

# Product Theater Reporter

## Current thinking in OTC Analgesia

Patient Considerations and Practical Insights



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PAINWeek, an international conference focused on pain management, was held September 2 to 6, 2014, in Las Vegas, where world leaders in pain management gathered to share ideas with more than 1,800 conference attendees. On September 3, the symposium “Current Thinking in OTC Analgesia: Patient Considerations and Practical Insights” (sponsored by McNeil Consumer Healthcare Division of McNeil-PPC, Inc.) focused on over-the-counter (OTC) analgesics, highlighting key considerations when recommending these medications. Discussion during the symposium emphasized the importance of healthcare providers (HCPs) considering patient ailments and current medications when recommending OTC analgesics, as well as the critical need to educate patients on the safe use of these medications.

### Pain in the United States

Chairing the symposium, Charles P. Vega, Jr, MD, FAAFP, from the University of California, Irvine, School of Medicine, spoke to HCPs about key epidemiologic considerations beyond pain, given the importance of this issue in the US healthcare system. In a 2010 internet-based survey of US adults, 30% of the 27,000 respondents said they were experiencing chronic pain, defined as pain lasting more than 6 months.<sup>1</sup>

In addition to affecting patient well-being, the pain epidemic has other implications for the healthcare system. The estimated healthcare cost of pain management ranges from \$261 to \$300 billion annually, with an additional \$299 to \$335 billion in lost productivity due to pain.<sup>2</sup> These estimates highlight the need for increased focus on effective pain management regimens.

### Critical Comorbid Illnesses

Although efficacy is an important factor in proper pain management, consideration must also be given to the safety profile of certain analgesics for patients with comorbid conditions. During his presentation, Dr. Vega discussed a number of critical comorbid conditions that add complexity to the selection of an appropriate pain management regimen. Among these, peptic ulcer disease (PUD), chronic kidney disease (CKD), and coronary heart disease (CHD) may all be initiated or exacerbated by the use of certain OTC analgesics, such as nonsteroidal anti-inflammatory drugs (NSAIDs).<sup>3-8</sup> In addition, although acetaminophen is safe when taken as directed, exceeding the recommended

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dose of acetaminophen is the leading cause of acute liver failure in the United States.<sup>9</sup> Patients with depression, liver dysfunction, or a history of alcohol or opioid use may be at a greater risk of acetaminophen-associated liver toxicity.<sup>9</sup> Dr. Vega stressed that, if you want to be a holistic caregiver, it is important to consider these comorbid conditions when managing pain in patients.

Although OTC analgesics are generally considered safe when taken as directed, it is important to factor in the potential increased risk of certain ailments when recommending OTC analgesics. Comorbidities inform recommendations that HCPs make for their patients; however, patients do not always consider their own comorbidities when choosing an OTC analgesic. For this reason, it is important for HCPs to educate their patients on how comorbid conditions can and should impact pain management strategies.

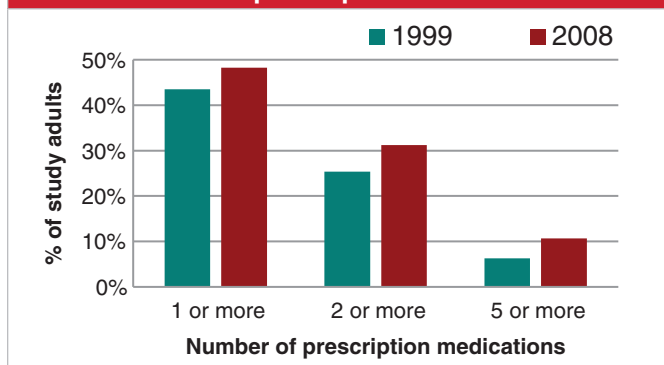
### Impact of Pain on Comorbidities and Patient Outcomes

Recent literature suggests that there is an association between patient pain status and medical outcome. A 2014 mail-based survey asked general practice patients 25 years of age or older to rank their pain experience on a scale from 1 (least severe) to 5 (most severe). In addition, subjects were asked to indicate if a doctor had ever diagnosed them with any diseases from a list that included osteoarthritis, rheumatoid arthritis, diabetes, high blood pressure, angina, heart attack, stroke, and depression. The researchers found that increased cardiovascular (CV) risk was correlated with greater pain intensity.<sup>10</sup> Other studies have shown significant association between pain and psychiatric disorders, such as major depressive disorder, generalized anxiety disorder, and alcohol use disorder.<sup>11,12</sup> These studies underscore the need for proper pain management in patients with comorbidities, in order to improve patient outcomes.

### Pain Management for Patients Taking Concomitant Medications

Another important patient characteristic that must be considered when recommending OTC analgesics is the concomitant use of other medications. According to a 2010 survey of 12,000 noninstitutionalized adults, the percentage of US adults using prescription medications increased from 1999 to 2008 (see **Figure 1**).<sup>13</sup>

**FIGURE 1. Percentage of study population taking 1 or more prescription medications.<sup>13</sup>**



Dr. Vega pointed out that use of concomitant medications poses a great challenge for HCPs when recommending an OTC analgesic. He also discussed the challenge of treating those patients taking other prescription and nonprescription medications, because taking multiple medications may increase the risk of certain adverse events.

### Benefits of OTC Analgesics

Christopher M. Chappel, MD, from Chappel Health and Wellness in Kissimmee, Florida, provided insights into pain management in daily practice. He began with a discussion of pain management strategies, including both pharmacologic (opioids and OTC oral analgesics) and nonpharmacologic (physical therapy, massage therapy, acupuncture, and electrostimulation) regimens. He then discussed benefits of OTC analgesics, such as those listed in **Table 1** below.

TABLE 1. Benefits of OTC Analgesics
<ul style="list-style-type: none"> <li>• Strong safety profiles, when taken as directed</li> <li>• Not associated with physical addiction, as seen with prescription opioids</li> <li>• Minimal drug–drug interactions</li> <li>• Track record of efficacy</li> </ul>

### Risks of OTC Analgesics

Although OTC analgesics have strong safety profiles when used as directed, there are risks associated with these medications, and they must be considered. Gastrointestinal (GI) complications, CV risks, renal dysfunction, and bleeding are all potential adverse events known to be associated with NSAIDs.<sup>14</sup> It is important to consider which analgesics are appropriate for individual patients, based on the potential for these medications to exacerbate or initiate medical conditions in at-risk patients. Dr. Chappel used the management of CV risks as a way to illustrate the recommended stepwise management of pain. Physicians are encouraged to follow this approach when treating pain in patients with known CV risks. Among other therapies, typically acetaminophen can be used as a first-line therapy for these patients, since acetaminophen is not known to increase the risk of CV events or interfere with low-dose aspirin heart therapy.<sup>15,16</sup>

In addition, known risks exist when OTC analgesics are combined with other medications. For example, GI bleeding risk may be increased by: taking NSAIDs and anticoagulants; taking NSAIDs and steroids; taking multiple prescription and nonprescription NSAIDs; and taking NSAIDs while consuming 3 or more alcoholic drinks daily.<sup>17–20</sup> Similarly, severe liver damage may occur if the patient uses multiple acetaminophen-containing products, or uses acetaminophen while consuming 3 or more alcoholic drinks daily.<sup>21,22</sup> Because of these potential risks, it is important to consider concomitant medication use when recommending an OTC analgesic.

There are certain risks associated with OTC analgesics when

taken with other drugs. For example, geriatric patients tend to have multiple comorbidities, such as CKD, CV diseases, and GI complications, which may make them poor candidates for the use of NSAIDs.<sup>23</sup> Conversely, there may be patients for whom acetaminophen may not be appropriate.<sup>24</sup> Dosing concerns and combinations of medications make pain management in this older population a challenge. In addition, HCPs may not have a complete patient medical history for several reasons, including because patients may neglect to disclose comorbidities, current medication use, or other OTC supplements and herbals they might be taking. Dr. Chappel recommended that HCPs always ask patients specifically about everything that they are taking, in order to recommend the most appropriate option.

Based on the benefits and risks associated with OTC analgesics, it is important that HCPs educate patients to make informed decisions. Patient considerations based on analgesia needs, concomitant illnesses, and medication use; correct dosing; and adverse events are key factors in promoting safe and effective pain management with OTC medications.

### A Nursing Perspective

Brett Badgley Snodgrass, MSN, APRN, FNP-BC, from Saint Francis Hospital—Bartlett Interventional Pain Management clinic in Bartlett, Tennessee, spoke about translating efficacy and safety considerations into daily practice, with a focus on individual patient care. She began with an introduction to the daily routine of nurse practitioners (NPs), physician assistants (PAs), and nurses. Most of the daily activities of all HCPs are similar. NPs and PAs are focused on managing the disease or diagnosis, but Ms. Snodgrass noted that they also tend to focus on the effect of chronic pain on the whole patient and restoring the patient's daily life.

A major difference that separates some NPs and PAs from other HCPs comes in their prescribing habits. Some states and regions allow NPs and PAs to prescribe only Schedule III medications. This means these HCPs have difficulty obtaining prescription analgesics that could be appropriate as treatment regimens for their patients. Instead, these HCPs often rely more heavily on OTC analgesics for management of their patients' pain.

### Not All Analgesics Are Appropriate for Every Patient

When recommending a pain management strategy, one important consideration is that not all analgesics are appropriate for every patient. Every patient's pain is unique. Data from twin studies suggest that individuality in pain sensitivity accounts for up to 60% of the variance in pain experience.<sup>25</sup> Depression and anxiety also affect pain sensitivity, so it is important for HCPs to screen for psychiatric disorders before making recommendations for pain management.

With all of these challenges, it is important to have flexibility in pain management. Choosing treatments that can accommodate the individual needs of patients is a key factor in achieving proper patient outcomes. Variations such as long-acting vs. short-acting and extra-strength vs. regular-strength formulations assist patients in properly managing their pain state with the correct amount of medication. However, for many patients, knowing when to use these formulations can be a challenge.

### Patients' Safe Use of OTC Analgesics

Although most patients take OTC analgesics appropriately, there are some who use these medications incorrectly, with potentially harmful effects.<sup>26</sup> Thirty-three percent of Americans admit that they have taken more than the recommended dose of an OTC medication at some point.<sup>27</sup> **Table 2** lists common reasons why patients misuse OTC analgesics.

**TABLE 2. Reasons Why Patients May Misuse OTC Analgesics**

- Rely on past behaviors or recommendations when selecting current treatments
- Take medications that are inappropriate for their specific pain type
- Misunderstand ingredients or take multiple products with the same ingredient
- Misunderstand dosing or take more than recommended, in hopes of achieving faster or stronger relief
- Take next dose too soon

Ms. Snodgrass discussed the importance of patient education on the use of OTC analgesics, because educating patients may change the misperceptions around these medications. This is an important step in patient education, because HCP guidance can impact health outcomes, minimize drug–drug interactions, encourage use of the correct dose or medication for the current ailment, and reiterate the danger of using multiple medications with the same active ingredients. Ms. Snodgrass directed the audience to resources available for promoting patient education. Websites such as the American Gastroenterological Association's <http://www.gutcheck.gastro.org/> and the Acetaminophen Awareness Coalition's <http://www.knowyourdose.org/> encourage patients to take medications appropriately, which includes reading labels, understanding the ingredients in their medications, and consulting their HCPs if they have questions or concerns about the medications they are taking.

### Conclusions

The PAINWeek symposium “Current Thinking in OTC Analgesia: Patient Considerations and Practical Insights” focused on the need for patient education when HCPs recommend OTC analgesics. Symposium speakers stressed the need for HCPs to think critically about comorbidities, concomitant medications, and other patient-related factors when recommending pain management. Because a large number of Americans have comorbid conditions and take concomitant medications unrelated to their current pain states, pain management can be a challenge for HCPs. Although generally safe when taken as directed, all OTC analgesics carry risks. While HCPs are aware of these risks, many patients are not, leading them to potentially manage their pain in unsafe ways. This knowledge gap highlights the need for patient education and for guidance from their HCPs in order to make safe decisions about the use of OTC analgesics.

## References

1. Johannes CB, Le TK, Zhou X, Johnston JA, Dworkin RH. The prevalence of chronic pain in United States adults: results of an internet-based survey. *J Pain*. 2010;11:1230-1239.
2. Gaskin DJ, Richard P. The economic costs of pain in the United States. *J Pain*. 2012;13:715-724.
3. Larkai EN, Smith JL, Lidsky MD, Graham DY. Gastroduodenal mucosa and dyspeptic symptoms in arthritic patients during chronic nonsteroidal anti-inflammatory drug use. *Am J Gastroenterol*. 1987;82:1153-1158.
4. Manuel D, Cutler A, Goldstein J, Fennerty MB, Brown K. Decreasing prevalence combined with increasing eradication of *Helicobacter pylori* infection in the United States has not resulted in fewer hospital admissions for peptic ulcer disease-related complications. *Aliment Pharmacol Ther*. 2007;25:1423-1427.
5. Murray MD, Brater DC, Tierney WM, Hui SL, McDonald CJ. Ibuprofen-associated renal impairment in a large general internal medicine practice. *Am J Med Sci*. 1990;299:222-229.
6. National Kidney Foundation. Pain medicines (analgesics). [http://www.kidney.org/atoz/content/painMeds\\_Analgesics.cfm](http://www.kidney.org/atoz/content/painMeds_Analgesics.cfm). June 2009. Accessed 8/21/14.
7. Plantinga L, Grubbs V, Sarkar U, et al. Nonsteroidal anti-inflammatory drug use among persons with chronic kidney disease in the United States. *Ann Fam Med*. 2011;9:423-430.
8. Hreinsson JP, Kalaitzakis E, Gudmundsson S, Björnsson ES. Upper gastrointestinal bleeding: incidence, etiology and outcomes in a population-based setting. *Scand J Gastroenterol*. 2013;48:439-447.
9. Larson AM, Polson J, Fontana RJ, et al. Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study. *Hepatology*. 2005;42:1364-1372.
10. Parsons S, McBeth J, Macfarlane GJ, Hannaford PC, Symmons DP. Self-reported pain severity is associated with a history of coronary heart disease. *Eur J Pain*. 2014. Epub ahead of print. doi:10.1002/ejp.533.
11. Subramaniam M, Vaingankar JA, Abdin E, Chong SA. Psychiatric morbidity in pain conditions: results from the Singapore Mental Health Study. *Pain Res Manag*. 2013;18:185-190.
12. Bair MJ, Wu J, Damush TM, Sutherland JM, Kroenke K. Association of depression and anxiety alone and in combination with chronic musculoskeletal pain in primary care patients. *Psychosom Med*. 2008;70:890-897.
13. Gu Q, Dillon CF, Burt VL. Prescription drug use continues to increase: US prescription drug data for 2007-2008. *NCHS Data Brief*. 2010;42:1-8.
14. US Food and Drug Administration. Medication guide for non-steroidal anti-inflammatory drugs (NSAIDs). <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM106241.pdf>. Accessed 8/21/14.
15. Catella-Lawson F, Reilly MP, Kapoor SC, et al. Cyclooxygenase inhibitors and the antiplatelet effects of aspirin. *N Engl J Med*. 2001;345:1809-1817.
16. Antman EM, Bennett JS, Daugherty A, et al. Use of nonsteroidal anti-inflammatory drugs: an update for clinicians: a scientific statement from the American Heart Association. *Circulation*. 2007;115:1634-1642.
17. Bhatt DL, Scheiman J, Abraham NS, et al. ACCF/ACG/AHA 2008 expert consensus document on reducing the gastrointestinal risks of antiplatelet therapy and NSAID use: a report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. *Circulation*. 2008;118:1894-1909.
18. García Rodríguez LA, Hernández-Díaz S. The risk of upper gastrointestinal complications associated with nonsteroidal anti-inflammatory drugs, glucocorticoids, acetaminophen, and combinations of these agents. *Arthritis Res*. 2001;3:98-101.
19. Clinard F, Sgro C, Bardou M, et al. Association between concomitant use of several systemic NSAIDs and an excess risk of adverse drug reaction. A case/non-case study from the French Pharmacovigilance System Database. *Eur J Clin Pharmacol*. 2004;60:279-283.
20. Ibuprofen. [www.nsaid-list.com/nsaid-list/ibuprofen](http://www.nsaid-list.com/nsaid-list/ibuprofen). Accessed 8/21/14.
21. US Food and Drug Administration. Acetaminophen overdose and liver injury—background and options for reducing injury. [www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/UCM164897.pdf](http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/UCM164897.pdf). 2009. Accessed 8/21/14.
22. Know Your Dose. How to read your medicine label. [www.knowyourdose.org/how-read-your-label](http://www.knowyourdose.org/how-read-your-label). Accessed 10/10/14.
23. Barber JB, Gibson SJ. Treatment of chronic non-malignant pain in the elderly: safety considerations. *Drug Saf*. 2009;32:457-474.
24. American College of Gastroenterology. Medications and the liver. <http://patients.gi.org/topics/medications-and-the-liver/>. 2007 (updated 2012). Accessed 10/10/14.
25. Nielsen CS, Price DD, Vassend O, Stubhaug A, Harris JR. Characterizing individual differences in heat-pain sensitivity. *Pain*. 2005;119:65-74.
26. Kaufman DW, Kelly JP, Rohay JM, Malone MK, Weinstein RB, Shiffman S. Prevalence and correlates of exceeding the labeled maximum dose of acetaminophen among adults in a US-based internet survey. *Pharmacoepidemiol Drug Saf*. 2012;21:1280-1288.
27. American College of Preventive Medicine. Over-the-counter medications: use in general and special populations, therapeutic errors, misuse, storage and disposal. <http://cymcdn.com/sites/www.acpm.org/resource/resmgr/time-tools-files/otcmedsclinicalreference.pdf>. 2011. Accessed 8/21/14.

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