

EMBARGOED FOR RELEASE UNTIL MONDAY, JULY 25, 2016, 8 AM ET

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FROM THE 2016 ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE

FOCUS ON HEALTH POLICY AND HEALTH ECONOMICS

NEW STUDY SUGGESTS THAT TREATING PEOPLE WITH ALZHEIMER'S MAY INCREASE SURVIVAL AND INCUR LESS COST OF CARE (vs. NON-TREATMENT)

- *1 in 7 U.S. hospital admissions of people with Alzheimer's are potentially avoidable, cost Medicare \$2.6 billion annually -*
- *Medicare Annual Wellness Visit implemented on a broad scale in one large Midwestern health system; offers an opportunity to identify cognitive impairment -*
- *World Health Organization identifies dementia prevention, risk reduction and delivery of high quality care as global dementia research priorities -*

TORONTO, July 25, 2016 – Important health policy and health economic research findings were reported today at the Alzheimer's Association International Conference 2016 (AAIC 2016) in Toronto, that shed light on system changes that may lead to potential costs savings, increased survival and reduced burden of Alzheimer's disease - on individuals, families and the healthcare system.

One study revealed that even without a treatment that changes the underlying course of the disease, there is an economic benefit of ensuring people with Alzheimer's receive the current standard of care for indicated medications. The study showed that treated patients cost the healthcare system less than those who do not receive medication for Alzheimer's disease; they also had lower mortality rates during the study compared to untreated patients.

“The new results support that early Alzheimer's treatment - even with today's first generation therapies - has significant potential to benefit the person with the disease, and the economy,” said Maria C. Carrillo, PhD, chief science officer, Alzheimer's Association. “Today, Alzheimer's is incurable and progressive, and some assume that treating dementia is an unjustified cost drain on our healthcare system, but this study presents compelling arguments for prescribing the standard of care.”

In other studies reported at AAIC 2016:

- More than 369,000 U.S. hospital admissions of people with Alzheimer's in 2013 were potentially avoidable; these preventable hospital visits cost Medicare \$2.6 billion.
- The Medicare Annual Wellness Visit (AWV) offers an opportunity to establish a cognitive baseline, identify changes over time, and detect cognitive impairment. The AWV is being successfully implemented on a wide scale by a large Midwestern health system. The study shows that better communications are needed to draw more males, African-Americans, Hispanics, and older people into the program.

- To advance the global dementia research agenda, the World Health Organization has identified priority areas for focus and investment by funders, researchers and policymakers by a globally representative and systematic mechanism.

Comparison of All-Cause Mortality Rate and Economic Burden Between Newly Diagnosed Alzheimer's Disease Patients Who Received Anti-Dementia Treatment Versus Not: A Longitudinal Retrospective Study

Because there is currently no treatment that changes the underlying course of Alzheimer's disease, few studies have examined existing medical therapies for their economic and mortality impact, including comparing treated versus untreated people with newly diagnosed Alzheimer's disease in the U.S.

Researchers sought to understand all-cause mortality rates and healthcare costs among people with incident Alzheimer's disease through a longitudinal retrospective study. They identified 6,553 incident individuals with Alzheimer's, mostly female (74.5%), average age 83, from Medicare fee-for-service claims over two years. Participants were followed until death, disenrollment or the end of the study period - whichever happened first. Patients were assigned to Treated and Non-treated groups based on whether they were prescribed an existing Alzheimer's drug after diagnosis. Groups were matched based on demographics and health status.

The researchers found that, among 1,338 matched patients:

- Those who had never been treated were generally older, had more comorbidities and a death rate that was almost twice as high as the people who received treatment during the analyzed time period.
- Healthcare expenditures were higher for the people who did not receive an Alzheimer's treatment.

Average health care costs more than tripled in the first month following an Alzheimer's diagnosis for all study participants. Those receiving an Alzheimer's treatment had lower overall health care costs in the month they were diagnosed compared with those who did not receive a treatment (\$5,535 vs. \$6,711). Following the month of diagnosis, all-cause healthcare costs decreased but the average cost per-patient per-month still remained considerably higher than baseline.

The biggest contributor to this cost increase was inpatient care, which accounted for 30% of the total expenditures for both groups. Though individuals who initiated taking medications approved for treating dementia experienced an increase in pharmacy costs, on average, their total health expenditure was less than the individuals who did not take approved medications (\$2,207 vs. \$2,349 per patient per month) during the follow-up period.

“The arguments for early treatment are myriad, but this study shows greater survival and less all-cause healthcare costs among those receiving treatment for dementia,” said Christopher M. Black, MPH from Merck Research Laboratories. “These results indicate that choosing not to treat, or even a delay in starting treatment, may lead to less favorable results. Early diagnosis and time to treatment should be a priority for policymakers, physicians and the public.”

National Estimates of Potentially Avoidable Hospitalizations Among Medicare Beneficiaries with Alzheimer's Disease and Related Dementias

The great majority of people with Alzheimer's are older adults and at least 75% of them have multiple health problems, such as heart disease and diabetes, that require regular and specific medical management. Because of its impact on memory, thinking and behavior, Alzheimer's disease can significantly complicate management of other chronic conditions, putting people with dementia at high risk for hospitalizations that may be preventable with proactive care.

Using Medicare claims data, a group of researchers from Boston and New York measured potentially avoidable hospitalization (PAH) rates for Ambulatory Care Sensitive Conditions, and the associated Medicare expenditures, for 2,749,172 people diagnosed with Alzheimer's or other dementia. PAH rates were examined for acute (i.e., bacterial pneumonia, urinary tract infection and dehydration) and chronic conditions (i.e., diabetes, cardiovascular diseases and respiratory conditions), and overall composite PAH rates.

They found that, in 2013:

- One in ten (10%) people in the study had at least one PAH.
- One in seven (14%) hospital admissions among study participants was a PAH.
- 369,165 PAHs (13,428 hospitalizations per 100,000 population) were identified in the study group, totaling \$2.58 billion in Medicare expenditures, of which:
 - 188,870 were for acute conditions, accounting for 47% of overall PAH costs.
 - 180,307 were for chronic conditions, representing 53% of total PAH costs.
- Late-stage dementia and having multiple chronic comorbidities were significantly associated with PAHs, after adjusting for other patient characteristics.

“Our findings suggest that management of co-existing diseases remains suboptimal among many people with Alzheimer's or other dementias, especially those with advanced disease,” said Pei-Jung Lin, Ph.D., from the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center, Boston, who was first author on the study. “In 2013, for example, more than 369,000 hospital stays and \$2.58 billion in Medicare costs could have been prevented with better ambulatory care and effective treatment. Case management programs for people with Alzheimer's and other dementias should involve strategies to reduce avoidable hospitalizations in order to improve patient outcomes and lower costs.”

The Medicare Annual Wellness Visit as an Opportunity for Improving Detection of Cognitive Impairment: The Experience of a Large Midwestern Health System

The Medicare Annual Wellness Visit (AWV) must include an assessment of an individual's cognition. In 2013, only 11% of Medicare beneficiaries nationally used the AWV, raising concerns about whether the AWV is promoting cognitive health and early detection of cognitive impairment (CI). Researchers at Allina Health, a large Midwest health system, examined the uptake and demographics of their outpatient Medicare population that received an AWV.

Researchers extracted data from electronic health records (EHR) of 105,387 Allina ambulatory patients age 65 and older with at least one outpatient Medicare claim during the prior 12 months and at least two visits to an Allina primary clinic during the study period (1/1/11 to 3/1/15), and who consented to use of their health care data for research.

Findings revealed that 44.2% of eligible participants had at least one AWV during the study period, with annual increases in the proportions of eligible individuals participating (22.2% in 2011; 31.1% in 2014).

- The proportion with at least one AWV was significantly higher among patients who were female, white or Asian, non-Hispanic, age 70-74, and who were patients in the system's South and East metro regions (all $p < 0.01$).
- Demographic groups shown to have higher rates of dementia in epidemiological studies (e.g., people age > 74, African Americans, Hispanics/Latinos) were less likely to have had an AWV, suggesting opportunities for further improvement.

“The Medicare annual wellness visit can be implemented on a broad scale and sustained over time in health systems, and offers a regular opportunity to establish a baseline measurement and identify changes that may indicate Alzheimer's or another dementia,” said Pamela Mink, PhD, MPH, of Allina Health, Minneapolis, and presenting author on the study. “Unfortunately, even in our study, the people most vulnerable to dementia are skipping the annual wellness visit, while healthier people show higher usage. Our ongoing research will examine how providers can use the data in subsequent clinical care.”

“It is concerning to see that - even in this more successful study group - still less than half of eligible people are participating in the annual wellness visit, thus missing out on a vital opportunity for detection of cognition impairment,” said Carrillo. “Policymakers and healthcare providers need to deliver a powerful message to seniors to take part in the annual wellness visit, especially those in the most at-risk groups.”

From the WHO Research Priorities and Research Portfolio Analysis to the Identification of Research Gaps to Reduce the Global Burden of Dementia

Alzheimer's disease and related dementias are a global epidemic. According to the World Alzheimer Report 2015 from Alzheimer's Disease International, at least 46.8 million people worldwide were living with dementia. This number will nearly double every 20 years, reaching 74.7 million in 2030 and 131.5 million in 2050. The Report says the global costs of dementia have increased 35.4% from 2010 to 2015.

At the March 2015 World Health Organization (WHO) First Ministerial Conference on Global Action Against Dementia, 160 delegates adopted a Call for Action to reduce the global burden of dementia. The WHO's Executive Board in May 2016 noted that the response to the global burden of dementia can be greatly enhanced by a shared commitment among countries to put in place the necessary policies and resources for care of people with dementia, promote research, and give adequate priority to action against dementia in national and global political agendas.

In order to advance the global dementia research agenda and inform investment priorities, the WHO led a research prioritization exercise, and reported the results at AAIC 2016. This was the most globally representative priority setting exercise in dementia to date. WHO coordinated the process adapted from the Child Health and Nutrition Research Initiative (CHNRI) to produce the priority list. More than 200 researchers and stakeholders contributed research questions that were consolidated into 59 research avenues. These avenues were scored anonymously by 162 researchers and stakeholders from 39 countries according to five criteria: potential for success, impact on burden reduction, potential for conceptual breakthrough, potential for translation and equity.

Overarching research goals identified by the exercise were:

- Prevention and risk reduction.
- Diagnosis, biomarker development and disease monitoring.
- Drug and non-drug treatment research.
- Quality and delivery of care for people with dementia and their caregivers.
- Physiology and progression of normal ageing and disease.
- Increasing public awareness and understanding.

“Our hope is that the research priorities identified by this intensive and systematic international process will inform and motivate policymakers, funders and researchers to reduce the global burden of dementia,” said Hiral Shah, MD, Columbia University Medical Center, presenting author of the study. “Future aims include identifying culture and system-specific research priorities, and identifying gaps and opportunities for increased investment.”

“The urgency is clear, yet more governments still need to make funding dementia research a high priority,” said Heather M. Snyder, PhD, Alzheimer’s Association senior director of medical and scientific operations, and a member of the Advisory Group for the project. “Because resources are limited, even if recently increasing, there is an urgent need to set research priorities to guide policymakers and funders as they work to advance dementia research.”

About AAIC

The Alzheimer’s Association International Conference (AAIC) is the world’s largest gathering of researchers from around the world focused on Alzheimer’s and other dementias. As a part of the Alzheimer’s Association’s research program, AAIC serves as a catalyst for generating new knowledge about dementia and fostering a vital, collegial research community.

AAIC 2016 home page: www.alz.org/aaic/

AAIC 2016 newsroom: www.alz.org/aaic/press.asp

About the Alzheimer’s Association®

The Alzheimer’s Association is the leading voluntary health organization in Alzheimer’s care, support and research. Our mission is to eliminate Alzheimer’s disease through the advancement of research, to provide and enhance care and support for all affected, and to reduce the risk of dementia through the promotion of brain health. Our vision is a world without Alzheimer’s. Visit alz.org or call 800.272.3900.

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- Christopher M. Black, MPH, et al. Comparison of All-Cause Mortality Rate and Economic Burden Between Newly Diagnosed Alzheimer’s Disease Patients Who Received Anti-Dementia Treatment Versus Not: A Longitudinal Retrospective Study. (Funder: Merck)
- Pei-Jung Lin, PhD, et al. National Estimates of Potentially Avoidable Hospitalizations Among Medicare Beneficiaries with Alzheimer’s Disease and Related Dementias. (Funder: Alzheimer’s Association)
- Pamela Mink, PhD, MPH, et al. The Medicare Annual Wellness Visit As an Opportunity for Improving Detection of Cognitive Impairment: The Experience of a Large Midwestern Health System. (Funder: Allina Health)
- Hiral Shah, MD, et al. From the WHO Research Priorities and Research Portfolio Analysis to the Identification of Research Gaps to Reduce the Global Burden of Dementia. (Funder: The UK Department of Health)

Proposal ID: O2-11-02

Oral session, Monday, July 25, 2016: 4:15-5:45 PM

Topic selection: Health Economics and Policy: Understanding and Modeling Health Economics

Comparison of All-Cause Mortality Rate and Economic Burden Between Newly Diagnosed Alzheimer's Disease Patients Who Received Anti-Dementia Treatment Versus Not: A Longitudinal Retrospective Study

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Background: Few studies have evaluated all-cause mortality and economic burden of treated versus untreated patients newly diagnosed with Alzheimer's disease (AD) in the U.S. This study examined all-cause mortality rates and burden of illness among incident AD patients.

Methods: Patients with ≥ 1 primary or ≥ 2 secondary AD diagnoses claims [International Classification of Disease, 9th Revision Clinical Modification (ICD-9-CM) code 331.0] were identified from Medicare fee-for-service claims from 01JAN2011–30JUN2013. Study sample included Medicare beneficiaries age 65-100 years with continuous medical and pharmacy benefits for ≥ 12 months pre-index (baseline period) and ≥ 6 months post-index date (first AD diagnosis date). Patients were followed until the earliest of death, disenrollment or 31DEC2013 (follow-up period). Patients were assigned to Treated and Non-treated cohorts based on anti-dementia treatment received post-index date. Mortality incidence rate (100 person-years), healthcare costs and utilizations were evaluated post-index date. One-to-one propensity score matching (PSM) used to adjust for baseline differences between the study cohorts. Time-to-death was assessed using Kaplan-Meier curve and Cox regression over PSM-matched population.

Results: A total of 6,553 incident AD patients were identified, mostly female (74.22%) between 75-84 years (39.72%). Patients received anti-dementia medication (N=2,322; 35%) on average 34 days post-AD diagnosis; mean follow-up days for treated and untreated patients was 611.18 vs. 592.40, $p < 0.0055$. Treated patients received donepezil (66.86%), memantine (18.59%), rivastigmine (12.54%) and galantamine (2.02%) as their first treatment. Untreated patients were older (83.85 vs. 81.44 years, $p < 0.0001$), with more severe baseline comorbidities (Mean Charlson comorbidity index: 3.54 vs. 3.20, $p < 0.0001$) and high unadjusted incidence rate of death (17.36 vs. 10.00 ; in 100 person-years, $p < 0.0001$). After 1:1 PSM, 694 patients with well-balanced baseline characteristics were matched from treated and untreated cohorts. Treated AD patients had better survival (Hazard ratio= 0.722, $p = 0.0079$), less monthly hospice visits (0.04 vs. 0.09, $p = 0.0001$), and lower monthly all-cause cost (\$2,207 vs. \$2,349, $p = 0.3037$) compared to untreated patients.

Conclusions: Newly diagnosed AD patients who did not receive anti-dementia treatment were older patients with more severe comorbidities. Even after adjusting for demographic and clinical differences, results suggested that treated AD patients had lower all-cause healthcare costs and lower mortality rates compared to untreated patients.

Proposal ID: O2-11-01

Oral session: Monday, July 25, 2016: 4:15-5:45 PM

Topic selection: Health Economics and Policy: Understanding and Modeling Health Economics

National Estimates of Potentially Avoidable Hospitalizations Among Medicare Beneficiaries with Alzheimer's Disease and Related Dementias

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Background: Alzheimer's disease and related dementias (ADRD) can complicate management of some comorbidities, putting patients at high risk for hospitalizations that may be preventable with proactive ambulatory care.

Methods: Using Medicare claims data, we identified 2,749,172 fee-for-service beneficiaries aged ≥ 65 who were continuously enrolled in Medicare Parts A and B during 2013 and had a coded diagnosis of ADRD. We measured ADRD patients' potentially avoidable hospitalization (PAH) rates for Ambulatory Care Sensitive Conditions, as defined by the Agency for Healthcare Research and Quality, and the associated Medicare expenditures. We examined PAHs for acute (i.e., bacterial pneumonia, urinary tract infection and dehydration) and chronic conditions (i.e., diabetes, cardiovascular diseases and respiratory conditions), and overall composite PAH rates.

Results: In 2013, one in ten ADRD patients had at least one PAH, and one in seven (14%) hospital admissions among ADRD patients was for a potentially avoidable condition. We identified 369,165 PAHs (13,428 hospitalizations per 100,000 population) in the ADRD population, totaling \$2.58 billion in Medicare expenditures. Of these hospitalizations, 188,870 were for acute conditions, accounting for 47% of overall PAH costs; 180,307 hospitalizations were for chronic conditions, representing 53% of total PAH costs. Of the 280,547 ADRD patients with any PAHs, 50% were classified as having late-stage disease. Patients with advanced ADRD had a substantial number of PAHs (32,027 hospitalizations for acute conditions and 25,106 hospitalizations for chronic conditions, per 100,000 population). Late-stage ADRD patients accounted for 59% (\$1.53 billion) of the total PAH costs in the ADRD population. Late-stage ADRD and multiple chronic comorbidities were significantly associated with PAHs, after adjusting for other patient characteristics.

Conclusions: Our findings suggest that comorbidity management remains suboptimal among many ADRD patients, especially those with advanced ADRD. In 2013, as many as 369,165 hospital stays and \$2.58 billion in Medicare costs incurred by ADRD patients could have been prevented with better ambulatory care and effective treatment. Complex case management programs for ADRD patients should involve strategies to reduce PAHs in order to improve patient outcomes and lower costs.

Proposal ID: O2-01-05 (Monday oral)

Oral session. Monday, July 25, 2016: 2:00-3:30 PM

Topic selection: Dementia Care Practice: Innovative Programs and System Improvements

The Medicare Annual Wellness Visit As an Opportunity for Improving Detection of Cognitive Impairment: The Experience of a Large Midwestern Health System

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Background: The Centers for Medicare and Medicaid Services (CMS) require that the Medicare Annual Wellness Visit (AWV) include an assessment of cognition. In 2013, only 11% of Medicare Part B enrollees nationally used the AWV, raising doubt about its value in promoting cognitive health and early detection of cognitive impairment (CI). Allina Health, a large Midwest health system, was an early adopter of the AWV, using the Mini-Cog as its system-wide assessment tool. This study assesses the uptake and potential impact of the AWV at Allina.

Methods: Data were extracted from electronic health records (EHR) of Allina ambulatory patients, age 65 and older with at least one outpatient Medicare claim during the prior 12 months and at least two visits to an Allina primary clinic during the period of interest, and who consented to use of their health care data for research. There were 105,387 eligible patients identified for the period 1/1/11 – 3/1/15. Mini-Cog data were available beginning in 2/2012, with scores of 0-2 (out of 5) considered positive for CI.

Results: Overall, 44.2% of eligible patients had at least one AWV during the study period, with annual increases in the proportions of eligible patients participating (22.2% in 2011; 31.1% in 2014). The proportion with at least 1 AWV was significantly higher among patients who were female, white or Asian, non-Hispanic, age 70-74, and who were patients in the South and East metro regions (all $p < 0.01$). By contrast, positive Mini-Cog scores (6.1% overall) were more prevalent among patients who were male, African-American, Hispanic, or in older age strata (all $p < 0.01$).

Conclusions: The AWV can be implemented on a wide scale and sustained over time in health systems, and offers an opportunity to identify cognitive impairment among older Medicare recipients. Demographic groups with higher rates of dementia in epidemiological studies were more likely to have Mini-Cog scores consistent with CI (e.g., ages > 74 , African Americans, Hispanics/Latinos) but less likely to have had an AWV, suggesting opportunities for further improvement. Ongoing research examines how providers use AWV data on possible CI in subsequent clinical care.

Proposal ID: 12426

Focused Topic Session: Apples to Apples? Comparing National Alzheimer's Research Programs and Global Research Priorities (FTS2-01-05)

Monday, July 25, 2016: 2:00-3:30 PM, Metro Toronto Convention Centre, 104

From the WHO Research Priorities and Research Portfolio Analysis to the Identification of Research Gaps to Reduce the Global Burden of Dementia

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Background: WHO has conducted a dementia research prioritization exercise to inform investment priorities, and has examined the research portfolios of the G7 countries, with the aim to advance the global dementia research agenda.

Methods: We identified the global dementia research priorities using an adapted Child Health and Nutrition Research Initiative (CHNRI) methodology. The CHNRI methodology consists of five steps: i) Scope definition ii) Collection of research topics from a wide range of researchers and stakeholders iii) Consolidation of topics iv) Scoring of consolidated topics v) Computation of scores to produce the priority list. 59 research questions were identified and ranked. We used a matrix defined by research themes and domains to categorize these priorities and to systematize the research landscape analysis. We identified four themes of prevention, diagnosis, treatment, and care, and three research domains: Basic, Clinical-Translational, and Implementation Science.

Results: The theme of dementia risk reduction was the most dominant and received the highest overall research priority score. Prevention, identification and reduction of dementia risk, and delivery and quality of care for people with dementia and their caregivers were the broad themes of 6 of the top 10 overall research priorities. In the extended top 20 priorities list, diagnosis and biomarker research and treatment development represented 7 of the top priorities. Basic research into disease mechanisms was considered to have the greatest potential for conceptual breakthrough. The country data on funded, ongoing research were categorized according to the three research domains only as insufficient level of detail precluded further analysis. The categorization was validated by two independent researchers by: (1) the number of research projects by year (and sub-categorized by agency, when able) and (2) categorization of unique research projects by year.

Conclusions: Research priorities identified by this systematic international process should inform and motivate policymakers, funders and researchers to support and conduct research to reduce the global burden of dementia. Key to future efforts to examine research portfolios globally is the development of a harmonized categorization system and data collection effort. Ultimately, countries may best address funding gaps in research as they review and revise their plans to match identified priorities.

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