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FDA Dockets Management System
2004S-0170 Medicare Prescription Drug, Improvement, and Modernization
Act of 2003, Section 1013: Suggest Priority Topics for Research

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The American Association of Geriatric Psychiatry (AAGP), an organization of about 2,000 geriatric psychiatrists and mental health-professionals trained to provide care for elderly, frail, and chronically ill older patients, is pleased to respond to the request for comments to help develop a Department of Health and Human Services (HHS) research agenda on outcomes and clinical effectiveness in relation to the Medicare prescription drug benefit.

In this, we would like to focus on the use of psychotherapeutic medications in the elderly, including the antidepressant, antipsychotic, antianxiety, and anti-dementia medications that are used to treat the psychiatric disorders of late life, including major depression, psychosis and memory-impairing illnesses such as Alzheimer's disease and related disorders.

Neuropsychopharmacological treatment is increasingly based on advances in basic and clinical neuroscience, and it has been shown to increase the mental health, overall health, thinking, and quality of life of older people with affective, psychotic, anxiety, and cognitive disorders.

The use of these medications is second only to the use of cardiovascular medications among older patients, including the frail and chronically ill elderly. However, the research and evidence base underlying this use is limited. In fact, most of the medications used in the elderly, psychiatric medications and others, have been tested only in younger and healthier patients.

Indications that this can compromise care comes from recent findings from the body of available research, including evidence that commonly used antidepressants may have marginal effects for depression in the oldest-old, that another antidepressant that is safe and effective in younger adults may be poorly tolerated in the frail elderly, that the atypical antipsychotic agents often used for the treatment of the psychotic and aggressive symptoms that can complicate Alzheimer's disease may lead to cerebrovascular events and increased mortality in nursing home residents, and that anti-dementia agents may have efficacy of borderline significance. Moreover, these medications are costly. Newer antidepressants are consistently among the most widely prescribed medications. In addition, both the newer antidepressants and the atypical antipsychotic agents are consistently among the agents that are most costly to health systems and formularies, especially those in the public sector.

We suggest the following specific priorities for research in this area:

HHS and its partners should create data systems that include both Medicare (Parts A and B) and pharmacy claims data as well as those that include both Minimum Data Set information from nursing homes and ongoing records of medication use to support the evaluation of treatment outcomes and surveillance for adverse effects that emerge specifically in the elderly. Findings from these data systems could serve to guide clinical care, and to identify specific questions of clinical, economic, and public health importance that could only be answered by clinical trials. These data systems and support for analyses should be made available to investigators in academic settings as well as to those in relevant governmental agencies.

The FDA should conduct or facilitate analyses of the safety and clinical effectiveness of neuropsychiatric medications in the elderly from the data that is available to it. These analyses should extend from antipsychotic medications to the other classes of psychiatric treatments, including antidepressants and anti-dementia medications.

HHS should establish Geriatric Neuropsychopharmacology Research Units in academic settings to provide the infrastructure needed to conduct clinical trials (including comparative studies as well as tests of efficacy and effectiveness) of medications in the elderly, especially those who are among the oldest-old, and the frail elderly. These urgently needed units would be similar to the Research Units on Pediatric Psychopharmacology supported by the National Institute of Mental Health, and would collaborate with both public and private partners to implement specific trials.

Because Medicare is now a payor for both pharmacy costs and professional services, HHS should support comparative studies and clinical demonstrations evaluating the extent to which disease management strategies can improve the efficiency and value of pharmacological treatments for the elderly. It should also support studies of the comparative effectiveness and value of pharmacological and time limited behavioral treatments. Recent findings from the NIMH-supported PROSPECT study and the Hartford Foundation-supported IMPACT study demonstrate the effectiveness of disease management strategies for major depression for elderly primary care patients. With the changes in the scope of Medicare, further research on these and related strategies that combine clinical services and medications could point the way to major improvements in the quality, value, and efficiency of care for the elderly.

HHS and Medicare should support the NIH in extending clinical trials of psychopharmacological treatments to the elderly. NIMH has a highly productive program of geriatrics interventions research that has supported the acquisition of much of the current evidence base in this area. However, given the scope of the problem, the costs, and the risks of treating older people with unvalidated medications tested in younger individuals, this program is grossly under-funded.

If you should have comments or questions on this letter, please contact Christine deVries, AAGP Executive Director, at 301-654-7850 x101; cdevries@aagponline.org.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Anand Kumar', with a stylized flourish at the end.

Anand Kumar, MD
President