alixaRx

June 2015 Issue

From the Front Lines

AlixaRx Clinical Pharmacists Address Everyday Challenges in Long-Term Care

Consensus List of Signals to Detect Potential Adverse Drug Reactions

Many adverse drug reactions (ADRs) have signals that can be used to reduce risks to nursing home patients.

Some of the laboratory and medication combination signals for detecting ADRs in nursing homes include:

- Hypoglycemia in a patient receiving a drug known to lower blood glucose (oral hypoglycemic or insulin)
- Supratherapeutic INR in a patient on warfarin therapy
- Clostridium Difficile infection (C. Diff) in a patient on high dose proton-pump inhibitor (PPI, such as omeprazole)
- Hyperkalemia in a patient on potassium supplement and/or spironolactone
- Elevated BUN in a patient on an nonsteroidal anti-inflammatory drug (NSAID, such as ibuprofen, naproxyn) especially if the patient is also on fluid restriction or is dehydrated

Some of the antidote signals include

- Vitamin K use for a patient on warfarin
- Glucagon or liquid glucose for a patient on insulin or oral hypoglycemic
- Oral vancomycin or metronidazole for a patient on high-dose PPI
- Sodium polystyrene (Kayexalate) for a patient on potassium supplement and/or spironolactone

Your AlixaRx clinical pharmacist monitors for these ADR signals as part of their monthly medication regimen review (MRR). The pharmacist can also alert you if they are seeing multiple signals for the same drug across multiple patients. This is an opportunity to discuss these signals at the QAPI meeting with your medical director to see if a medication performance improvement project (PIP) can be implemented to improve drug prescribing and patient outcomes.

Reference: Consensus List of Signals to Detect Potential Adverse Drug Reactions in Nursing Homes JAGS 56:808–815, 2008

In this issue:

The Next Generation of Lantus (Insulin Glargine)

There are a number of different insulin products available. Toujeo® (Too-Jay-o) is a recent addition to the line of long-acting basal insulin. Toujeo® is the same type of basal insulin (glargine) as Lantus, but is more concentrated. In Toujeo®, each milliliter (mL) of liquid carries 300 units of insulin ("U300"), whereas Lantus® only carries 100 units of insulin per milliliter ("U100").

Toujeo®, as with other long-acting insulin analogs, is indicated to improve glycemic control in adults with diabetes mellitus. The dosage and administration is similar to that of Lantus®. It should be administered daily at the same time each day and dosing adjustments should not be made more frequently than every 3 to 4 days.

Toujeo® will only be available in a new SoloStar pen that will carry 450 units, 50% more than the 300-unit Lantus® pen – a major improvement for the many people who require larger doses of insulin. It is imperative that prescribers differentiate when writing orders on the number of units they are ordering, 100 units/ml for Lantus® and 300 units/ml for Toujeo®. Nursing should always verify the insulin label before each injection and compare it to the administration record, verifying the concentration and dose.

Toujeo® may cause hypoglycemia (low blood sugar), hypokalemia (low potassium) and fluid retention. In addition, patients could have adverse reactions due to allergies, injection site reactions, rash, edema and weight gain. Regardless of the type of antidiabetic therapy, minimizing the risk of hypoglycemia must always be at the forefront of the caregiver's mind. Patients should have routine blood glucose monitoring and insulin dosing should be modified based upon those values.

The recommended dose of Toujeo® for Type 2 diabetic patients that are insulin naïve is 0.2 units/kilogram of body weight once daily. Please note that it may require dosage adjustments of other anti-diabetic drugs to minimize the risk of hypoglycemia. For those patients already taking insulin, the starting dose of Toujeo® can be the same as the once daily long-acting dose. If the patient is taking a twice-daily NPH, the recommendation is to dose Toujeo® at 80% of the daily total NPH. See Figure 1:

Prior Treatment	Start With:	
	Type 1	Type 2
No current basal insulin	0.2 to 0.4 units/kg for total insulin dose. The recommended starting dose of Toujeo® is approximately 1/3 to 1/2 of the total daily insulin dose	0.2 units/kg for intial dose of Toujeo®
Once-daily basal insulin	1:1 conversion	1:1 conversion
Twice-daily basal insulin	80% of total daily basal dose	80% of total daily basal dose

Figure 1: Mealtime insulin should be used to complete the remainder of the daily insulin requirements.

The EDITION clinical trial program, once-daily Toujeo® was compared to that of once-daily Lantus® in open-label, randomized, active-control, parallel, treat-to-target studies of up to 26 weeks of duration with 6 months safety extension.

The results of the study met all criteria by showing that Toujeo® demonstrated similar blood sugar control to

that of Lantus® and that it's safety profile was favorable with a lower incidence of hypoglycemia. The most common adverse events (excluding hypoglycemia) reported for Toujeo® included nasopharyngitis (12.8% in type 1 patients and 7.1% in type 2 patients) and upper respiratory tract infection (9.5% in type 1 patients and 5.7% in type 2 patients).

Warning and precautions

- Insulin pens, needles or syringes must never be shared between patients and never reuse needles
- Do not dilute or mix Toujeo® with any other insulin or solution
- Discard 28 days after opening
- Dosage reduction may be necessary for patients with renal or hepatic impairment
- Potassium monitoring should be monitored in patients at risk for hypokalemia

A huge proportion of diabetic patients (around 50% globally) on insulin are still failing to achieve adequate blood sugar control. Toujeo® allows flexibility for your diabetic patients, allowing titration of dosing to reach higher limits while still only giving one injection per 24 hour period.

For more information on managing your diabetic patients, please contact your AlixaRx Clinical Pharmacist.

Reference: 1. "Toujeo® (insulin Glargine Injection) 300 Units/mL." Toujeo® (insulin Glargine Injection) 300 Units/mL. Sanofi-aventis U.S. LLC, 1 May 2015. Web. 9 June 2015. 2. "Toujeo Launches in the US – The Next Generation Lantus." DiaTribe. 5 Mar. 2015. Web. 31 May 2015. 3. Berkrot, Bill. "FDA Approves Sanofi's Diabetes Drug Toujeo." Reuters. Thomson Reuters, 25 Feb. 2015. Web. 31 May 2015.

Policy Review: Returns and Credits

AlixaRx policy number ARX-016 found in the Facility Resource guide outlines the medications that may be returned to the pharmacy for credit, as permitted by state and federal law.

Medications that may be returned to the pharmacy for credit include those medications that are in the manufacturer's unopened original package or full punch cards of medications. Doses may not be removed from the punch card if the card is to be returned for credit. A medication disposition sheet must be completed with the Rx number, original dispense date, medication name, strength and dosage form, quantity dispensed and reason code indicated on the form. The white and yellow copies of the disposition sheet must be sent with each medication returned to the hub pharmacy.

In an effort to better serve our customers and improve our business processes, AlixaRx has published documentation regarding our medication return guidelines and credit policy. Determination of credit will be made by the pharmacy, following returns processing and based upon criteria established by the state board of pharmacy. Our policy states as follows:

- The pharmacy may issue credit for medications returned to the pharmacy in reusable condition only where allowed by law and subject to good standards of practice. Please reference policy # ARX-016.
- Medications that cannot be returned to the pharmacy include:
    - o Schedule II, III, IV, V Medications
    - o Expired medications
    - o Compounded drugs or dosage forms
    - o IV medications
    - o Temperature sensitive medication (arrived in a cooler) and/or those requiring refrigeration
    - o Special order items
    - o Partial or opened containers (including creams, ointments, etc…)
    - o Partial punch cards

- o ADU Packets
- o Altered dosage form (half tablets)
- o Opened vials or flushes
- o Medications in prescription vials from back-up pharmacies
- o Third party paid
- o Defaced packaging
- o Products with a manufacturer overwrap that has been removed
- o Any product over 30 days from dispense date

Any non-creditable medications sent back to the AlixaRx Pharmacy Hub will be returned to the facility by the pharmacy. The facility will be charged a fee for shipping and return handling of these non-creditable medications. These medications must be destroyed at the facility in compliance with applicable state laws and facility policy. If you are unsure if your state permits medications to be returned to the pharmacy for credit or need assistance with medication destruction procedures, check with your AlixaRx Clinical Pharmacist.

**** Credit may be applied in the case of pharmacy error to the above mentioned items**
**** Credits only applicable to states that allow medication to be returned to a pharmacy**

PRN Medications for Blood Pressure and State Survey

Be mindful of orders for 'PRN' blood pressure medication; e.g. "clonidine 0.1mg every 6 hours as needed for systolic blood pressure greater than 160." Remember these are in essence also orders for routine blood pressure checks. In the preceding example, you would need to document the patient's blood pressure reading routinely every 6 hours. Otherwise, as many surveyors have noted, you have no way of showing the PRN order for medication was not indicated. In most cases these are acute care orders not appropriate for long-term care patients. Occasionally elevated blood pressures are not clinically relevant, and the medications most often ordered have the potential to cause orthostatic hypotension and increased falls. Prescribers should be encouraged to discontinue orders for 'PRN' blood pressure medications and instead check the patient's blood pressure twice daily for 7-10 days to see if an increase in the patient's routine antihypertensive medication is warranted. Otherwise it is critical to ensure that all such orders are accompanied by an order for routine blood pressure documentation with a note of the parameter(s) for which the 'PRN' order is indicated.

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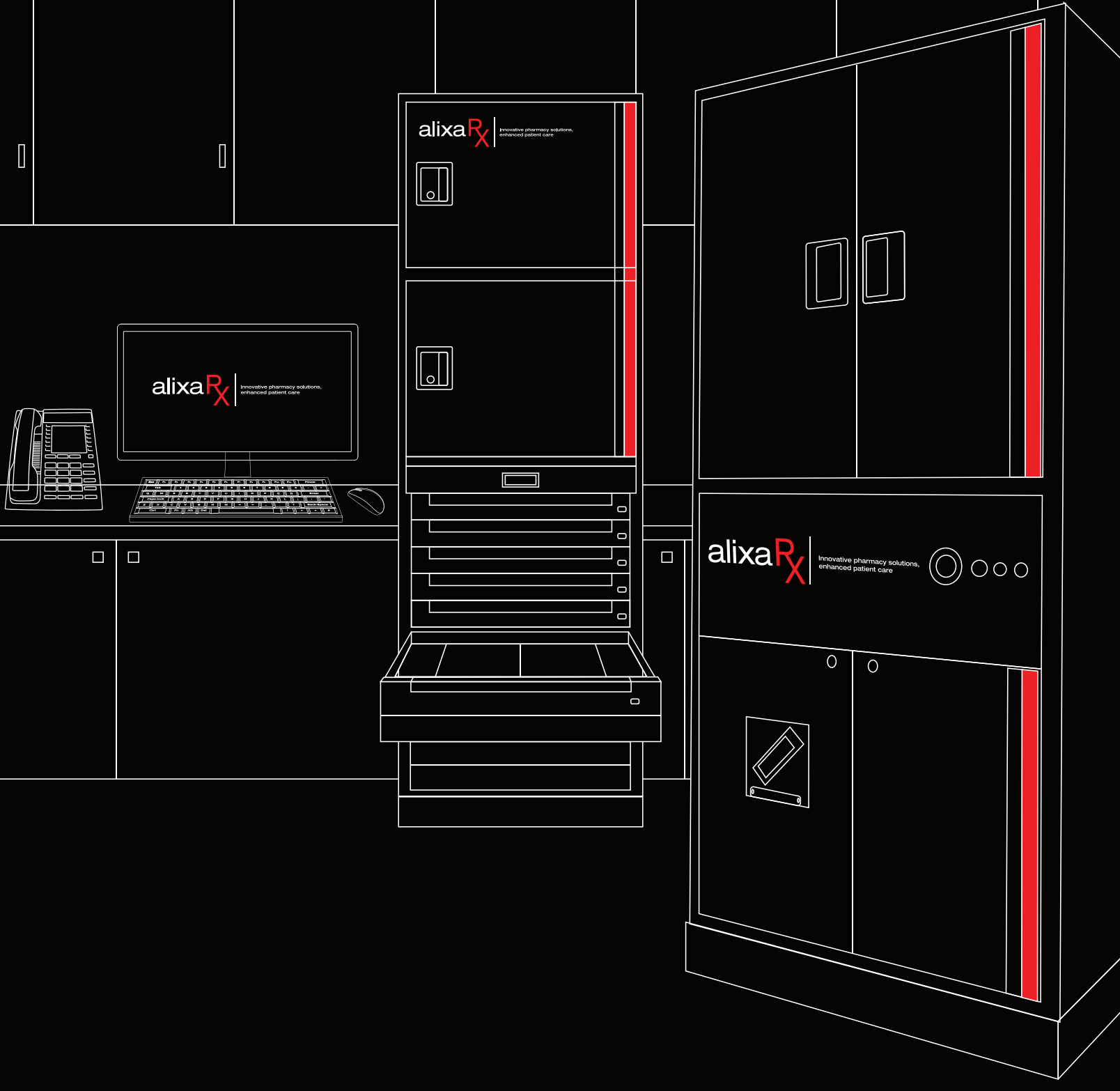

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