



Medication Safety Alert!®

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Community/Ambulatory Care Edition

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Little patches...Big problems - Part 3 Widespread education necessary!

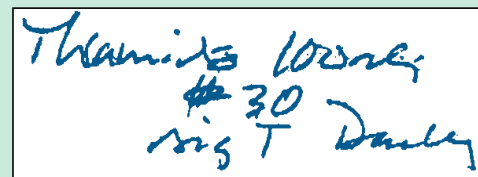
In the previous 2 issues, we have shared many safety issues surrounding the use of fentanyl patches and offered recommendations to safeguard their use. We have also urged practitioners to thoroughly review the recent FDA Public Health Advisory and an alert from Janssen about updated safety information that was added to the fentanyl patch (DURAGESIC and generic brands) product labeling. (Links to these documents can be found at <http://www.ismp.org/MSAarticles/fdasafetyalerts.htm>.) As noted by FDA, some healthcare providers and patients may not be completely aware of the dangers regarding the misuse, storage, and disposal of these products as well as the important recommendations to safeguard their use. ISMP considers fentanyl a high-alert medication, which means that it is not necessarily more prone to errors but, when used in error, it carries a greater risk of patient harm or death. In this final article, we will highlight errors that may arise due to lack of proper patient and practitioner education.

The updated boxed warning for fentanyl patches includes information related to abuse, misuse, and diversion of these patches. Certainly, it may not seem unusual to hear about a death or serious harm resulting from abuse or misuse of *unused* patches. For example, error reports have described cases in which patients have chewed patches, injected fentanyl that was withdrawn from a patch, or intentionally applied multiple patches. However, people might be surprised that death or serious harm can result from misuse and abuse of *used* fentanyl patches. Several error reports have described patients who died after chewing on used patches. Another fentanyl-related death occurred in a 31-year-old funeral home transporter who was moving a deceased nursing home resident wearing both a 75 mcg/hour and 100 mcg/hour patch (Yerasi AB, Butts JD. Disposal of used fentanyl patches. *Am J Health-Syst Pharm* 1997;54:85-6). The transporter apparently removed the patches from the body and abused them. In addition to ensuring patches are removed from deceased patients, the authors recommended that increased education about the potentially lethal amounts of drug left in used patches be provided.

Although one may think that used patches do not contain
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Safety Briefs

■ **A positive spin on restricted distribution programs.** We received a recent report involving an alcoholic patient who was discharged from the hospital with several prescriptions, including the one below. A community pharmacist interpreted the prescription as **THALOMID** (thalidomide) 100 mg daily.



Thalomid is approved for treatment of

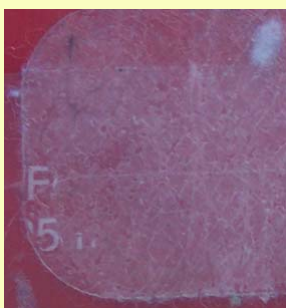
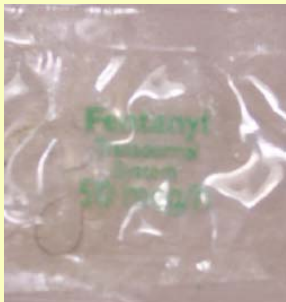
erythema nodosum leprosum (leprosy), but is also being studied in various cancers and HIV wasting syndrome. Due to its teratogenic nature, dispensing is handled through a restricted distribution program that requires physicians and pharmacies to be registered before prescribing or dispensing Thalomid. In addition, patients must complete an informed consent process and participate in a mandatory and confidential surveillance registry. In this case, the physician was not registered, so the pharmacist tried to contact him about it. The physician was off duty and the message was given to the covering physician. This physician investigated the situation and realized that the prescription was actually for **THIAMINE** (vitamin B 1) 100 mg daily and called the pharmacy to clarify. Had the restricted distribution program not been in place, Thalomid may have been dispensed. Although restricted distribution programs (and prior authorizations) are often viewed as aggravating and time-consuming, they often require practitioners to verify the indication of the medication, a known error-prevention strategy that can help prevent errors such as this.

■ **Bicitra – Polycitra mix-up.** A 15-month-old child with renal impairment was recently prescribed **BICITRA** solution (sodium citrate 500 mg and citric acid 334 mg/5 mL) upon discharge from a pediatric hospital. The parents had the prescription filled at a community pharmacy, but the pharmacist incorrectly prepared the prescription using
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Fentanyl patches (cont'd from previous page)

significant amounts of fentanyl, this is not the case. According to the prescribing information, a Duragesic 50 mcg/hr patch contains 5 mg or 5,000 mcg of fentanyl. At a delivery rate of 50 mcg/hr, approximately 1,400 mcg (28% of the medication) remains in each patch after the recommended 72-hour application period. It is important that practitioners as well as patients and their caregivers be aware of this and take necessary precautions to avoid diversion of used and unused patches. A comprehensive risk management plan for fentanyl patches could help to reduce diversion and abuse of discarded patches.

Another safety issue related to the amount of medication remaining in used patches are cases of serious harm or death that result from a used patch being kept in place after a new



Labels on patches from Janssen (Top), Sandoz (Middle), and Mylan (Bottom) are difficult to see after application. Print on the Mylan patch also rubs off easily.

patch was applied. There may not be a good mechanism in place to remind patients or caregivers to remove old patches. Also, patients may not mention that they wear a patch and practitioners may fail to inquire if the patient has a patch in place. Also contributing to lack of awareness about a patch being in place is that various manufacturers' patches are clear or translucent, which makes them hard to detect, especially on some skin types (see photos). Although drug name and strength may be printed on the patch, this may not increase visibility sufficiently. One nurse alerted a long-term care (LTC) pharmacy that the printing on Mylan fentanyl patches is difficult to read and in some cases even rubs off, making it difficult for nurses to verify the drug and dosage throughout the application period. Poor visibility of the patch may also hinder the ability of emergency medical personnel to properly identify and treat patients who suffer a fentanyl overdose.

Patient confusion about proper application is also a concern. An elderly woman was hospitalized after she applied six patches at the same time, believing *cont'd on page 3*

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CYTRA-3 solution (sodium citrate 500 mg, citric acid 334 mg, and potassium citrate 550 mg/5 mL), a generic equivalent for **POLYCITRA** syrup. Bicitra and Polycitra are used in conditions where long-term maintenance of an alkaline urine is desirable and in the management of chronic metabolic acidosis associated with conditions such as chronic renal insufficiency or renal tubular acidosis. Selection of a specific preparation is guided by the sodium and potassium contents. The consequences of an incorrect substitution could be dangerous for patients with renal impairment who would be at risk of hyperkalemia and possible cardiac manifestations if they were unable to properly excrete the potassium found in Polycitra preparations. In this case, the child was readmitted to the hospital with hyperkalemia after receiving the wrong medication for 12 days. The patient was stabilized, but required a 7-day hospitalization as a result of the error. To facilitate learning from this error, the case was presented at the hospital's Medication Safety Committee meeting. Subsequently, the hospital pharmacy prepared a dispensing "tip sheet" for staff, which contained a comparison of drug information for Bicitra, Polycitra, and their generic equivalents. The hospital pharmacy also followed up with the community pharmacy about the error and shared the "tip sheet" with them. Such cross sharing of safety recommendations between acute care and ambulatory care practice sites is vitally important for ongoing error prevention.

■ **New package labeling for NovoLog Mix 70/30 and NovoLog.** Novo Nordisk Inc. and FDA recently announced that package labeling changes were implemented to help prevent product selection mix-ups between **NOVOLOG MIX 70/30** (70% insulin aspart protamine suspension and 30% insulin aspart injection, [rDNA origin]) and **NOVOLOG** (insulin aspart [rDNA origin] injection). Previous packaging for both product lines was very similar, using a white background with a blue band. The new packaging for NovoLog Mix 70/30 products retains a similar design using a white background with a blue band, but the new packaging for NovoLog products utilizes a white background with an orange band (see photos page 3).

Although color differentiation can help with product *cont'd on page 3*

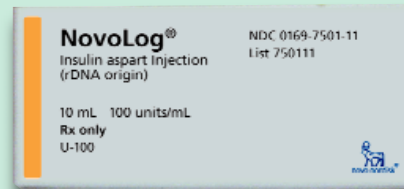
Fentanyl patches (cont'd from previous page) the patches were supposed to be placed “wherever it hurt.” Some patients have been known to apply two patches when only one was prescribed. One practitioner working in a pain clinic noted that situations like this might be more likely in patients who have used the much larger **LIDODERM** patch (lidocaine 5%) and later receive a significantly smaller sized fentanyl patch. Also, since Lidoderm provides local anesthesia, patients using these patches are directed to cover the most painful area with one to three patches and, unlike fentanyl patches, these may be cut into smaller pieces before use. Practitioners must explain administration procedures explicitly and verify that they have been understood, especially in patients who have previously used Lidoderm.

We have also received reports in which patients did not receive pain relief because patches were applied using tape rather than removing the patch’s adhesive backing. The backing may be clear or the same color as the patch, making it difficult to see, and there is no note on the backing stating that it should be removed. Practitioners should ensure awareness of the backing and the need for its removal before use. This is especially important for patients with visual impairment or neuropathies that make it difficult to see or feel the adhesive backing. Inadequate pain relief has also resulted when a caregiver has removed the wrong patch. For example, a nurse inadvertently removed a patient’s fentanyl patch instead of his nitroglycerin patch. For LTC or hospitalized patients receiving fentanyl patches (or any other patch), medication administration records (MARs) could include an order to check the placement and location of the patch each day or each shift. This “check” helps to assure that nurses are aware of a patient’s patch and its appearance.

Improved methods of documentation could help to guard against inadvertent application of multiple patches. MARs in LTC facilities should prompt nurses to document the location and time of patch application as well as the time and date for removal. Prescribers and pharmacists should instruct ambulatory patients and their caregivers about how to set up a dosing calendar or develop a calendar that can be distributed when prescribing or dispensing these patches that also incorporates when and where a patch was applied and when it should be removed. The importance of removing the old patch before a new patch is applied must be emphasized. Knowing that it may be difficult to keep track of patches, prescribers should avoid using regimens that utilize multiple fentanyl patches at the same time. However, if this is necessary, recommend that the application and removal of patches occur at the same

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Safety Briefs (cont'd from previous page) recognition, it should not be relied on as the sole means of identification. Practitioners should also use the product name and NDC number to distinguish insulin formulations. Keep in mind that this recent



packaging change will not help to prevent name confusion errors involving these two products or other Novo insulin products (i.e., NovoLog Mix 70/30 and **NOVOLIN 70/30** or NovoLog and

NOVOLIN) that may occur during prescribing, prescription interpretation, and order entry. To view the FDA alert, go to

<http://www.ismp.org/MSAarticles/fdasafetyalerts.htm>.

Announcement

■ **ISMP Teleconference.** An exciting new accountability model has been winning widespread praise from healthcare organizations for helping to maximize safety and balance *system* and *individual* responsibility for errors. On **October 27, 2005**, from 1:30 to 3:00 p.m. EST, ISMP will hold a teleconference “**Just Culture—An Emerging Safety-Centered Accountability Model**” to help practitioners learn more about this groundbreaking way to promote an open and fair healthcare environment. **David Marx, JD**, developer of the “Just Culture” model and a safety innovator with more than a decade of experience, will be the guest speaker. “For successful error reporting, we need to encourage cultures where employees are willing to come forward in the interest of system safety. However, no one can offer a completely blame-free system where any kind of behavior can be tolerated without penalty,” he says. His recent work with several statewide safety culture initiatives in healthcare has been extremely well received, even by “skeptics.” For details and to register, visit www.ismp.org/T/200510/.

Fentanyl patches (cont'd from previous page)

time. Certain inks may be poorly visible or rub off if written directly on the patch (and a pen may puncture the patch). If one must write directly on a patch, a permanent marker should be used so it will not fade or puncture the patch. Manufacturers need to provide highly visible, waterproof auxiliary labels that can be marked with the date and time of application and/or removal and applied to the patch while in use. Practitioners should consider updating medication history forms to include prompts for information about transdermal and other non-oral medications. Also, patients need to understand the importance of including fentanyl patches and any other patches they may be wearing on medication lists.

Fentanyl prescribing information now contains a list of 23 points that should be addressed with patients. Some of this is covered in patient information handed to patients along with their prescription but, all too often, this important information is overlooked or deemed too difficult to read. Practitioners need to take the time to review this list (found in the "Precautions" section under "Information for Patients") and consider how the information can best be conveyed to patients or their caregivers. Some manufacturers have websites that contain a more patient-friendly presentation of selected information using color and graphics, which can be printed out for patients. Janssen is planning to release updated educational materials that will offer advice to patients about application and disposal of patches and special precautions.

Although not part of the previously mentioned list, practitioners should also make patients and caregivers aware of the warning signs of fentanyl overdose: troubled or shallow breathing; tiredness, extreme sleepiness or sedation; inability to think, talk, or walk normally; and feeling faint, dizzy, or confused. Alert them to remove their patch and seek medical attention right away if these signs occur. Practitioners should refrain from initiating therapy if medical staff will be unavail-

able for calls during the first 3 days after initial patch placement, as this is when serum fentanyl concentrations will peak and life-threatening hypoventilation could occur. Practitioners might even consider a follow-up phone call during this time period to assess the patient's initial response to therapy.

Clearly, past experience with fentanyl patches demonstrates an underlying need for improved patient and practitioner education. The recent Janssen alert and FDA Advisory could go a long way in improving the safety of transdermal fentanyl, but only if healthcare practitioners are fully aware of the dangers, appropriately select patients, thoroughly educate patients, and take steps to ensure safe use, storage, and disposal of the products. Sadly, too many practitioners have been prescribing, dispensing, and administering fentanyl patches, and patients have been using them, without knowledge of these risks.

Share Your Stories with Us

Articles in this publication are based on actual reports from practitioners. We'd like to hear from you too! Please share reports of medication errors and prevention recommendations, in confidence, with colleagues in the US and worldwide. Errors may be reported on the ISMP (www.ismp.org) or USP (www.usp.org) web sites or communicated directly to ISMP by calling 1-800-FAIL SAF(E) or through e-mail at ismpinfo@ismp.org. Reports are forwarded automatically to the FDA and to pharmaceutical companies whose products are mentioned in reports. Reporter identity and location are strictly confidential and never published. Be sure to visit our website for additional information.



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