March 11, 2021 ■ Volume 26 Issue 5

ISMP An ECRI Affiliate

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

Analysis of transdermal medication patch errors uncovers a "patchwork" of safety challenges

Problem: A recent cluster of error reports associated with transdermal medication patches submitted to the ISMP National Medication Errors Reporting Program (ISMP MERP) led us to look back a few years at all transdermal patch error reports submitted to the ISMP MERP to identify contributing factors and make recommendations to avoid errors with this type of drug delivery system. A transdermal patch is a medicated adhesive patch placed on intact skin to provide regular, controlled release of medication doses into the bloodstream through the skin. Transdermal patches are used to deliver a wide variety of pharmaceuticals, including medications used for smoking cessation, motion sickness, hormone replacement therapy, hormonal contraception, hypertension, angina, pain, depression, overactive bladder, and Alzheimer's disease.

Our analysis included more than 50 reports associated with 12 different transdermal medication patches submitted to the ISMP MERP within the past 4 years. During analysis, four reports were excluded because the contributing factors were not unique to medication patch delivery systems (e.g., wrong patient). Patches most frequently involved in reported errors included fenta**NYL** (n = 16), clo**NID**ine (n = 10), scopolamine (n = 7), and estradiol (n = 6). While ISMP has repeatedly published reports of errors associated with transdermal patches, we now provide details about the error types we discovered during our recent analysis of patch errors.

Errors in the Frequency of Patch Application or Removal

ISMP received 10 reports associated with an error in the frequency of patch application or removal. Four of these errors involved estradiol patches. Depending on the brand or formulation, estradiol patches are applied either twice a week (**ALORA**, **DOTTI**, **LYLLANA**, **MINIVELLE**, **VIVELLE-DOT**, generics) or once a week (**CLIMARA, MENOSTAR**, generics). In two of the cases, a weekly estradiol patch was prescribed, but a twice weekly formulation was dispensed with directions to apply one patch weekly, which resulted in underdoses. In another case, a physician prescribed a twice weekly estradiol patch with directions to change the patch weekly, also resulting in an underdose. In the fourth event, a prescriber ordered a twice weekly estradiol patch, but the pharmacy dispensed a weekly patch with directions to apply the patch twice weekly. Some dispensing errors continued for several refills. In some cases, the manufacturers' outer carton did not clearly specify if the patch was to be applied weekly or twice weekly.

Three of the 10 frequency errors involved dispensing fenta**NYL** patches with the wrong directions for application, sometimes due to a transcription error in the pharmacy. Another error in this category involved misinterpretation of a consultant's note to "Increase Clonidine patch to TTS-2 to mitigate ketamine side effects and help with opioid withdrawal symptoms." A hospitalist interpreted the "TTS-2" to mean Tuesday, Thursday, and Saturday, and did not know that "TTS-2" was the nomenclature used for the 0.2 mg/24 hour **CATAPRES-TTS-2** (transdermal therapeutic system) brand of clo**NID**ine patches, which should only be applied weekly. We also received two error reports associated with removing a patch at the wrong time—one involving the removal of a fenta**NYL** patch instead of a lidocaine patch after 12 hours, and the other involving the removal of a nitroglycerin patch after 24 hours instead of after 12-14 hours.

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SAFETY briefs

HIGH-ALERT

Cisatracurium barcode is not scannable. It will be difficult or impossible to scan the **NIMBEX** (cisatracurium besylate from AbbVie) vial barcode for proper medication identification. The product is packaged in a very slim, tall vial with the barcode printed horizontally, curving around the circumference of the vial (**Figure 1**). The curvature renders barcodes unscannable with a laser scanner. This is not the first time this particular barcode problem has been reported, so manufacturers and the US Food and Drug Administration (FDA) need to be aware as products with a horizontal barcode on a curved surface might not be considered useable in locations that depend on barcode scanning at the point of drug dispensing and/or administration. The FDA Barcode Rule requires a linear barcode that encodes the product's National Drug Code (NDC) number (in this case, NDC 0074-4378-05). Linear barcodes on round vials should only be printed perpendicular to the curve of the vial, usually along the edge of the label on one side, rather than horizontally around the curve of the vial. Purchasers should avoid this product where barcode scanning is used during product selection.

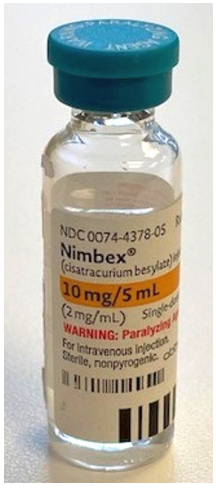

Figure 1. Curvature of vial renders barcode unscannable as its placement is parallel to the circumference.

SIRVA persists. We have received several reports of shoulder injury related to vaccine administration (SIRVA) in recent weeks. A 68-year-old man who received his second coronavirus disease 2019 (COVID-19) vaccination with the Moderna product

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Lack of Awareness of Patches on the Patient's Skin

ISMP received seven reports associated with practitioners failing to identify patches on the patient's skin (which had been applied prior to admission), not removing an old patch when applying a new patch, and/or finding multiple patches on patients that had been left on longer than prescribed. Five of these events involved fenta**NYL** patches. In one case, two patches were found on an unexpectedly somnolent patient during rounds. In another case, three 100 mcg/hour fenta**NYL** patches were found on an over-sedated patient with respiratory depression. One health system reported an increase in reports of patients with an applied fenta**NYL** patch that was missed upon admission and not found on their skin until days later. We have also received reports of finding multiple nicotine patches and rivastigmine (**EXELON**) patches (used for Alzheimer's) on patients during their admission. Because many patches are clear or beige, they might easily be missed on the skin of some patients.

Dose Confusion Due to Labeling

ISMP received seven error reports related to confusing the dose expression on the label of scopolamine patches. In the most recent report received just last month, a pharmacy technician noticed that the dose listed on the carton and inner patch pouches of the Perrigo brand of scopolamine patches was 1 mg/3 days (**Figure 1, left**), which did not match the dose of 1.5 mg/3 days needed to refill an automated dispensing cabinet (ADC). The technician also checked the electronic health record, order sets, medication administration record (MAR), and an electronic drug information resource, and found that the dose was expressed as 1.5 mg/3 days in all of these technologies. On the back of the Perrigo scopolamine carton, the technician noticed that the patch actually contains 1.3 mg of scopolamine base but only delivers 1 mg over 3 days. When examining other scopolamine patch products, the technician found that many have changed to a 1 mg/3 days dose expression, while others still display the dose as 1.5 mg (**Figure 1, right**), even though each patch only delivers 1 mg over 3 days.

Figure 1. Scopolamine transdermal system from Perrigo (left) expresses the dose as 1 mg/3 days, while **TRANSDERM SCŌP** (scopolamine) from Sandoz (right) expresses the dose as 1.5 mg, although the patch delivers 1 mg over 3 days.

This label confusion has led to prescribing, dispensing, and administration errors. In one reported event, a prescriber ordered 1 mg of a 1.5 mg/3 days patch (0.667 of the patch), and the nurse cut off one-third of the dispensed patch before applying the other two-thirds of the patch on the patient. Scopolamine patches should not be cut. In another case, a prescriber ordered a 1.5 mg scopolamine patch for a patient, and the pharmacy dispensed 1½ patches. Serious toxic effects are possible with a scopolamine overdose.

According to the US Food and Drug Administration (FDA), transdermal scopolamine product labeling should be standardized at the nominal delivery rate of 1 mg/3 days. Based on the recent reports we received in 2021, there might be a few products that have not yet transitioned to the newer dose expression (1 mg/3 days) on container labels. Or, some products with the older label (1.5 mg) may still be in circulation.

Inappropriate Patch Prescribing

ISMP received six reports of inappropriate prescribing of fenta**NYL** patches. In a July 2, 2020 newsletter article (www.ismp.org/node/18707), we described three examples of fenta**NYL** patches inappropriately prescribed for opioid-naïve patients discharged from the emergency department (ED) to treat acute pain or due to an "allergy" to codeine

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developed pain at the injection site and the back of the shoulder joint and was unable to raise his arm up from the side of his body. He stated that the injection was given high on his upper arm, "hitting a nerve or injected into or too close to the shoulder bursa." He reported that the person giving the vaccine did not use any landmarks or fingerbreadths to locate the proper deltoid injection site.

Another patient, a 43-year-old man, also suffered a vaccine injury when he received the injection high in the upper arm. Shoulder pain started after 4 to 5 hours and then worsened, with an impingement in movement. Pain and difficulty moving the arm persisted after 3 weeks and he contacted an orthopedist. His x-ray revealed a ligament tear and capsule involvement with the possibility of requiring surgical repair.

A third patient who received his second dose of the Pfizer-BioNTech COVID-19 vaccine had severe left arm and shoulder pain beginning the afternoon following his early morning vaccination. The discomfort continued to worsen until it was excruciating. Again, the vaccine was administered high on the upper arm.

As we stated in our December 17, 2020 issue (www.ismp.org/node/21977), it is critical for healthcare workers who administer the vaccine to understand proper intramuscular (IM) administration technique in order to avoid a preventable and disabling SIRVA. This is especially important because healthcare workers who may not normally administer vaccines are often volunteering in the national effort to vaccinate people against COVID-19. The December article also provided links to several excellent print and video resources that everyone giving vaccinations needs to review before administering their first injection. Just 'eyeballing' the injection site is not acceptable.

Praxbind label information needs repositioning. A pharmacist misunderstood the **PRAXBIND** (idaru**CIZU**mab) carton label and dispensed two cartons of the product for a 5 g intravenous (IV) dose, although each carton contained the full 5 g

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that was only a minor drug intolerance. Prescribing information recommends fenta**NYL** patches only be used in opioid-tolerant patients for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment. Since then, we have received three more error reports associated with inappropriate prescribing of fenta**NYL** patches to opioid-naïve patients in long-term care (LTC) facilities. Reliance on product labeling and practitioner education alone will not do enough to solve this life-threatening problem.

Wrong Dose Dispensing Errors

ISMP received six reports of dispensing the wrong dose of patches that are available in more than one strength. We previously published one of these errors in our September 24, 2020 newsletter (www.ismp.org/node/20596). An order for 50 mcg/hour fenta**NYL** patches included "72 hours" for the duration of patch application. The "72" was mistaken as the strength, leading to erroneous dispensing of a 75 mcg/hour instead of the intended 50 mcg/hour fenta**NYL** patch. Including the duration of controlled drug delivery (i.e., 72 hours) in the order and the drug description field contributed to this dispensing error. In another event, a technician filling an order for rivastigmine patches 9.5 mg/24 hour for a LTC resident prepared 13.3 mg/24 hour patches and failed to notice the error because he bypassed the usual barcode scanning process. The pharmacist verifying the product did not notice a discrepancy between the 13.3 mg/24 hour patches and the image of the 9.5 mg/24 hour patches on the computer screen and dispensed the patches. The remaining event reports did not include information regarding the primary causes of the wrong dose dispensing errors.

Patch Cover Applied without the Medication Patch

ISMP received five reports of applying a clo**NID**ine patch adhesive cover directly to the skin, without first applying the clo**NID**ine patch. In one case, only the adhesive cover was retrieved from the carton and applied; in all other cases, the active medication patch was accidentally discarded. The errors contributed to uncontrolled blood pressure. In an ***FDA AdviseERR*** published in our March 28, 2019 newsletter (www.ismp.org/node/1499), FDA described reports they had received regarding *patients* and *caregivers* who had applied only the adhesive cover to the skin. The clo**NID**ine transdermal system (Catapres-TTS) is packaged in a carton containing individually labeled pouches of four clo**NID**ine patches and four adhesive covers. Once removed from the pouches, the clo**NID**ine patch is a different size, shape, and color than the adhesive cover, but the patch and cover do not specify which is which. Application of the adhesive cover is optional; the cover should be applied directly over the clo**NID**ine patch *only* if the patch begins to separate from the skin.

Wrong Patch Prescribed Due to Similar Ingredients

This month, we received a report about a patch error we have not previously described. A pharmacist noticed that a hormone replacement therapy drug, **COMBIPATCH** (estradiol and norethindrone), had been prescribed for a 20-year-old woman. Because CombiPatch is typically used to treat vasomotor symptoms associated with menopause, the pharmacist contacted the prescriber to ask whether he had instead intended to prescribe the hormonal contraceptive patch, **XULANE** (ethinyl estradiol and norelgestromin), for the young woman. The prescriber confirmed that he had selected the wrong patch and prescribed the intended product, Xulane.

After a second, similar prescribing error was made, the pharmacist investigated further and found that the same error had occurred with several different prescribers. Because there are so many hormonal contraceptives with similar ingredients, most prescribers had searched for "patch" and then selected the product with ingredients consistent with a contraceptive patch. However, the only hormonal "patch" available for selection in the facility's system was CombiPatch; "patch" was not included in the Xulane drug description and had not appeared as a choice when the prescribers searched for a "patch."

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dose divided into two 2.5 g vials. Praxbind is used to reverse the anticoagulant effects of the direct thrombin inhibitor dabigatran. The recommended dose of 5 g should be administered as two separate 2.5 g IV doses no more than 15 minutes apart, according to the prescribing information. Thus, the manufacturer, Boehringer Ingelheim, packages two 2.5 g (50 mL) vials in each carton. The Praxbind carton label states, "2.5 g/50 mL," which the pharmacist misunderstood to mean that each carton contained only 2.5 g. Below that, the carton label states, "Administer 2 vials for a complete dose of 5 g." However, the pharmacist did not notice that the label also states "Contains 2 single-dose vials each containing 2.5 g/50 mL" at the very bottom of the principal display panel (**Figure 1**). The dispensing error was caught by a nurse who called to clarify the number of cartons needed for the 5 g dose prior to administration.

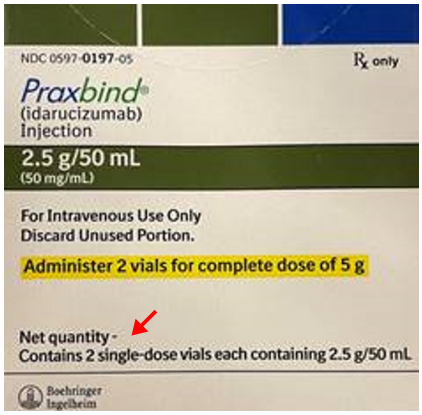

Figure 1. On the current Praxbind carton label, information that two vials are contained within each carton may be missed.

Because practitioners may not handle this product often, they might not be familiar with the carton contents. Although it seems clear that 2 vials are needed for the complete dose of 5 g, less clear is that the 2 vials are contained within a single carton. This important information should appear prominently on the label, within the same color band. Perhaps the best way to label the carton would be to state the full 5 g contents, with "2 x 2.5 g/50 mL single-dose vials" immediately following the full contents in parentheses. Because the prescribing information recommends administering the medication as an infusion by hanging the vials (each infusing over 5-10 minutes), or

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Miscellaneous Errors

ISMP also received numerous reports of miscellaneous errors associated with patches, including a drug interaction between a clo**NID**ine patch and a tricyclic antidepressant; a complaint about an estradiol patch that would not adhere to the skin; two reports of patches placed on skin that was not intact; two barcode issues (now resolved); and two reports of unsecured fenta**NYL** patch disposal that could allow diversion, abuse, or accidental poisoning by children who might chew or stick the patches on their skin.

Safe Practice Recommendations: Managing patients receiving medication patches can be challenging given the variety of strengths and dosing intervals. To prevent errors with patches, consider the following recommendations, many of which are specific to the unique contributing factors associated with patch errors:

Upon Admission

All Patches

- Collect a medication history from each patient upon admission and at each encounter. Use scripted questions or prompts to help identify all medications and substances that may not be readily identified by patients. Specifically question patients regarding the use of any type of patch. Identify the current location of the patch and when it was applied.
- Perform a full skin assessment looking specifically for patches, noting that many are small in size and may either be clear or beige in color.

Specific Patches

- **Opioid:** Verify and document the patient's opioid status (naïve versus tolerant) and the type of pain (acute versus chronic) (see the ***Targeted Medication Safety Best Practices for Hospitals*** [#15]: www.ismp.org/node/160).

Patch Prescribing and Order Verification

All Patches

- Verify the indication and assess the appropriateness of patch use for each patient.
- Within electronic prescribing systems, create medication patch order sentences that include the appropriate application frequency. Consider allowing prescribers to enter certain medication patches at ONLY the appropriate application frequencies. For example, only allow entry of the frequency of fenta**NYL** patch application every 72 hours or every 48 hours, not every 24 hours.

Specific Patches

- **Contraceptive:** Include the word "patch" or "transdermal" along with the drug description for Xulane in your electronic health record and pharmacy software.
- **Estradiol:** Include brand names when prescribing estradiol patches since they have different application frequencies.
- **FentaNYL:** Do not include the duration of medication delivery in the patch drug description field (which could be confused as the dose). The patient's dosing instructions should communicate the frequency of changing the patch.
- **Hormone replacement therapy:** Consider requiring documentation of the indication when prescribing these patches, and/or build an alert for younger patients who are prescribed a hormone replacement therapy patch typically intended for menopausal women.
- **Opioid:** Enhance clinical decision support with pain-related order sets that are specific to patients' opioid tolerance and prevent the ordering of fenta**NYL** patches for opioid-naïve patients with acute pain.
- **Opioid:** Default order entry systems to the lowest initial starting dose and frequency.

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as an IV bolus dose via syringe immediately after the medication has been removed from the vials, it may not be feasible for pharmacy to dispense the product ahead of time in ready-to-administer syringes. While we surmise that the medication was studied according to the prescribing information to administer two separate 2.5 g IV doses no more than 15 minutes apart, we wonder why the full 5 g dose cannot be packaged in a single vial.

ASPEN-ISMP error-reporting project. For more than 10 years, ISMP and the American Society for Parenteral and Enteral Nutrition (ASPEN) have worked collaboratively to educate clinicians about the benefits of reporting errors involving

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Your *Reports* at *Work*

Updated label for NovoLOG Mix 70/30 generic equivalent. In our March 12, 2020 newsletter (www.ismp.org/node/14833), we mentioned that Novo Nordisk Pharma was marketing a generic equivalent of **NOVOLOG MIX 70/30** (insulin aspart protamine/insulin aspart), which unlike the brand product from the parent company (Novo Nordisk), did not specify the 70/30 ratio expression on the pen, vial, or carton labels. Only the package insert mentioned the 70/30 mix. Furthermore, the 100 units/mL strength was printed on the back of the products' labels, away from the drug name. ISMP contacted the manufacturer and the US Food and Drug Administration (FDA) at the time to request label clarification, specifically to indicate the ratio of insulin aspart protamine and insulin aspart. The good news is that the company recently confirmed to us that "Mix 70/30" and "100 units/mL" now appear on the pen, vial, and carton labels. The updated labels can be viewed on DailyMed (www.ismp.org/ext/652). Please note: the older labels may still be in circulation, as evidenced by a recent report to ISMP concerning the lack of "70/30" on the labels. Please check your current stock, and if you find you have insulin products with the older labels, apply auxiliary labeling to clarify the product contents.

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Patch Dispensing

All Patches

- Employ barcode scanning during the dispensing process to ensure correct product selection.
- Identify which patches on formulary can be safely cut and which cannot; share the information with nursing staff.

Specific Patches

- **ClonIDine:** For inpatients, consider dispensing the medication patch and adhesive cover in a ziplock bag with a label explaining the two components of the product.
- **FentaNYL:** Eliminate the storage of fenta**NYL** patches in ADCs or as unit stock in clinical locations where acute pain is primarily treated (e.g., in the ED, operating room, post-anesthesia care unit, procedural areas).
- **Opioid:** Confirm the patient's opioid status (naïve versus tolerant) prior to dispensing (and administering) patches appropriate only for opioid-tolerant patients.
- **Scopolamine:** Edit prescriber and pharmacy order entry systems, order sets, and MARs to indicate the drug delivery rate of 1 mg over 3 days (**Figure 2**), and ensure that the labeling on patches purchased match this newer dose expression.

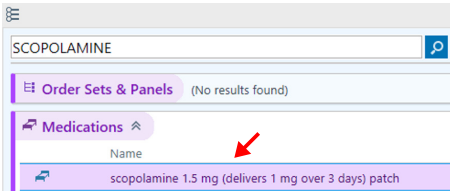

Figure 2. Example of one health system's edits in the electronic health record to communicate the 1 mg over 3 days delivery of scopolamine patches.

Patch Administration/Removal

All Patches

- Employ barcode scanning during the administration process to ensure correct product selection.
- On MARs, prompt for documentation of the location of all medication patches applied, and link all entries for medication patches to an order for removal at the appropriate interval.
- Provide nurses with a documentation prompt each shift to verify placement of each medication patch and to record the location, if necessary.
- Provide and implement secure waste disposal systems for patches containing controlled substances.

Specific Patches

- **ClonIDine:** Consider building an MAR note to remind nurses to apply the medication patch and not just the cover. If the adhesive cover is used over the medication patch, it is best to label the adhesive cover with the drug name, strength, and date, *before* applying it.

Patient/Caregiver Education

All Patches

- Provide verbal and written education to patients/caregivers on the use of patches (e.g., when to remove and replace the patch) and any related safety concerns and error potential; verify patient understanding. (For an ISMP fenta**NYL** patch consumer leaflet, visit: www.ismp.org/ext/653.)
- Remind patients/caregivers to read the accompanying leaflet or *Patient Instructions* (found in the carton) before using the patches.
- Teach patients/caregivers to safely discard used or unneeded patches according to guidance in the prescribing information. For example, a fenta**NYL** patch should be disposed by folding the sticky side together and flushing it down the toilet.

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nutrition support therapy and associated devices. Aside from educating the healthcare community about medication errors involving nutrition care, our goals are to learn about the underlying causes of these errors, publish and present the findings, develop educational materials and strategies to reduce errors with parenteral and enteral nutrition therapies, and foster national initiatives that address risk reduction for nutrition support.

To report errors involving nutrition support, please visit our error-reporting page (www.ismp.org/report-medication-error). For more information about the project, please visit the ASPEN-ISMP project site at: www.ismp.org/ext/645.

Special Announcement

ISMP safety experts can "zoom in"

Need input on a medication safety issue? Have a focused safety project? Need to address a specific challenge and want recommendations regarding the best direction to take? The national safety experts on ISMP's consulting staff can help! We can provide cost-effective and time-effective virtual assistance that can make a huge impact on your medication safety efforts. For more information, please contact us by visiting: www.ismp.org/service-inquiry.

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ISMP Medication *Safety Alert!* Acute Care (ISSN 1550-6312)

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Editors: Judy Smetzer, BSN, RN, FISMP; Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP; Ann Shastay, MSN, RN, AOCN; Russell Jenkins, MD; Ronald S. Litman, DO, ML. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ispinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492.

ISMP Safe Medication Management Fellowships

ISMP is now accepting applications for three unique **Fellowship** programs commencing in **2021**

ISMP Safe Medication Management Fellowship

Location and Term: This Fellowship commences July 2021. The Fellow will spend 12 months with ISMP, which is located in the suburbs of Philadelphia (Montgomery County), Pennsylvania. Relocation to the Philadelphia area will depend on the state of the COVID-19 pandemic.

Description: Now in its 29th year, this Fellowship offers a **healthcare professional with at least 1 year of postgraduate experience in a healthcare setting** an unparalleled opportunity to work collaboratively with the nation's experts in medication safety to assess and develop interdisciplinary medication error-prevention strategies.

FDA/ISMP Safe Medication Management Fellowship

Location and Term: This Fellowship commences late summer/fall 2021. The Fellow will spend 6 months with ISMP, which is located in the suburbs of Philadelphia (Montgomery County), Pennsylvania, and 6 months with the US Food and Drug Administration (FDA), which is located in Silver Spring (near Washington, DC), Maryland. Relocation to these areas will depend on the state of the COVID-19 pandemic.

Description: This Fellowship, open to a **healthcare professional with at least 1 year of postgraduate experience in a healthcare setting**, is a joint effort between ISMP and FDA's Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis. The Fellowship allows the candidate to benefit from ISMP's years of medication safety experience along with FDA's valuable regulatory experience focused on medication error prevention.

ISMP International Medication Safety Management Fellowship

Location and Term: This Fellowship commences July 2021. The Fellow will spend 12 months with ISMP, which is located in the suburbs of Philadelphia (Montgomery County), Pennsylvania. Relocation to the Philadelphia area will depend on the state of the COVID-19 pandemic.

Description: This Fellowship, open to a **healthcare professional with at least 1 year of postgraduate experience in a healthcare setting**, will help train a medication safety leader interested in seeking a long-term career at an international level. The Fellow will be involved in both US and international medication safety initiatives, helping to address medication safety issues on a national and global level.

Applicants for all three Fellowship programs must be legally eligible to work in the US and have excellent written and verbal communication skills. A competitive stipend is provided with all Fellowship programs.

How to Apply

For a complete description of candidate qualifications and the online application, visit: www.ismp.org/profdevelopment/.
For questions regarding the Fellowships or the application process, please contact ISMP at: fellowship@ismp.org or 215-947-7797.

The application deadline for all three Fellowship programs is March 31, 2021.