AGS Geriatrics Healthcare Professionals

40 FULTON STREET, 18TH FLOOR
NEW YORK, NEW YORK 10038
212.308.1414 TEL 212.832.8646 FAX
www.americangeriatrics.org

***AGS Comments to the U.S. Department of Health and Human Service, Office of the Assistant Secretary for Health, Attn: Alicia Richmond Scott, Task Force Designated Federal Officer (submitted April 1, 2019) on*: Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations Draft Report**

The American Geriatrics Society (AGS) appreciates the opportunity to review and comment on the U.S. Department of Health and Human Services' Draft Report on *Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations*. Founded in 1942, the American Geriatrics Society (AGS) is a nationwide, not-for-profit society of geriatrics healthcare professionals dedicated to improving the health, independence, and quality of life of older people. Our nearly 6,000 members include geriatricians, geriatric nurses, social workers, family practitioners, physician assistants, pharmacists, and internists who are pioneers in advanced-illness care for older individuals, with a focus on championing interprofessional teams, eliciting personal care goals, and treating older people as whole persons.

**GENERAL COMMENTS**

The U.S. Census Bureau projects that the number of people age 65 and older will more than double between 2014 and 2060 to 98.2 million or 23.5 percent of the population; and those 85 and older will increase threefold to 19.7 million.[1] Even as we live longer, diseases and conditions that threaten the health of older people remain a serious concern. This is particularly true for the "oldest old"(age 80 and older) who are at the highest risk of having multiple health problems and constitute the fastest growing age group in the U.S.[2] In Medicare, older adults with 2 or more chronic conditions account for 93% of Medicare spending.[3] Over 52% of older adults report experiencing bothersome pain in a preceding month.[4]

As a general comment, given the size and heterogeneity of this population, AGS recommends that HHS review all sections of this report to determine if there are additional ways in which the report should draw attention to the needs of older adults with persistent pain. For example, Section 2.2 (Medication), should be expanded in two ways: (1) include for each specific medication class a discussion of any data that are available for special populations (e.g., older adults, women); (2) add a discussion of management of patients with complex pain conditions and multiple comorbidities. We do not believe it is sufficient to recommend development of condition-specific treatment algorithms, without addressing how these can be used in patients with multiple morbidities and frailty. As another example, reference should be made throughout to the role of caregivers in caring for those with cognitive decline and/or physical and mental disabilities in ensuring that this patient population is not living with persistent pain.

**INCLUSION ACROSS THE LIFESPAN**

Older adults currently make up 13% of the U.S. population, and more than 90% of this population uses at least one prescription while more than 66% use three or more in any given month.[5] Yet much existing clinical research evidence is focused on disease-specific conditions or on younger populations. Older adults, particularly those who are frail with multiple chronic conditions, are under-represented in clinical trials and the number of controlled studies involving only patients aged 75 and older remains low. Furthermore, high-quality studies involving older patients from different ethnic groups are rare. As a result, current evidence-based literature does not serve as an adequate guide in many decision-making situations that are routinely encountered in clinical practice. The National Institutes of Health (NIH) has acknowledged this significant gap. Following enactment of the 21st Century Cures Act in December 2016, the NIH convened an Across the Lifespan Workshop. Subsequently the NIH released an Inclusion Across the Lifespan policy, that supports research involving traditionally underrepresented age groups—specifically older people and children—by requiring approved justifications before any study participants can be excluded from NIH-funded work based on age alone. The policy became effective for all grants submitted after January 25, 2019[6]

---

[1] Colby SL, Ortman JM. Projections of the Size and Composition of the U.S. Population: 2014 to 2060, Current Population Reports, P25-1143, U.S. Census Bureau, Washington, DC, 2014.
[2] Wan He, Daniel Goodkind, and Paul Kowal U.S. Census Bureau, International Population Reports, P95/16-1, An Aging World: 2015, U.S. Government Publishing Office, Washington, DC, 2016.
[3] https://www.cdc.gov/chronicdisease/about/multiple-chronic.htm.
[4] https://www.bmj.com/content/350/bmj.h532.full
[5] https://www.cdc.gov/nchs/data/hus/2017/079.pdf
[6] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html)

The Food and Drug Administration (FDA) has approached changes to its policies around inclusion across the lifespan by updating its policy guidance focused on geriatrics populations (ICH-E7) to "encourage" inclusion of adults age 75 and older in clinical trials.[7] In March 2019, the FDA released new guidance for public comment that is specific to inclusion of individuals with organ dysfunction or concurrent malignancies in clinical trials, citing the aging of the population as a reason for this guidance.[8] Private industry funds approximately 60% of biomedical research[9] in the United States and in light of the FDA's significant regulatory role in approving new drugs and devices coming to market, AGS believes that the incremental steps the FDA has taken are unlikely to meaningfully increase inclusion of older adults, particularly those with multiple chronic conditions in clinical trials that are supported by industry.

**EXISTING RESEARCH GAPS**

Because of the lack of inclusion of frail older adults with multiple chronic conditions in studies and clinical trials, there are significant gaps in the evidence base for how best to manage acute and persistent pain in this population. In addition to the work that is underway to promote greater inclusion of older adults in research, AGS recommends that HHS prioritize research that is focused on this population. Examples of the research that is needed include:

1. Support studies that enroll older adults with additional conditions common in this population (e.g. multi-morbidity, polypharmacy, and frailty) with a special emphasis on recruiting adults age 75+ and those with multiple chronic conditions. Such studies should examine the treatment efficacy of pharmacologic as well as non-pharmacologic modalities in these populations. Additionally, such studies should examine efficacy of alternate approaches to managing post-operative pain at discharge.
2. Support research that expands our understanding of non-pharmacologic approaches to pain management, which could include studies on how to augment treatment effects of psychological and movement based therapies; studies on how to optimally engage older adults in the use of these therapies; and identification of strategies that promote adoption and maintenance of self-management strategies (e.g., mindfulness meditation, exercise, tai chi, yoga).
3. Support research to determine the prevalence and specific types of patient beliefs and attitudes that negatively impact pharmacologic treatment engagement and adherence, and develop and evaluate interventions to successfully address them.
4. Support policy research that leads to increased access to those therapies that are proven effective.
5. Support research that will improve our understanding of whether telehealth will improve access for rural older adults and those living where best practice interventions are not available.

In addition, HHS should commission the Agency for Healthcare Research and Quality to do a focused review of the evidence (or a series of such reviews) that is specific to older adults with persistent pain. Such an AHRQ review (or reviews) should be designed to both identify evidence gaps and support the development of future guidelines or updating of the current CDC guideline with new evidence specific to this population.

**SPECIFIC COMMENTS ON SECTION 2.7.2 – OLDER ADULTS**

AGS believes the introduction section should be expanded to include the unique issues related to pain management in older adults (as was done in section 2.7.1). Further, AGS recommends that this report take a lifespan approach to management of persistent pain in older adults and recognize the heterogeneity of this population. By this we mean that managing persistent pain in healthy, active older adults differs from managing persistent pain in frail older adults.

***Gap 1: There is a lack of opioid prescribing guidelines for the aging population given this population's increased risk of falls, cognitive decline, respiratory depression, and renal impairment.***

**Recommendation 1a: Develop pain management guidelines for older adults that address their unique risk factors.**
HHS should review the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain[10] to

---

[7] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073131.pdf)

[8] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM633137.pdf

[9] https://jamanetwork.com/journals/jama/article-abstract/2089358?resultClick=1

[10] https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm

determine what additional guidance is needed when caring for older adults with persistent pain. In our own review of the CDC guideline, we note that the CDC identifies the population covered by its guideline as 18 or older, excluding people receiving palliative or end-of-life care. In its review, we recommend that the HHS assess whether the CDC recommendations are reducing access to appropriate pain management for frail older adults with multiple chronic conditions who meet the definition of advanced illness as outlined in that guideline but are not currently receiving palliative care. If HHS determines that an additional guideline or expansion of the CDC guideline is required to explicitly address pain management for frail older adults with multiple chronic conditions, we believe that such a guideline should consider all treatment options as these relate to older adults, including frail older adults. Specifically, any future guidance should address the scope of concerns with older adults regarding analgesic options beyond opioids to NSAIDs and other pharmacologic treatments as well as addressing non-pharmacologic treatments. Organ impairments common in older adults impact the safety of analgesic options, particularly NSAIDs and anxiolytics, and could limit analgesic therapy options. In patients with advanced illness, opioids continue to be a reasonable option for frail older adults with multiple chronic conditions and opioids should be available to this patient population as clinicians develop treatment plans for managing their persistent pain regardless of whether they are receiving palliative care. We are concerned that recent regulatory actions, including Medicare reduction in opioid prescribing, will adversely impact the treatment of pain in frail older adults with comorbidities.

**Recommendation 1b: Use a multidisciplinary approach with a nonpharmacologic emphasis given the increased risk of medication side effects in this population.** *AGS Comment:* There is limited evidence about non-pharmacologic interventions and the evidence that does exist shows that the treatment effects are modest. AGS recommends that HHS take a holistic approach to management of persistent pain in older adults with a focus on developing guidance that helps clinicians develop a treatment plan that mitigates patient suffering.

**Recommendation 1c: Establish appropriate pain management education for physicians and other health care providers who treat older adults.** *AGS Comment:* HHS should give consideration to how this pain management education would complement and not duplicate existing educational requirements from the FDA under REMS.[11] Specifically, REMS should be expanded to require inclusion of education on other pain treatment modalities.

**ADDITIONAL GAPS AND RECOMMENDATIONS HHS SHOULD ADDRESS IN THIS REPORT Workforce Gap:** There is a significant shortage of geriatricians and geriatric pain specialists, as well as comprehensive pain service centers with interdisciplinary team members who are knowledgeable about the unique needs and issues of older adults. This creates a barrier to addressing the pain management needs of older adults. HHS should

1. Increase geriatrics pain workforce through enhanced education of pre-licensure health professionals and primary care providers on problems and needs/challenges of pain management in older persons, particularly those who are frail or with multiple chronic conditions.
2. Assure that all health professionals, particularly those in primary care, have sufficient training to be competent in the comprehensive evaluation and treatment planning that is essential when working with older adults with complex histories, multiple pain problems and medical comorbidities.

**Access Gap:** Older adults (and their caregivers), particularly those living in rural or low-income communities, have limited access to care and to the full scope of pain interventions.

1. Increase third party reimbursement for non-drug therapies appropriate for older adults and coverage for sustained durations needed for persistent pain management.
2. Medicare reimbursement so that health professionals who are providing the essential comprehensive evaluation and treatment planning that is needed when caring for older adults with complex histories, multiple pain problems and medical comorbidities are adequately reimbursed.
3. Use a comprehensive interdisciplinary approach to treatment planning and evaluation that addresses the unique needs of older adults across a continuum of health and frailty.

If you have questions, please contact Mary Jordan Samuel, mjsamuel@americangeriatrics.org or 212-308-1414.

---

[11] https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm