On-Demand Clinical News

DEA Rolls out Plan to Reduce Opioid Production in 2017: 9 Tips for Hospice to Manage the Challenge

By: Brett Gillis, PharmD, Tracey Gordon, PharmD and Kristin Speer PharmD, BCPS

For years, the Drug Enforcement Agency (DEA) and allied parties have been educating practitioners, pharmacists, manufacturers, and the public about the dangers associated with the misuse of opioid medications. The 2015 National Survey on Drug Use and Health (NSDUH) found that 6.5 million Americans over the age of 12 used controlled prescription medicines non-medically during the past month. The Centers for Disease Control and Prevention (CDC) has also issued guidelines to practitioners recommending a reduction in prescribing opioid medications for chronic pain.

On October 4, 2016, the DEA announced a plan to reduce the amount of almost every Schedule II opioid medication that may be manufactured in the United States in 2017 by at least 25%. A few opioids will be reduced by more, such as hydrocodone, which may be reduced by as much as 34%. Aggregate Production Quotas (APQ) have been developed to identify the total amount of a controlled substance necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance of reserve stocks. As such, the DEA has "determined that the proposed aggregate production quotas are sufficient to provide for the 2017 estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks." Much of this reduction is achieved by eliminating the 25% buffer that was added in the past few years to guard against shortages. When Congress passed the Controlled Substances Act (CSA), this quota system was developed to reduce or eliminate diversion of controlled substances that have a potential for abuse from "legitimate channels of trade" while still maintaining adequate and uninterrupted supply for legitimate medical need. The DEA establishes APQs for more than 250 Schedule I and II controlled substances on an annual basis.

Continued on Page 2

Use of Naloxone in the Hospice Patient

By: Meri Madison, PharmD

Medication-related overdoses are now a leading cause of death in the US and this number has nearly doubled since 2013. As such, Prescription Drug Monitoring Programs (PMPs) are now active in a majority of states and Narcan (Naloxone) has mainstream accessibility to the public in overdose situations.

As hospice clinicians, it is important for us to recognize the differences between opioid toxicity and opioid overdose. With opioid toxicity, the symptoms include: sleepiness (sedation), hyperalgesia, delirium/confusion and/or myoclonus. Toxicity can typically be averted by holding or decreasing the opioid in question. Opioid overdose, in contrast, includes sedation (difficult to arouse with external stimuli), respiratory depression, miosis and/or cyanosis of extremities. Often, signs of opioid toxicity mimic the end stage trajectory. In the case of an opioid overdose, naloxone use may be appropriate.

Naloxone is an opioid antagonist, indicated for the complete or partial reversal of opioid overdose and respiratory depression caused by natural opioids (heroin) or synthetic opioids (morphine, oxycodone, etc.). Off label uses include opioid-induced pruritus and constipation. Naloxone can be administered via intravenous (IV), intramuscular, inhalation or intranasal routes and the onset of action varies from 2 mins (IV) and up to 13 mins (intranasal).

Continued on Page 3

9 Tips for Hospice continued from page 1

The impact on hospice and palliative care patients may be significant. There are no provisions or guidance in the DEA mandate to protect these particularly vulnerable populations. While it is expected that much of the opioid reduction would be eliminating a 25% buffer (or implied surplus), it is challenging to imagine how it would not affect (reduce) overall pharmacy supplies. If all pharmacies do not experience an overall opioid supply shortage, this mandate may still affect supplies at each pharmacy differently, depending on local demands and usage patterns. Regardless, it is generally expected that, due to an overall lower supply, and no reason to anticipate a lower demand, costs of opioids and other CII medications are expected to increase.

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Here are some helpful tips to best serve our hospice patients:

1. Nurses, caregivers and patients should establish a good relationship with their local pharmacist so that he/she will be vigilant toward reserving supplies for their hospice patients.
2. Write for up to 60 days of an opioid or needed CII medication on a single prescription (this is allowed by Federal law), with partial fills for a certain number of days that is appropriate for your patient, usually not more than 15 days for hospice. This will help eliminate delays on additional fills as soon as they are needed, and before pharmacy runs short.
3. Order a higher a strength tab or higher concentration, and cut tabs or give less volume. Though, do NOT cut ER opioids or fentanyl patches.
4. Ensure your patient is optimized on a long-acting opioid when appropriate, to eliminate need for much breakthrough opioid medication. When optimized for pain control, a patient should not need more than 2-3 short-acting doses/day. If they need more than this, increase the long-acting opioid.
5. Early fills and hoarding large quantities of opioids or other CIIs is not recommended.
6. Utilize, as clinically appropriate, non-CII opioids, or non-opioid pain adjuncts: acetaminophen with codeine, tramadol, gabapentin, oral and topical NSAIDs, oral steroids, topical lidocaine, and tricyclic antidepressants.
7. Consider non-pharmacologic management of pain, as clinically appropriate: guided imagery/relaxation techniques, pet therapy, massage, ice/warm packs, acupuncture, and/or physical therapy.
8. In addition to, or in place of (when appropriate), opioid therapy for dyspnea, consider non-opioid or non-pharmacologic management of dyspnea: lorazepam or other anxiolytic when fear/anxiety is causing shortness of breath; blowing a fan toward those suffering with COPD/obstructive dyspnea; nebulizer therapies and/or systemic steroids for patients with COPD and other lung diseases; diuretics for CHF patients and others who have difficulty breathing due to fluid accumulation in the heart/lungs.
9. Remember that pain often has psycho-social or other components that may not be managed with opioids or other analgesics. Continue to evaluate and address the underlying components of “total pain.”

Contact a ProCare HospiceCare clinical pharmacist to help optimize your patient’s pain and dyspnea regimen, learn which strengths or concentrations may be available for certain medications, find out if a medication may be cut, or for any questions about opioid management or dispensing. We are here to help 24/7!

The DEA Public Affairs release may be found at: https://www.dea.gov/divisions/hq/2016/hq100416.shtml

The Final Rule in its entirety may be found at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-23988.pdf

Use of Naloxone in the Hospice Patient continued from page 1

Naloxone Pearls:

- The duration of action is from 30 to 120 minutes and this is important because the half-life of Morphine sulfate can be longer than 120 minutes; patients may require repeat dosing of naloxone to account for this.
- The higher the dose of naloxone, the higher the risk of opioid withdrawal effects.
    - Withdrawal from opioids post-naloxone use is more severe than abruptly discontinuing the opioid itself.
    - Aim to use smallest dose possible to achieve reversal of overdose symptoms without losing symptom control (0.4 mg initially; may repeat every 2-3 minutes and again at 20-60 minutes, depending on type of opioid used)
- While newer naloxone products are now being marketed (Evzio Autoinjector and Narcan nasal spray), Naloxone IV solution combined with atomizer for intranasal administration remains most cost effective.
- Shelf life of **unopened** IV solution is 12-18 months

One of the goals of hospice/palliative care is to maintain the delicate balance between symptom relief and adverse effects. In most cases, it is best to avoid use of naloxone in our patients as this has the potential of precipitating undue suffering. If opioid toxicity is suspected, encourage use of other interventions first (decrease dose of opioid, hold doses or switch to another narcotic class). Conduct a patient-specific risk vs. benefit analysis before attempting use of naloxone.

Resources:

1. Prescribe to Prevent: Overdose Prevention and Naloxone Rescue Kits for Prescribers and Pharmacists. J Addict Med. 2016 Sep-Oct;10(5):300-8.
2. Gallagher R. Palliative Care Files: Killing the symptom without killing the patient. Canadian Family Physician. Vol 56: June ed. Pgs. 544-546.
3. Naloxone package insert. Available from: http://www.narcan.com/pdf/NARCAN-Prescribing-Information.pdf.
4. Opioid emergencies. Evzio website. Available from: https://www.evzio.com/opioid-emergencies/index.php.
5. Clary PL, Lawson P. Pharmacologic Pearls of End-of-Life Care. Am Fam Physician. 2009; 79(12):1059-1065.
6. Mandredi PL, Ribeiro S, Chandler SW et al. Palliative Care Rounds: Inappropriate Use of Naloxone in Cancer Patients with Pain. J Pain Symptom Manage 1996; 11:131-134.
7. Weissman DE. FAST FACTS AND CONCEPTS #3: SYNDROME OF IMMINENT DEATH. Available from: http://www.mypcnow.org/blank-iwkmp.
8. Arnold R, Dunwoody CJ. FAST FACTS AND CONCEPTS #39: USING NALOXONE. Available from: http://www.mypcnow.org/blank-fnbfg.

Upcoming Lunch and Learn Presentations

January

"Methadone: Advanced Concepts for the Hospice and Palliative Care Practitioner"

Presenter: Kristin Speer, PharmD, BCPS

Tuesday, Jan 10, 2017 at 3:00pm ET; Wednesday, Jan 11, 2017 at 12:00pm ET

February

"Managing Terminal Secretions at End of Life"

Presenter: Kiran Hamid, RPh

Tuesday, Feb 14, 2017 at 3:00pm ET; Wednesday, Feb 15, 2017 at 12:00pm ET

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