Aligning the 4Ms of Age-Friendly Health Systems With Statin Use for Primary Prevention

This editorial comments on the article by Forman et al.

The United States has an estimated 21.2 million persons (6.5% of the total population) older than 75 years.1 In the next 30 years, the number of older adults older than 75 years is anticipated to increase to 48.4 million (11.0% of the total population).2 To promote high-quality, cost-effective, evidence-based geriatric care, the “4Ms” model of the Age-Friendly Health System Initiative was developed to focus on what matters most to the older person (honors choice) along with critical care concepts related to mentation, mobility, and medication.3 “What matters” emphasizes the primacy of shared decisions to develop person-centered goals of care, including but not limited to wishes about end-of-life care. Mentation refers to cognitive and affective changes that are age associated, mobility focuses on the importance of function to health and quality of life, and medication examines the commission and omission of important pharmacologic interventions.4 In this issue of the Journal of the American Geriatrics Society, O’Neill et al highlight the need to strike a balance among each of the “4Ms” when decisions regarding statin use for primary prevention in older adults need to be made in clinical practice.5

As a pharmaceutical class, statins have become one of the most commonly prescribed medications. Healthcare providers and older adults are advised to have a conversation regarding whether to initiate treatment and, in some cases, whether to discontinue statins. Based on the Medical Expenditure Panel Survey, one-third of community-dwelling adults older than 79 years without vascular disease reported being prescribed a statin between 2011 and 2012 in the United States.6 The prevalence of statin use in older adults between 2011 and 2012 was almost four-fold higher than between 1999 and 2000.6 Given that age is one of the most potent parameters of the atherosclerotic cardiovascular disease risk score (which now is recommended to guide initiation of cholesterol-lowering medications),7 changes in longevity mean more persons aged 75 years and older will require discussions with their healthcare providers about statin use.

However, guidelines in cardiovascular disease outcomes currently acknowledge that there is insufficient evidence for statin initiation in persons aged 75 years and older, which results in personalized decisions mainly driven by extrapolation of evidence from younger population segments.7 The use of three case studies regarding statin use for primary prevention in older adults by O’Neill et al5 provides an important glimpse into current decision-making dilemmas. The first case is that of an 80-year-old woman with multiple health conditions, including cardiovascular risk factors but not cardiovascular disease. She is fully independent and now thinking about the decision to initiate a statin. The second case is an 82-year-old man with cardiovascular risk factors but a highly functional “superager” who is already taking a statin. The third case is a frail, 80-year-old woman on statin therapy who has fatigue that requires use of a walker for short distances and a wheelchair for longer distances and is dependent in all her instrumental activities of daily living. Through the case discussions, O’Neill et al highlight the need for shared decision making with older adults regarding statins for primary prevention “as absolute therapeutic directives are rarely advantageous to (or desired by) all older adults at all times.”5

How do the “4Ms” align with the clinical conundrums illustrated in these real-world clinical examples? First, the question of what disease is being prevented for each case is not always clear. Indeed, the “primary prevention” cited in the title may be ambiguous, commonly referring only to the prevention of cardiovascular disease or mortality. In each of the three cases, the patients described their primary goals in functional terms rather than disease-specific terms—“remain living independently with her husband until ‘their final days,’” “wishing to remain highly active for as long as possible,” and “avoiding a nursing home level of care,” respectively. However, a subtle but important shift occurred when the authors addressed the person-centered goals of disability-free longevity (or the more inclusive concept, ability maximized longevity) and began to address “what matters.” As there is no current evidence to address how statins might affect the various desired person-centered outcomes, a discussion of the outcomes (mainly composite cardiovascular disease and cardiovascular mortality) where evidence has been generated was offered instead. Many factors might explain why this substitution occurred, including, but not limited to, the requirements of regulatory agencies to approve treatments for commercial use based on disease-specific conditions rather than person-centered, geriatric syndrome outcomes. We consider it an
important omission that the article does not explicitly state that evidence regarding the desired ability to maximize longevity free of cognitive impairment or functional disability as an outcome in older people does not exist.

Second, there is a need to balance mortality (a component of “what matters”) with the mentionation and mobility “Ms.” The person-centered goals of function preservation with statin use in older adults are assumed to be congruent. In other words, statins can achieve increased longevity AND maintain mentionation AND maintain mobility. However, several other combinations including increased longevity AND mentionation OR mobility, increased longevity AND mobility OR mentionation, or increased longevity OR mentionation OR mobility could be possible. While recent analyses have suggested that statins may not worsen brain structure and function, statins still carry an adverse effect warning in the package labeling of worsening cognitive function. Also, as the authors mention in the third case, myopathy could be worsened with statin use in a small group of older adults. Despite extensive discussion in the article of many possible trade-offs, there are still limitations in terms of how the “4Ms” of geriatrics relate to these three cases, and to other cases not considered.

Finally, a focus on the medication “M” itself is needed. As mentioned in the first case study, the participant (already on six medications) expressed “concerns, having heard ‘dreadful things’ about that class of medications,” which was referring to cholesterol-lowering medications. So, what is the best way to handle the conflict of polypharmacy by continuing to add medications vs the potential action of the additional treatment on ability maximized longevity? One suggestion made by the authors is to reduce the need for medications by obtaining a coronary artery calcium (CAC) test. If the CAC score is zero, then avoidance of statin would be justified in most cases. However, if the CAC score is greater than zero, it is not clear how the findings should influence subsequent decision making.

Taken in their entirety, the three clinical case studies spur the need for more actionable information to align the “4Ms” care and statin use in adults older than 75 years. The authors mention the recently funded Pragmatic Evaluation of evENts And Benefits of Lipid-Lowering in older adults (PREVENTABLE) clinical trial that will be conducted in 20,000 older adults aged 75 years and older, recently funded by the National Institute on Aging. Fortunately, it will obtain information about cognitive physical function, and its primary outcome is survival free of incident dementia or persistent disability. However, even if the results will be more than 5 years before the trial results will be known, this information is not available to affect clinical care today. Results from PREVENTABLE and others from closely related trials around the world are eagerly awaited, given the high prevalence of statin eligibility in older adults.

In summary, the three case studies on statins, primary prevention, and aging, provided by O’Neill et al., provide important opportunities to align the “4Ms” of age-friendly health systems with decisions surrounding statin use in adults aged 75 years and older. The authors highlight the balanced approach needed in shared decision making among the “4Ms” of the model. The cases identify the need for more high-quality evidence and the potential mechanisms for obtaining the needed knowledge. Finally, they provide a litmus test for anticipating that shared decision making will not disappear but its content will be better informed once high-quality evidence becomes available.

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REFERENCES


