Implementation of a quality improvement initiative to ensure the safe transition from prior-to-admission concentrated insulins to a formulary insulin regimen

Disclosures

- IRB Status: Exempt Status Approved
- Co-Investigators:
  - Carla Federici, PharmD, BCPS
  - Jayme Hartzell, PharmD, BCPS
  - Amanda Patel, PharmD
- Conflicts of Interest: none. The use of brand names for insulin products will be used to clarify/simplify the presentation of treatments. No specific product endorsement is implied.
- Project Sponsorship: none

Learning Objectives

1. Identify products with high risk for error when transitioning patients from their home regimen to a formulary insulin regimen
2. Explain the process for ensuring accurate assessment of prior-to-admission (PTA) insulin dosing
Background

- Increasing availability and utilization of concentrated insulin as well as insulin with novel mechanisms of protraction
- When patients with insulin-dependent diabetes are hospitalized they must be continued on an insulin regimen
- Often, patients will need to be transitioned to an insulin regimen using the hospital's formulary insulin options
- Conversion of outpatient concentrated insulin regimens to inpatient regimens using formulary insulin options has become more complicated and prone to medication errors
- Insulin is defined as a high-alert medication in the acute care setting by the Institute for Safe Medication Practices (ISMP)

Background: new & concentrated insulins

Short Acting
- Humalog® U-200 (insulin lispro)

Intermediate Acting
- Humulin® R U-500 (regular insulin)

Extended Action
- Toujeo® (U-300 insulin glargine)
- Tresiba® (U-100 and U-200 insulin degludec)

Background: new & concentrated insulins

- Toujeo® and Lantus® (insulin glargine)
  - Not bioequivalent
  - Toujeo® → Lantus®: requires 20% dose reduction
  - Toujeo® available in pen only
- Humulin® R U-500
  - Available in both a vial and insulin pen
  - Can be delivered using volumetric syringe, U-100 insulin syringe, or U-500 insulin syringe (new in 2016)
  - Most patients still use a U-100 insulin syringe
- Tresiba® (U-100 and U-200 insulin degludec)
  - Duration of action of 42 hours
  - Dosing window can vary from 8-40 hours
  - Pen only
Objectives of study

- Develop concentrated insulin conversion process to safely transition patients to an inpatient formulary insulin regimen
- Implement an educational program for pharmacy staff and a standardized insulin conversion and documentation process
- Determine if the quality improvement (QI) initiatives implemented decrease the rate of concentrated insulin medication errors

Methods: Study Design

- Retrospective, single-center, observational review of voluntary reporting of medication errors
- Will include all patients admitted to our institution who were previously prescribed a concentrated insulin from:
  - January 2016 through September 2016 for the pre-QI group
  - October 2016 through May 2017 for the post-QI group

Methods: Data Collection

- Information collected from the electronic medical record (EMR) and from medication event reports included:
  - Presence of medication error
  - Severity and stage at which the error occurred as determined by Medication Safety Officer
  - Date of admission and length of stay
  - Type of concentrated insulin product PTA
  - Point of care blood glucose (BG) levels
  - Pharmacist adherence to protocol and documentation for the post-QI group
  - Provider acceptance of pharmacist recommendations for the post-QI group
Methods: Endpoints

The primary outcome to be evaluated:
- Self-reported medication error rates during the study period utilizing the hospital's error reporting software

Secondary outcomes to be evaluated:
- Medication errors stratified by stage at which they occurred
- Medication errors stratified by severity category
- Medication errors stratified by PTA insulin product
- Blood glucose control
- Pharmacist adherence to protocol
- Prescriber acceptance to pharmacist recommendations

Medication Error Categories

<table>
<thead>
<tr>
<th>Error Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Circumstances or events with the capacity to cause error</td>
</tr>
<tr>
<td>B</td>
<td>Error occurred but did not reach the patient</td>
</tr>
<tr>
<td>C</td>
<td>Error reached patient but did not cause harm</td>
</tr>
<tr>
<td>D</td>
<td>Error reached patient and required additional monitoring or intervention to assure no harm</td>
</tr>
<tr>
<td>E</td>
<td>Error caused temporary harm and required intervention</td>
</tr>
<tr>
<td>F</td>
<td>Error caused temporary harm and required intervention and prolonged hospitalization</td>
</tr>
<tr>
<td>G</td>
<td>Error caused permanent harm to the patient</td>
</tr>
<tr>
<td>H</td>
<td>Error required intervention to sustain life</td>
</tr>
<tr>
<td>I</td>
<td>Error contributed to patient death</td>
</tr>
</tbody>
</table>

Quality Improvement Initiatives

- QI strategies implemented September 2016 included:
  - Development of insulin dosing conversion spreadsheet
  - Pharmacist continuing education sessions (1.0 CE credits)
    - Discussed unique pharmacokinetic and dynamic attributes of new and concentrated insulins and compared them to formulary insulin products
    - Identification of insulin products with high risk for error
    - Accurate assessment of PTA insulin dosing
    - Demonstrated how to utilize the new pharmacy tools to correctly transition patients from their PTA regimen to a formulary inpatient insulin regimen
    - Pharmacist documentation of process in EMR
Concentrated insulin dose verification

- Vial and syringe – highest risk of dosing errors
- With Humulin® R U-500 vials: must determine type of syringe used to measure dose
  - Pharmacist asks patient/caregiver to demonstrate how dose is drawn up using sample syringes
  - Need to determine if they are using syringe incorrectly, which with U-500 could be a significant difference in dose due to concentration
- Record syringe type, volume, and units of U-500 in EMR patient home medication list

Concentrated Insulin Pharmacy Process

- Verify correct documentation of insulin in patient’s home medication list
- Order inpatient Certified Diabetes Educator (CDE) consult
- Required documentation in EMR
  - Verification of home concentrated insulin dosing and delivery device
  - Ordering of CDE consult
  - Dose of Lantus®/Humalog® recommended to provider
  - Provider response and changes, if applicable
Results: Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Pre-QI (n=23)</th>
<th>Post-QI (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Age (years)</td>
<td>60.8</td>
<td>58.9</td>
</tr>
<tr>
<td>Male (%)</td>
<td>73.9</td>
<td>53.3</td>
</tr>
<tr>
<td>Length of stay (days)</td>
<td>7.3</td>
<td>4.6</td>
</tr>
<tr>
<td>A1c (%)</td>
<td>7.8</td>
<td>8.0</td>
</tr>
<tr>
<td>BG at admn (mg/dL)</td>
<td>178</td>
<td>186</td>
</tr>
<tr>
<td>Toujeo® (%)</td>
<td>65.2</td>
<td>66.7</td>
</tr>
<tr>
<td>Tresiba® (%)</td>
<td>4.3</td>
<td>6.7</td>
</tr>
<tr>
<td>Humulin R U-500® (%)</td>
<td>30.4</td>
<td>26.7</td>
</tr>
</tbody>
</table>

Results: Pre-QI Medication Errors

- 23 patient encounters
- 2 concentrated insulin medication errors reported
- Both involved Humulin® R U-500 with a vial and U-100 syringe as the delivery device

<table>
<thead>
<tr>
<th>Error Number</th>
<th>Stage</th>
<th>Severity</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Physician</td>
<td>B</td>
<td>Patient on Humulin® R U-500 concentrated insulin PTA, taking 140 units every morning and 150 units every evening. Patient reported dose he measures with U-100 insulin syringe as 28 units every morning and 30 units every evening. Admitting hospitalist entered orders as reported by patient instead of true dose.</td>
</tr>
<tr>
<td>2</td>
<td>Nurse administration</td>
<td>C</td>
<td>Patient on Humulin® R U-500 concentrated insulin PTA. Nurse administered correct amount using U-100 insulin syringe but documented incorrect number of units.</td>
</tr>
</tbody>
</table>
Results: Post-QI Medication Errors

- Data collection and analysis complete through the April 15, 2017
- Primary endpoint:
  - 15 patient encounters
  - No medication errors involving concentrated insulin reported thus far in the post-QI initiative period
  - Error reporting system software upgrade occurred in December 2016
  - Decrease in voluntary error reporting occurred, most likely due to user unfamiliarity

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Medication Error Reporting by Month

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Results: Blood Glucose Control

- Pre-QI patients converted to Lantus®/Humalog®
  - <70 mg/dL: 36%
  - 70-180 mg/dL: 62%
  - >180 mg/dL: 2%

- Post-QI patients converted to Lantus®/Humalog®
  - <70 mg/dL: 51%
  - 70-180 mg/dL: 47%
  - >180 mg/dL: 2%
Results: Blood Glucose Control Stratified by PTA Insulin

Pre-QI Initiative BG Control by PTA Insulin Type

<table>
<thead>
<tr>
<th>Type</th>
<th>Percent</th>
<th>&lt;70 mg/dL</th>
<th>70-180 mg/dL</th>
<th>&gt;180 mg/dL</th>
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<tbody>
<tr>
<td>Tresiba (n=1)</td>
<td>0%</td>
<td>10%</td>
<td>90%</td>
<td>0%</td>
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<tr>
<td>Toujeo (n=15)</td>
<td>0%</td>
<td>10%</td>
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<td>0%</td>
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<tr>
<td>Humulin R U-500 (n=7)</td>
<td>0%</td>
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<td>0%</td>
<td>10%</td>
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<td>0%</td>
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<tr>
<td>Humulin R U-500 (n=4)</td>
<td>0%</td>
<td>10%</td>
<td>90%</td>
<td>0%</td>
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Results: Blood Glucose Control by Presence of Pharmacist Documentation

Post-QI Patients without Pharmacist Documentation

- Percent: 52% <70 mg/dL, 47% 70-180 mg/dL, 3% >180 mg/dL

Post-QI patients with Pharmacist Documentation

- Percent: 54% <70 mg/dL, 42% 70-180 mg/dL, 4% >180 mg/dL

Results: Pharmacist Adherence & Provider Acceptance Post-QI

Pharmacist Adherence

- Pharmacy list correct: 93%
- Pharmacy documentation present: 53%
- CDE consult ordered: 42%
- All items complete: 33%

Prescriber Acceptance

- Accepted: 47%
- Accepted, with changes: 33%
- No Rx documentation: 20%

Results: Blood Glucose Control Stratified by PTA Insulin

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Results Summary

- Small population and sample sizes
- No concentrated insulin medication errors reported following implementation of QI initiative
- A greater percentage of BG checks were >180 mg/dL in the post-QI group regardless of PTA concentrated insulin type
- Overall pharmacist adherence to the concentrated insulin process and documentation was poor

Limitations

- Extremely small sample size
- A major limitation is the use of a voluntary self-reported medication error reporting system to collect data
- Error reporting system software upgrade during post-QI data collection with subsequent decrease in voluntary error reporting
- Poor pharmacist adherence to process, including ordering of CDE consult, may have contributed to decrease in BG control

Conclusion

- Unable to attribute lack of self-reported medication errors post-QI to actual impact versus a decrease in error reporting
- Increased pharmacist adherence to process and documentation may improve BG control
  - CDE consult ordering
- May need to adjust spreadsheet to allow 1:1 conversion from concentrated insulin to Lantus®/Humalog® regimen
Future Directions

- Complete and review remaining 1.5 months of data collection
- Perform statistical analysis on finalized data
- Present results to medication safety committee, inpatient diabetes subcommittee, and pharmacy staff
- Edit and streamline pharmacy processes to increase pharmacist adherence
- Continue to encourage staff education about new insulin formulations as they come to market

References

5. Humalog® U-500 [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC 2015.

Questions?

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