Managing the risks associated with concentrated insulin during care transitions

Vizient Patient Safety Organization Safety Alert

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Background

The use of insulin — whether delivered subcutaneously, intravenously or via continuous subcutaneous insulin infusion pumps — has long been considered high risk and problem prone.[1] Insulin-resistant patients require large doses of insulin to achieve glycemic control.[2] To limit the volume of insulin required by these patients, drug companies have developed additional concentrations. However, adding multiple, new concentrations as well as types of insulin has increased the challenges and complexity that has already existed with insulin for years.

As patients move in and out of the hospital, dosing conversion between insulin types (U-100, U-200, U-300 and U-500) and devices (syringes, pens and pumps) may be required due to formulary restrictions and physical and dietary changes that impact insulin requirements. Consequently, errors are common during changes in insulin concentration and dose conversion, which can lead to an overdose or underdose of up to five times the usual dose, depending on the concentration involved.[3] To mitigate risks associated with conversion errors, the Food and Drug Administration (FDA) requires that all concentrated insulins have a matching delivery device. The newer concentrated insulins are only available in a pen delivery device, while U-500 is available in a pen as well as a vial for use with a dedicated U-500 syringe. Although the FDA recommends the use of a matching delivery device, some patients continue to use the U-100 syringe or a 1-mL tuberculin syringe with the U-500 vial. Additionally, a U-500 insulin safety-engineered syringe has not been developed for use in health care facilities, creating another barrier to its use.

Despite the FDA's recent safety measures, hospitals continue to face challenges in managing the intricacies of patients' home insulin regimens. One of the greatest safety concerns described by clinical experts at Vizient® member organizations is the increased use of concentrated insulin (e.g., U-200 and U-500) in insulin pumps that were designed by manufacturers for U-100 insulin. For patients who require a larger volume of insulin, the use of U-500 in insulin pumps may be necessary, but the potential for errors in dose conversion is high. To compound the issue, physicians have recently started to prescribe U-200 for use in pumps, creating the need for a workaround for pharmacists. Because U-200 is only available in a pen, hospital pharmacists as well as patients are drawing up U-200 from the pen for use in the insulin pump — a practice

that is not recommended by product manufacturers and the FDA because of the risk of conversion errors and air bubbles, which can cause improper dosing.[2,4]

Additional challenges identified in the literature and by clinicians include:

- Lack of organizational policies, procedures and clinical guidelines to guide safe insulin administration within the inpatient setting.[5]
- Hospital restrictions on the use of U-200 and U-300 insulin pens due to the risk of cross contamination from accidental use of pens on more than one patient, as well as financial considerations related to the cost of these pens.[6,7]
- Inaccuracies during medication reconciliation, including confusion about commercially available insulin products marketed under the same name but available in different concentrations; inadequate information gathering; and lack of knowledge.

Assessment

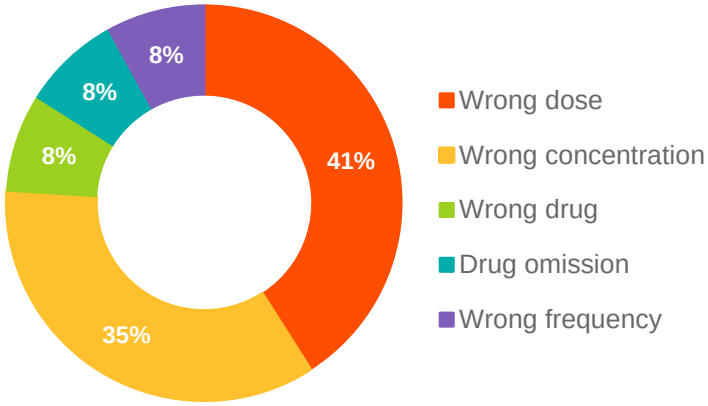
The Vizient Patient Safety Organization (PSO) conducted a search of event reports involving U-200, U-300 and U-500 insulins and analyzed 54 voluntarily reported near-miss and adverse events from January 2016 to May 2018. The data were examined to improve our understanding of common errors, where they occurred in the medication process and contributing factors.

Forty-five percent of events involved U-500, 33 percent U-200 and 22 percent U-300. While U-500 insulin was most commonly involved in events, the past year saw a rise in the number of reports involving U-200 and U-300. Most of the U-500 events were due to miscalculations in dose conversion, whereas many U-200 and U-300 events involved the wrong concentration being dispensed. Product identification issues in which two different concentrations have the same brand name (e.g., Tresiba and Humalog) and look-alike packaging of vials and pens may have also contributed to errors during prescribing and dispensing.[8]

Event types

Almost 80 percent of the reported events involved errors or mix-ups in insulin dosing or drug concentration (Figure 1) during ordering and dispensing, especially those involving the more commonly used U-100 insulin and the less frequently used concentrated products.

Figure 1. Event types involved in concentrated insulin events

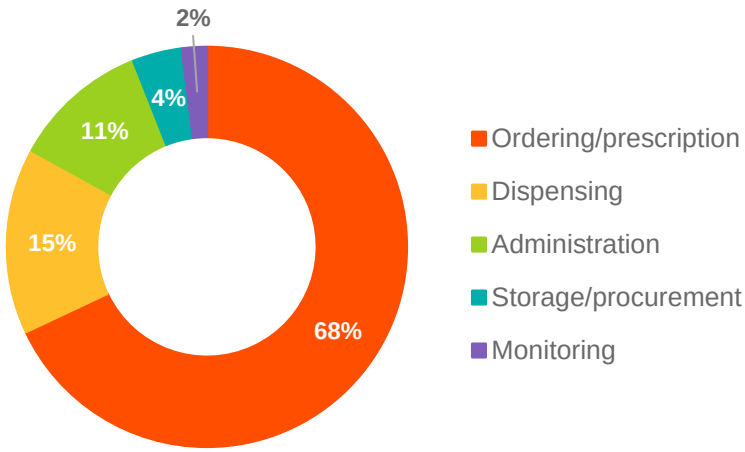


Data source: Vizient Patient Safety Organization.
Period of data: January 2016-May 2018; number of events: 54.

Most events occurred during the prescribing stage at the time of admission (Figure 2) and largely resulted from errors made during medication history collection with gaps in communication between patients and staff and also between clinicians about the home medication list. In some cases, patients did not accurately communicate the dose in syringe units, leading to the wrong dose being ordered. In other cases, prescribing errors occurred during electronic order entry. The provider either selected the wrong drug, concentration or dose, or the correct drug was not available in the electronic drug library. Other errors stemmed from incomplete concentrated insulin orders that were missing either the units or volume. Administration errors primarily occurred during dose conversions from one insulin concentration to another.

Errors were common at discharge because the insulin was not accurately reconciled, such as when patients were transitioned from an insulin U-100 inpatient regimen to their home concentrated insulin regimen. Other factors included the use of the wrong syringe for the type of insulin ordered (e.g., U-100 instead of U-500), delays due to formulary restrictions requiring special drug procurement, inadequate communication between providers, and gaps in patient and provider knowledge. Patients who used U-100 syringes to administer their concentrated insulin may find it difficult to transition to the new U-500 syringes on the market, which may lead to mistakes. Therefore, it is important that patients receive education about how to convert the dose and demonstrate understanding to clinicians using a teach-back method.[5]

Figure 2. Stage at which concentrated insulin events occurred



Data source: Vizient Patient Safety Organization.
Period of data: January 2016–May 2018; number of events: 54.

Recommendations

The Vizient PSO, in collaboration with an expert advisory team (Appendix A), developed leading practices for providers, patients and manufacturers to prevent errors associated with concentrated insulin.

Product design

Manufacturers should take the following steps to address the challenges and risks associated with managing patients on concentrated insulin during transitions to inpatient care:

- Address issues associated with product identification errors during ordering and dispensing by using different brand names for different concentrations of insulin. In addition, reduce potential errors related to look-alike product design by addressing similarities in color and labeling.[9]
- Design insulin pumps that can be programmed for concentrated insulins to prevent dose conversion errors. Once insulin pumps can safely accommodate concentrated insulin, develop a vial to draw up U-200 insulin for pumps so that patients and pharmacists do not have to draw up insulin from the pen.
- Develop a U-500 insulin safety-engineered syringe or syringe that safety needle can be applied for use in health care facilities.

Medication reconciliation at admission

- Require that a pharmacist, technician or intern review patients' medication history at the bedside to verify the insulin name; concentration; dose and method of delivery (vial, pen, syringe type and insulin pump); and if applicable, the product in the pump, prior to order verification.

- Ask patients to explain and demonstrate how they use their insulin. When their home supplies are not available, use photographs of syringes, pens and vials to assist with the verification process. Patients can then identify the mark that their insulin is drawn up to on the syringe.
- Include patients, caregivers and family members in medication reconciliation.
- Contact patients' preferred outpatient pharmacies to reconcile the insulin products that patients receive. Verify both the insulin product and the concentration, as some products are branded under the same name but are available in different concentrations.[5,9] For example:
  - Degludec is available in U-100 and U-200, but both are marketed as Tresiba.[5]
  - Lispro is available in U-100 and U-200, but both are marketed as Humalog KwikPen.
  - Lispro U-100 is available as Humalog or Admelog; however, there is no Admelog U-200.
  - Insulin glargine may refer to Lantus U-100, glargine U-300 (marketed as Toujeo) or Basaglar (biosimilar glargine U-100 product).[5]
  - Insulin aspart refers to NovoLog and Fiasp.
- Document all information obtained in the pharmacy clinical note in the electronic health record.

Prescribing

- Require that orders specify the insulin concentration and dose in units to prevent over- or underdosing of concentrated insulin.[5,9-11]
- Evaluate the risks associated with the use of insulin pens in the hospital and develop systemwide policies and procedures for their use.
- Develop computerized order sets that specify all essential components of care for patients on concentrated insulin, an insulin pump or both, including[1,5]:
  - An order for a consultation by a clinician who is knowledgeable in the use of concentrated insulin and insulin pump therapy — such as an endocrinologist, a certified diabetes nurse practitioner, a certified diabetes educator or the glucose management team — to determine appropriate use and evaluate patients' knowledge and competence.[1]
  - The strength of the concentrated insulin dose, as well as method of delivery.[11] For insulin pump therapy, include basal rate(s), insulin-to-carbohydrate ratios, sensitivity factors, active insulin times and blood glucose targets to be programmed in the order.[1]
- Review the manufacturer's guidelines for converting insulin based on bioequivalency. Adjust the dose to achieve target ranges of plasma glucose level when switching patients between insulin concentrations that are not bioequivalent.[11] Ensure that a pharmacist calculates or verifies the accuracy of any conversion.

  - Calculate the dose unit-for-unit when changing from U-100 to U-200 bioequivalent insulins, including the conversion from degludec 100 units/mL to degludec 200 units/mL, or from lispro 100 units/mL to lispro 200 units/mL.[3]
  - An upward titration may be needed when switching from glargine 100 units/mL to glargine 300 units/mL to maintain the same level of glycemic control. When changing patients from twice-daily neutral protamine Hagedorn (NPH) insulin to once-daily glargine 300 units/mL, the recommended starting dose is 80% of the total daily NPH dosage. When switching from glargine 300 units/mL to glargine 100 units/mL, the recommended initial dose is 80% of the glargine 300 units/mL dose.[3]
- Develop alerts and multidisciplinary clinical care protocols in the electronic health record.

Storage

- Store concentrated insulin vials and syringes (U-200, U-300 and U-500) in a separate location with limited and controlled access, such as a central pharmacy refrigerator used for controlled substances. Do not stock concentrated insulin in the nursing unit.[5]

Dispensing

- Ensure insulin vials are distinctly labeled in the pharmacy to prevent the selection of the incorrect formulation during dispensing or verification.[5] Use bar code scanning during product selection when dispensing.[7]
- Only dispense concentrated insulin to a specific patient with a patient-specific label that does not obscure important product information. Store insulin pens in a patient-specific medication drawer or container.[7]
- Require that pharmacists or pharmacy technicians draw up each dose of insulin before dispensing to reduce miscalculations on the unit. For each dose that is drawn up in the pharmacy, require an independent double check by two pharmacists before dispensing.[5]
- For patients prescribed U-200 for use in their insulin pump prior to admission, consider alternative treatment rather than withdrawing U-200 insulin from the prefilled pen with a syringe for use in the pump.
- When short- and long-acting concentrated insulins are prescribed, highlight the differences in appearance between the two pen devices and the intended use of each.[11]

Administration

- Require an independent double check by two nurses before administering concentrated insulin.
- Use bar code medication administration when dispensing concentrated insulins.[7]
- Provide reference materials on the administration of concentrated insulin and the various methods of administration. In addition, provide contact information for individuals who can answer questions.[5]

- Establish protocols for nursing care such as routine checks of the infusion site for infection and the pump for adequate insulin supply, as well as reassessments for changes in clinical status affecting glycemic management.[1]
- Use safety needles for pens to prevent staff needle-stick injuries.[8] Safety needles that fit all insulin pens are available on the market. Currently, there is not a U-500 insulin safety-engineered syringe or safety needle that can be applied to U-500 syringe.
- Educate patients and staff to remove both the outer and the inner needle cover of standard pen needles before injection. Failure to remove the inner cover prevents the needle from entering the skin and insulin from being administered to the patient. The FDA reports cases in which the inner needle cover was not removed by the patient and led to hyperglycemia, hospitalization and even death.[12]

Medication reconciliation at discharge

- If patients are transitioned to a different insulin regimen on admission, ensure that patients are correctly transitioned to their previous insulin regimen on discharge unless changes are warranted.[5]
- Reconcile the preadmission medication list with the medication administration record and the discharge orders.[5]
- Ensure accountability for communication about changes in insulin regimens between inpatient and outpatient providers and the glucose management team.[13] A warm handoff should occur between the inpatient pharmacist, the community pharmacist and the patient prior to discharge to ensure the dose is correct and confirm that other insulins on the patient's profile are discontinued.

Patient education

- Include patients, caregivers and family members in patient education.
- Provide patient education, including teach-backs, to ensure that patients and their families or caregivers understand their follow-up plan of care, as well as how to accurately measure, dose and administer their insulin. Develop standardized patient information sheets on concentrated insulins and insulin pumps.
- If the patient is converting to a U-500 syringe, provide instructions to remove all U-100 syringes and supplies from the patient's house. Visually confirm that patients using a pen are dialing up, or, for patients using a syringe, are drawing up the correct units based on the device used instead of what they were previously doing on an U-100 syringe.
- Instruct patients to remove both the outer and the inner needle cover of standard pen needles before injection as part of insulin teaching.[12]

Measure process and outcomes

- Monitor the percentage of patients that met appropriate indications for the use of concentrated insulin.

- Monitor the number of patients that received a consult by an endocrinologist, a certified diabetes clinical nurse specialist, a certified diabetes educator, a pharmacist or the glucose management team.
- Monitor incidents of hypo- or hyperglycemia in patients on concentrated insulin.[7]
- Monitor and trend product identification errors and the phase in which they occur in the medication process.

For more information, contact Tammy Williams or Ellen Flynn.

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Appendix A. Expert advisory team

The Vizient PSO developed leading practice recommendations with an expert advisory committee and is grateful for its contributions to this work.

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