FDA Approves Abstral® (fentanyl transmucosal tablets) to help manage pain in Cancer patients

Kassie Castranove, PharmD Candidate 2011, University of Charleston
Lorin Yolch, PharmD, Director of Clinical Services, ProCare HospiceCare

On January 7, 2011 the FDA approved Abstral® (fentanyl transmucosal tablets) for the management of breakthrough pain in adults 18 years of age and older with cancer who already use opioid pain medications and are able to safely use high doses of an additional opioid medication. These transmucosal tablets are administered on the soft surfaces of the mouth (inside the cheek, gums, tongue) or in the nasal passages or throat where they dissolve and are absorbed. The FDA has required that Abstral® can only be available through a REMS (Risk Evaluation and Mitigation Strategy) program to minimize risk of misuse, abuse, addiction, and overdose. Therefore, this product can only be obtained through a limited network of pharmacies with a delay of 48-72 hours in order to obtain this medication for patients. Prescribing physicians, pharmacies, and distributors must be registered with the REMS program in order to prescribe, distribute, or dispense this medication.

The limited distribution of this drug parallels another medication by the name of Onsolis® (fentanyl buccal soluble film), which also has an extremely restrictive Risk Evaluation and Mitigation Strategy (REMS) program and was approved for use in July 2010.

Due to the REMS program in place for both Onsolis® and Abstral®, and the resultant access to medication problems caused by the REMS, this medication is not practical for use in end of life care. The ProCare HospiceCare Preferred Drug List considers all commercially available forms of immediate release Fentanyl as Tier 3, thus these medications require prior authorization.

Hospice clinicians desiring the use of a fentanyl immediate release product for their patients may want to consider the use of compounded fentanyl oral solution which was discussed in a previous 2010 edition of On Demand News which is available on the ProCare HospiceCare website: www.ProCareRx.com under the Hospice tab.

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HospiceCare 2020 Hits the Road in March

Last year over 300 hospice professionals attended our annual HospiceCare 2020 Conference. This year we expanded the series from six cities to eight one-day regional events.

HospiceCare 2020 offers hospice professionals a free, stress-free day with three educational tracks to choose from. The agenda was created through the feedback we received last year and offer 6 CE credit hours. In fact, over 900 Continuing Education contact hours were earned last year. If you haven’t attended - you really need to go!

2011 Session Topics:

- Palliative Wound Care Basics
- How to Recognize Your Hospice Team for Long Term Results
- Making Cents of Hospice Cost Report and CAP Issues
- Difficult Symptom Management in End of Life Care
- The New Pediatric Palliative Care Movement
- Managing the Perfect Storm by Disease State
- The Legacy of Elisabeth Kübler-Ross
- The Pharmacology of Pain Management
- Effective Management of Hospice in the Skilled Nursing Facility
- The ABC's of CoPs, ADR's, RAC and ZIP Audits
- The Art and Science of Communicating with Physicians - Panel Discussion

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Communicating with Physicians

By Dr. Lorin Yolch, PharmD

Communication Perls:

1. **Physicians are BUSY, respect their time.** What that means in the trenches of care is **BE PREPARED** to have a professional conversation with the physician. It is essential that the hospice nurse have the skill to present a patient to a listener accurately, quickly and concisely.

2. If you get the physician to the phone and you don’t know the patient, the past medical history, drug allergies and COMPLETE medication list you project to the physician that they need to cover all those bases themselves because they can not count on you or the information you are sharing.

3. **If you need the physician to help you, SAY SO! Remember, when you ask another person for help, it is rare to be told no, I won’t help you!**

   Start the conversation like this: "Doctor J, THANK YOU for taking my call. I am calling because I NEED YOUR HELP with our patient, Mrs. Sick. Mrs. Sick is an 85 y.o., African American with a terminal diagnosis of whatever, she has a past medical history of A, B, C and D. She is allergic to Drugs A and B, her current PPS score is X%, she lives alone. Her current chief complaint is WHATEVER which has been a problem for her for the last 12 hours (or days). Thus far we have tried XXXXXX which has not worked.

4. **Communicate the facts, nothing but the facts! Don’t ramble on.**

5. Before you can get the physician on the telephone to speak with you, you have to get past the gatekeeper who answers the phone! Take away message: **BOND WITH THE GATEKEEPER, they are a powerful ally. Let them know you appreciate how hard they work, because they DO!**

6. **When calling the physician to request refills on medications for your patient, place the call at LEAST 48 hours before the patient will be out of their medication.** No one likes to be pressured, including physicians. **Provide the physician with the name of the pharmacy the patient uses, the telephone number of the pharmacy and the fax number.**

7. **Many physicians tell us they prefer communicating by fax.** This is a great option. Create a fax cover sheet for yourself that includes all of your contact information so that if the physician has to call you back they have your cell phone and office telephone number handy. Remember time is money to EVERYONE.

8. **Prescriptions can not be e-mailed or sent by text message.** It is illegal to do so, don’t ask physicians to do it.

9. **Your tone of voice when communicating with anyone, especially physicians, is very important.** It says a lot about you at any given moment. If your tone of voice projects that you are hurried, exasperated, impatient or disrespectful your ability to advocate for your patient will be impaired. **Smile through the phone! No one likes to talk to a downer.**

10. **Look the physician in the eye through the phone.** This sounds silly, but it is very important. How you carry yourself during the conversation is very important. Physicians, just like all other humans, respect others who respect themselves. **Your confidence in yourself should be respectfully and politely projected. Your respect for the physician should be obvious to them as they listen to you.**

11. Remember, physicians are **ultimately liable** for every single event a patient experiences. We live in a liability-laden society which physicians understand at a level that other healthcare professionals do not. If the physician does not accept your recommendation, that is ok.

12. **Keep the physician INFORMED about their patient.** Sending a follow-up fax to let the physician know how an intervention worked for your mutual patient is a must. No one likes to be left out of the loop, including physicians.

13. **Recognize physicians that you think are stellar!** Once or twice a year, send the physician a short thank you note that recognizes that you appreciate the opportunity to work with her. **Saying THANK YOU means a lot to everyone, including physicians.**
Pain Management in Patients with Addiction and/or Dependency

Kassie Castranove, PharmD Candidate 2011, University of Charleston
Jeremy Prunty, PharmD Candidate 2011, West Virginia University
Lorin Yolch, PharmD, Director of Clinical Services, ProCare HospiceCare

Appropriate management of pain with current or past opioid addiction or dependency issues can be quite challenging. Experts recommend following these tips when dealing with this patient population.

- The goal to treating any patient with addiction or dependency is the same as individuals without addictive disorders.
- Obtain reasonable pain relief while maintaining maximum level of function.
- Develop a therapeutic relationship with your patients and their family so pain medications can be used without abuse concerns.
- Patients with a history of addiction or dependency normally require larger doses of opioids and more frequent dosing intervals to adequately control their pain.
- Ensure patients with drug dependency or addiction receive appropriate level of pain relief.
- Use a nonjudgmental approach to ask patients about prescription and illicit drug use.
- Methadone is the opioid of choice in patients with current or past addiction problems.

When a patient is or has a history of abusing alcohol it creates physical changes in the body that may require larger doses of opioids to adequately control their pain. Be aware that in some instances, when certain medications (such as a central nervous system depressant) are taken with alcohol it can cause a potentially fatal overdose. In addition, when certain dosage forms of medications are given with alcohol, the sustained release dosage form may be adulterated resulting in a potentially lethal release of opioid which could result in a fatal overdose. A common product used in end-of-life care that is known to exhibit this effect is Avinza®, a 24 hour sustained release capsule form of morphine sulfate.

For end-of-life pain, addiction should not be an issue for the patient, caregiver or clinician. A patient's greatest fear during end-of-life care is control of their symptoms, with pain being identified as their biggest fear in addition to vomiting. Providing comfort during this time is the same regardless of any current or past history of addiction or dependency. If there is concern about addiction or abuse explore your therapy options. Patient specific therapies are an option and new drugs have recently been approved in the United States, which serve as anti-abuse and anti-diversion opioid dosage forms. Examples of these new products include Embeda® and Remoxy®. Both of these products have an inner core of naltrexone in the tablet which is then surrounded with sustained release morphine or oxycodone, respectfully. If the tablet is crushed, the naltrexone will be released to serve as a strong mu opioid antagonist and thus prevent the action of the opioid. The naltrexone core is inert and passes through the GI tract as long as the tablet is not crushed. Another example of an anti-diversion and anti-abuse dosage form is the recently reformatted OxyContin® which forms a sludge if the tablet is crushed.

Embeda®, Remoxy® and OxyContin® are all tier 3 medications on the ProCare HospiceCare Preferred Drug List thus requiring prior authorization since none of these medications unless there are special circumstances represent superior opioid efficacy for end-of-life care patients.

FDA Approves Abstral® (Continued from cover page)

The preferred medication for the management of breakthrough pain in the hospice patient is morphine concentrated solution 20 mg/ml or oxycodone concentrated solution 20 mg/ml in patients with significant renal insufficiency or renal failure regardless of the long acting opioid the patient may be using.

Reference
Decision Algorithm for Opioid Therapy in Addiction and Abuse

**Adapted from the "VA/DoD CLINICAL PRACTICE GUIDELINE FOR MANAGEMENT OF OPIOID THERAPY FOR CHRONIC PAIN" May 2010.**