March 29, 2019
Docket Number: HHS-OS-2018-0027, Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations

Dear Committee and Task Force Members:
The Society of Pain and Palliative Care Pharmacists (SPPCP) was developed to provide a professional organization for pharmacists practicing in the specialties of pain management, hospice, and palliative care. SPPCP aims to advocate for pharmacists to provide meaningful impact and practice at their maximum aptitude commensurate with their advanced professional education and post-graduate training. SPPCP's mission is to promote exceptional patient care by advancing pain and palliative pharmacists through education, development, and research in collaboration with the transdisciplinary team. We feel that it is in our mutual best interest to offer specific guidance and thoughts, particularly since our membership includes many nationally recognized pharmacologic pain specialists.

We see the trend in clinical practice of health care professionals declining to provide pain management care for patients, both in rural and in urban areas. In response to the call for this patient care need, the pharmacy profession has stepped up educational programs and specialty training in the past several years. The number of post-graduate residencies in pain management and palliative care has more than doubled in the past 5 years with expected continued growth. Pharmacists are a growing and essential part of the comprehensive treatment of pain and foundational members of interdisciplinary teams. We applaud the Task Force for recognizing the pharmacist as part of that team, as it reflects current practice.

Pharmacists are currently involved in every aspect of clinical pain practice including essential roles in acute and perioperative pain management, improving the safety and effectiveness of analgesic therapy, including opioids.[1-3] Surgical teams are not allowed the time to properly evaluate and educate patients, so the pharmacist is an integral part of peri-operative planning and follow-up. They conduct pre-operative pain assessments for complex surgical patients, including those taking chronic opioids and those being treated for opioid use disorder, formulate a patient-centered multimodal analgesic regimen, provide education and follow-up after surgery.

In the chronic pain setting, pharmacists are also an integral part of the multidisciplinary team, utilizing collaborative relationships with providers. Studies have shown that the pharmacist can reduce the number of opioids needed while providing education, monitoring disability and managing of analgesic pharmacotherapy, including opioids and risk management. [4-7] Given our credentials as pharmacotherapy experts, we would like to specifically address the section on medications.

2.2 Medication
As the analgesic pharmacotherapy experts, we would like to caution the Task Force on oversimplifying the categories of analgesics. Magnifying opioids as one of the main pharmacotherapeutic options in the management of chronic pain does not serve as a best practice, as there is minimal evidence to support their use. We would suggest that the Task Force break down pharmacotherapeutic options by type of pain (neuropathic and musculoskeletal), rather than pharmacologic activity, as current evidence-based treatment guidelines are classified using this nomenclature. The point of using NSAIDs and antineuralgics is that they are more efficacious than opioids, not because they are opioid-sparing - they are first-line agents. We advise the Task Force to either highlight the available pharmacotherapeutic guidelines for the different types of pain (as mentioned above), or to offer a separate supplement covering each analgesic class. The information currently provided is inadequate.

<u>Recommendations for guideline corrections:</u>
- NSAIDs – COX-2 selective agents such as celecoxib also cause GI toxicity, (>6 months and at higher doses). COX-2 selective agents also have a higher cardiovascular risk and all NSAIDs cause renal toxicity.
- Antineuralgics - sodium channel blockers are often considered first-line therapies for neuropathic pain (e.g. trigeminal neuralgia, migraine) and must be included as well as the extensive monitoring for lab work and drug interactions necessary for these agents.
- Anxiolytics – Data does not support the use of benzodiazepines for adjunctive treatment for chronic pain. First-line therapies include behavioral therapies to help patients accept and cope with chronic pain.

- Opioids- should be considered as adjunctive agents. Long-term adverse effects need to be addressed including, but not limited to, immunosuppression, HPA axis suppression, hypogonadism, osteoporosis and central sensitization.
- Antidepressants - Correction of the terminology "antidepressant" since we are using these agents as analgesics. Recommend such terminology as SNRI's or descending inhibitory pathway modulators. Tricyclic antidepressants are also SNRI's, making the category inclusive.
- Musculoskeletal agents - cyclobenzaprine, methocarbamol, metaxalone, orphenadrine, chlorzoxazone and carisoprodol have no data supporting efficacy in chronic musculoskeletal pain.

Gap 1: Clinical policies tend to treat the large population of patients with multiple conditions causing chronic pain with simple medication rules. Guidelines for medication use for specific populations of patients (e.g., different ages, genders, medical conditions, comorbidities) with chronic pain need to be developed for each specialty group and setting.
There are several condition-specific guidelines already in existence, including postherpetic neuralgia, trigeminal neuralgia, fibromyalgia, low back pain and osteoarthritis.[8-12] We would recommend updating and expanding these evidence-based guidelines to allow a more multimodal and patient-specific approach.

Gap 2: Opioids are often used early in pain treatment. There has been minimal pain education in medical school and residency programs, and little guidance for primary care providers (PCPs) on appropriate pain treatment approaches.
Curricula across healthcare professions have expanded significantly in the past 5 years to include more didactic and clinical application of pain management and substance use disorder treatment. This is not extensive enough to develop pain management experts until post-graduate training, but basic management, pharmacologic and otherwise, is taught across disciplines, including pharmacy and medicine. We endorse continued growth in this area, particularly with multidisciplinary learners and groups.

We are strongly supportive of CMS and payors providing reimbursement that aligns with medication guidelines herein. Reimbursement for pharmacist services, as advanced practice providers, is long overdue given the intimate role that we play in patient care. Many health systems allow only a 15-minute office visit with a physician, which is too abbreviated to have meaningful discussions with patients about pain. This is a natural and appropriate role for the pharmacist and our expertise and time should be reimbursed as with other professions. For example, some pharmacist-run clinics allow for 60 minutes for initial visits, similar to that of a psychologist initial visit, which is typically 60-120 minutes in duration. Initial visits include in-depth analgesic history, education about pain pathways and treatment guidelines, recommendations regarding therapies, ordering and review of appropriate drug monitoring lab work (including drug screens) and risk management strategies. Some advanced practice pharmacists also perform focused physical examinations.

Gap 3: There is often a lack of understanding and education regarding the clinical indication and effective use of nonopioid medications as part of a multimodal and multidisciplinary approach to acute and chronic pain management. Chronic pain is often ineffectively managed, which can in part be the result of a variety of factors, including physician training, patient access, and other barriers to care:
As stated above, educational efforts are expanding across all. Pharmacists are often the most accessible healthcare provider in a community (for example, in Iowa, there are 900 pharmacies for 99 counties, with at least 1 per county). They are the community medication experts for both prescription and non-prescription analgesics, and have access to a list of a patient's other medications ensuring safe use and avoidance of drug-drug and drug-disease interactions. We recommend that the Task Force consider support for multidisciplinary care at the community level to maintain access and to allow empowerment, access and collaboration.

Gap 4: Barriers, such as lack of coverage and reimbursement and understanding of proper usage, limit access to buprenorphine treatment for chronic pain:
We strongly endorse inclusion of all forms of buprenorphine on formularies as this is an appropriate and safe analgesic for many patient populations. We also endorse expanding access to this therapy, both for pain management and opioid use disorder. However, buprenorphine has some unique pharmacologic properties that should be considered. Pharmacists, as advanced practice providers, have the expertise to prescribe, educate and

monitor this therapy for pain as well as opioid use disorder in collaboration with our physician collaborators. We recommend that the Task Force consider this as an expansion to increase access to this life-saving therapy. Pilot practice models have already begun in hard-hit areas like Rhode Island.[13]

Gap 5: There is currently inadequate education for patients regarding safe medication storage and appropriate disposal of excess medications targeted at reducing outstanding supplies of opioids that may be misused by others or inadvertently accessed by children and other vulnerable members of the household. With regard to partial fills of C-II prescriptions, permission to do this was previously granted in the CARA legislation of 2016. While some states, insurance providers and pharmacies have not fully endorsed this, SPPCP offers its full support. Dispensing safer quantities of C-II medications, while ensuring access for future need, reduces both barriers to care and potential supply for diversion in the community.

In summary, we support the Task Force's efforts and encourage further action, in collaboration with profession-specific experts, such as advanced practice pharmacists.

Respectfully yours,

Christopher Herndon, PharmD, BCACP

President of the Society of Pain and Palliative Care Pharmacists

References

1. Ghafoor VL, Phelps P, Pastor J. Implementation of a pain medication stewardship program. Am J Health-Syst Pharm 2013;70:2070-5.
2. McGonigal KH, Giuliano CA, Hurren J. Safety and Efficacy of a pharmacist-managed patient-controlled analgesia service in postsurgical patients. Pain Practice 2017;17(7):859-65
3. Tran T, Taylor SE, Hardidge A, et al. Impact of pharmacists assisting with prescribing and undertaking medication review on oxycodone prescribing and supply for patients discharged from surgical wards. J Clin Pharm Ther. 2017:42:567-72.
4. Dole EJ, Murawski MM, Adolphe AB, et al. Provision of pain management by a pharmacist with prescribing authority. Am J Health-Syst Pharm 2007;64:85-9.
5. Cox H, Tak CR, Cochella SE, et al. Impact of pharmacist pre-visit input to providers on chronic opioid prescribing safety. J Am Board Fam Med 2018;31:105-12.
6. Jouini G, Choiniere M, Martin E, et al. Pharmacotherapeutic management of chronic noncancer pain in primary care: lessons for pharmacists. J Pain Res 2014;7:163-73
7. Hadi MA, Alldred DP, Briggs M, et al. Effectiveness of a pharmacist-led medication review in chronic pain management: systematic review and meta-analysis. Clin J Pain 2014;30(11):1006-14.
8. Bril V, England J, Franklin GM, et al. Evidence-based guideline: treatment of painful diabetic neuropathy: report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine and the American Academy of Physical Medicine and Rehabilitation. Neurology May 2011, 76 (20) 1758-1765; DOI: 10.1212/WNL.0b013e3182166ebe.
9. Dubinsky RM, Kabbani H, El-Chami Z, et al. Practice parameter: treatment of postherpetic neuralgia: an evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2004 Sep 28;63(6):959-65.
10. Cruccu G, Gronseth G, Alksne J, et al. AAN-EFNS guidelines on trigeminal neuralgia management. Eur J Neurol 2008;15:1013-28.
11. Koes BW, van Tulder M, Lin CW, et al. An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. Eur Spine J 2010 19(12):2075–94.
12. Hochberg MC, Altman RD, Toupin April K, et al. American College of Rheumatology 2012 Recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip and knee. Arthritis Care Res 2012;64(4):465-74.
13. https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-care-pharmacy/m1mcceVlLRXX1W9X3WdeOP/story.html