November 27, 2013

Virginia A. Moyer, M.D., M.P.H.
Chair
U.S. Preventive Services Task Force
540 Gaither Road
Rockville, MD 20850

RE: Draft Recommendation Statement: Screening for Cognitive Impairment in Older Adults

Dear Dr. Moyer:

We thank the U.S. Preventive Services Task Force (USPSTF) for the opportunity to provide comment on its Draft Recommendation Statement: Screening for Cognitive Impairment in Older Adults. We write today on behalf of more than 5 million Americans who have Alzheimer's disease and millions more who have vascular, Lewy body or frontotemporal dementia; many overcame enormous obstacles to receive their diagnosis, many others remain undiagnosed.

The LEAD Coalition[1] urges the USPSTF to include in its final Recommendation Statement a Grade A or B.

The draft Recommendation Statement risks reinforcing the discredited notion that physicians only need to or ought to diagnose that which they are able to cure. Think of the catastrophic damage done during the early years of the HIV/AIDS epidemic from such anti-detection biases which impeded efforts to account for the full scope of the public health burden, raise awareness and reduce stigma, and generate data for bench and social science researchers. The "I"

[1] Leaders Engaged on Alzheimer's Disease (LEAD) is a diverse and growing coalition of 61 member organizations including patient advocacy and voluntary health non-profits, philanthropies and foundations, trade and professional associations, academic research and clinical institutions, and biotechnology and pharmaceutical companies. The LEAD Coalition works collaboratively to focus the nation's strategic attention on Alzheimer's disease and related disorders and to accelerate transformational progress in care and support, detection and diagnosis, and research leading to prevention, effective treatment and eventual cure. One or more participants may have a financial interest in the subjects addressed.

recommendation equates to, and reinforces, “indifference” toward the many issues related to detection of cognitive impairment and dementia.

There are several significant barriers[2] to early detection[3] of dementia:

- Individuals are often unaware, deny or minimize the severity of symptoms.
- Access to quality care is a key issue for all individuals with dementia and for those of minority racial and ethnic backgrounds in particular.
- Clinician evaluation may be time consuming and not well reimbursed.
- Many, especially minority populations, believe that memory loss and cognitive decline are a normal part of aging.

Unfortunately, there are serious deficiencies in the healthcare system’s ability to recognize dementia. A 2009 article in the *American Journal of Geriatric Psychiatry* found that general practitioners miss about half of all dementia cases.[4] Persons with dementia cannot rely simply on relatives and friends, with whom they may have limited contact, to notice or be educated about memory problems. Physicians must play a greater role in discussing memory problems and in case identification. Failing to encourage screening for cognitive impairment risks similar damage and threatens to have a chilling effect on development of improved screening and diagnostic tools, delay diagnosis of people with Mild Cognitive Impairment (MCI) and undermine efforts to recruit clinical trial participants for research aimed at earlier and more effective interventions to improve functional and clinical outcomes.

The draft Recommendation Statement also appears unaware of or insensitive to the voluminous real-world experience of millions of Americans whose opportunity to participate fully in their own advance care planning and to accrue consequent non-medical benefits have been lost due to late detection and diagnosis that could have been avoided through screening for cognitive impairment in older adults. The NIA recognized in its 2008 report entitled “Alzheimer’s Disease: Unraveling the Mystery” that "it is best to find out sooner rather than later," because there are important medical and practical benefits to early detection. As NIA noted: "The drugs now available to treat AD can help some people maintain their mental abilities for months to years;" and "the sooner the person with AD and the family have a firm diagnosis, the more time they have to make future living arrangements, handle financial matters, establish a durable power of attorney and advance directives, deal with other legal issues, create a support network, and even consider joining a clinical trial or other research

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[2] Solomon PR, Murphy CA. Should we screen for Alzheimer’s disease? A review of the evidence for and against screening for Alzheimer’s disease in primary care practice. Geriatrics. 2005, 60(Nov): 26-31.

[3] Knopman D, Donohue JA, Gutterman EM. Patterns of care in the early stages of Alzheimer’s disease: impediments to timely diagnosis. J Am Geriatr Soc. 2000 Mar;48(3):300-4.

[4] Pentzek M, Wollny A, Wiese B, et al. Apart From Nihilism and Stigma: What Influences General Practitioners’ Accuracy in Identifying Incident Dementia? Am J Geriatr Psychiatry. 2009 Nov:17(11): 965-975.

study."[5] The value of knowing includes supporting the individual's right to information to make the best health care and support choices.

Recognition of impairment benefits the individual with the impairment, the caregiver, the family and society.[6] For the affected individual, identification of early stage dementia allows early aggressive use of most available treatments. The person can be offered support groups and other services to diminish the psychological impact of the disorder. Most individuals, regardless of their degree of impairment, tend to experience a sense of relief after receiving the diagnosis.[7] Moreover, the total medical care for this cognitively impaired individual can be adjusted to meet his or her needs. Issues such as patient education, self-medication, compliance and hospital care can be addressed to meet the needs of a person with mild dementia who is at risk for common complications such as delirium and depression. The early identification of dementia supports individual patient rights and self-determination. Most mildly impaired individuals are capable of charting the future course of their care and making substantial decisions on issues such as end-of-life care, resuscitation and disposition of wealth. It has long been established that informing individuals about abnormal screening results does not produce hardship or harm to the individual or family caregiver.[8–9–10–11–12]

Screening and early identification may benefit society by protecting individuals and reducing costs of healthcare. Unrecognized dementia can increase the likelihood of avoidable complications such as delirium, adverse drug reactions and noncompliance. These complications can reduce the autonomy of the individual with dementia. Enhancing compliance and protecting those with dementia have obvious financial benefits to the healthcare system. Adverse outcomes from screening programs are rarely reported in published peer-reviewed literature or experienced by community providers. Published studies on

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[5] National Institute on Aging, National Institutes of Health, "Alzheimer's Disease; Unraveling the Mystery," September 2008, 48-49, available at http://www.nia.nih.gov/NR/rdonlyres/0FA2EE06-0074-4C45-BAA3-34D56170EB8B/0/Unraveling_final.pdf.

[6] deVugt ME, Jolles J, van Osch L, et al. Cognitive functioning in spousal caregivers of dementia patients: findings from the prospective MAASBED study. Age Ageing 2006 Mar;35(2):160-6.

[7] Carpenter BD, Xiong C, Porensky EK, et al. Reaction to a dementia diagnosis in individuals with Alzheimer's disease and mild cognitive impairment. J Am Geriatr Soc. 2008 Mar;56(3):405-12.

[8] Lantz MS. Telling the patient the diagnosis of Alzheimer's disease: is truth-telling always best? Clinical Geriatrics 2004;12(4):22-25.

[9] Turnbull Q, Wolf AM, Holroyd S. Attitudes of elderly subjects toward "truth telling" for the diagnosis of Alzheimer's disease. J Geriatr Psychiatry Neurol. 2003 Jun;16(2):90-3.

[10] Post ST, Whitehouse PJ. Fairhill guidelines on ethics of the care of people with Alzheimer's disease: a clinical summary. Center for Biomedical Ethics, Case Western Reserve University and the Alzheimer's Association. J Am Geriatr Soc. 1995 Dec;43(12):1423-9.

[11] Johnson H, Bouman WP, Pinner G. On telling the truth in Alzheimer's disease: a pilot study of current practice and attitudes. Int Psychogeriatr. 2000 Jun;12(2):221-9.

[12] Maguire CP, Kirby M, Coen R, et al. Family members' attitudes toward telling the patient with Alzheimer's disease their diagnosis. BMJ. 1996 Aug;313(7056):529-30.

screening for community-based elders demonstrate effectiveness and acceptance.[13–14–15]

The practical reality is that the progressive cognitive decline intrinsic to Alzheimer's disease and related disorders places an absolute premium on making such advance care planning decisions as early in the disease course as possible; once decision-making skills diminish and competency is lost, the individual cannot participate in determining their own care. That is an unfair, unreasonable and – with the benefit of screening to aid in early detection and diagnosis – unnecessary burden on the individual and his or her family, friends or court-appointed guardians.

Value of currently available screening tools

Multiple screening instruments are available to assess individuals for cognitive decline.[16–17] The length of the screening test ranges from less than five minutes for the Brief Alzheimer's Screen (BAS) to approximately 15 minutes for the Mini-Mental Status Examination (MMSE).[18–19] A broad range of instruments, such as the GPCOG, Mini-Cog and MIS, are available with acceptable levels of sensitivity and specificity as well as interrater or rate-rerate reliability.[20–21]

Several screens have adequate sensitivity and specificity to serve as routine, cost-worthy evaluations. In fact, cognitive screening instruments demonstrate 80 percent to 90 percent or higher sensitivity and specificity in reviewed studies[22]—

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[13] Lawrence J, Davidoff D, Katt-Lloyd D, et al. A pilot program of improved methods for community-based screening for dementia. Am J Geriatr Psychiatry 2001 Summer;9(3):205-11.
[14] Lantz MS. Telling the patient the diagnosis of Alzheimer's disease: is truth-telling always best? Clinical Geriatrics 2004;12(4):22-25.
[15] Turnbull Q, Wolf AM, Holroyd S. Attitudes of elderly subjects toward "truth telling" for the diagnosis of Alzheimer's disease. J Geriatr Psychiatry Neurol. 2003 Jun;16(2):90-3.
[16] Burns A, Lawlor B, Craig S. *Assessment scales in old age psychiatry*. London: Martin Dunitz Ltd, 1999.
[17] Ashford JW. Screening for Memory Disorder, Dementia, and Alzheimer's disease.Aging Health. 2008 4(4):399-432.
[18]Mendiondo MS, Ashford JW, Kryscio RJ, Schmitt FA.Designing a Brief Alzheimer Screen (BAS). J Alzheimers Dis. 2003 Oct;5(5):391-8.
[19]Folstein MF, Folstein SE, McHugh PR. "Mini-mental state."A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res. 1975 Nov;12(3):189-98.
[20]Brodaty H, Clarke J, Ganguli M, Grek A, et al. Screening for cognitive impairment in general practice: toward a consensus. Alzheimer Disease and Associated Disorders 1998;12(1):1-13.
[21] Burns A, Lawlor B, Craig S. Assessment scales in old age psychiatry. London: Martin Dunitz Ltd, 1999.
[22] Solomon PR, Murphy CA. Should we screen for Alzheimer's disease? A review of the evidence for and against screening for Alzheimer's disease in primary care practice.Geriatrics. 2005, 60(Nov): 26-31.

similar to other established screening tests such as a mammography[23] and Pap smear.[24]

However, the effectiveness of available screening instruments is limited for special populations—particularly those with intellectual disabilities such as Down syndrome. This issue has been raised by the National Task Group on Intellectual Disabilities and Dementia Practice[25–26] and should be noted in the draft Recommendation Statement.

The necessary qualifications of the healthcare professional depend upon the screening instrument used, but registered nurses, and sometimes trained office staff, can perform most brief screening tests.[27] After receiving and reviewing the results, primary care providers have the opportunity to discuss the findings with screened individuals during an office visit.

Naturally, there is value in continuing to develop improved screening tools. The draft Recommendation Statement has the potential unintended consequence of diminishing the perceived and actual return on investment for research focused on developing new screening tools.

USPSTF/AHRQ should follow other agencies in moving the needle

Finally, the draft Recommendation Statement is at odds with both rapidly emerging scientific emphasis and current national policy. Particularly over the past several years, the National Institute on Aging, NIH Director Francis Collins, and the academic and industry research communities all have strongly supported new focus on the importance of pre-symptomatic pharmacological and non-pharmacological interventions predicated on the availability and increasing reliability of early detection. Existing national policy includes similar emphasis on early detection as evidenced in the National Plan to Address Alzheimer's Disease and provisions for cognitive screening as part of the Medicare Annual

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[23] National Cancer Institute. Breast Cancer Screening Modalities.http://www.nci.nih.gov/cancertopics/pdq/screening/breast/HealthProfessional/page5.

[24]Kulasingam SL, Hughes JP, Kiviat NB, et al. Evaluation of human papillomavirus testing in primary screening for cervical abnormalities: comparison of sensitivity, specificity and frequency of referral. JAMA. 2002 Oct 9;288(14):1749-57.

[25] Moran JA, Rafii MS, Keller SM, Singh BK, Janicki MP. The National Task Group on Intellectual Disabilities and Dementia Practices consensus recommendations for the evaluation and management of dementia in adults with intellectual disabilities. Mayo Clinic Proceedings, 2013; 88(8): 831-40.

[26] Jokinen J, Janicki MP, Keller SM, McCallion P, Force LT and the National Task Group on Intellectual Disabilities and Dementia Practices. Guidelines for structuring community care and supports for people with intellectual disabilities affected by dementia. Journal of Policy and Practice in Intellectual Disabilities, 2013;10(1):1-28.

[27] Solomon PR, Murphy CA. Should we screen for Alzheimer's disease? A review of the evidence for and against screening for Alzheimer's disease in primary care practice.Geriatrics. 2005, 60(Nov): 26-31.

Wellness Visit benefit. The National Plan's Strategy 2.B is explicit both about the urgency and evidence-based value from early detection to individuals and their families.[28]

The Food and Drug Administration (FDA) has been a leader in recognizing the need for innovative approaches in trial design and end-point selection for the treatment of Alzheimer's disease. In its review of new-drug applications for Alzheimer's disease, the FDA traditionally has maintained that claims of improved cognition should be accompanied by evidence of improvement in function. However, in its February 2013 draft guidance on drug development for early-stage disease, the FDA recognizes the lack of drug-development tools that are validated to provide measures of function in patients with Alzheimer's disease before the onset of overt dementia. An article in the March 28, 2013 *New England Journal of Medicine* further specifies their rationale:

> For patients whose disease is at an even earlier clinical stage, so that functional impairment would be more difficult to assess, it might be feasible to approve a drug through the FDA's accelerated approval pathway on the basis of assessment of cognitive outcome alone. The accelerated-approval mechanism allows drugs that address an unmet medical need to be approved on the basis of a surrogate end point or an intermediate clinical end point (e.g., a sensitive cognitive measure), with the stipulation that post approval studies will be conducted to verify the clinical benefit. Such a regulatory process may hold promise for facilitating the approval of treatments that appear to be effective in early Alzheimer's disease, when patients might be expected to derive the greatest benefit.[29]

Just as NIH and FDA have shifted thinking and/or regulatory frameworks in the research space, so should USPSTF and AHRQ in the clinical space.

Conclusion

At a time when we have within our grasp opportunities for profound advances in public attitudes and scientific research regarding Alzheimer's disease and related disorders, it is vitally important that USPSTF include in its final Recommendation Statement a Grade A or B. Such a decision would be evidence-based, in clear alignment with other federal agencies and established national policy. It also would be an ethical step forward in solidarity with people searching for answers about undetected and unexplained emergent cognitive decline.

We appreciate your leadership and are committed to helping develop appropriate screening guidelines that support established national policies encouraging early detection of cognitive impairment among older adults.

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[28] http://aspe.hhs.gov/daltcp/napa/NatlPlan2013.shtml#strategy2.B

[29] Kozauer N, Katz R. Regulatory innovation and drug development for early-stage Alzheimer's disease. N Engl J Med 2013; 368:1169-71.

Please contact Ian Kremer from the Leaders Engaged on Alzheimer's Disease (LEAD) Coalition (ikremer@leadcoalition.org or 571-383- 9916), with questions or for additional information.

Sincerely,

Abe's Garden

Academy of Radiology Research

ActivistsAgainstAlzheimer's Network

African American Network Against Alzheimer's

Alliance for Aging Research

Alliance for Patient Access

Alzheimer's & Dementia Alliance of Wisconsin

Alzheimer's Foundation of America

Alzheimer's Tennessee

AMDA – Dedicated to Long Term Care Medicine™

American Association for Geriatric Psychiatry

American Association for Long Term Care Nursing

Assisted Living Federation of America

Laura D. Baker, PhD (Wake Forest School of Medicine*)

Banner Alzheimer's Institute

B'nai B'rith International

BrightFocus Alzheimer's Disease Research

Caregiver Action Network

Cleveland Clinic Foundation

Coalition for Imaging and Bioengineering Research

Cognition Therapeutics

Cortica Neurosciences, Inc.

Critical Path Institute

Jeffrey Cummings, MD, ScD (Cleveland Clinic Lou Ruvo Center for Brain Health*)

Cure Alzheimer's Fund

Darrell K. Royal Fund for Alzheimer's Research

Rachelle S. Doody, MD, PhD (Baylor College of Medicine*)

Geoffrey Beene Foundation - Alzheimer's Initiative

Georgetown University Medical Center Memory Disorders Program

Gerontological Society of America

Home Instead Senior Care

Howard University, Aging and Memory Disorder Programs

Huntington's Disease Society of America

Inspire

Janssen Alzheimer Immunotherapy

Janssen Research & Development, LLC

Keep Memory Alive

Latino Alzheimer's and Memory Disorders Alliance

LeadingAge

Lewy Body Dementia Association

Linked Senior, Inc.

David G. Morgan, PhD (USF Health Byrd Alzheimer's Institute*)

National Association of States United for Aging and Disabilities

National Caucus and Center on Black Aged, Inc.

National Consumer Voice for Quality Long-Term Care

National Down Syndrome Society

National Task Group on Intellectual Disabilities and Dementia Practices

Neurotechnology Industry Organization

New York Academy of Sciences

NYU Langone Comprehensive Center on Brain Aging/NYU Langone Silberstein Alzheimer's Institute

NYU Alzheimer's Disease Center

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OWL-The Voice of Midlife and Older Women

Piramal Imaging

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Sage Bionetworks

Stephen Salloway, M.D., M.S. (The Warren Alpert Medical School of Brown University*)

Sanofi US

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R. Scott Turner, MD, PhD (Georgetown University Memory Disorders Program*)

USAgainstAlzheimer's

USF Health Byrd Alzheimer's Institute

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* *Affiliations of individual researchers are for identification purposes only and do not necessarily represent the endorsement of the affiliated institution.*