ISMP Update on Top Medication Safety Issues from 2018

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ISMP Targeted Medication Safety Best Practices (TMSBPs) for Hospitals 2018-2019

TMSBP #14
Lack of learning from external medication safety risks and errors

- One of the most important ways to prevent medication errors is to learn from errors that have occurred in other organizations and to use that information to identify potential risk points or practices within your organization to prevent similar errors.
- Experience has shown that a medication error reported in one organization is also likely to occur in another.
- Seeking out external sources for information about risk and errors prompts the evaluation of similar risks within YOUR organization, that may otherwise be hidden, lying dormant for years before an adverse outcome occurs.

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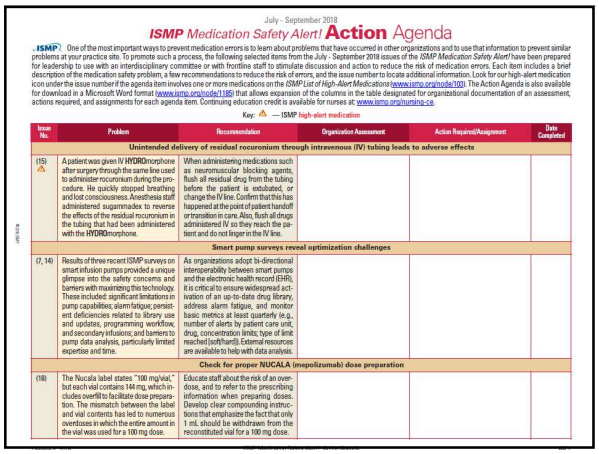


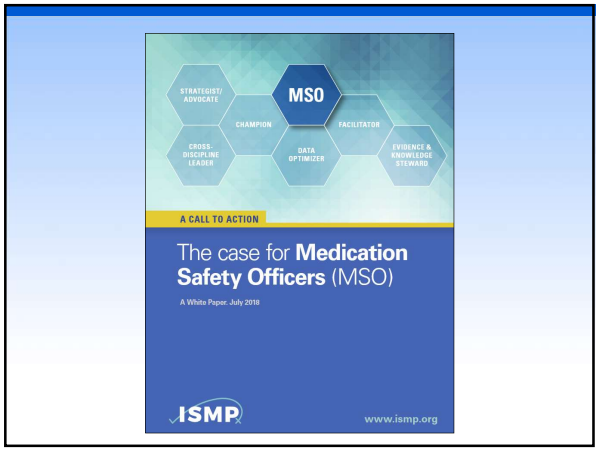
July - September 2018

ISMP *Medication Safety Alert!* **Action** Agenda

ISMP One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and to use that information to prevent similar problems at your practice site. To promote such a process, the following selected items from the July - September 2018 issues of the *ISMP Medication Safety Alert!* have been prepared for leadership to use with an interdisciplinary committee or with frontline staff to stimulate discussion and action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, a few recommendations to reduce the risk of errors, and the issue number to locate additional information. Look for our high-alert medication icon under the issue number if the agenda item involves one or more medications on the *ISMP List of High-Alert Medications* (www.ismp.org/node/100). The Action Agenda is also available for download in a Microsoft Word format (www.ismp.org/node/1185) that allows expansion of the columns in the table designated for organizational documentation of an assessment, actions required, and assignments for each agenda item. Continuing education credit is available for nurses at: www.ismp.org/nursing-ce.

Key: ⚠ — ISMP high-alert medication

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Unintended delivery of residual rocuronium through intravenous (IV) tubing leads to adverse effects					
(15) ⚠	A patient was given IV HYDROmorphone after surgery through the same line used to administer rocuronium during the procedure. He quickly stopped breathing and lost consciousness. Anesthesia staff administered sugammadex to reverse the effects of the residual rocuronium in the tubing that had been administered with the HYDROmorphone.	When administering medications such as neuromuscular blocking agents, flush all residual drug from the tubing before the patient is extubated, or change the IV line. Confirm that this has happened at the point of patient handoff or transition in care. Also, flush all drugs administered IV so they reach the patient and do not linger in the IV line.			
Smart pump surveys reveal optimization challenges					
(7, 14)	Results of three recent ISMP surveys on smart infusion pumps provided a unique glimpse into the safety concerns and barriers with maximizing this technology. These included: significant limitations in pump capabilities; alarm fatigue; persistent deficiencies related to library use and updates, programming workflow, and secondary infusions; and barriers to pump data analysis, particularly limited expertise and time.	As organizations adopt bi-directional interoperability between smart pumps and the electronic health record (EHR), it is critical to ensure widespread activation of an up-to-date drug library, address alarm fatigue, and monitor basic metrics at least quarterly (e.g., number of alerts by patient care unit, drug, concentration limits; type of limit reached [soft/hard]). External resources are available to help with data analysis.			
Check for proper NUCALA (mepolizumab) dose preparation					
(18)	The Nucala label states "100 mg/vial," but each vial contains 144 mg, which includes overfill to facilitate dose preparation. The mismatch between the label and vial contents has led to numerous overdoses in which the entire amount in the vial was used for a 100 mg dose.	Educate staff about the risk of an overdose, and to refer to the prescribing information when preparing doses. Develop clear compounding instructions that emphasize the fact that only 1 mL should be withdrawn from the reconstituted vial for a 100 mg dose.			



Misuse of standard insulin pen needles by patients at home after hospitalization

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Problem

While hospital staff often use insulin pens with a safety needle that does not require removal of the needle cover prior to injection, patients often use a standard insulin pen needle at home, which has a needle cover that must be removed before injection.

Safety Pen Needle

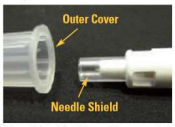

Figure 1. NovoFine Autocover is an example of insulin pen needle with a needle shield that automatically retracts upon injection and re-covers and locks over the needle when withdrawn from the skin. (BD AutoShield Duo, not pictured here, is another example of a safety needle used with pens.)

Standard Pen Needle

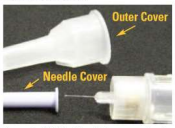

Figure 2. BD Ultra-fine III is an example of a standard pen needle. Both the outer cover and inner needle cover must be removed prior to injection.

Problem

- Some hospitalized patients who have been taught to inject insulin using a pen with a safety needle have tried to inject insulin at home without removing the needle cover on a standard needle, thus failing to administer the insulin.
- One elderly patient developed ketoacidosis and died.

Recommendations

- Do not rely on community pharmacists to query new insulin patients about which pen needle they require. They may not store pens with safety needles and these are more expensive.
- Manufacturer instructions in needle packaging may not be helpful in preventing this problem.
- Verify which pen needle the patient will be using and tailor the training to that needle. Require a return demonstration.
- Remind patients that a standard pen needle is different from what may have been used in the hospital.
- Review injection technique with the patient if blood glucose levels are elevated.
- A National Alert Network (NAN) communication offered further details.

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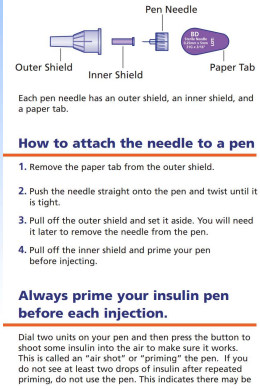
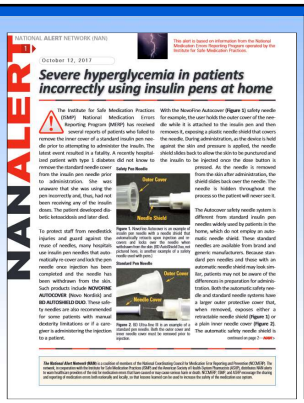
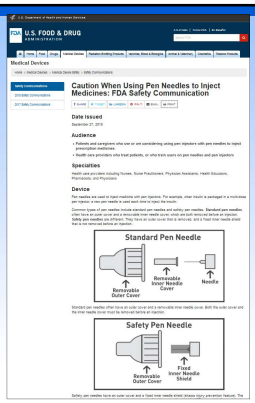


Use an "Air Shot"!!





http://ismp.org/NAN/files/NAN -20171012.pdf

Improper use of the BD AUTOSHIELD DUO and NOVOFINE AUTOCOVER insulin pen safety needles

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- BD Auto-Shield Duo pen needles (left) have a sliding sleeve encircling the needle that retracts when the pen and needle are pressed against the patient's skin. Afterwards, the shield slides back over the needle, locks into place, and a red indicator becomes visible. The NovoFine Autocover (right) uses a similar system.

Problem

- A patient required 5 emergency department (ED) visits and a hospital admission for hyperglycemia and ketoacidosis caused by nursing home staff misuse of the BD AutoShield Duo insulin pen safety needle.
- Some staff did not press hard enough for the needle cover to retract, and others injected the insulin at an angle that did not allow the retraction mechanism to work.
- Similar problems are possible with the NovoFine Autocover safety needles.

Recommendations

- Educate staff about the proper use of insulin pens and safety needles.
- Include a requirement to look for the red indicator on the BD AutoShield Duo and NovoFine Autocover post-injection to ensure that the needle has retracted properly.
- Patients rarely use safety needles unless a caregiver is administering the insulin. If this is the case, also educate the caregivers about proper use of the pen and safety needles.

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Problem

- A patient using a U-500 insulin pen showed a pharmacist how he turned the dose knob on the pen to “15” to deliver each prescribed dose of 75 units. He had previously used a U-100 syringe to measure each dose of U-500 insulin, stopping at the “15 units” marking on the syringe. But the U-500 pen delivers the actual dose dialed.

Recommendation

- Hospital staff should use U-500 insulin pens, or U-500 insulin syringes and vials, when measuring and administering U-500 insulin.
- For patients, perform a medication history on admission to determine whether they are using a U-500 insulin pen at home, or a vial and syringe, and tailor the education to the devices being used.

Differentiating insulin types by touch and separate storage

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Problem

- A visually impaired woman who uses both rapid-acting and long-acting insulin pens stored them both in the refrigerator. She accidentally administered 50 units of the rapid-acting insulin at night and developed hypoglycemia.

Recommendations

- Teach patients ways to differentiate insulin types by touch, such as applying adhesive tape or rubber bands to pens.
- Avoid storing insulin pens together; advise patients to keep long-acting insulins in the bedroom and rapid-acting insulins in the dining area.

Medication errors during insulin administration for patients with hyperkalemia

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Problem

- When treating hyperkalemia, harmful errors have occurred due to measuring IV insulin bolus doses in mL instead of units, misreading the measurement markings on syringes, delays in treatment, not using an insulin syringe to measure doses, and erroneous subcutaneous administration.
- In one event, a nurse withdrew insulin lispro to the first graduation mark on a 10 mL syringe, believing it represented 0.1 mL (10 units) but it measured 0.2 mL (20 units). In another a medical resident used a 3 m,L syringe and drew up 1 mL (100 units). And in yet another case, a resident administered the contents of a 3 mL (300 units) vial of regular insulin instead of 0.1 mL (10 units).

Recommendations

- Develop hyperkalemia treatment protocols that define interventions and monitoring. Include a threshold for treatment, and do not delay treatment due to the absence of symptoms or EKG changes.
- Require the use of standard order sets that automatically populate the correct insulin dose and route.

Recommendations

- Have pharmacy prepare all insulin doses or supply a hyperkalemia kit with a luer-compatible needleless insulin syringe.

- Require an independent double check of IV insulin doses and restrict administration to those with demonstrated competency.

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Caution advised with tamper-evident caps

Problem

- Red plastic tamper-evident caps used for oral and parenteral syringes containing controlled substances are designed in a way that can leave a small plastic ring on the syringe that may slide into a patient's mouth during administration (especially on 1 mL syringes).

- This poses a choking risk for children and adults with a decreased gag/cough reflex or altered mental status. A recommendation to discard the ring before administration is in printed material that is rarely seen by those administering the medication.

Recommendations

- Educate staff to follow the manufacturer's instructions to remove the ring before drug administration.
- Carefully inspect any delivery device and its component parts prior to drug administration.
- Do not leave any syringe caps at the patient's bedside as they may be confused as oral medications or aspirated by children.

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Expression of strength per mL on BRIDION (sugammadex) peel-off label causes confusion

Problem

- Bridion (sugammadex) had a peel-off label that expressed the strength as 100 mg/mL, but the label underneath expresses the strength as 200 mg/2 mL (2 mL vial) or 500 mg/5 mL (5 mL vial).
- The peel-off label has misled providers to believe the entire vial (2 mL or 5 mL) contains only 100 mg, leading to several reported overdoses.
- A similar problem has occurred with rocuronium vials that also have peel-off labels

Recommendations

- Practitioners should be aware of the risk of confusion with peel-off labels placed in this manner by the manufacturer. They should only rely on the label underneath for the total amount of drug in the vial.
- While ISMP supports peel-off labels to facilitate syringe labeling, we have asked FDA and manufacturers to provide peel-off labels in another location or separately.

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Confusion between SANDIMMUNE (cycloSPORINE) and NEORAL or GENGRAF (cycloSPORINE [MODIFIED]) capsules and oral solution

Problem

- Sand**IMMUNE** is a nonmodified form of cyclo**SPORINE** that has decreased bioavailability compared to NEORAL or GENGRAF (MODIFIED) capsules and oral solution.
- These are not interchangeable, yet patients often receive Sand**IMMUNE** when a cyclosporine modified oral formulation was intended.
- This happened recently when a nurse did not verify the brand of cyclo**SPORINE** the patient had been taking at home, and the physician prescribed Sand**IMMUNE** but the patient had been taking Gengraf.

Recommendations

- Indicate the brand name in orders, medication histories, and medication reconciliation records.
- Clarify orders for cyclo**SPORIN**E if the formulation is not specified.
- Clearly display the different drug forms in order entry systems and create a hard stop to force verification of the correct drug form during prescribing.
- Monitor blood levels if a transplant patient receives the wrong formulation.

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Confusing SHINGRIX (zoster vaccine recombinant, adjuvanted, GlaxoSmithKline) with ZOSTAVAX (zoster vaccine live, Merck)

Problem

- Shingrix and Zostavax have different schedules
- Shingrix lyophilized antigen and adjuvant suspension must both be refrigerated. The Zostavax lyophilized vaccine component must be frozen, and its sterile water diluent must be refrigerated or at room temperature
- Shingrix is administered intramuscularly (IM) while Zostavax is given subcutaneously
- https://pharmacist.com/sites/default/files/files/2018ZosterVaccinesChartv9Final.pdf?id=3102

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Recommendations

- Educate staff about the differences between Shingrix and Zostavax.
- Store the Shingrix lyophilized component and adjuvant suspension together to reduce the risk of using the wrong diluent.

Key Differences	Zostavax	Shingrix
Vaccine Type	Live attenuated	Inactivate recombinant adjuvated
Age recommendation	60 years or older	50 years or older
Vaccine Schedule	1 dose, 0.65 mL	2 doses, 0.5 mL @ 0, 2-6 months
Administration Route	Subcutaneous	Intramuscular
Storage	Frozen, reconstituted	Refrigerated, reconstituted

Source: https://theabofpharmacsite.wordpress.com/2017/12/08/shots-for-the-new-year/

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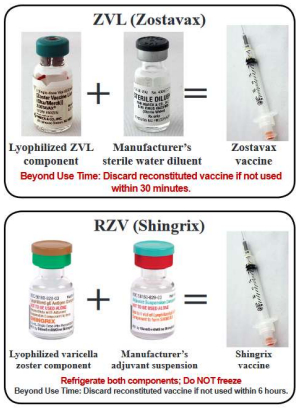
Recommendations

- Label the storage bins/shelves using the updated Centers for Disease Control and Prevention (CDC) vaccine labels, which draw attention to the differences in storage, component/diluent, and routes of administration.

https://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf?id=3101



Labeling practices by 503A and 503B compounders

Problem

- Some compounders deviate from USP <7> labeling standards and express the strength per mL as the primary expression on the label, not the strength per total volume, leading to inconsistencies.
- Errors occur when the per mL strength is mistaken as the total amount of drug in the syringe.

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Problem

- Recent examples include syringes of succinylcholine found in an anesthesia cart—one with the strength expressed per total volume (Cantrell Drug Company) and the other expressed per mL (PharMEDium).

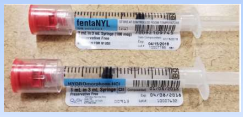
- Both syringes contain the same drug, strength, and volume, but the primary display of strength is expressed per total volume (top) on the syringe from Cantrell Drug Company and per mL on the PharMEDium syringe label (bottom).

Problem

- Other examples include high-dose, 1 mg per 10 mL (100 mcg/mL) EPINEPHrine syringes that were placed in OR syringe bundles that normally contained 100 mcg per 10 mL (10 mcg/mL) EPINEPHrine syringes outsourced from PharMEDium.

- To prevent look-alike product mix-ups, pharmacy staff had affixed auxiliary labels to the syringes to differentiate between the high- and low-dose EPINEPHrine. However, a technician misapplied a 10 mcg per mL auxiliary label to a high-dose syringe.

Problem



Look-alike fenta**NYL** and **HYDRO**morphone syringes from QuVa Pharma with the same ASTM International blue color on the label, a flagged white section of the label common to both syringes, and the same color tamper-evident caps.

Nephron phenylephrine and succinylcholine syringes differentiated by ASTM international standard color coding look identical when placed drug name down in the tray on the right.

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Misleading Labels

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Problem

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Recommendations

- Use only compounders that follow USP <7> labeling practices.
- Employ barcode scanning technology when possible to verify that the correct medication has been selected prior to dispensing and/or administration.

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U.S. FOOD & DRUG ADMINISTRATION

Drugs

Differences in strength expression on product labels of compounders and conventional manufacturers may lead to dosing errors

September 27, 2018

Summary

Case Reports

Ketamine HCl

Unintended delivery of residual rocuronium through intravenous (IV) tubing leads to adverse effects

Problem

- A patient was given IV **HYDRO**morphone after surgery through the same line used to administer rocuronium during the procedure.
- He quickly stopped breathing and lost consciousness.
- Anesthesia staff administered sugammadex to reverse the effects of the residual rocuronium in the tubing that had been administered with the **HYDRO**morphone.

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Recommendations

- When administering medications such as neuromuscular blocking agents, flush all residual drug from the tubing before the patient is extubated, or change the IV line.
- Confirm that this has happened at the point of patient handoff or transition in care.
- Flush all drugs administered IV so they reach the patient and do not linger in the IV line.

Misconnections between IV and tracheostomy pilot balloon ports can result in fatal outcomes

Problem

- Errors in which intravenous (IV) tubing is connected to a tracheostomy pilot balloon port continue to occur. These misconnections have led to respiratory arrest and death.
- In a recent event, a nurse accidentally connected an IV antibiotic to the balloon port, which inflated the tracheostomy cuff, occluded the airway, and burst, causing fluid to enter the lungs, resulting in the patient going into respiratory arrest.

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Example of a tracheostomy cuff filled with 85 mL of saline and ready to rupture.

FDA case study of a misconnection is based on an actual event in which a child died after connecting an IV line to a tracheostomy pilot balloon port.

Recommendations

- Evaluate products used in your organization that may lead to misconnections and take steps to mitigate the risk (see self-assessment tool at: www.ismp.org/ext/82).
- Affix line labels close to insertion sites, position pumps on the same side as the port, trace lines before connection, decrease the frequency of disconnecting and reconnecting tubing, and conduct independent double checks before administering certain high-alert medications.

Confusion with the abbreviation “tPA” - again

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Problem

- A nurse calling the pharmacy about a STAT order for alteplase asked if the patient's "tPA" was ready.
- The pharmacist heard "TPN" and stated it was on its way since he was ready to deliver parenteral nutrition solutions.
- When the nurse called again, another pharmacist dispensed the "tPA" infusion but forgot to remove the bolus dose.
- This delay led to worsening of the patient's condition.

Recommendations

- Avoid the abbreviations "tPA" or "TNK" in all forms of communication (e.g., verbal, electronic, paper) and refer to the drug only by its generic and/or brand name.
- Include the indication with orders. Issue an alert during order entry and on automated dispensing cabinet screens to remind staff to verify the indication.

Results of high-alert medication survey lead to several changes for 2018

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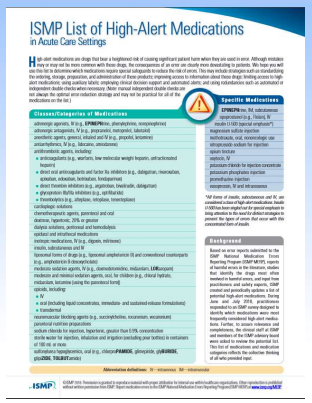
Problem

- According to a recent ISMP survey on high-alert medications in acute care settings, almost all inpatient settings maintain a facility-specific list but only two-thirds have special precautions in place to prevent errors with these drugs, a quarter of which were rated as somewhat or weakly effective.
- The medications that caused the most concern with regards to medication errors included anticoagulants, insulin, neuromuscular blocking agents, chemotherapy, and opioids.

Recommendations

- The ISMP List of High-Alert Medications in Acute Care Settings was updated in August 2018.
  - oral hypoglycemics narrowed to sulfonylureas;
  - removed IV radiocontrast agents;
  - added all parenteral routes for promethazine.
- Review the updated list to determine if changes are indicated on your list.


ISMP List of High-Alert Medications in Acute Care Settings

http://www.ismp.org/node/103

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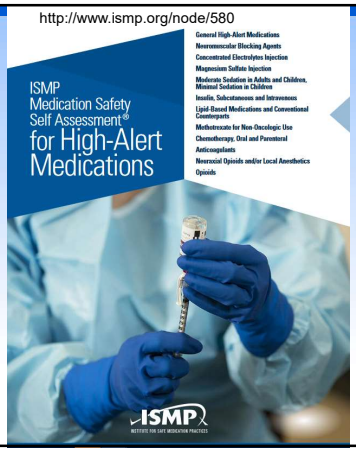
Recommendations

- Employ effective risk-reduction strategies, especially for anticoagulants, insulin, neuromuscular blocking agents, chemotherapy, and opioids.
- See the ISMP Medication Safety Self Assessment for High-Alert Medications for assistance.

http://www.ismp.org/node/580



Oral OTC fat soluble vitamin label changes

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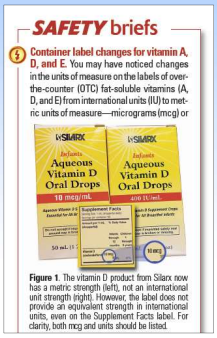
Vitamins A, D and E strength now listed in mcg or mg, not units



SAFETY briefs

Container label changes for vitamin A, D, and E. You may have noticed changes in the units of measure on the labels of over-the-counter (OTC) fat-soluble vitamins (A, D, and E) from international units (IU) to metric units of measure—micrograms (mcg) or

Figure 1. The vitamin D product from Silarx now has a metric strength (left), not an international unit strength (right). However, the label does not provide an equivalent strength in international units, even on the Supplement Facts label. For clarity, both mcg and units should be listed.

ISMP National Medication Errors Reporting Program

Medication Error Reporting Program
Vaccine Error Reporting Program
Consumer Error Reporting Program

www.ismp.org