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EDITORIAL

NAMS supports judicious use of systemic hormone therapy for women aged 65 years and older

Members of The North American Menopause Society (NAMS) have become increasingly concerned over the last several years about the challenges they face trying to provide appropriate treatment for older postmenopausal women who have persistent moderate to severe vasomotor symptoms or other indications for systemic hormone therapy (HT). The challenge for these and other clinicians results from the fact that systemic HT is included on the list of potentially inappropriate medications (PIMs) for adults aged older than 65 years. This list has been incorporated into many quality-of-care measures, and these metrics are being used to evaluate the performance of clinicians and healthcare systems. Scores from these metrics can affect public opinion and even credentialing of healthcare systems.

The origin of the list of PIMs, commonly known as the Beers list, dates back to 1991 when geriatrician Mark H. Beers, MD, created the list after observing that some medications appeared to generate more adverse events when given to older adults compared with younger adults.[1] The list was first published in *Archives of Internal Medicine* in 1991 and then updated two more times in the same journal in 1997[2] and 2003.[3] Both oral and transdermal estrogens, with or without progestogens, were placed on the list in 2003. This decision was based on evidence of carcinogenic potential of estrogen in the breast and the endometrium as well as the lack of evidence for cardioprotective effect and cognitive protection in older women.

With the 2012 update of the Beers list, a partnership was forged with the American Geriatrics Society (AGS) to achieve more transparent and systematic updates that would allow for wider input from experts in other specialties and from public comment.[4] Of note, a new category was added in 2012 for medications that should be used with caution.

The Beers list of PIMs, or a variation thereof, has been increasingly incorporated into a number of quality-improvement efforts and health plan accreditation programs. These measures are being used by entities such as the Centers for Medicare and Medicaid Services (Medicare Part D), the URAC Health Plan Accreditation program, and the Physician Quality Reporting System, to name a few. Both the Pharmacy Quality Alliance and the National Committee for Quality Assurance (NCQA) have considered the AGS Beers list when updating their quality measures.

The Healthcare Effectiveness Data and Information Set (HEDIS), a registered trademark of NCQA, is a tool that measures performance with respect to quality of care and service. It is used by more than 90% of the health plans in the United States, including Medicare.[5] The result of these well-intentioned quality programs is that clinicians who prescribe systemic HT to women aged older than 65 years are likely to receive letters from the insurance companies pointing out the risks of hormone use in these women, perhaps denying coverage for the medication. On a larger scale, healthcare systems may be concerned that a lower score on this measure will result in a lower ranking for their healthcare system.

A potential application of the Beers list is incorporation of PIMs into the electronic medical record.[6,7] The addition of alternative therapy suggestions for a specific PIM incorporated into the electronic chart could be of value to the clinician at point of care. In the case of estrogens, however, there are no equally effective alternatives, and the one nonhormonal prescription drug alternative approved by the US Food and Drug Administration is also on the Beers list along with other selective serotonin reuptake inhibitors because of an association with falls and fractures.[4]

The Beers list has provided a valuable service to prescribing clinicians by creating a list of medications that are potentially more harmful in people aged older than 65 years.[4] The authors clearly state, "This list is not meant to supersede clinical judgment or an individual patient's values and needs. Prescribing and managing disease conditions should be individualized and involve shared decision-making." NAMS strongly endorses this statement. "The Beers Criteria alone should never dictate prescribing, nor should they be used punitively. They are intended to inform thoughtful prescribing decisions," said Todd Semla, PharmD, MS, co-chair of the panel that updated the criteria in 2012.[8]

The NAMS 2012 hormone therapy position statement acknowledges that HT carries fewer risks in younger postmenopausal women.[9] NAMS recommends that a woman use the lowest dose for the time appropriate to meet her needs. NAMS further states that, provided that the woman is aware of the risks and has clinical supervision, extending HT use is acceptable under certain circumstances, including 1) for the woman who has determined that the benefits of symptom relief outweigh the risks, and 2) for the woman at high risk of fracture for whom alternate therapies are not appropriate or cause unacceptable adverse events.

Two recent publications have confirmed that the duration of vasomotor symptoms is longer than previously believed and

extends well into the 60- to 70-year-old age group.[10,11] This information, combined with the lack of effective alternatives that are not on the list of PIMs, suggests that exceptions need to be made in terms of quality-of-care metrics for the symptomatic menopausal woman, or alternatively, HT might be better placed in the "use with caution" category. "The North American Menopause Society Statement on Continuing Use of Systemic Hormone Therapy After Age 65" is a succinct statement that may be of use to clinicians seeing older symptomatic postmenopausal women in their practices.[12]

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REFERENCES

1. Beers MH, Ouslander JG, Rollingher I, Reuben DB, Brooks J, Beck JC. Explicit criteria for determining inappropriate medication use in nursing home residents. *Arch Intern Med* 1991;151:1825-1832.
2. Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly. An update. *Arch Intern Med* 1997;157: 1531-1536.
3. Fick DM, Cooper JW, Wade WE, Waller JL, Maclean JR, Beers MH. Updating the Beers criteria for potentially inappropriate medication use in older adults: results of a US consensus panel of experts. *Arch Intern Med* 2003;163:2716-2724.
4. American Geriatrics Society 2012 Beers Criteria Update Expert Panel. American Geriatrics Society updated Beers Criteria for potentially inappropriate medication use in older adults. *J Am Geriatr Soc* 2012; 60:616-631.
5. HEDIS & performance measurement. National Committee for Quality Assurance Website. Available at: http:www.ncqa.org/HEDISQuality Measurement.aspx. Accessed March 21, 2015.
6. Hume AL, Quilliam BJ, Goldman R, Eaton C, Lapane KL. Alternatives to potentially inappropriate medications for use in e-prescribing software: triggers and treatment algorithms. *BMJ Qual Saf* 2011;20: 875-884.
7. Elseviers MM, Vander Stichele RR, Van Bortel L. Quality of prescribing in Belgian nursing homes: an electronic assessment of the medication chart. *Int J Qual Health Care* 2014;26:93-99.
8. American Geriatrics Society. Beers criteria for potentially inappropriate mediation use in older adults (3/12) [press release]. American Association of Nurse Assessment Coordination Website. Available at: http:www.aanac.org/information-resources/mds30/full-article/2012/03/23/updated-beers-criteria-for-potentially-inappropriate-medication-use-in-older-adults-(3-12). Accessed March 21, 2015.
9. North American Menopause Society. The 2012 hormone therapy position statement of: The North American Menopause Society. *Menopause* 2012;19:257-271.
10. Gartoulla P, Worsley R, Bell RJ, Davis SR. Moderate to severe vasomotor and sexual symptoms remain problematic for women aged 60 to 65 years. *Menopause* 2015;22:XXX-XXX.
11. Avis NE, Crawford SL, Greendale G, et al. Study of Women's Health Across the Nation (SWAN). Duration of menopausal vasomotor symptoms over the menopause transition. *JAMA Intern Med* 2015; 175:531-539.
12. North American Menopause Society. The North American Menopause Society statement on continuing use of systemic hormone therapy after age 65. *Menopause* 2015;22:XXX-XXX.