



July 26, 2017

USPSTF Coordinator  
c/o USPSTF  
5600 Fishers Lane  
Mail Stop 06E53A  
Rockville, MD 20857

RE: USPSTF Draft Research Plan for Cognitive Impairment in Older Adults:  
Screening

Dear USPSTF Members:

Thank you for the opportunity to provide comment on the U.S. Preventive Services Task Force (USPSTF Draft Research Plan for Cognitive Impairment in Older Adults: Screening. Please note: this public comment letter reflects my own views based on more than 20 years of professional experience in dementia policy and working with many thousands of affected individuals, but does not purport to speak for the views of LEAD Coalition member organizations.

I write in support of the Draft Research Plan, which should help to erode the harmful notion that physicians only need to or ought to diagnose that which they are able to cure. More important, screening for cognitive impairment in community-dwelling older adults in primary care-relevant settings (“tailored screening”) would create a pathway for beneficial patient, family/caregiver, and societal outcomes.

Ideally, such tailored screening would result in each patient having a cognitive health baseline recorded in the medical record and then periodically reassessed at regular intervals (or upon subjective complaint or provider observation of concerns) much like standard vital signs to detect change over time. Such tailored screening and routine monitoring would ease the worry of those who, in fact, do not have cognitive impairment or allow them to explore non-cognitive impairment explanations for their subjective complaints. When such tailored screening does indicate potential cognitive impairment (even in the absence of subjective complaint or provider observation), the provider will be able to proceed to more formal assessment and diagnosis. In turn, early and accurate diagnosis

would lead to better outcomes and higher quality of life for patients and their families by:

- Reducing disease-related stigma;
- Maximizing the opportunity for patients to consider their wishes and preferences for care and quality of life, communicate those wishes and preferences to family and providers, and begin taking action to facilitate and ensure adherence to those wishes and preferences to the greatest extent possible (including legal, financial, medical, spiritual and lifestyle planning, along with decisions about participation in research studies);
- Allowing the development of an integrated informal and formal care team, including time to secure education and supportive services;
- Providing timely access to approved medications and social/behavioral interventions.
- Enabling family and other informal caregivers time to make their own plans about balancing other personal and professional responsibilities (including, but not limited to, their own financial, physical and spiritual wellbeing).

The National Institute on Aging recognized in its 2008 report entitled “Alzheimer’s Disease: Unraveling the Mystery” ([http://adrccares.org/wp-content/uploads/2016/01/alzheimers\\_disease\\_unraveling\\_the\\_mystery\\_0.pdf](http://adrccares.org/wp-content/uploads/2016/01/alzheimers_disease_unraveling_the_mystery_0.pdf)) 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 study.” The value of knowing includes supporting the individual’s right to information to make the best health care and support choices.

Done properly, tailored screening, followed by appropriate detection and diagnosis would help account for the full scope of the public health burden and generate data for bench and social science researchers, policy makers, and health system decision-makers (e.g. payers, accreditation organizations, etc.).

Such tailored screening also is consistent 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 assessment as part of the Medicare Annual 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. Additionally, CMS clearly conveyed its recognition for the value of care planning support in its 2017 Physician Fee Schedule (see the new code G0505).

Put succinctly, it is better for everyone – individual patients, their families, their providers, and society as a whole – to replace ignorance or fear with knowledge and the opportunity to take constructive action.

*However, the Draft Research Plan specifically excludes people with Down syndrome without sufficient rationale. As noted by the National Task Group on Intellectual Disabilities and Dementia Practices, there are three primary reasons for concern about this exclusion:*

- 1. There is a wealth of studies related to dementia and Down syndrome, many of which offer value and can add to the empirical base for the analyses to be undertaken;*
- 2. There is an implicit danger that the Draft Research Plan will expand its exclusion to people with intellectual disability in general and thus create an exclusion bias simply because of population group generalization; and*
- 3. There already exists a bias in screening efforts against instrumentation appropriate for people with Down syndrome and intellectual disability, so their omission from this Draft Research Plan will continue that bias and set back national efforts for inclusion of screening instruments tailored to populations with pre-existing cognitive limitations.*

*The omission of studies entailing people with Down syndrome and those with other intellectual disability would overlook the amount of dementia-related work currently being undertaken with these groups. It also would create significant barriers to the effective early detection and screening for dementia of people with intellectual disability.*

Multiple instruments are available to assess individuals for cognitive impairment and decline. 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). 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. A number of 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— similar to other established screening tests such as a mammography and Pap smear. 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. After receiving and reviewing the results, primary care providers have the opportunity to discuss the findings with screened individuals during an office visit.

- Burns A, Lawlor B, Craig S. *Assessment scales in old age psychiatry*. London: Martin Dunitz Ltd, 1999.
- Ashford JW. Screening for Memory Disorder, Dementia, and Alzheimer's disease. *Aging Health*. 2008 4(4):399-432.
- Mendiondo MS, Ashford JW, Kryscio RJ, Schmitt FA. Designing a Brief Alzheimer Screen (BAS). *J Alzheimers Dis*. 2003 Oct;5(5):391-8.
- 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.
- 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.
- Burns A, Lawlor B, Craig S. *Assessment scales in old age psychiatry*. London: Martin Dunitz Ltd, 1999.
- 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.
- National Cancer Institute. *Breast Cancer Screening Modalities*. <http://www.nci.nih.gov/cancertopics/pdq/screening/breast/HealthProfessional/page5>.
- 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.
- 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.
- 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.
- 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.

The potential for harm lies not in tailored screening and establishment of a cognitive health baseline, but in whether some providers fail to take the appropriate steps beyond screening. If providers fail to communicate results from such tailored screening in a clear, timely, compassionate, and actionable manner, it would impede patients and families from making informed choices. When tailored screening shows no indication of cognitive impairment, patients and families properly informed of the results are able to work with providers to look for other explanations of subjective complaints or concerning provider observations. When tailored screening indicates possible cognitive impairment, patients and families properly informed of the results are able to work with providers to seek full assessment and diagnosis as appropriate. That full work-up is the opportunity to catch false-positives or to act on confirmed cognitive impairment, which then gives patients and families the opportunity for planning to start as early as possible and with the highest degree of patient decision-making. But if providers fail to communicate results, do so after significant delay, or with a lack of compassion, clarity or support for access to services, all the benefits are squandered. So the potential harm lies in failing to equip providers with the available tools (see: <https://www.geron.org/programs-services/alliances-and-multi-stakeholder-collaborations/cognitive-impairment-detection-and-earlier-diagnosis>) to do the full job appropriately.

Undetected cognitive impairment increases the likelihood of avoidable medical complications such as delirium, adverse drug reactions and noncompliance, each of which can reduce the health and autonomy of individual patients. Additionally, unexplained changes in cognition and/or behavior can be attributed wrongly to other medical or personal explanations with the attendant risk of unnecessary and potentially harmful health and personal consequences. For example, it is not uncommon for people who have undiagnosed young onset Alzheimer's disease or other less common forms of dementia to be misdiagnosed and treated for non-existent mental health conditions and suffer loss of employment or breakdown of familial relationships. For the healthcare system, precious provider time and payer funds can be wasted on misdiagnosis and consequent mis-treatment of people who have undiagnosed cognitive impairment.

Adverse outcomes from screening programs are rarely reported in published peer-reviewed literature or experienced by community providers. Published studies on screening for community-based elders demonstrate effectiveness and acceptance.

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

- *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*

That said, there is value in continuing to develop improved tools for screening for cognitive impairment in community-dwelling older adults in primary care–relevant settings.

The practical reality is that the progressive cognitive decline intrinsic to most forms of dementia places a premium on making planning decisions as early in the disease course as possible. Delay in reaching a diagnosis risks the individual having lost the ability to fully participate in decision-making. That is an unfair, unreasonable and – with the benefit of tailored screening to aid in early detection and diagnosis – unnecessary burden on the individual and his or her family and other caregivers.

## **Conclusion**

**At a time when opportunities are within grasp for profound advances in public attitudes, scientific research, and quality of life interventions, it is vitally important that USPSTF move forward with its Draft Research Plan (amended to include people with Down syndrome and other intellectual disabilities). 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.**

If at any time and in any way, the LEAD Coalition<sup>1</sup> community may be of assistance in moving the Research Plan forward, please do not hesitate to contact me.

Sincerely,

Ian Kremer, Esq.  
Executive Director  
LEAD Coalition

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<sup>1</sup> <http://www.leadcoalition.org> Leaders Engaged on Alzheimer’s Disease (the LEAD Coalition) is a diverse national coalition of member organizations including patient advocacy and voluntary health non-profits, philanthropies and foundations, trade and professional associations, academic research and clinical institutions, and home and residential care providers, and biotechnology and pharmaceutical companies. The LEAD Coalition works collaboratively to focus the nation’s strategic attention on dementia in all its causes -- including Alzheimer’s disease, vascular disease, Lewy body dementia, and frontotemporal degeneration -- and to accelerate transformational progress in detection and diagnosis, care and support, and research leading to prevention, effective treatment and eventual cure.