ChloropAMIDE</td>
<td>ChlorproMAZINE</td>
</tr>
<tr>
<td>GlynDIDE</td>
<td>GlyBURIDE</td>
</tr>
<tr>
<td>Janumet</td>
<td>Januvia, Sinemet, Jantoven</td>
</tr>
<tr>
<td>Januvia</td>
<td>Enjuva</td>
</tr>
<tr>
<td>Lantus</td>
<td>Latida</td>
</tr>
<tr>
<td>MetFORMIN</td>
<td>MetformNDAZIDE</td>
</tr>
<tr>
<td>Stat5UPhin</td>
<td>SUMAtriptan</td>
</tr>
</tbody>
</table>

Incorrect Insulin Administration

<table>
<thead>
<tr>
<th>Error</th>
<th>Risk to patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-using pen devices between patients (+/- needle change)</td>
<td>Transmission of bloodborne pathogens (HIV, Hep C, Hep B)</td>
</tr>
<tr>
<td>Failure to “re-suspend” NPH</td>
<td>Pharmacokinetic/Pharmacodynamic changes leading to hypoglycemia or poor glycemic control</td>
</tr>
<tr>
<td>Intramuscular injection</td>
<td></td>
</tr>
<tr>
<td>Failure to rotate injection sites</td>
<td></td>
</tr>
<tr>
<td>Failure to prime before use</td>
<td></td>
</tr>
<tr>
<td>Failure to wait 5-10 sec after injection</td>
<td></td>
</tr>
<tr>
<td>Failure to remove pen needle inner shield</td>
<td>Insulin underdosing</td>
</tr>
<tr>
<td>Using pen cartridge as a vial</td>
<td>Insulin overdosing, contamination</td>
</tr>
</tbody>
</table>

Strategies to Improve Patient Safety

*ISMP Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults* - ISMP 2017 - www.ISMP.org
Education

Mandatory Patient Education

- Discharge/Pick up
- Basic "Survival Skills"
  - How to self-administer (dial/draw up doses, rotate injection sites, re-suspend?)
  - When to inject with regard to meals?
  - Blood glucose monitoring
  - Recognize and treat hypoglycemia

- "Teach Back" Method
- Written materials
- Revisit at each visit

- "Insulin Injection Resources"
  [Website]
- "ISMP Safety Center"
  [Website]

Education

Mandatory Patient Education

- "Teach back" method
- Written materials
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- "Insulin Injection Resources"
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- "ISMP Safety Center"
  [Website]

Education

Continuing Professional Development

- Pharmacist
  - Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults, ISMP 2017. [Website]
- Staff
  - Pharmacist’s Letter "Technician Tutorial: Dispensing Insulin and Other Injectable Meds"
FDA Approvals

2015
- Tresiba® (insulin degludec injection)
- Humalog® 70/30 insulin isophane injection
- Basaglar® (insulin glargine injection, 100 units/mL)
- Admelog® (insulin lispro injection, 300 units/mL)

2016
- Humulin® R U-500 (regular insulin 500 units/mL) KwikPen®

2015
- Tresiba® (insulin degludec injection)
- Fiasp® (insulin aspart injection)

Insulin Agents

**Basal (Background Insulin)**

<table>
<thead>
<tr>
<th>Intermediate Acting</th>
<th>Long Acting</th>
<th>Ultra Long Acting</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPH (Humulin N, and Novolin N®)</td>
<td>Glargine U-100 (Lantus®, Basaglar®)</td>
<td>Detemir (Levemir®)</td>
</tr>
<tr>
<td>Glargine U-100 and U-200</td>
<td>Degludec (Tresiba®)</td>
<td>Glargine U-300 (Toujeo®)</td>
</tr>
<tr>
<td>Onset 3-6 hrs</td>
<td>Onset 1 hr</td>
<td>Onset 30-90 mins</td>
</tr>
<tr>
<td>Onset over 6 hrs</td>
<td>Onset 8-24 hrs (dose-dependent)</td>
<td>Duration 36 hours (takes 5 days for Css)</td>
</tr>
<tr>
<td>Peak 4-12 hrs</td>
<td>Duration 4-24 hrs</td>
<td>Duration 6-24 hrs</td>
</tr>
<tr>
<td>Duration 12-24 hrs</td>
<td>Duration 8-24 hrs</td>
<td>Duration 36 hours</td>
</tr>
</tbody>
</table>

**Bolus (Prandial Insulin)**

<table>
<thead>
<tr>
<th>Short Acting</th>
<th>Rapid Acting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular U-100 (Humulin R, Novolin R®)</td>
<td>Liapro U-100 and U-200 (Humalog®, Admelog®)</td>
</tr>
<tr>
<td>Regular U-500 (Humulin R U-500® CONCENTRATED)</td>
<td>Aspart (Novolog®)</td>
</tr>
<tr>
<td>Glulisine (Apidra®)</td>
<td>Aspart (Fiasp®)</td>
</tr>
<tr>
<td>Onset 30 mins</td>
<td>Onset 15-30 mins</td>
</tr>
<tr>
<td>Peak 3-5 hrs</td>
<td>Peak 4-8 hrs*</td>
</tr>
<tr>
<td>Duration 6-10 hrs</td>
<td>Duration 12-24 hrs*</td>
</tr>
<tr>
<td>30 mins before meal</td>
<td>5-15 mins before meal</td>
</tr>
</tbody>
</table>
The Role of the Pharmacist

Standardization

- Prescribing
  - Abbreviations, trailing and leading zero
  - Prandial insulin sig should include direction related to mealtime
  
  \[ \text{Carbohydrate \% Daily Value} \]

- Storage and Dispensing
  - Products with similar packaging or names stored separately
  - TALLman Lettering
  - Limiting access to high-alert medications
  - U-500 insulin
  - Formulary processes

- Abbreviations, trailing and leading zero

- Prandial insulin sig should include direction related to mealtime

- Home med list included Humalog® 75/25 Mix; physician inadvertently ordered Humalog® resulting in symptomatic hypoglycemia
Summary

- Insulin is often associated with significant patient harm when used in error.
- Medication errors related to the treatment of diabetes can occur at any step in the medication use process.
- Pharmacists play a critical role in implementing multifaceted strategies and interventions targeting error prevention to ensure patient safety.