Hydrocodone Combination Analgesic Products

Clinical Impact of a Schedule Change

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January 24-25, 2013

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Dental Pain Management

- Acute dental pain: mild – moderate – severe.
- Post-surgical and acute tooth pain
  - Primarily from hard tissue (bone, dentin) and associated pain fibers.
  - This pain is generally moderate to severe.
- The range of medications to treat moderate to severe pain is limited to codeine (C-III), hydrocodone (C-III), and oxycodone (C-II).
- The drug of choice is a hydrocodone-containing combination product (HCC)

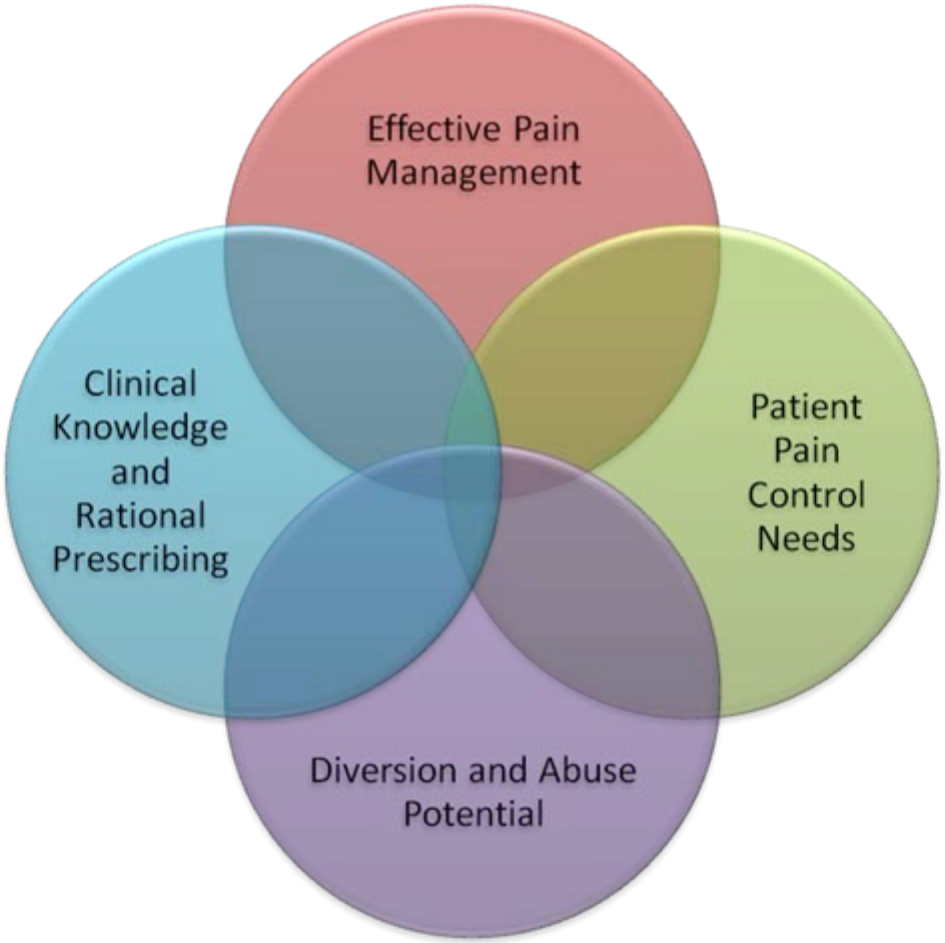
Dental Pain Management

- Codeine is a pro-drug (morphine active)
  - Poor metabolizers (2-10%): poor pain management, higher doses, potential to increase adverse effects
  - High metabolizers (0.5-2%): more risk of adverse effects at typical recommended doses
- HCC's have improved pain management and reduced adverse effects generally for dental patients versus codeine

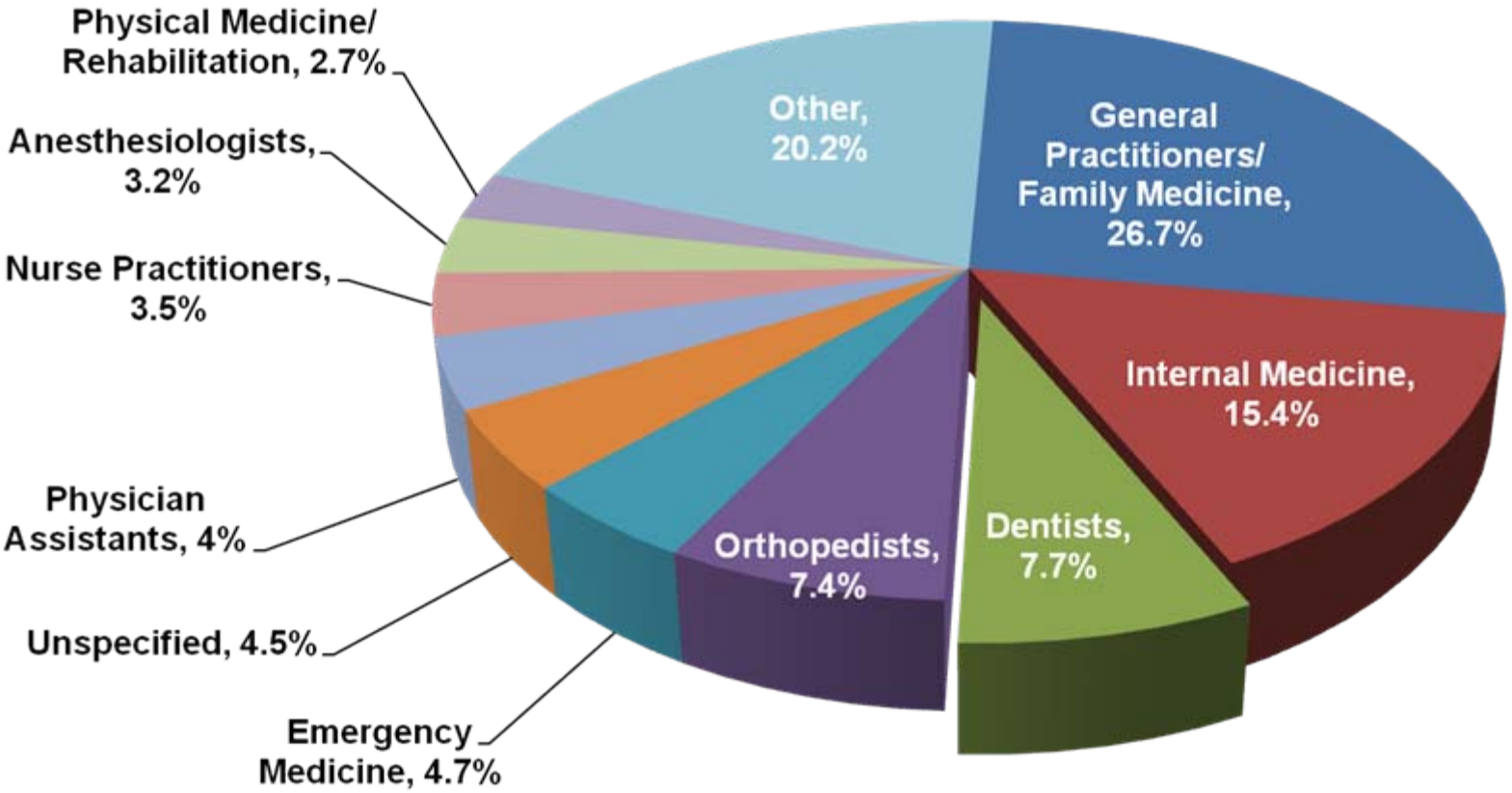
Dental Pain Management

- NSAIDS are an option - can have limitations
  - Pain control dental patients not always adequate
  - GI pain, bleeding
  - Lack of CNS effects which can help patients rest/sleep
- Hydrocodone combined with ibuprofen is a good alternative to hydrocodone with acetaminophen
- HCCs can be very useful for some patients with oral facial pain syndromes

The Role of HCC Products



Opioid Prescriptions in Dentistry



Source: SDI: Vector One® National, Total number of prescriptions dispensed in the U.S. by top 10 prescribing specialties for immediate-release opioids, Year 2009, Extracted June 2010.

Considerations

- Would public health benefits of rescheduling HCCs to C-II from C-III outweigh the risks and/or costs?

- Would the proposed schedule change significantly reduce drug diversion/abuse?

Hydrocodone - Semi-synthetic Opioid

- Schedule III includes a dose limit of 15 mg.
- Hydrocodone…
  - An alternative for patients who do not tolerate natural opioids, like morphine or codeine.
  - Stronger than codeine but one-tenth as potent as morphine
- Oxycodone is 1.5 times more potent than morphine.
- Hydrocodone is an intermediate strength opioid appropriately placed in C-III.

Patient Impact of Schedule Change

- Patients will be the primary group impacted by the proposed change:
  - Though not a good replacement, codeine prescriptions will increase. Effective pain management is likely to decrease while adverse events increase as a result…further impacting cost.
  - More visits to the ER if pain is not controlled
  - Patient will be burdened to call provider for refills or take other medications with consequences
  - Cost of medication will increase
- Advantages for the proposed change are unclear given the disadvantages for patients in pain
- Root issue is not addressed by the schedule change

Dental Practitioner Impact

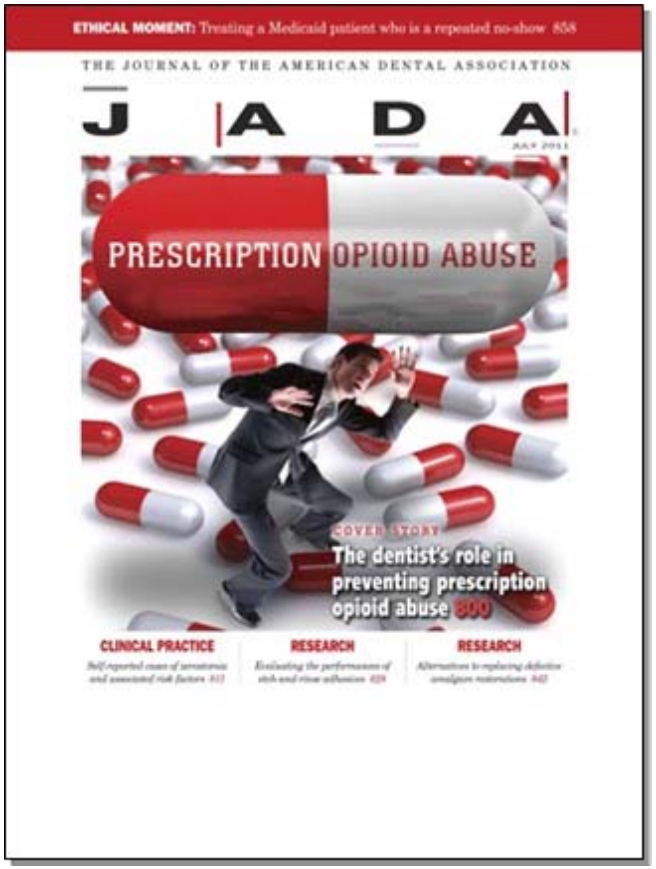
- Risk management
  - C-III alternative (codeine): more adverse effects and lower potency
  - Less consistent activity (pro-drug)/pain control
- Inconvenience
  - More after hours calls: for alternate medication or need for a new Rx

Impact on diversion, abuse, misuse

- Moving HCC's from C-III to C-II is passive-does not address problem.
- Prescription drug abusers will simply modify drug-seeking behavior(s)
  - Unknown / limited potential to decrease diversion / abuse
- For HCC's as C-II meds, prescribing habits may change (increase doses prescribed) to help address issues with patient pain management, cost, and inconvenience
- C-III Codeine Rx's are likely to increase: poor pain control may increase doses available for diversion

Dentistry is aware, responding

- JADA (July 2011) cover
- National Prescription Drug Abuse Prevention Plan
- National Prescription Drug Take-Back Initiative
- Medicine Abuse Project
- National Recovery Month
- www.ada.org/rxabuse



Maximize alternatives to Schedule change

- ADA is committed to prescriber education as a key part of diversion prevention.
  - Member of drugfree.org initiative.
  - Active participant in upcoming professional and public education campaigns.
- Use of a Patient Provider Agreement to educate the patient on use, abuse & proper disposal.
- Patient follow-up after the Rx is filled:
  - Assess efficacy and avoid over-prescribing
  - Emphasize proper disposal of remaining doses
  - Educate about the societal costs of diversion/abuse

Clinical support consortium

- Prescribers' Clinical Support System for Opioid Therapies (PCSS-O)
  - ADA participating in a consortium of seven health professional organizations
  - Free online information on safe, appropriate opioid prescribing
  - Continuing education credit
  - Start-up funding from SAMHSA
  - www.pcss-o.org

Commitment to useful CE on opioids

- Judicious prescribing for legitimate pain
  - Use of patient-provider agreements
- Recognizing signs that a patient may be seeking prescription drugs for non-medical purposes
- Counseling, referring chemically dependent patients for treatment
- Educating parents
  - Proper at-home storage, disposal of unused meds
  - Talking with children about the dangers of using prescription drugs for non-medical purposes

Conclusions

- Unnecessary suffering for legitimate patients
  - Compromised access to C-III (office, ER visits)
  - Effectiveness, adverse effects with C-III alternatives
  - May forego pain meds, self medicate, go to ER
- Higher out-of-pocket costs, inconvenience
  - C-II medications are more expensive
  - C-II refills require more office visits, copays
  - Limited availability of C-II meds at pharmacies
  - Patients may forego meds, self medicate, visit ER
- Increased costs, risks, inconvenience for dentists
- Unknown impact on diversion, abuse, misuse
  - Abusers could simply modify their drug-seeking behavior

Conclusions (cont'd)

- Education is critical to preventing diversion, abuse
- Dentistry is responding
  - Online, classroom, published CE courses
  - Media campaigns
- Results will be publicly available
- For more info, visit www.ada.org/rxabuse

Questions?

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