State of New Jersey
Department of Human Services
Division of Medical Assistance & Health Services
New Jersey Drug Utilization Review Board

NEWSLETTER

Volume 01 No. 07 **October 2011**

TO: Physicians, Advanced Practice Nurses, Midwives, Independent Clinics, Hospital Outpatient Departments – **For Action**
Providers of Pharmaceutical Services, Health Maintenance Organizations **– For Information Only**

SUBJECT: **Clinical News from the New Jersey Drug Utilization Review Board (DURB)**

PURPOSE: To provide practitioners useful clinical information that may be helpful to the prescribing of prescription drugs.

BACKGROUND: The New Jersey Drug Utilization Review Board (NJDURB) serves as an advisory board to the New Jersey Department of Human Services and the New Jersey Department of Health and Senior Services. The Board's responsibilities include recommending drug utilization review (DUR) standards based, in part, on evaluations of prescription drug use by beneficiaries that participate in the State's pharmacy benefit programs. The Board is also responsible for disseminating information that the Board has determined would encourage appropriate drug utilization.

ACTION: Attached is a bulletin regarding the **Safe and Appropriate Use of Oxycodone**. This bulletin may also be viewed on line at http://www.nj.gov/humanservices/dmahs/durb.html. The NJDURB welcomes your comments regarding the information shared in the bulletin. These comments may be sent to www.state.nj.us/humanservices/dmahs/durb.html. When submitting comments, please include the phrase "DURB Comments" in the subject area of the email.

RETAIN THIS NEWSLETTER FOR FUTURE REFERENCE

Safe and Appropriate Use of Oxycodone (CR)

October 2011

In October 2010, the New Jersey Drug Utilization Review Board approved a protocol for the safe and efficient use of oxycodone controlled release (CR) formulations. The purpose of this Newsletter is to educate healthcare providers about this protocol.

Background

Oxycodone is FDA-approved for treating moderate to severe pain that is either acute or chronic in nature. It has been widely used in pain management practice for decades but has recently been receiving much negative attention due to abuse, overdose, and deaths associated with the controlled release (CR) formulation.[1] Experts have suggested that the abuse of oxycodone CR is due in part to the fact that this formulation contains a much larger amount of oxycodone as compared with other prescription opioid pain relievers, thereby increasing its potential for abuse. Also, of particular concern, when this formulation is inappropriately administered the results can be fatal.

Statistics

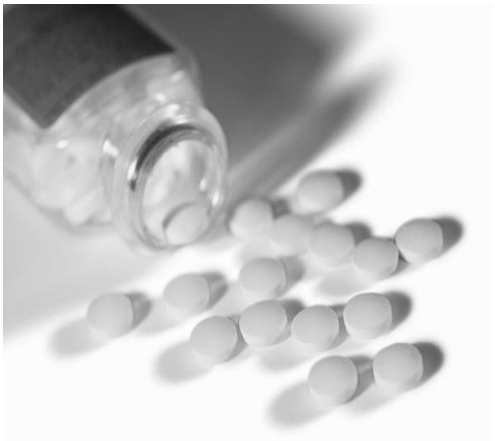
Findings from Drug Abuse Warning Network (DAWN) report states that during 2008, nonmedical use of pain relievers among persons aged 12 or older in the United States was a leading form of drug abuse, second only to marijuana.[1] Emergency room visits involving oxycodone products, hydrocodone products, and methadone – the three most frequently listed narcotic pain relievers in each year – increased 152, 123, and 73 percent, respectively, between 2004 and 2008 **(Table 1).** According to Dr. Ruck with NJ Poison Information and Education System, oxycodone abuse-related calls increased 56% between 2007 and 2009 in the State.

Table 1

Emergency Department (ED) Visits Involving the Nonmedical Use of Selected Narcotic Pain Relievers: 2004 to 2008

Narcotic Pain Relievers	2004	2008
Oxycodone Products (152%)	41,701	105,214
Hydrocodone Products (123%)	39,844	89,051
Methadone (73%)	36,806	63,629
Morphine Products (106%)	13,966	28,818
Fentanyl Products (105%)	9,823	20,179
Hydromorphone Products (259%)	3,385	12,142

Percentages shown in parentheses represent the percent increases between 2004 and 2008.
Source: 2008 (08/2009 update) SAMHSA Drug Abuse Warning Network (DAWN).



Treatment Options

Based on the potential for abuse associated with the extended release form of oxycodone, caution is needed in the use of this product including evaluation of other treatment choices (non-steroidal anti-inflammatory drugs [NSAIDs]; short-acting opioids; other extended release medications; or transdermal products) when appropriate. The guideline below could also be helpful (adapted from reference 5).

- Medications should be administered on a *scheduled* basis (long-acting agents are preferred).
- Appropriate doses of *short-acting* agents are preferred for the treatment of *breakthrough* pain.
  - Rescue dose = 5% to 15% of the 24-hour dose given orally every 1 or 2 hours.
  - The same long-acting and short-acting opioids should be used for most pain regimens to ease conversions.
- When using equianalgesic tables, start conservatively, then titrate to effect. With the exception of methadone and transdermal fentanyl, reduce the calculated equianalgesic dose by at least 30% to 50% (to account for incomplete cross-tolerance) when *changing* drugs. Dose titration may be necessary. Methadone and fentanyl transdermal systems require unique dosing conversions (see Table 2).
- Adverse drug events (ADEs) should be anticipated.
- A bowel regimen (stool softener and stimulant laxative) should be prescribed when necessary to prevent opioid-induced constipation (OIC).

*Table 2. Equinalgesic Doses of Some Opioid Agonists**			
Drug	***Route***	***Dose Approximately Equivalent to 10 mg IM Morphine***	***Comments***
Fentanyl	IM TD TM	0.1 mg 0.2 mg 0.2 mg	TD not used as first line for opioid-naïve patients.
Hydromorphone	IM PO	1.5 mg 7.5 mg	
Levophanol	SC PO	2 mg (single dose) 1 mg (chronic pain) 4 mg (single dose) 1 mg (chronic pain)	
Meperidine	IM PO	75-100 mg 300 mg	
Methadone	IM PO	10 mg (single dose) 1 mg (chronic pain) 20 mg (single dose) 2 mg (chronic pain)	• Start low, go slow on dosing • Not recommended for first line therapy
Morphine	IM PO	10 mg 30 mg	
Oxycodone	PO	15-20 mg	
Oxymorphone	IM PO	1 mg 10 mg	
*When switching from one opioid to another, half the equianalgesic dose should be used initially, and then retitrated. Further dose adjustments may be required for elderly patients. TD = transdermal; TM = transmucosal			

Based on: Drugs for Pain. *Treatment Guidelines from The Medical Letter 2010*, 8 (92), 25-33.

Abuse and Prevention

The abuse and diversion of oxycodone CR have not been a secret to the public, law enforcement, pharmaceutical companies, or even patients[3]. In April 2010, the FDA approved a new formulation of controlled-release oxycodone HCl (Oxycontin®, Purdue Pharmaceuticals) designed to discourage misuse and abuse of this medication. However, the agency noted that the product still can be misused or abused by simply ingesting doses larger than recommended. The healthcare provider is therefore faced with a dilemma in making treatment choices.

Leaks in the drug distribution system contribute to the problems of patients experiencing undertreated and untreated pain. Limiting access in response to those who abuse controlled substances also limits access for those who legitimately need these drugs and the problem of uncontrolled pain is aggravated[4]. There are several excellent approaches that can be used by healthcare professionals to reduce the risk of diversion and abuse in patients who need controlled substances. A five-step process called VIGIL incorporates the available advice and has practical applications for patient care (see Table 3).

The Code of Federal Regulations (CFR) requires that all registrants provide effective physical security for all controlled substances (and prescriptions pads) including the use of lock boxes when necessary.

Signs of diversion to watch for:

- Requesting an appointment at the end of office hours
- Arriving without an appointment
- Arriving late for an appointment when office staff are anxious to leave
- Reluctance to undergo thorough physical or diagnostic tests
- Failing to keep follow-up appointments
- Unwillingness to provide medical records or identify previous health care professionals
- Unusual stories that cannot be corroborated

Prepared by: Sam Emenike, Pharm.D., Dalia Hanna, Pharm.D.
Edited by: Dr. David E. Swee, MD, Edward Vaccaro, RPh

Conclusion

Long acting preparations, such as oxycodone sustained release, should not be prescribed for the management of acute pain. Educating health care providers in addiction and the careful assessment of patients help alleviate abuse associated with oxycodone and other narcotics. Determining patient risk for using an opioid versus its benefits requires paying special attention to the individual's psychological, social and other risk factors that could lead to abuse. Several technologies such as electronic prescribing are becoming available to assist healthcare professionals in managing patients prescribed controlled substances.

Table 3

Responsibilities in the VIGIL Process			
Step	**Prescriber**	**Pharmacist**	**Patient**
Verification	Confer with previous prescriber	Contact prescriber on first Rx	Provide accurate information
Identification	Check ID	Check ID	Provide ID
Generalization	Specify expectations of patient verbally or in writing	Participate in agreement if asked	Meet expectations as specified
Interpretation	Use screening tool	Report patient behavior to prescriber	Keep diary if asked
Legalization	Physical exam and documentation	Patient education and drug use review	Keep controlled substances secure

Adapted from CE: David B. Brushwood, RPh, JD.Professor of Pharmaceutical Outcomes and Policy. The University of Florida College of Pharmacy

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