FDA DRUG TOPICS: How to Avoid Medication Errors with Pen Injectors

Zachary Oleszczuk, PharmD, MSPharm, BCGP
LCDR, U.S. Public Health Service
Deputy Director, FDA, CDER, OSE, OMEPRM, Division of Mitigation Assessment and Medication Error Surveillance (DMAMES)

Michael R. Cohen RPh, Ms, ScD (hon), DPS (hon)
President emeritus, Institute of Safe Medication Practices (ISMP)

Learning Objectives

- Identify at least 3 drugs that are available in pen injectors.
- Describe at least 3 medication error types that have been reported to FDA or ISMP that involve insulin pens.
- Discuss how you can identify opportunities that can help minimize safety risks for drugs available in pen injectors.

Agenda

- Food and Drug Administration (FDA)
  - Insulin Pens
    - Overview of insulin
    - Differences in insulin products
    - Insulin pen features
    - Review of medication errors and recommendations to prevent errors
    - Safe Disposal of insulin pens
- Institute for Safe Medication Practices (ISMP)
  - Examples of Medication errors reported to ISMP
  - Autoinjectors vs. Pen Injectors
  - Misusing pen injectors as vials
  - Wrong dose errors
  - Error involving pen cartridges
  - Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults

Background

- 37.3 million people have diabetes (11.3% of the US population) [1]
- Roughly 8.4 million Americans use insulin[2]
- Starting in 2014, insulin pens were being dispensed to patients more often than vials[3]
- Insulin may be implicated in 33% of medication error–related deaths[4]

1 https://www.cdc.gov/diabetes/data/statist2
2 https://diabetes.org/newsroom/press-releases/2022/american-diabetes-association-announces-support-for-insulin-act-at-senate-press-conference
3 https://onlinelibrary.wiley.com/doi/10.1002/pds.5212
4 https://health.gov/about-odphp/previous-initiatives/national-ade-action-plan

Insulin Products

Type of Insulin	Examples
Rapid-acting	Insulin aspart (Novolog, Fiasp), Insulin glulisine (Apidra), Insulin lispro (Humalog, Admelog), Insulin oral inhalation (Afrezza)
Short-acting	Insulin regular (Humulin R, Novolin R)
Intermediate-acting	NPH insulin (Humulin N, Novolin N)
Long-acting	Insulin detemir (Levemir), Insulin glargine (Lantus, Toujeo, Basaglar)
Ultra long-acting	Insulin degludec (Tresiba)
Premixed insulins	NPH/Regular 70%/30% (Humulin 70/30, Novolin 70/30), Protamine/Lispro 50%/50% (Humalog Mix 50/50) Protamine/Lispro 75%25% (Humalog Mix 75/25) Protamine/Aspart 70%/30% (Novolog Mix 70/30)

https://www.cdc.gov/diabetes/basics/type-1-types-of-insulin.html

Insulin Presentations

Insulin Pen

Insulin Pump

Insulin Syringe and Syringe

Insulin Inhaler

Syringe and needle picture: https://diabetes.org/blog/insulin-now-biologic-what-does-mean
Insulin pen picture: https://www.salon.com/2018/09/15/after-a-century-insulin-is-still-expensive-could-diyers-change-that_partner/
Insulin pump picture: https://www.fda.gov/files/minimed770GSystem_0.jpg
Insulin inhaler picture: https://afrezza.com/about-afrezza/

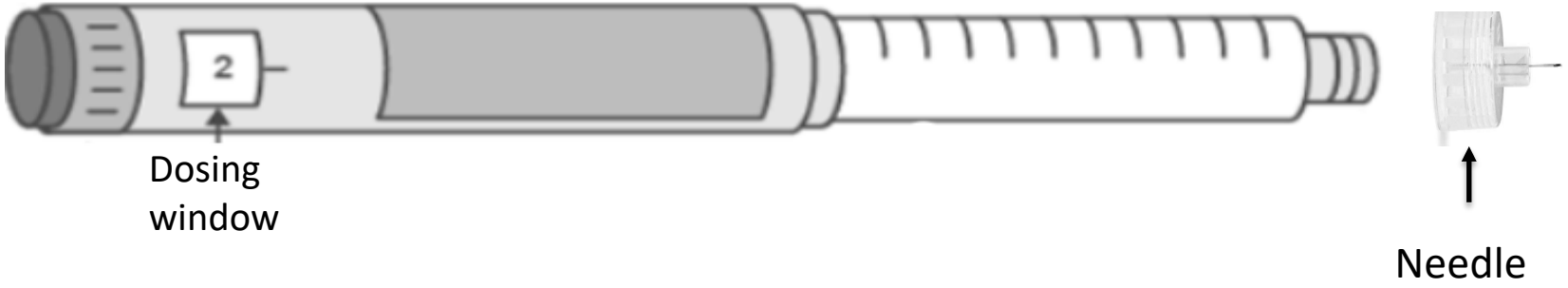
Insulin Pen Features

- Regulated as combination products by FDA
- Have short needles that are used to administer insulin subcutaneously
- Insulin pens are generally portable and discreet.
- Insulin pens are available with different features;
  - Disposable pens vs. Reusable pens
  - Doses in half unit increments
  - Memory function
  - Smart insulin pen
  - Works with smartphone app

https://forum.fudiabetes.org/t/insulin-pen-comparison/5017

https://consumerguide.diabetes.org/collections/insulin-pens

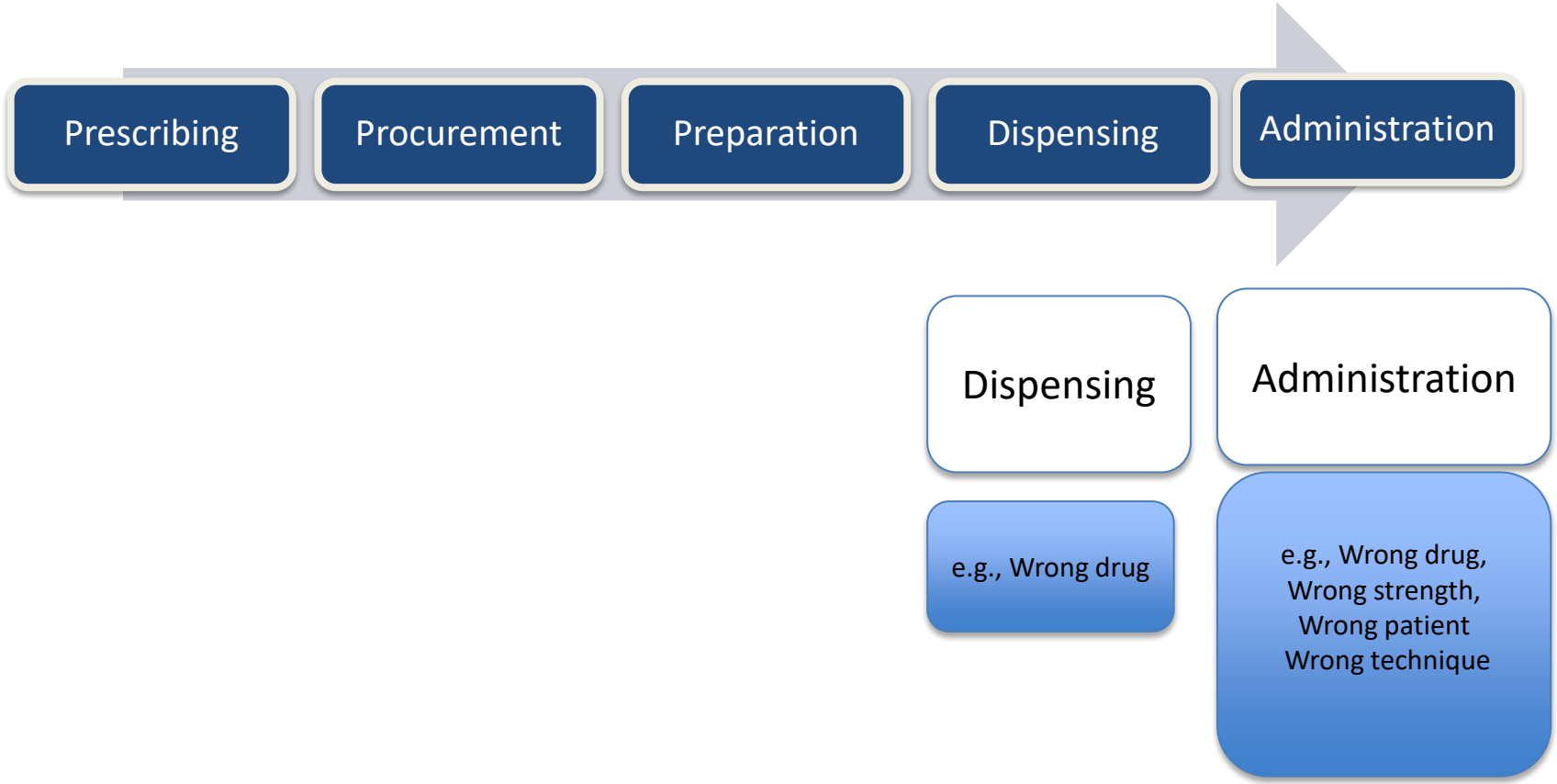
Insulin Pen User Interface



- The difference in the insulin pen design features will affect the end user (e.g., patient) interaction with the pen to administer the dose.

- The similarity in the insulin pen platforms may predispose end users to medication errors. Therefore, it is important to refer to the product specific label and labeling information (e.g., instruction for use) prior to administration.

Where do Medication Errors Occur in the Medication Use Process for Insulin Pens?



Dispensing

Description of Medication Errors and Contributing Factors	Preventive Actions for HealthCare Providers
Wrong drug dispensed: -Similar product names -Look-alike pens -Look-alike labels/labeling	The Product name and strength are on each pen and carton labeling. May need to rotate pen to confirm information.
	Dispense insulin pens in original sealed carton*.
Wrong strength/concentration: -Look-alike labels and labeling -Knowledge deficit - some insulin pens come in different concentrations (i.e. 100 units/mL vs. 200 units/mL)	The Product name and strength are on each pen and carton label. May need to rotate pen
Dose omission -Did not dispense with Pen Needles: -Knowledge Deficit	Check the carton labeling and package insert labeling to see if needles are included**

*https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-health-care-professionals-and-patients-about-insulin-pen-packaging-and-dispensing
** https://www.ismp.org/resources/fda-advise-err-pen-injectors-need-pen-needles

Administration

Description of Medication Errors and Contributing Factors	Preventative Actions for Healthcare Providers and Patients
Wrong drug administer: -Look-alike pens -Look-alike labels/labeling -Similar product names -Patients had multiple pens	The Product name and strength are on each pen and carton label. May need to rotate pen to confirm information.
Wrong strength/concentration: -Look-alike labels and labeling -Patients had multiple pens	The Product name and strength are on each pen and carton label. May need to rotate pen
Incorrect route of administration (oral, intravenous and intramuscular) -Knowledge deficit	Pens are labeled for subcutaneous route only. Healthcare providers should remind patients this is for subcutaneous use only and confirm that the patient knows the correct technique to use the insulin pen

Administration Wrong Technique

Description of Medication Errors and Contributing Factors	Preventative Actions Healthcare Providers and Patients
Use of the same insulin pen for multiple patients -Knowledge deficit*	Insulin pens are labeled for single patient use. Never share pens or use them for more than one patient.
Use of same needle multiple times -Knowledge deficit -Ran out of needles/cost	Use each needle once and then appropriately discard into sharps container
Failure to remove inner needle cap** -Knowledge deficit -Switched Pens	Check FDA approved product labeling for detailed diagrams identifying all the parts of the insulin pen and detailed instructions on how to prepare the insulin pen
Using pen cartridge/pen as a vial*** -Knowledge deficit -No pen needles available	Check FDA approved product labeling for detailed diagrams identifying all the parts of the insulin pen and detailed instructions on how to prepare the insulin pen
Lack of injection site rotation -Knowledge deficit	Check FDA approved product labeling for detailed instructions on how and where to inject insulin
Use of insulin pen after the Beyond-Use-date -Knowledge deficit	Check product labeling for the number of days to keep the insulin pen unrefrigerated (e.g., 28 days, 42 days, 56 days) and product expiration date

*https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-requires-label-warnings-prohibit-sharing-multi-dose-diabetes-pen
**https://wayback.archive-it.org/7993/20201224130048/https://www.fda.gov/medical-devices/safety-communications/caution-when-using-pen-needles-inject-medicines-fda-safety-communication
***https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5380504/

Safe Disposal

Safety Concern	Preventative Action
Incorrect disposal (throwing used needles and pens in regular trash leading to possible needle sticks) -knowledge deficit -No Sharps container available.	Check product labeling for instruction on how to dispose insulin pens including disposal of needles. If no sharps container is available a heavy-duty plastic household container, such as a laundry detergent container can be used as an alternative*

**

*https://www.fda.gov/medical-devices/consumer-products/safely-using-sharps-needles-and-syringes-home-work-and-travel
**https://mhpd.org/needles-%26-sharps-disposal

Key Messages from FDA

- The insulin pens available in the US share some similarities in their design, but differ in certain design features
- The FDA approved label and labeling for insulin pens have important information for healthcare providers and patients
- Healthcare providers and patients should review the product label and labeling carefully and follow the administration and disposal instructions specific for the product.

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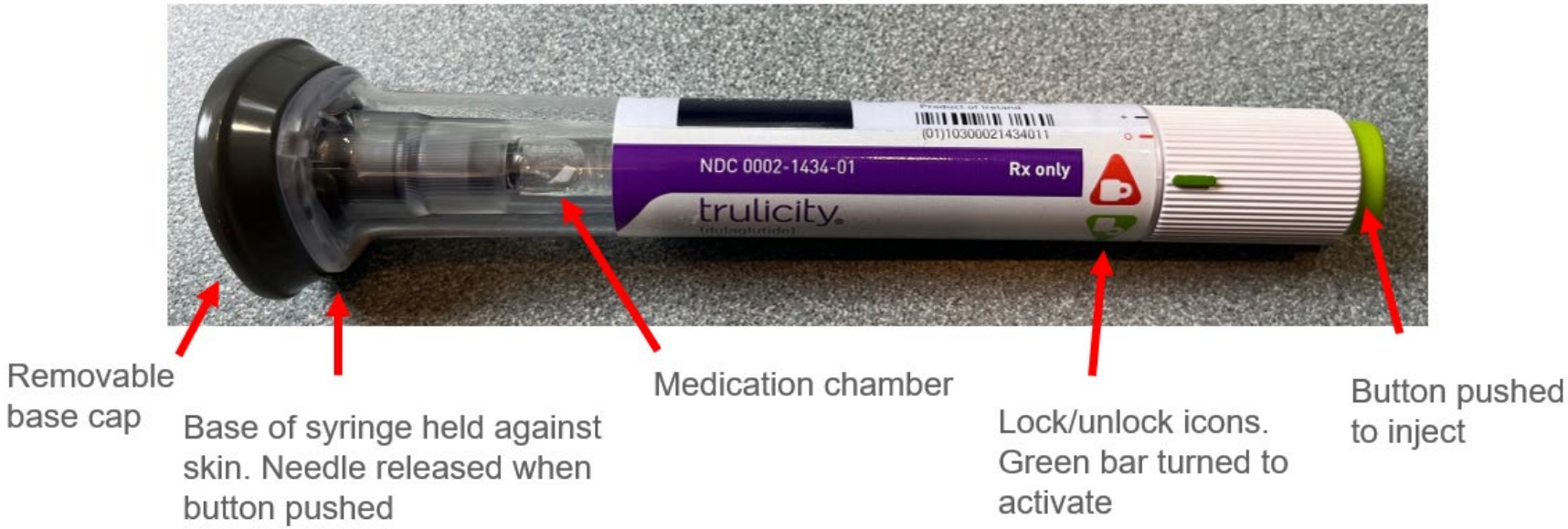
Recognizing and responding to pen injector safety concerns in the hospital and at home

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP
President
Institute for Safe Medication Practices
mcohen@ismp.org

Are we meeting patient needs when they must inject medications at home?

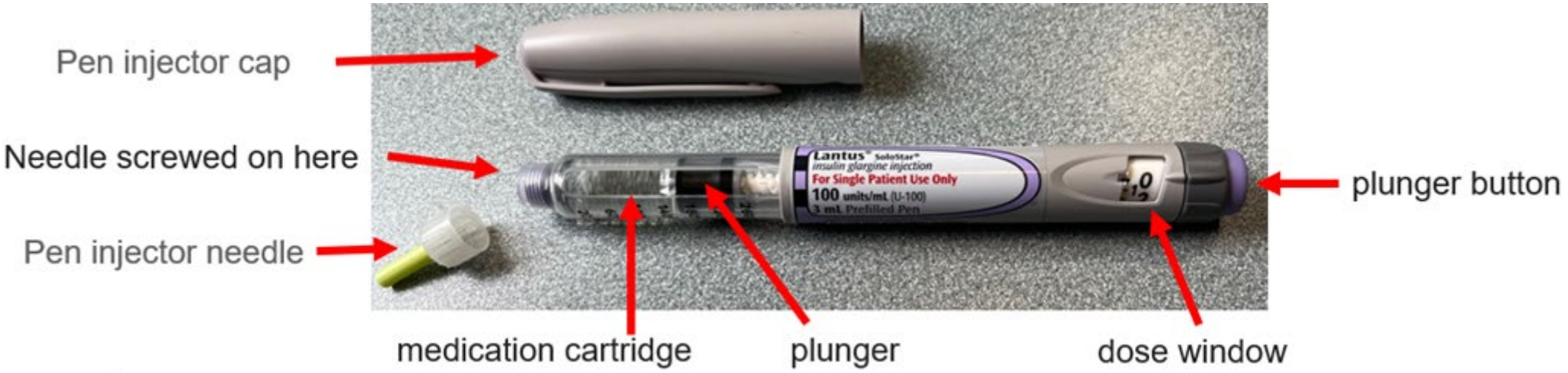
Autoinjector

- Autoinjectors already have an attached needle, provide a single medication dose for onetime use by the patient, and are then disposed. The needle is retracted after injection. Some doses may be given in hospital.
- Examples include: EpiPen and Auvi-Q (both epinephrine), TRULICITY (dulaglutide), BYDUREON BCISE (exenatide), MOUNJARO (tirzepatide) subcutaneous sumatriptan injection.
- Autoinjectors help some patients overcome the hesitation with injecting themselves or making it easier to inject in emergency.



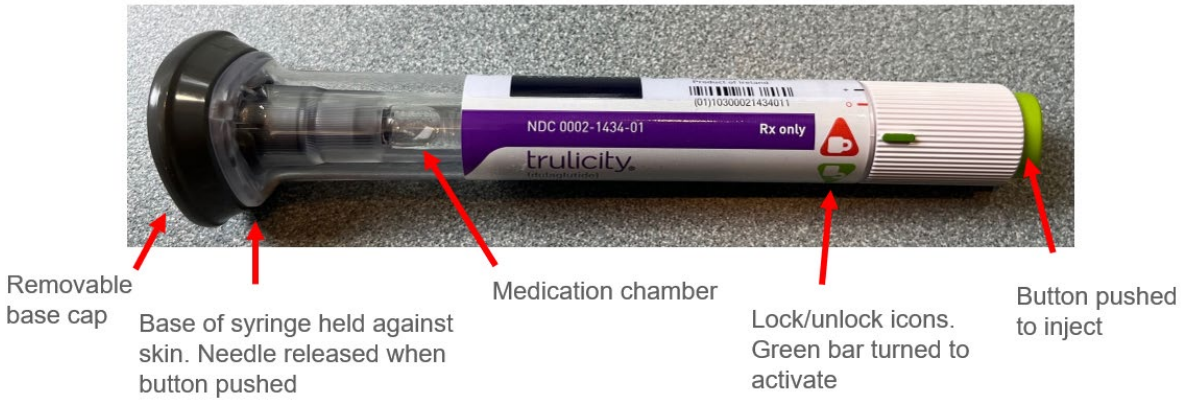
Pen injector

- Unlike autoinjectors that already have a needle attached, pen injectors require patients to manually attach a pen needle.
- Pen injectors contain more than one dose (e.g., insulin pens). Doses may be adjusted.
- Some pen injectors, including OZEMPIC (semaglutide), come with a supply of disposable needles.
- HUMALOG KWIKPEN(insulin lispro) and FORTEO (teriparatide) are examples of pen injectors that require the purchase of pen needles separately.



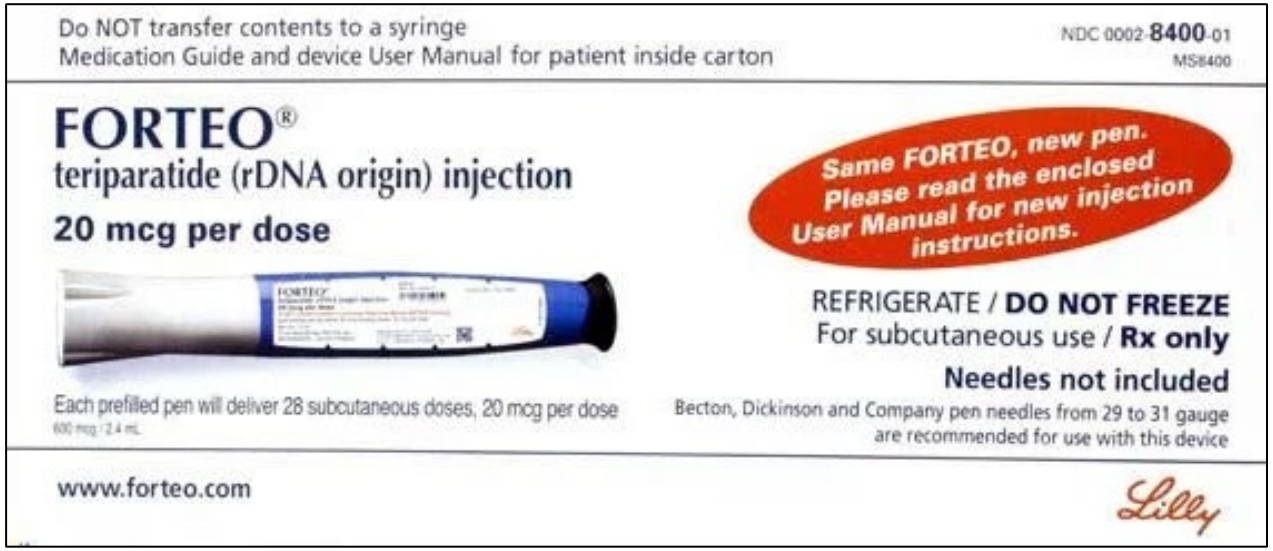
Autoinjector vs. pen injector

- Important to know the differences between autoinjector and pen injector
- For example, some healthcare professionals have been priming TRULICITY pens, as they do with other glucagon-like peptide 1 (GLP-1) agonists such as VICTOZA (liraglutide), OZEMPIC (semaglutide), and BYETTA (exenatide), which are pen injectors.
- “Priming” a Trulicity pen will empty its contents and waste the entire amount of drug in the syringe.



Pen injectors contain more than one dose

- Patients and clinicians have administered the entire dose contained in a multiple-dose pen injector because they thought that the injector was a single-use device.
- In one instance, a nurse administered the full contents of a teriparatide (FORTEO) pen who did not realize it contained enough medication for more than 28 daily doses (typically 20 mcg/day). The notation that the pen (originally labeled 750 mcg /3 mL) contains a 28-day supply was at bottom of the carton's principal display panel and was overlooked.
- Because the pen had been dispensed accidentally without a needle, the nurse had drawn its entire contents into a syringe and administered it to the patient during the hospital stay.



Misuse of Concentrated Insulins with U-100 Syringe

- Caution! Patients and caregivers have sometimes used U-100 insulin syringe and pen cartridge to prepare dose of concentrated insulin from a U-200 (Tresiba or Humalog), U-300 (Toujeo) or U-500 (Humulin) pen!
- Patient discharged from hospital with U-500 insulin pen, but no pen needles. She used a U-100 insulin syringe to withdraw “70 units” of insulin from the U-500 pen, not realizing she had withdrawn 350 units. Patient’s children found her unresponsive and called for emergency care. Fortunately, the patient recovered.

Byetta overdose – due to withdrawal from pen cartridge

- Nurse reported accidentally giving entire contents of a Byetta (exenatide) syringe to a patient; this resulted in a 60-fold overdose.
- Nurse saw the prescribed dose of 5 mcg on the pen's label and missed the concentration designation and total volume listed in fine print. Nurse had never used Byetta and was unsure how to activate it, then withdrew the entire contents (1.2 mL) from the pen's drug cartridge and administered that amount to the patient.
- According to the drug's labeling, patients who've experienced 10-fold overdoses have developed severe nausea and vomiting, rapidly declining blood glucose concentrations, and hypoglycemia that may require glucose administration.
- Nurses should receive adequate training, including hands on use of a sample pen device, before they are expected to administer a drug using the device.

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Infection Prevention during Blood Glucose Monitoring and Insulin Administration

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Summary

The Centers for Disease Control and Prevention (CDC) has become increasingly concerned about the risks for transmitting hepatitis B virus (HBV) and other infectious diseases during assisted blood glucose (blood sugar) monitoring and insulin administration.

CDC is alerting all persons who assist others with blood glucose monitoring and/or insulin administration of the following infection control requirements:

- Fingerstick devices should **never** be used for more than one person
- Whenever possible, blood glucose meters should **not** be shared. If they must be shared, the device should be cleaned and disinfected after every use, per manufacturer's instructions. If the manufacturer does not specify how the device should be cleaned and disinfected then it should not be shared.
- Insulin pens and other medication cartridges and syringes are for single-patient-use only and should **never** be used for more than one person

Blood Glucose Monitoring and Insulin Administration

Monitoring of blood glucose levels is frequently performed to guide therapy for persons with diabetes. Blood glucose monitoring and insulin administration can be accomplished in two ways: *self-monitoring of blood glucose and insulin administration*, where the individual performs all steps of the testing and insulin administration themselves, and *assisted monitoring of blood glucose and insulin administration*, where another person assists with or performs testing and insulin administration for an individual.

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Safhttps://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

Severe Hyperglycemia in Patients Incorrectly Using Insulin Pens at Home

Safety Pen Needle

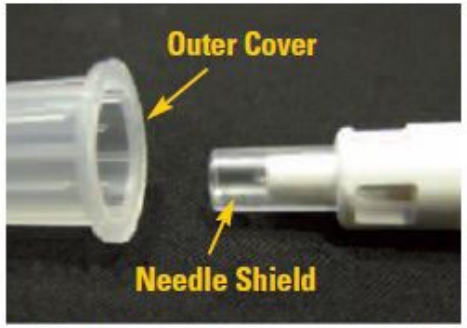
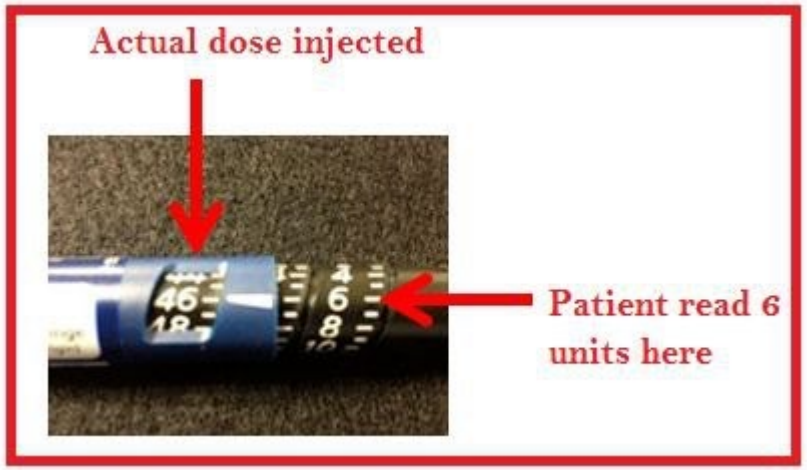


Figure 1. NovoFine Autocover is an example of insulin pen needle with a needle shield that automatically retracts upon injection and recovers and locks over the needle when withdrawn from the skin. (BD AutoShield Duo, not pictured here, is another example of a safety needle used with pens.)

Standard Pen Needle

Figure 2. BD Ultra-fine III is an example of a standard pen needle. Both the outer cover and inner needle cover must be removed prior to injection.

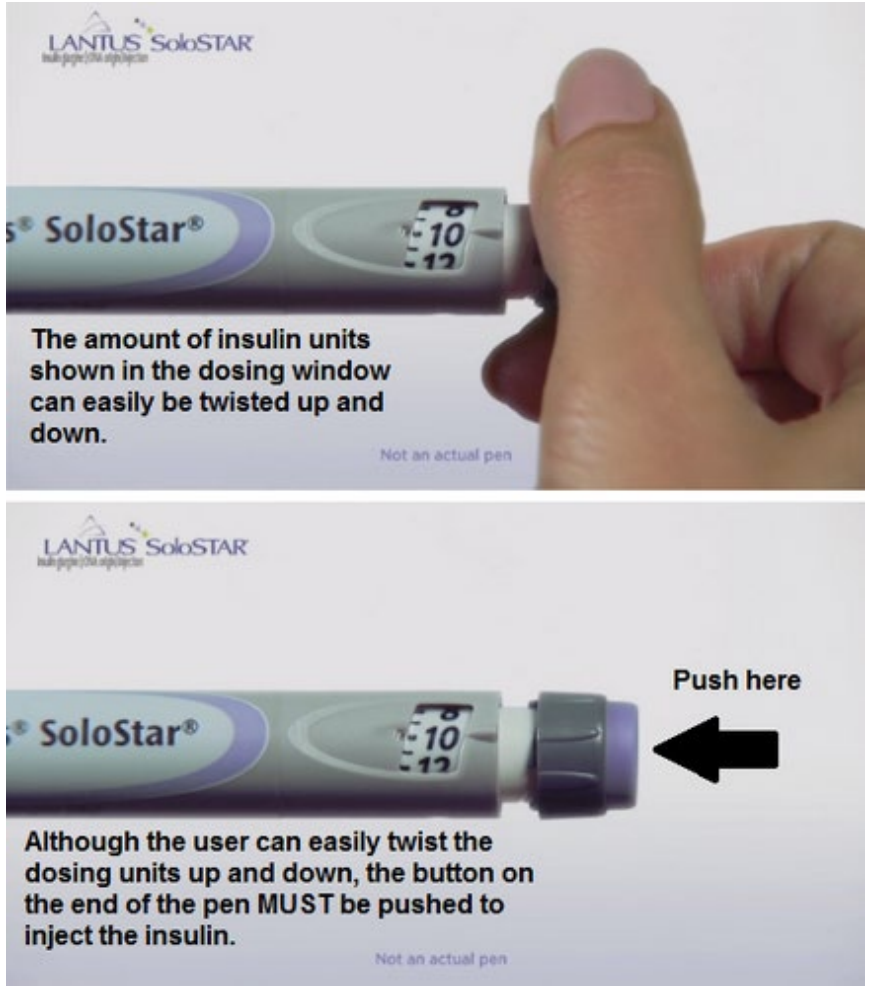
Errors made by patient when dialing doses using an insulin pen injector



Note: The Novo Nordisk **FlexTouch** does not have this attribute

Unusual explanation for hyperglycemia in patients using insulin pen injector

- Insulin pen error. Improper injection technique with an insulin pen led to elevated blood sugars in two patients
- The caregivers put needle on the pen, dialed to 10 units, pushed the needle into the injection pad and then proceeded to dial back to zero.



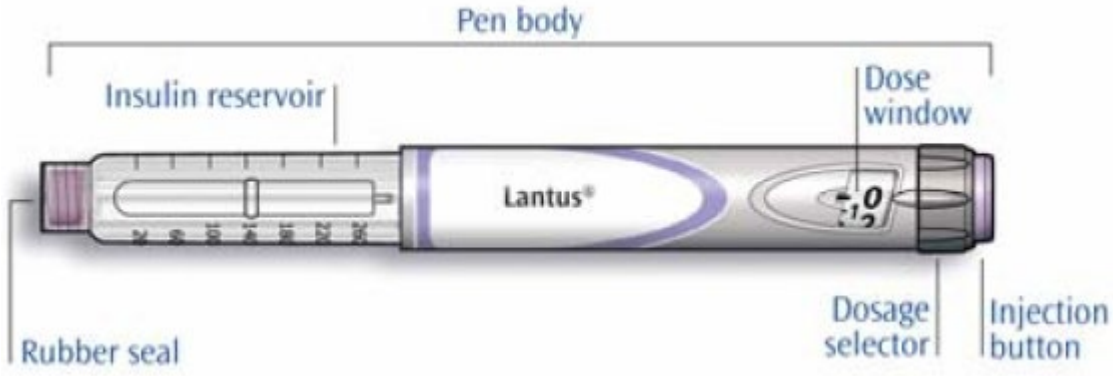
(Shah A, Sullivan MM, Rushakoff RJ. A New "Twist" on Insulin Pen Administration Errors. Endocr Pract. 2014;20(6):617 - http://www.medscape.com/viewarticle/827765).

Patient Education and Monitoring

- In a case reported to ISMP by physician:

  "…. Upon demonstrating how she used her insulin pen, I found that she was not priming the pen, and was dialing up dosage and sticking herself but not pushing the injection button to administer the insulin. She thought that the pen administered the medication on its own."

Errors Made by Patients When Dialing Doses



A patient received a three-fold overdose of insulin (which resulted in an emergency department visit) when he misunderstood how to use the SoloStar insulin delivery device. Pen devices may not have features–such as the ability to see the plunger moving–that patients rely on to tell if a dose has been given.

Educating the healthcare community about safe medication practices

Acute Care

ISMP Medication Safety Alert!®

November 15, 2007 ■ Volume 12 Issue 23

SafetyBriefs

Patient confused by insulin pen design. An error with the new **LANTUS** (insulin glargine rDNA origin) **SOLOSTAR** pen from sanofi aventis has important implications for those who dispense this product or similar insulin pen devices from Novo Nordisk. A Lantus Solostar pen was prescribed for a patient who had prior experience administering Lantus from vials using insulin syringes. When the patient picked up the pen at the pharmacy, he was not counseled. Each pen contains 300 units of Lantus. The dose is set in the pen's dosing window by turning a dosage knob (see picture below). The dose is then released by pressing an injection button, which sets a plunger in motion within the pen's insulin reservoir. The physician had instructed the patient to inject 75 units of insulin every morning. Unfortunately, the patient administered 225 units of Lantus instead of the prescribed amount, resulting in an emergency department (ED) visit. The pen looks like it works like a syringe or other pen devices, where the plunger moves all the way to the hub of the needle as it releases a dose. However, the plunger of the Solostar pen is not designed to deliver the

The insulin reservoir shows how much is left in the Lantus Solostar pen after injection.

entire amount of insulin in the reservoir; thus, the plunger only moves partially, resting on a reservoir scale that shows the remaining quantity of Lantus in the pen. The patient, who expected the plunger to move like a typical syringe, didn't notice the subtle movement and repeated the injection three times, delivering 75 units each time. Patients should receive instructions about use of the device from a diabetes educator and the dispensing pharmacist. Fortunately, the patient was monitored and discharged from the ED without permanent harm. He has now received proper instruction on how to use the device. If you provide this product, we recommend that you view an instructional

continued on page 2 ▸

Errors with injectable medications:
Unlabeled syringes are surprisingly common!

PROBLEM: Research shows that the incidence of errors with injectable medications is higher than with other forms of medications.[1-2] Studies also suggest that half of all harmful medication errors originate during the drug administration phase; of those errors, about two-thirds involve injectable medications.[3-4]

Several factors, such as those listed below, can increase the risk of errors and patient harm with injectable medications:[5]

- Narrow therapeutic index drugs
- Availability of concentrates, where further dilutions are required
- The need for complex calculations, such as converting a dose from mmol to mg
- Multiple manipulations required to prepare the drug (e.g., vial-to-syringe transfer, syringe-to-syringe transfer, dilution, use of a filter)
- Reconstitution of powders often requiring special diluents
- Use of part of a vial/ampul or more than one vial/ampul for a single dose
- Non-standard handling/special precautions (e.g., light protection, inline filter, incompatibilities) required
- Inadequate and/or inaccessible drug information
- Preparation of the drug in clinical areas instead of the pharmacy, with limited or sometimes absent labeling of the product.

Unlabeled syringes are a significant risk associated with preparation of injectable products in clinical areas. In our March 20, 2002 newsletter, we wrote about a 15-year-old boy with a history of malignant hyperthermia who received the contents of an unlabeled syringe that a surgeon thought contained **MARCAINE** (bupivacaine) with epinephrine. The syringe actually contained 30 mL of epinephrine 1:1,000, which a nurse had drawn into a syringe. She had planned to add the drug to several bags of normal saline, but she was called away unexpectedly and left the unlabeled syringe on a tray near the patient. The patient's blood pressure increased after local injection of the epinephrine into his limb, initially leading staff to believe he was experiencing malignant hyperthermia. But the error was recognized after the patient developed ventricular tachycardia and pulmonary edema. He was sent to ICU and fortunately recovered without permanent harm.

Unlabeled syringes are problematic outside of surgical areas, too. Despite Joint Commission Medication Management Standard MM.4.30, which requires the labeling of all medications, ISMP staff consultants frequently visit healthcare facilities and confirm that unlabeled syringes are observed in every patient care area, from typical nursing areas to diagnostic testing areas, as in the reported error that follows. Just before a **PERSANTINE** (dipyridamole) stress test, a nurse prepared a syringe of aminophylline 75 mg from a multiple-dose vial, but did not label the syringe. The aminophylline (used for emergency reversal of the effects of dipyridamole) was not needed, and the unlabeled syringe was left in the room with the patient. The nurse stepped out of the room as a nuclear medicine technician stepped into the room to administer an IV dose of thallium. Since the unlabeled syringe had been placed where saline flushes were usually kept, the technician assumed that it was saline and used it to flush the patient's IV access port. The nurse returned to the room just as the technician finished giving the aminophylline. The patient was monitored but experienced no serious adverse effects.

A few months ago, the American Nurses Association released the results of an online survey about the challenges of labeling syringes that contain injectable

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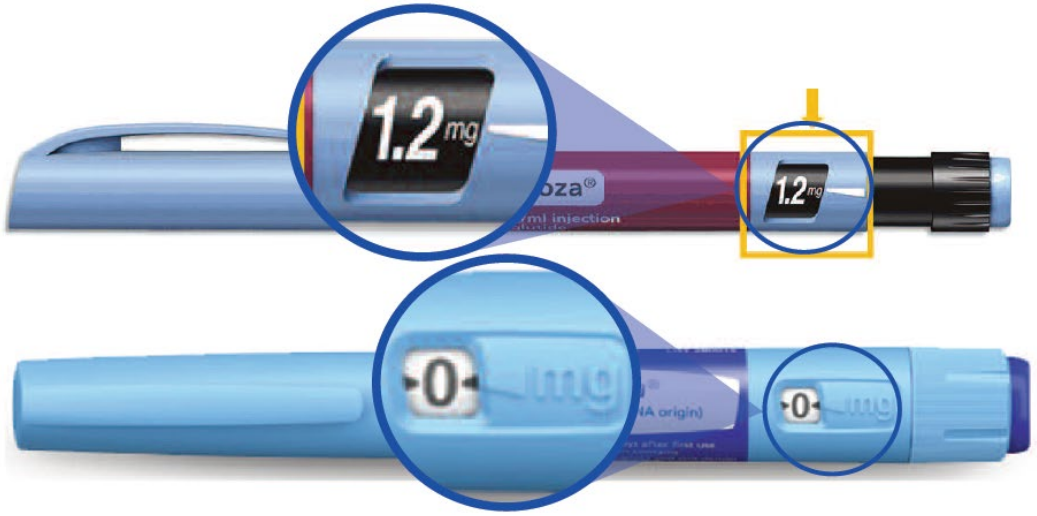
Analog and Digital Scales Can Be Misread

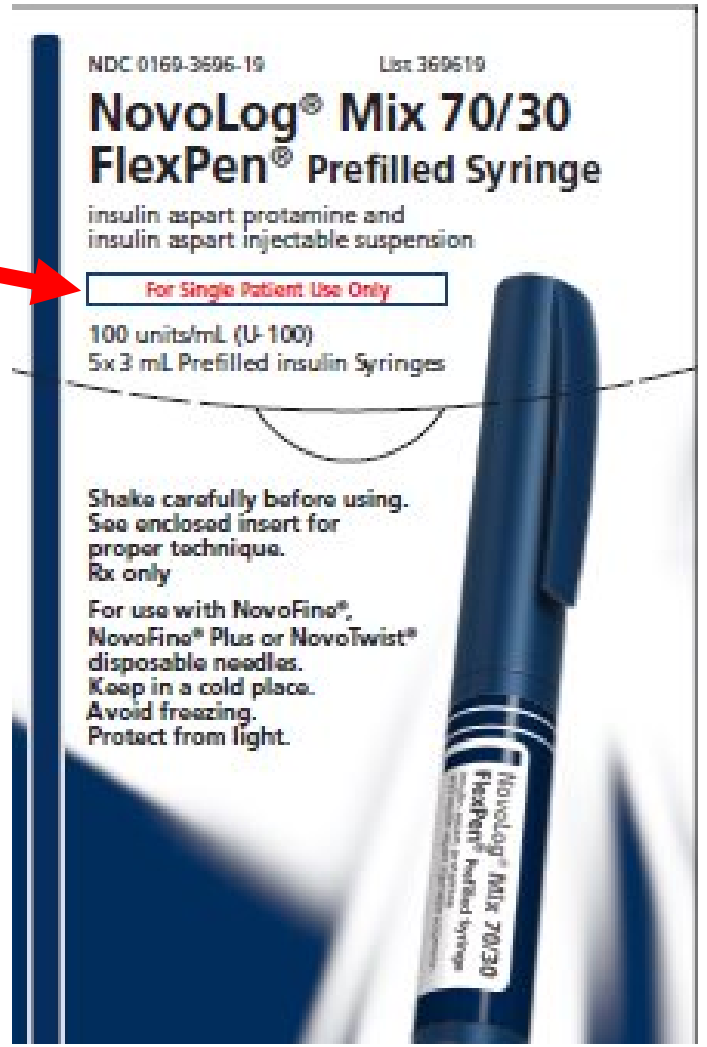
Liraglutide dosage unit confusion

- Some prescriptions for VICTOZA (liraglutide) and SAXENDA (liraglutide) pen injectors have contained inaccurate dosage information due to free text typing of “mL” as the dosing unit in the patient directions, rather than “mg.”
- Since the concentration of liraglutide in either product is 6 mg/mL, prescribing 1.2 mL would result in a 6-fold overdose (7.2 mg).
- The pen injectors display “mg” in the dosage window although with either pen, the “mg” markings are difficult to see. Both Victoza and Saxenda are pen injectors that allow doses to be dialed and modified.
- Electronic health record (EHR) vendors have been asked to ensure that dose creation tools do not allow “mL” as a dose unit option.
- Orders for Victoza or Saxenda with a “mL” dosage amount need to be clarified with the prescriber to verify the dose.



Errors Made by Patients When Dialing Doses

- Patient was newly started on Novolog 70/30 mix pen and did not receive any education related to administration technique or dosing.
- Patient's daughter read "single patient use" and thought it meant to give the entire contents at once.
- Patient became unresponsive and was brought to the hospital with glucose in the 20s.
- Started on glucose infusion and became responsive.
- Better patient education by physician who prescribed and outpatient pharmacy who dispensed would have been critical to preventing this error.



Patients confused by use of a U-100 insulin syringe to prepare U-500 insulin dose

- Patient taught to use a U-100 syringe for U-500 insulin doses where 5 units on U-100 scale = 25 units of insulin when using U-500.
- Patient started using a U-500 pen; Dialed “15 units” for a 75 unit dose.
- What you see on U-500 pen window is what you get!

Severe underdosing of insulin with U-500 pen. An emergency department (ED) pharmacist was talking to a patient about his U-500 insulin dose. The patient, who had been using a U-500 insulin pen, told the pharmacist that his dose was 75 units but proceeded to show the pharmacist how he turned the dose knob on the pen to "15" to deliver each dose. The patient thought his physician had told him to dial to "15" to deliver 75 units. Prior to using the U-500 pen, the patient used a U-100 syringe to measure each dose of 75 units from a vial of U-500 insulin. Before U-500 syringes or pens were available, patients using U-500 insulin were commonly taught to use a U-100 insulin syringe and to measure their dose in "syringe units," meaning the U-100 scale was used for dose measurement, but the actual dose was 5 times more than the measured dose. Thus, the patient had been drawing up the U-500 insulin into the U-100 syringe to the "15" units marking. The patient was then shown how to deliver the correct dose by dialing the U-500 insulin pen to 75 units.

Even with the availability of U-500 insulin pens, patient and provider confusion about the dose may still occur, especially when patients previously relied on a U-100 syringe to inject U-500 insulin. Dangerous underdosing with a U-500 pen should be considered in patients who exhibit severe hyperglycemia or diabetic ketoacidosis. For U-500 insulin, ISMP recommends using a U-500 insulin pen or a U-500 insulin syringe. Unfortunately, patients still use U-100 syringes with U-500 insulin, thus risking confusion.

Concentrated Insulin Pens and the Visually Impaired

- Visually impaired patients commonly use touch and sound to assist when preparing doses.
- In the past, a patient was using Lantus (insulin glargine) U-100 when using a pen injector.
- With the U-100 pen, you can hear and feel a faint click for each unit as you turn the dial to set the dose. Each click is 1 unit.
- For Tresiba, the doctor had prescribed 18 units daily, unaware that the patient had been setting her previous Lantus dose by listening to the number of clicks, not reading the dose in the window. Uncertain why U-200 prescribed for such a small dose.
- The patient prepared the dose by counting 18 clicks.
- Later, she mentioned to her daughter that the clicks seemed different than with other pens.
- Her daughter looked at the pen and realized that, for Tresiba U-200 (which is also available in a U-100 concentration), each click represents 2 units rather than 1. The patient had taken twice (18 clicks = 36 units) the prescribed amount of Tresiba!

Tresiba U-200 Won't Allow Odd Number Dosing of Insulin Units

- Physician prescribed 25 units daily of Tresiba U-200
- An odd numbered dose is not possible with U-200 because the pen only allows dosing increments in even numbers, starting at 2 units and going up to 160 units
- Elderly patient tried to dial 25 units by estimating the proper position between 24 units (marked on pen) and a notch or score that represents 26 units. Impossible to do
- Use U-100 Tresiba for odd units

Need for needles with safety guards

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ISMP
An ECRI Affiliate

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Controlled substance drug diversion by healthcare workers as a threat to patient safety—Part II

In **Part I**, we discussed how drug diversion not only endangers healthcare workers diverting drugs, but also causes harm to coworkers, employers, and can otherwise compromise patient safety. We reviewed the widespread scope of diversion in healthcare, commonly involved medications, barriers to recognition, at-risk behaviors, and other signs associated with possible diversion. In accordance with state and federal laws, consider implementing the following recommendations as a proactive approach to prevent, identify, report, and respond to drug diversion:

PREVENT

- Establish a Controlled Substance Diversion Prevention Program that includes an interdisciplinary diversion response committee (e.g., consider including pharmacy, nursing, anesthesia staff, medical staff, security, human resources, compliance, risk management, administration, legal, media/communications, informatics, and employee health). Ideally, a dedicated diversion officer with a thorough knowledge of medication management systems and technologies (e.g., pharmacist, pharmacy technician, nurse), as well as knowledge of regulatory requirements, should oversee the response team and be the subject matter expert when diversion is suspected.[1,2]
- Have members of the team conduct unannounced quarterly diversion risk rounds in the pharmacy and in key patient care units.[3] During rounds, identify and rectify conditions that might allow diversion (e.g., unsecured controlled substances).
- Support a "trust but verify" approach in relation to controlled substance handling. Leaders must recognize that no news is not good news, as many diverters are never caught.[4] A culture of safety must take precedence in relation to controlled substance diversion.
- During orientation and at least annually, educate staff who handle or may be in proximity to controlled substances about the steps that have been implemented to prevent drug diversion, the signs of drug diversion, and how to report and respond to drug diversion.[4,5,6] Emphasize recognition and reporting, the health and safety of the patient and the diverter, as well as other associated professional and criminal implications. Education of staff is an essential component of any diversion program!
- For patients discharged with prescriptions for controlled substances, provide them with information on the signs and risks of substance use disorder and available resources if help is needed. Discuss the importance of storing the medications in a secure location at home and provide resources for the safe disposal of medications, including information about the Drug Enforcement Administration (DEA) National Prescription Drug Take Back Day (www.ismp.org/ext/3).
- Follow the ***ISMP Hierarchy of Effectiveness of Risk-Reduction Strategies*** (www.ismp.org/node/18343) when considering processes and safeguards to prevent drug diversion, using high-leverage strategies such as forcing functions instead of low-leverage strategies such as rules and policies.[1,7] The American Society of Health-System Pharmacists (ASHP) provides recommendations for preventing diversion throughout the entire life cycle of controlled substance medications.[1] Many of these prevention recommendations are summarized below and categorized by nodes of the medication-use process.

continued on page 2 — Drug diversion >

SAFETY brief

Safety mechanism needed for Evenity syringe needle to prevent needlestick injuries! We continue to receive reports of needlestick injuries involving **EVENITY** (romosozumab-aqqg), risking transmission of blood-borne pathogens such as hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV) to healthcare providers and patients. Evenity is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, or for patients who have failed or are intolerant to other available osteoporosis therapies. The medication, which is manufactured by Amgen, is supplied in a carton containing two prefilled syringes (both syringes are needed to administer the total dose of 210 mg subcutaneously) and is labeled to be administered by a healthcare provider (**Figure 1**).

Figure 1. A dose of Evenity requires the administration of two subcutaneous injections. The manufacturer, Amgen, packages two prefilled syringes in one carton. The syringe needles do not have safety guards, so the potential for needlestick injuries is high.

In a recent report, a nurse in an outpatient infusion setting experienced an accidental needlestick injury when administering a subcutaneous injection of Evenity to a patient. The needles on Evenity syringes lack a safety device; they are not retractable or even removable, so the nurse was unable to change the needle to one that has a safety guard. Other organizations have reported the same concern about accidental needlesticks with this product, which we wrote about in

continued on page 2 — SAFETY brief >

SAFETY brief

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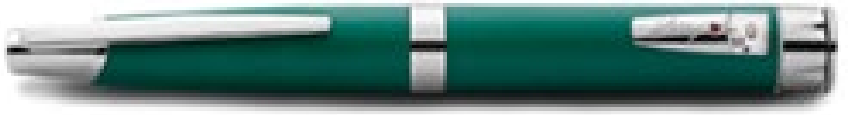
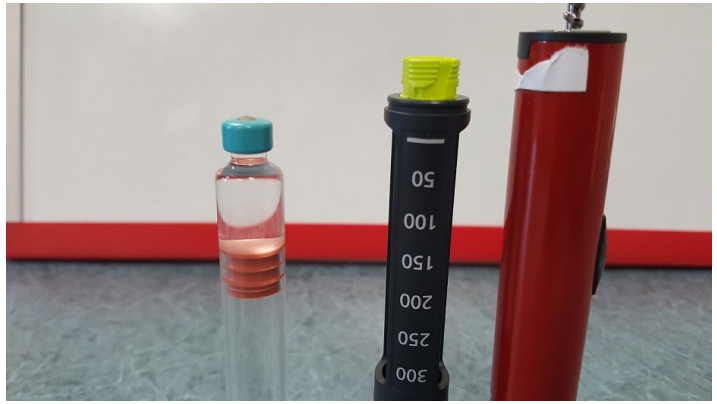
Label states "must be administered by a health professional." The fixed syringe needles do not have safety guards, so the potential for needlestick injuries is high. Lupron Depot-Ped is another requiring administration by a health professional.

Patients may use pen cartridge as an insulin vial

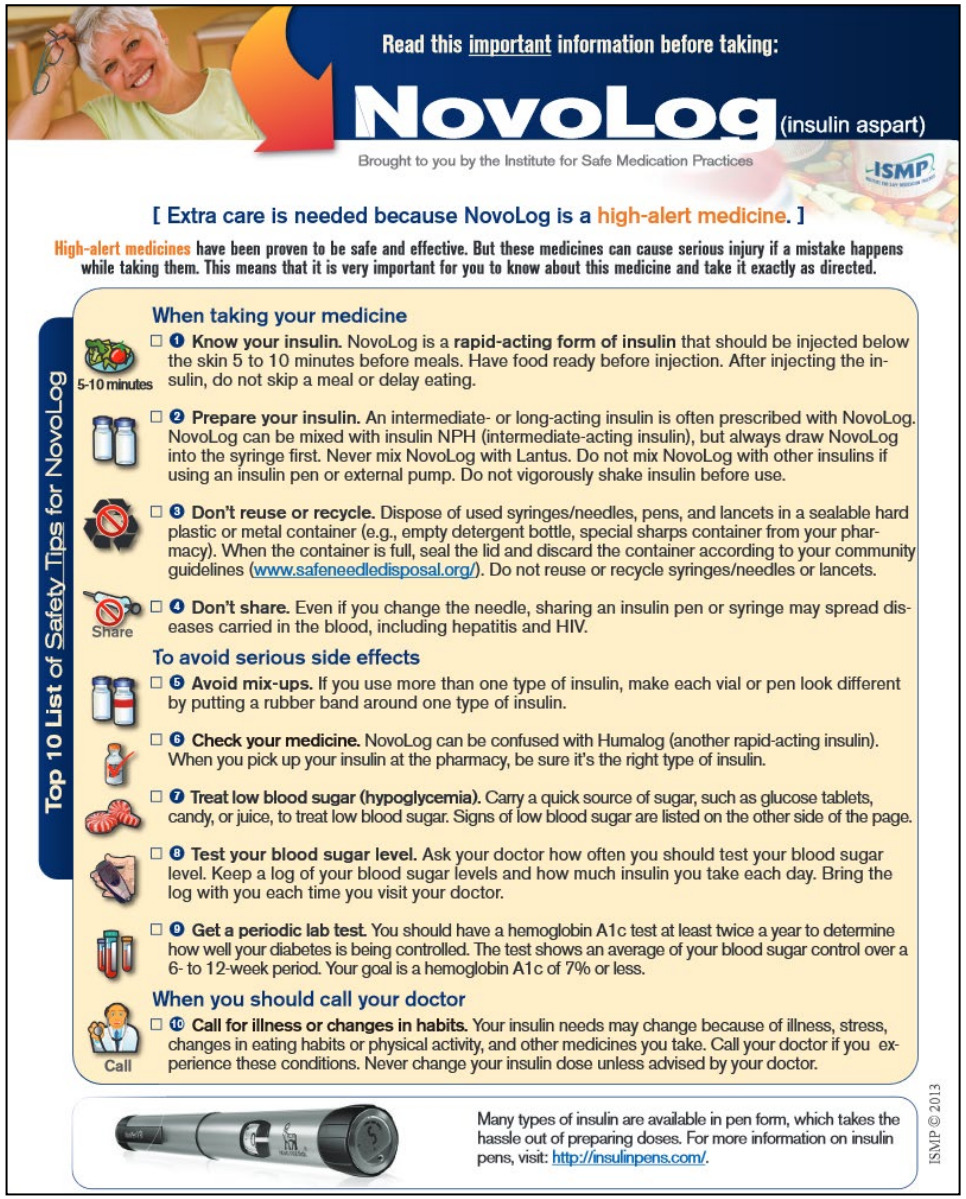
- Withdrawing insulin from pen cartridge





- Patients may also take cartridge from prefilled disposable pen to use in permanent pen. The cartridge will not have a label.

Adding Insulin to Pen Cartridge



Read this important information before taking:

NovoLog (insulin aspart)

Brought to you by the Institute for Safe Medication Practices

ISMP

[Extra care is needed because NovoLog is a high-alert medicine.]

High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is very important for you to know about this medicine and take it exactly as directed.

Top 10 List of Safety Tips for NovoLog

When taking your medicine

5-10 minutes

☐ ❶ **Know your insulin.** NovoLog is a **rapid-acting form of insulin** that should be injected below the skin 5 to 10 minutes before meals. Have food ready before injection. After injecting the insulin, do not skip a meal or delay eating.

☐ ❷ **Prepare your insulin.** An intermediate- or long-acting insulin is often prescribed with NovoLog. NovoLog can be mixed with insulin NPH (intermediate-acting insulin), but always draw NovoLog into the syringe first. Never mix NovoLog with Lantus. Do not mix NovoLog with other insulins if using an insulin pen or external pump. Do not vigorously shake insulin before use.

☐ ❸ **Don't reuse or recycle.** Dispose of used syringes/needles, pens, and lancets in a sealable hard plastic or metal container (e.g., empty detergent bottle, special sharps container from your pharmacy). When the container is full, seal the lid and discard the container according to your community guidelines (www.safeneedledisposal.org/). Do not reuse or recycle syringes/needles or lancets.

Share

☐ ❹ **Don't share.** Even if you change the needle, sharing an insulin pen or syringe may spread diseases carried in the blood, including hepatitis and HIV.

To avoid serious side effects

☐ ❺ **Avoid mix-ups.** If you use more than one type of insulin, make each vial or pen look different by putting a rubber band around one type of insulin.

☐ ❻ **Check your medicine.** NovoLog can be confused with Humalog (another rapid-acting insulin). When you pick up your insulin at the pharmacy, be sure it's the right type of insulin.

☐ ❼ **Treat low blood sugar (hypoglycemia).** Carry a quick source of sugar, such as glucose tablets, candy, or juice, to treat low blood sugar. Signs of low blood sugar are listed on the other side of the page.

☐ ❽ **Test your blood sugar level.** Ask your doctor how often you should test your blood sugar level. Keep a log of your blood sugar levels and how much insulin you take each day. Bring the log with you each time you visit your doctor.

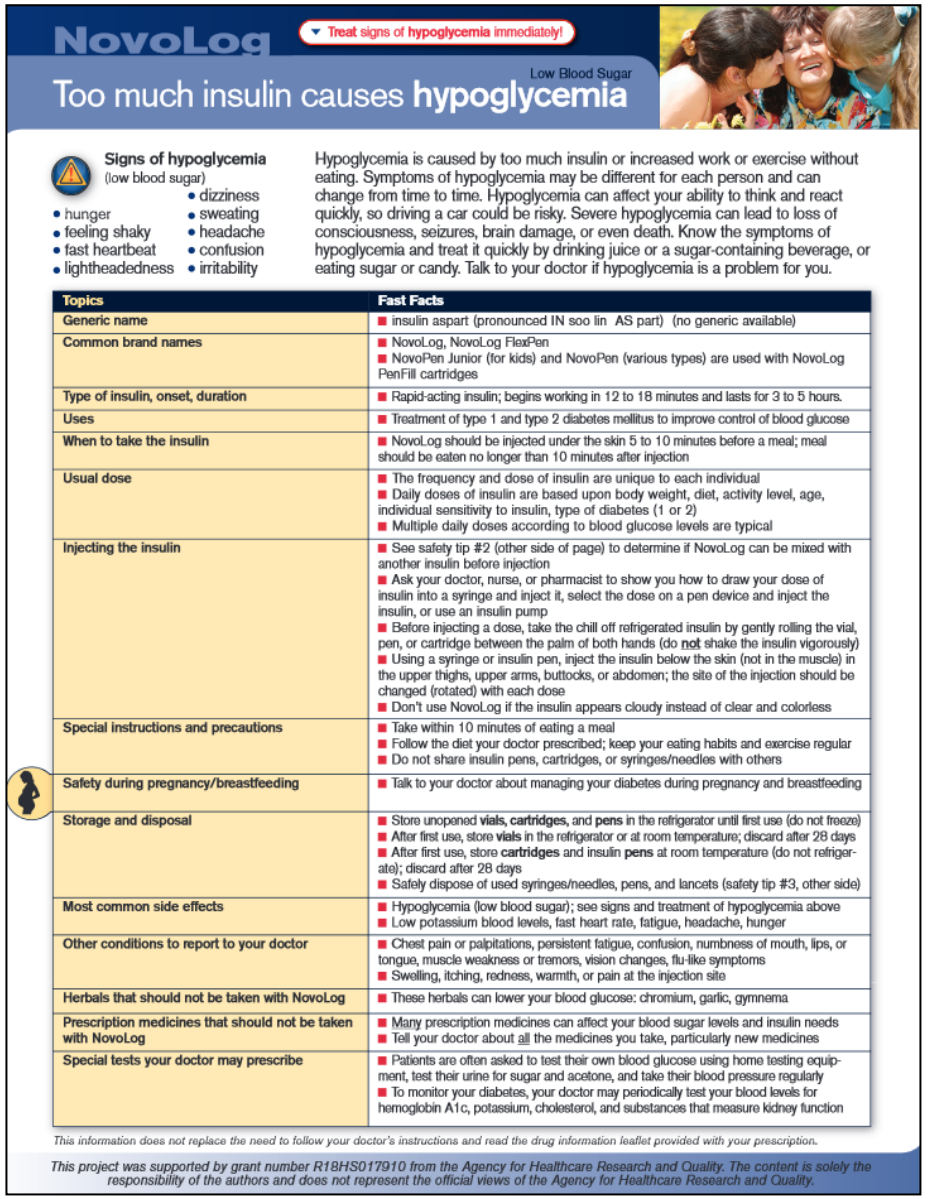
☐ ❾ **Get a periodic lab test.** You should have a hemoglobin A1c test at least twice a year to determine how well your diabetes is being controlled. The test shows an average of your blood sugar control over a 6- to 12-week period. Your goal is a hemoglobin A1c of 7% or less.

When you should call your doctor

Call

☐ ❿ **Call for illness or changes in habits.** Your insulin needs may change because of illness, stress, changes in eating habits or physical activity, and other medicines you take. Call your doctor if you experience these conditions. Never change your insulin dose unless advised by your doctor.

Many types of insulin are available in pen form, which takes the hassle out of preparing doses. For more information on insulin pens, visit: http://insulinpens.com/.



NovoLog

Treat signs of hypoglycemia immediately!

Too much insulin causes hypoglycemia

Low Blood Sugar

Signs of hypoglycemia
(low blood sugar)

- hunger
- feeling shaky
- fast heartbeat
- lightheadedness
- dizziness
- sweating
- headache
- confusion
- irritability

Hypoglycemia is caused by too much insulin or increased work or exercise without eating. Symptoms of hypoglycemia may be different for each person and can change from time to time. Hypoglycemia can affect your ability to think and react quickly, so driving a car could be risky. Severe hypoglycemia can lead to loss of consciousness, seizures, brain damage, or even death. Know the symptoms of hypoglycemia and treat it quickly by drinking juice or a sugar-containing beverage, or eating sugar or candy. Talk to your doctor if hypoglycemia is a problem for you.

Topics	Fast Facts
Generic name	■ insulin aspart (pronounced IN soo lin AS part) (no generic available)
Common brand names	■ NovoLog, NovoLog FlexPen ■ NovoPen Junior (for kids) and NovoPen (various types) are used with NovoLog PenFill cartridges
Type of insulin, onset, duration	■ Rapid-acting insulin; begins working in 12 to 18 minutes and lasts for 3 to 5 hours.
Uses	■ Treatment of type 1 and type 2 diabetes mellitus to improve control of blood glucose
When to take the insulin	■ NovoLog should be injected under the skin 5 to 10 minutes before a meal; meal should be eaten no longer than 10 minutes after injection
Usual dose	■ The frequency and dose of insulin are unique to each individual ■ Daily doses of insulin are based upon body weight, diet, activity level, age, individual sensitivity to insulin, type of diabetes (1 or 2) ■ Multiple daily doses according to blood glucose levels are typical
Injecting the insulin	■ See safety tip #2 (other side of page) to determine if NovoLog can be mixed with another insulin before injection ■ Ask your doctor, nurse, or pharmacist to show you how to draw your dose of insulin into a syringe and inject it, select the dose on a pen device and inject the insulin, or use an insulin pump ■ Before injecting a dose, take the chill off refrigerated insulin by gently rolling the vial, pen, or cartridge between the palm of both hands (do not shake the insulin vigorously) ■ Using a syringe or insulin pen, inject the insulin below the skin (not in the muscle) in the upper thighs, upper arms, buttocks, or abdomen; the site of the injection should be changed (rotated) with each dose ■ Don't use NovoLog if the insulin appears cloudy instead of clear and colorless
Special instructions and precautions	■ Take within 10 minutes of eating a meal ■ Follow the diet your doctor prescribed; keep your eating habits and exercise regular ■ Do not share insulin pens, cartridges, or syringes/needles with others
Safety during pregnancy/breastfeeding	■ Talk to your doctor about managing your diabetes during pregnancy and breastfeeding
Storage and disposal	■ Store unopened **vials, cartridges,** and **pens** in the refrigerator until first use (do not freeze) ■ After first use, store **vials** in the refrigerator or at room temperature; discard after 28 days ■ After first use, store **cartridges** and insulin **pens** at room temperature (do not refrigerate); discard after 28 days ■ Safely dispose of used syringes/needles, pens, and lancets (safety tip #3, other side)
Most common side effects	■ Hypoglycemia (low blood sugar); see signs and treatment of hypoglycemia above ■ Low potassium blood levels, fast heart rate, fatigue, headache, hunger
Other conditions to report to your doctor	■ Chest pain or palpitations, persistent fatigue, confusion, numbness of mouth, lips, or tongue, muscle weakness or tremors, vision changes, flu-like symptoms ■ Swelling, itching, redness, warmth, or pain at the injection site
Herbals that should not be taken with NovoLog	■ These herbals can lower your blood glucose: chromium, garlic, gymnema
Prescription medicines that should not be taken with NovoLog	■ Many prescription medicines can affect your blood sugar levels and insulin needs ■ Tell your doctor about all the medicines you take, particularly new medicines
Special tests your doctor may prescribe	■ Patients are often asked to test their own blood glucose using home testing equipment, test their urine for sugar and acetone, and take their blood pressure regularly ■ To monitor your diabetes, your doctor may periodically test your blood levels for hemoglobin A1c, potassium, cholesterol, and substances that measure kidney function

This information does not replace the need to follow your doctor's instructions and read the drug information leaflet provided with your prescription.

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https://www.consumermedsafety.org/high-alert-medications

Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults

- Recommendations for avoiding errors and at-risk behaviors involving subcutaneous insulin use across the entire medication-use process.

https://www.ismp.org/node/93

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Questions?