Understanding The Issues: The Epidemiology of Prescription Opioid Misuse

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Pain in the United States

- Acute pain
- Recurrent or intermittent pain
- Chronic pain
  - Diagnosed and managed
    - Periodic interruptions
  - Undiagnosed or unmanaged
- Chronic pain is not just prolonged acute pain
  - Nociceptive pain, Cancer pain
  - Neuropathic pain
    - Complex regional pain syndrome
    - Myofascial pain syndrome

http://www.iasp-pain.org/
Pain in the United States

- Quantifies that chronic pain affects 116 million people in the US
  - 37% of the US population
  - 47% if children are removed from the calculation
- Suggests that pain is woefully undertreated, despite...
  - The 5th vital sign (Joint Commission)
  - Patient satisfaction scores

IOM April 2011
Focus Article
Guideline Warfare Over Interventional Therapies for Low Back Pain: Can We Raise the Level of Discourse?
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Abstract: As guidelines proliferate and are used to inform efforts to improve the quality and efficiency of care, disputes over guideline recommendations are likely to become more common and contentious. It is appropriate for guidelines to come under close scrutiny, given their important clinical and policy implications, and critiques that point out missing evidence, improper methods, or errors in interpretation can be valuable. But for critiques to be valid, they should be based on accurate information and a sound scientific basis. A 2009 guideline sponsored by the American Pain Society (APS) on the use of invasive tests and interventional procedures found insufficient evidence to make recommendations for most interventional procedures. It was subsequently the subject of lengthy critiques by the American Society of Interventional Pain Physicians (ASIPP) that sought to challenge the methods used to develop the APS guideline, point out alleged errors in the evidence review commissioned to inform the guideline, and question the integrity of the APS guideline development process. We show that the ASIPP critiques contain numerous errors and fail to adhere to scientific standards for reviewing evidence, and provide suggestions on how future disputes regarding guidelines might be addressed in a more constructive manner.

Perspective: In order to best serve patients and clinicians, debates over guidelines should be based on accurate information, adhere to current methodological standards, acknowledge important deficiencies in the evidence when they are present, and handle conflicts of interest in a vigorous and transparent manner.

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Key words: Guidelines, evidence-based medicine, systematic reviews, low back pain, interventional therapies.

In 2009, a guideline sponsored by the American Pain Society (APS) on the use of invasive diagnostic tests and interventional procedures for low back pain was published,10 along with a summary8 of the evidence review on which the guideline was based. The full review was posted on the APS website.9 APS found insufficient evidence to make recommendations for most interventional procedures. The American Society of Interventional Pain Physicians (ASIPP) subsequently published 2 lengthy critiques30,31 that seek to challenge the methods used to develop the APS guideline, point out alleged errors in the evidence review, and question the integrity of the APS guideline development process. The ASIPP has published its own guideline recommending most interventional therapies.29

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Opioids are over- and under-utilized

Opioids do not work for all pain

- Have significant adverse effects

Opioid analgesics

- In-hospital administration
- Outpatient prescribing*
## Top Products by Prescriptions

<table>
<thead>
<tr>
<th></th>
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<td><strong>Total US Market</strong></td>
<td>3,995.2</td>
<td>3,949.2</td>
<td>3,866.3</td>
<td>3,825.1</td>
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<td>128.2</td>
<td>124.1</td>
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<td>112.4</td>
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<td>45.4</td>
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<td>53.8</td>
<td>51.0</td>
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<td>30.2</td>
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<td>28.5</td>
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<td>23 Plavix®</td>
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<td>22.2</td>
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<tr>
<td>25 Singulair®</td>
<td>28.7</td>
<td>28.6</td>
<td>29.0</td>
<td>31.0</td>
<td>28.1</td>
</tr>
</tbody>
</table>

Source: IMS Health, National Prescription Audit, Dec 2010
“The US accounts for 4% of the world’s population but uses 80% of its prescription opioid”
Unintentional Opioid Overdose Deaths
Parallel Opioid Sales

- **Sales of OPR quadrupled between 1999 and 2010.**
  - Enough for every American to take 5 mg Vicodin every 4 hrs for 1 month
- **Overdose deaths**
  - 2,901 in 1999
  - 11,499 in 2007

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Paulozzi L. MMWR. Nov 2011
Risk of Overdose by Prescribed Opioid Dosage among Medical Users of Opioids

Nonmedical Use

- Prescription drug misuse
  - Amounts not recommended
  - Routes not recommended
  - No harm intended by user
- Original use of drug might have been relief of pain
  - Tolerance developed
  - Dependence developed
  - Addiction developed

NEJM 1980
Prescription for Addiction
Generation Rx: Abuse

Terrell Owens, NFL free agent, hospitalized in possible prescription drug overdose: report

BY NANCY DILLON
DAILY NEWS WEST COAST BUREAU CHIEF
Monday, October 10, 2011

LOS ANGELES - Football star Terrell Owens was rushed to a hospital last Thursday after a 911 call for a possible prescription pill overdose, TMZ reported Monday.

The unsigned free-agent, who's currently rehabbing from knee surgery, spoke to police at the unnamed Southern California hospital before his release, TMZ said.

Messages sent to Owens' publicists were not returned and Owens' girlfriend declined to comment when reached by the Daily News.

The record-breaking wide receiver with five NFL teams under his belt, most recently the Cincinnati Bengals, was famously hospitalized in 2006 for what he called a bad reaction to painkillers.

Whitney Houston’s Death: Hallmarks of a Battle Against Addiction and Overdose

The cause of the legendary singer's death on Saturday is still unknown, but it bears the signs of overdose.

Heather Locklear in drink and drugs overdose

by Paul Bonn, Daily Mirror 14052011
OXYCONTIN®
(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS

OxyContin 80 and 100 mg Tablets for use only in opioid-tolerant patients requiring daily oxycodone equivalent dosages of 160 mg and 320 mg respectively.

OxyContin® Tablets are to be swallowed whole, and are not to be broken, chewed or crushed. Taking broken, chewed or crushed OxyContin Tablets could lead to the rapid release and absorption of a potentially toxic dose of oxycodone.

One OxyContin 160 mg Tablet is comparable to two 80 mg tablets when taken on an empty stomach. With a high fat meal, however, there is a 25% greater peak plasma concentration following one 160 mg tablet. Dietary caution should be taken when patients are initially titrated to 160 mg tablets.

The most serious risk associated with opioids, including OxyContin, is respiratory depression.

Common opioid side effects are constipation, nausea, sedation, dizziness, vomiting, pruritus, headache, dry mouth, sweating and weakness.

OxyContin Tablets are contraindicated in hypersensitivity to oxycodone, or in any opioids are contraindicated. (Please see section in package insert.)

For more information about pain management or prevention, visit our Web Site: www.purduepharma.com

Please read attached professional product labeling.

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**Drug Is Harder to Abuse, but Users Persevere**

By ABBY GOONDOUGH and KATIE ZEIZMA
Published: June 19, 2011

BROCKTON, Mass. — Michael Capece had been snorting OxyContin for five years when a new version of the drug, intended to deter such abuse, hit the market last summer. The reformulated pills are harder to crush, turning instead into a gummy substance that cannot be easily snorted, injected or chewed.

Instructed by his dealer, Mr. Capece, 21, tried microwaving one of the new pills, then sniffing up the burnt remains. Other addicts have tried to defeat the new formula by freezing, baking or soaking the pills in solvents ranging from soda to acetone. Many are ending up frustrated.
<table>
<thead>
<tr>
<th>Drug</th>
<th>Location</th>
<th>Price</th>
<th>Date</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Klonopin, 1mg pill</td>
<td>Denver, Colorado</td>
<td>$5</td>
<td>Nov 29</td>
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<tr>
<td>Hydrocodone (generic Vicodin), 7.5mg</td>
<td>Minnesota</td>
<td>$5</td>
<td>Nov 20</td>
<td></td>
</tr>
<tr>
<td>Hydrocodone (generic Vicodin), 7.5mg</td>
<td>Minnesota</td>
<td>$5</td>
<td>Nov 20</td>
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</tr>
<tr>
<td>Oxycodone, 80mg pill</td>
<td>Phoenix, Arizona</td>
<td>$30</td>
<td>Nov 28</td>
<td>Not Bad</td>
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<tr>
<td>Valium, 10mg pill</td>
<td>Cincinnati, Ohio</td>
<td>$3</td>
<td>Nov 28</td>
<td>Reasonable</td>
</tr>
<tr>
<td>Xanax, 2mg pill</td>
<td>Redondo Beach, California</td>
<td>$3</td>
<td>Nov 27</td>
<td>Reasonable</td>
</tr>
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</table>

www.streetrx.com
In the eyes of many patients, these opioids “are essentially legal heroin...”
FIGURE 1. Rates of emergency department (ED) visits* for nonmedical use of selected opioid analgesics, by type — United States, 2004–2008


* Per 100,000 population.
† 95% confidence interval.
§ Rate significantly less than the rate in 2008, by two-sided t test (p<0.05).
¶ Drug types include combination products (e.g., combinations of oxycodone and aspirin).
Unintentional Death: MVC vs Poisoning

NOTE: In 1999, the *International Classification of Diseases, Tenth Revision* (ICD-10) replaced the previous revision of the ICD (ICD-9). This resulted in approximately 5% fewer deaths being classified as motor-vehicle traffic-related deaths and 2% more deaths being classified as poisoning-related deaths. Therefore, death rates for 1998 and earlier are not directly comparable with those computed after 1998. Access data table for Figure 1 at [http://www.cdc.gov/nchs/data/databriefs/db81_tables.pdf#1](http://www.cdc.gov/nchs/data/databriefs/db81_tables.pdf#1).

Unintentional Death: Poisoning

![Graph showing trends in number of deaths due to poisoning from 1999 to 2008.]

1 Opioid analgesics include natural and semi-synthetic opioid analgesics (for example, morphine, hydrocodone, and oxycodone) and synthetic opioid analgesics (for example, methadone and fentanyl). Some deaths in which the drug was poorly specified or unspecified may involve opioid analgesics.

NOTES: Drug categories are mutually exclusive. Access data table for Figure 3 at http://www.cdc.gov/nchs/data/databriefs/db61_tables.pdf#3.


Unintentional Overdose Deaths Involving Opioid Analgesics, Cocaine and Heroin

United States, 1999–2007


Staten Island Doctor Charged in a Prescriptions Scheme

Dr. Felix Lamling, 33, appeared in Federal District Court in Brooklyn. He was released on a $100,000 bond.

By MICHAEL WILSON
Published: November 16, 2010
Volkow et al. JAMA, 2011; 305:1299

- Diversion
- Doctor shopping

National Survey on Drug Use and Health. Summary of national findings, 2008-2009
www.oas.samhsa.gov
For every 1 overdose death there are:

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abuse treatment admissions</td>
<td>9</td>
</tr>
<tr>
<td>ED visits for misuse or abuse</td>
<td>35</td>
</tr>
<tr>
<td>People with abuse/dependence</td>
<td>161</td>
</tr>
<tr>
<td>Nonmedical users</td>
<td>461</td>
</tr>
</tbody>
</table>

Treatment admissions are for primary use of opioids from Treatment Exposure Data set.
Emergency department (ED) visits are from DAWN, Drug Abuse Warning Network, https://dawninfo.samhsa.gov/default.asp.
Abuse/dependence and nonmedical use in the past month are from the National Survey on Drug Use and Health.
Conclusions

- Many patients have legitimate use for opioid analgesics
  - Need to refine indications and patient expectations
- A substantial minority of prescription opioids are misused with significant personal and public health consequences
- Healthcare providers bear much of the responsibility for access to these drugs of abuse
  - It is unclear how much of the problem is due to well-intentioned but under-educated prescribers
- We are now responsible to help with the solution!
“The Pharmaceuticalization of America”
Questions??