CURRICULUM VITAE

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EDUCATION

2020 **University of Maryland School of Pharmacy, Baltimore, MD**
Department of Pharmaceutical Health Services Research (PHSR)
PhD anticipated May 2020, CER/PCOR Concentration
Dissertation Title: *Impact of the Medicare Annual Wellness Visit on Geographic Variation in Dementia Diagnosis*
Advisor: Eleanor M. Perfetto, PhD, MS

2007 **Yale School of Epidemiology and Public Health, New Haven, CT**
MPH, Biostatistics Concentration
Master's Thesis Title: *Propensity Score Analysis of Longitudinal Depressive Symptom Severity among Enrollees of the New Haven Healthy Start Program*
Advisor: Haiqun Lin, PhD

2005 **Spelman College, Atlanta, GA**
BS, Mathematics
Senior Research Project: *Understanding Singular Value Decomposition and its Significance beyond Linear Algebra*
Advisor: Sylvia S. Bozeman, PhD

WORK EXPERIENCE

2019- **Boehringer Ingelheim, Inc, Ridgefield, CT**
Associate Director, HEOR Value Demonstration Team, Immunology

– Developed and currently executing a HEOR strategy and evidence generation plan for pipeline immunology assets

- Includes conducting RWE studies, US payer and patient engagement, economic modeling to inform evidence needs and,
- Leading a cross-functional team to obtain US payer input to inform clinical trial design and evidence requirements for pre- and post-approval value dossiers

2014 –2019 **University of Maryland School of Pharmacy, Baltimore, MD**
Graduate Research Assistant, PHSR Department

– Deep Learning Prediction for Alzheimer's and Dementia project

- Served on a Technical Expert Team that applied deep learning techniques to build predictive models using 10 years of

longitudinal combined data set (claims, EHR, and NLP-derived concepts)

- Use of Big data for the Development of an Alzheimer's/Dementia Predictive Tool
    - Characterized longitudinal patterns of medical resource utilization (claims) of individuals with Alzheimer's/dementia prior to and after diagnosis, using a case-control design
    - Assessed differences in patterns of medical resource utilization (overall and disease-specific) to construct a predictive model to identify and facilitate more timely Alzheimer's/dementia
- International Society of Pharmacoeconomics and Outcomes Research (ISPOR) Patient-Centered Special Interest Group (SIG) initiative
    - Lead a systematic review and qualitative analysis of definitions for 'patient engagement' and 'patient centeredness'; specifically in the context of research and health care delivery
- Internship Summer 2017: Boehringer Ingelheim- Patience Advocacy and Relations Group
    - Conducted Key Informant Interviews on Understanding the Value of Patient Engagement Across the Pharmaceutical Development Lifecycle project
    - Developed a Patient-Engagement Evaluation plan to best assess the impact of patient engagement throughout the organization

2011-2014 **Pfizer Inc., Worldwide Research & Development, Cambridge, MA**
Manager, Research Statistics, Pharmatherapeutics Division

- Project Statistician for preclinical studies in the Cardiovascular and Metabolic Diseases (CVMED) Research Unit specializing in assay validation, study design, and analysis of best-in-class compounds in animal models
- Statistician for Safety Pharmacology Good Laboratory Practices (GLP) and Non-GLP Cardiovascular Assessment Studies

2007-2010 **Pfizer Inc., Worldwide Research & Development, Groton, CT**
Senior Associate, Nonclinical Statistics, Pharmatherapeutics Division

- Project statistician for a Zyvox® follow-up study commissioned by EMA to investigate Cytokine response in the presence of Lipopolysaccharide
- Project statistician for a PDE10 Huntington's Disease study to assess behavioral treatment differences in mice *Individual Performance Award*
- Team statistician for Regulatory Toxicology studies in Drug Safety R&D involving the analysis of ECG and clinical pathology endpoints for Neurological, Cardiovascular, and Antibacterial disease areas

- Site Subject Matter Expert for the statistical functionality of the *Biobook*; an electronic lab notebook for research biologists

2006-2007 **Yale University Department of Psychiatry, New Haven, CT**
Research Associate, Office of PMS and Postpartum Research

- Conducted eligibility screening and follow-up data collection for Cymbalta® efficacy studies
- Statistician for a study evaluating the effect of discontinuation of treatment for premenstrual dysphoric disorder

COMPUTER SKILLS

Proficiency: SAS, STATA, Spotfire DXP, ArcGIS, and Microsoft Office Suite
Working knowledge: R and SQL programming languages

PUBLICATIONS

Hanna ML, Love TR, Majid T, Rosenthal I, Albrecht JS, Simoni-Wastila L, Palumbo F, Perfetto EM. Pathway to Diagnosis: Persons with Dementia and Caregiver Experiences with Obtaining a Diagnosis (in development)

Hanna ML, Folley M, Albrecht JS, Simoni-Wastila L, Palumbo F, Majid T, Rosenthal I, Perfetto EM. Impact of Medicare Annual Wellness Visit on Geographic Variation in Dementia Diagnosis. (in development)

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Hanna ML, Oehrlein EM, Perfetto EM. An Introduction to Unit-of-Analysis Error. ISPOR Value & Outcomes Spotlight. May/June Issue 2016.

Benjamin S. Maciejewski, Jennifer L. LaPerle, Danny Chen, Avijit Ghosh, William J. Zavadoski, Thomas S. McDonald, Tara B. Manion, Dawn Mather, Terrell A. Patterson, **Maya Hanna**, Steven Watkins, E. Michael Gibbs, Roberto A. Calle, Claire M. Steppan. Pharmacological inhibition to examine the role of DGAT1 in dietary lipid absorption in mice and man." *American Journal of Physiology - Gastrointestinal and Liver Physiology.* Vol. 304 (2013) no. G958-G969

PRESENTATIONS AND POSTERS

Onasanya O, **Hanna ML**, Crawford T, Perfetto EM. Patients with Anti-Dementia Drug Use but No Documented Dementia-Related Diagnosis: How Do They Compare to Those with a Diagnosis? ISPOR. May 2019. New Orleans, Louisiana.

Hanna ML, Oehrlein EM, Perfetto EM. A Comparison of FDA and EMA Guidance on Medicines for the Treatment of Alzheimer's Disease. ISPOR Europe. November 2018. Barcelona, Spain.

Hanna ML, Albrecht JS, Kim D, Perfetto EM. Examining Disease-Specific Healthcare Utilization in Individuals with Dementia Prior to Diagnosis. Alzheimer's Association International Conference. July 2018. Chicago, Illinois.

Albrecht JS, **Hanna ML**, Kim D, Perfetto EM. Predictive Model for Earlier Diagnosis of Dementia. ISPOR. May 2018. Baltimore, Maryland.

Albrecht JS, **Hanna ML**, Kim D, Perfetto EM. Increased Healthcare Utilization in Dementia Subtypes Prior to Diagnosis. ISPOR. May 2018. Baltimore, Maryland.
Albrecht JS, **Hanna ML**, Kim D, Perfetto EM. A Method to Use Administrative Claims to Categorize Dementia Cases by Subtype. ISPOR. May 2018. Baltimore, Maryland.

Crawford T, **Hanna ML**, Perfetto EM. Anti-dementia Drug Use among Individuals without a Documented Dementia Diagnosis. Pharmacy Quality Alliance Conference. May 2018. Baltimore, Maryland.

Crawford T, **Hanna ML**, Perfetto EM. A Comparison of Patients Treated for Dementia With and Without a Documented Dementia Diagnosis. Academy of Managed Care Pharmacy. April 2018. Boston, Massachusetts.
Hanna ML, Albrecht JS, Kim D, Perfetto EM. Examining Disease-Specific Healthcare Utilization in Individuals with Dementia Prior to Diagnosis. UMB Graduate Research Conference. March 2018. Baltimore, MD.

Hanna ML, Smalley JB. Understanding the Value of Patient Engagement across the Pharmaceutical Development Lifecycle. Research Conference. Boehringer Ingelheim, August 2017. Ridgefield, CT.

Hanna ML, Kim D, Albrecht J, Perfetto EM. A Method for Identifying Long-Term Care Use in Claims Data. ISPOR 22st Annual International Meeting. May 2017. Boston, Massachusetts.

Berner T, **Hanna ML**, Wheeler R, Camp R. Patient Engagement, Patient Centric, What Does it All Mean? ISPOR 19th Annual European Congress Meeting. October 2016. Vienna, Austria.

Berner T, Perfetto EM, **Hanna ML**, Wheeler R, Camp R. Patient Engagement: Stopping to Define It. ISPOR 19th Annual European Congress Meeting. October 2016. Vienna, Austria.

Hanna ML, Oehrlein EM, Perfetto EM, Astratinei V, Berner T, Burke LB, Camp R, Hareendran A, Harrington R, Houÿez F, Patrick DL, Scott A, von Gizycki R, Wheeler R. Attributes Defining Patient Engagement and Centeredness in Health Care Research and Practice: A Framework Developed By The ISPOR Patient-Centered Special Interest Group. ISPOR 19th Annual European Congress Meeting. October 2016. Vienna, Austria.

Hanna ML, Oehrlein EM, Cooblall CA, Nguyen F, Perfetto EM, Patient Centered Special Interest Group. Definitions For Patient Engagement and Centeredness in Health Care Research and Practice: A Systematic Review by the ISPOR Patient Centered Special Interest Group. ISPOR 21st Annual International Meeting. May 2016. Washington, DC.

Hanna ML, Pickering MK, Albrecht JS, Oehrlein EM, Patterson CR, Musallam, AJ, Perfetto EM. Twenty-Year Trends in Diagnosis and Treatment of Alzheimer's Disease. ISPOR 18th Annual European Congress Meeting November 7-11, 2015 Milan, Italy.

Oehrlein EM, **Hanna ML**, Perfetto EM. IQWIG Early Benefit Assessments of Type 2 Diabetes Therapies. ISPOR 20th Annual International Meeting May 16-20, 2015 Philadelphia, PA.

Lederer HT, Perfetto EM, Pickering MK, **Hanna ML**. A Pilot Study Investigating Unit-of-Analysis Error in Studies of Pharmacist-Led Interventions for Hypertension. AMCP's Annual Meeting; April 7-10, 2015, San Diego, CA.

PROFESSIONAL AND ACADEMIC AFFILIATIONS

Association of Managed Care Pharmacy (AMCP)
International Society of Pharmacoeconomics and Outcomes Research (ISPOR)
International Society of Pharmacoepidemiology (ISPE)
International Society to Advance Alzheimer's Research and Treatment (ISTAART)
Rho Chi Society – Academic Honor Society in Pharmacy
Alpha Kappa Alpha Sorority, Inc.

LEADERSHIP AND COMMUNITY SERVICE

ISPOR Patient-Centered Special Interest Group - Leadership Team (2016-present)
UMB PHSR - Department Strategic Planning Committee (2016-2017)
UMB PHSR - Department Seminar Committee (2018-2019)
ISPOR-Public Relations Coordinator (2016-2017)
International Society of Pharmacoepidemiology - Treasurer (2016-2017)
UMB CURE Program www.umaryland.edu/cure-scholars/ - Mentor (2015-2018)

AWARDS AND GRANTS

2018 PHSR Student Travel Scholarship
2018 Md-Public Health Association Donald O. Fedder Research Competition 3rd Place
2017 PATIENTS Pilot Funding for PCOR (UMB/AHRQ)
2017 PhRMA Foundation Pre-doctoral Fellowship in Health Outcomes
2016 American Society of Health Economics conference Student Travel Fellowship
2016 ISPOR conference Student Travel Fellowship
2015 PHSR Donald O. Fedder Memorial Fellowship
2015 UMB Global Health Interprofessional Travel Grant – Cape Coast, Ghana
2015 UMB Center of Excellence in Regulatory Science & Innovation (M-CERSI)
Regulatory Science Talent Competition -1st Place

ABSTRACT

Title of Dissertation: Impact of the Medicare Annual Wellness Visit on Geographic Variation in Dementia Diagnosis

Maya Lee Hanna, Doctor of Philosophy, 2020

Dissertation Directed by: Eleanor M. Perfetto, Ph.D., Professor, Pharmaceutical Health Services Research, University of Maryland, Baltimore School of Pharmacy

Background: Alzheimer's-disease-and-related-dementia (ADRD) is often misdiagnosed or diagnosis is late in disease progression. Diagnosis variations can be driven by access variations related to geographic location. To improve timely and accurate ADRD diagnosis, the Medicare Annual Wellness Visit (AWV) required a cognitive assessment, starting in 2011, which may reduce diagnosis variations.

Objective: Assess impact of the AWV on geographic variation in ADRD diagnosis and outcomes.

Methods: Aim 1: ADRD patients and caregivers from western, central, and eastern Maryland were interviewed to understand diagnosis-pathway geographic differences. Data were analyzed using interpretative phenomenological analysis to identify themes. Aim 2: Using the CMS Chronic Condition Data Warehouse (CCW) and HRSA Area Health Resource Files, 5-year, county-level ADRD cumulative incidence were compared pre- (2006-2010) and post- (2011-2015) AWV implementation in Mid-Atlantic states. Geographically-weighted, generalized linear models assessed the association between the AWV and ADRD cumulative incidence, controlling for demographic and access measures. Aim 3: A retrospective cohort study using CCW was conducted in newly

diagnosed ADRD individuals. Health care utilization (HCU) was compared for individuals with an AWV pre-diagnosis versus no AWV. Difference-in-difference models assessed 10-month outcomes between exposure groups.

Results: Aim 1: Average time from first doctor visit (concerning signs/symptoms) to ADRD diagnosis was 3.3, 2, and 5.3 years for western, central, and eastern regions, respectively. Aim 2: AWV participation was not significantly associated with increased 5-year ADRD cumulative incidence. The association between AWV and 5-year ADRD cumulative incidence varied by county with stronger associations clustered in eastern Virginia, Maryland, and Delaware. Aim 3: Receiving an AWV pre-diagnosis was associated with increased HCU [ED (rate ratio [RR]: 1.20, 95% confidence interval [CI]: 1.11, 1.30), hospitalizations (RR: 1.26, 95% CI: 1.13, 1.40), and outpatient (RR: 1.08, 95% CI: 1.04, 1.12)].

Conclusions: Longer times to ADRD diagnosis were observed in rural versus urban regions. The AWV demonstrates the potential to minimize geographic differences by increasing diagnosis rates and HCU. Due to low and variable participation during early implementation, the true impact of the AWV is yet to be established. It may take longer to see impacts on longer-term outcomes.

Impact of the Medicare Annual Wellness Visit on Geographic Variation in Dementia Diagnosis

by
Maya Lee Hanna

Dissertation submitted to the Faculty of the Graduate School of the
University of Maryland, Baltimore in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy
2020

DEDICATION

To my mother, Melba Lee, my father, John Hanna, Jr., my grandparents, Thomas Lee, Nancy Lee, John Hanna, Ruby Hanna, and my ancestors.

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First, I give glory and honor to Jesus Christ for providing me the strength to endure my graduate studies with grace and tenacity. In the Bible, Proverbs 3:5-6 which says, “Trust in the Lord with all your heart, lean not to your own understanding; in all your ways acknowledge Him, and He shall direct your paths.” My faith to trust God’s plan for my life has truly been rewarding.

I would like to thank my committee chair and mentor, Dr. Eleanor Perfetto, for supporting my research interests, challenging me to think critically, and to write with purpose. Dr. Perfetto has spent countless hours advising, teaching, and molding me into the researcher I have become. During my time at the University of Maryland in the department of Pharmaceutical Health Services Research (PHSR), I have served on research teams under Dr. Perfetto’s leadership which enabled me to build an invaluable network of patients, researchers, and policymakers who have shaped my graduate experience. I truly respect Dr. Perfetto’s expertise and strategic mindset both academically and professionally.

I would also like to acknowledge the rest of my dissertation committee: Dr. Jennifer Albrecht, Dr. Tabassum Majid, Dr. Francis Palumbo, Ms. Ilene Rosenthal, and Dr. Linda Simoni-Wastila. I am truly grateful for their time and dedication throughout my entire dissertation process. They challenged me by setting a high standard for policy and patient-centered outcomes research. Dr. Majid (and Stephanie Arcadia) and Ms. Rosenthal played a unique role by allowing me the opportunity to conduct research

involving primary data collection. The experience of interviewing members of the dementia community on their diagnosis experiences has changed my life. It has truly been a pleasure working on such relevant work with my committee members. I am indebted to Abree Johnson and Matthew Folley, who supported my desire to learn advanced methods in geospatial analysis. I would also like to thank Rosie Love for her collegiate spirit, friendship, and support on my dissertation.

My experience at the University of Maryland would not be the same without my "PHSR family." To my cohort, Laura Bozzi, Juan-David Rueda, Husam Albarmawi, Rahul Khairnar, and Anna Hung, thank you for being true friends and research colleagues. We have memories in room 413 and across the world that will never be forgotten. I am grateful to have taken this journey with such smart, talented, and genuine individuals. To my sister-friends, O'mareen Spence (Little Sib), Elisabeth Oehrlein, Laura Bozzi, Priyanka Gaitonde, Doyinsola (Dee Dee) Bailey, Aparna Chauhan, Aida Kuzucan, Binny Bhandary, Patience Moyo (Big Sib), Chinenye Anyanwu, Jacquelyn McCrae, and India Taylor: I am blessed to have you in my life. You have been my guardian angels, confidants, sounding boards, voices of reason, supporters, and biggest cheerleaders throughout this journey. I'd be remiss if I didn't mention Aakash Ghandi, and the next generation of PhDs. You all continue to amaze me by setting a high standard for excellence in research. I would also like acknowledge the faculty and staff for creating an uplifting research community. Dr. Daniel Mullins, Colleen Day, Jamie Hoots, and the members of the administrative team have truly been instrumental in my success and academic stability.

To my friends and family near and far; there are too many to name. However, I would like to especially thank Alexis Palmer and her loving family, Todd Minor and his family, Taquita Marion, Willette Elder, Nicole Fuller, Natalie Hippolyte, Sharnita Solomon (deceased), Jerry Minor-Gordon, Rene Herbert, Meklit Workneh, Stephanie Hall, and Sheila Bell (deceased) for your prayers and encouragement. Nancy St. Louis and Elaine Hanna thank you for encouraging me, reminding me that I deserve the best in life, and loving me unconditionally.

To my mother, Melba Lee, thank you for instilling in me grace, determination, and faith at an early age. Your prayers, love, support, advice, and frequent visits were invaluable and gave me a sense of purpose. To my father, John Hanna, thank you for your love, support, voice of reason, provision and strength. You are both my role models and a source of inspiration. Thank you for your sacrifices to ensure I could fulfill my aspirations. Finally, I would like to thank my significant other, Raymond Lloyd. You gave me unwavering love and unconditional support when I needed it the most. You created a foundation of faith and security in my life that kept me focused on the completion of my PhD.

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1. OVERVIEW

1.1 Specific Aims and Hypothesis

1. Describe the pathway to diagnosis for persons with dementia (PWD) and their caregivers.

Approach: Conduct semi-structured interviews in counties representing three distinct geographical regions of Maryland to understand PWD and caregiver experiences with obtaining an ADRD.

2. (2A) Evaluate geographic variation in ADRD diagnosis rates across counties in Delaware, Maryland, Virginia, and Pennsylvania (DELMARVA+PA) and (2B) the impact of the Medicare AWV implementation on geographic variation in ADRD cumulative incidence.

Approach: (2A) Map county-level 5-year ADRD cumulative incidence rates by pre- and post- Medicare AWV implementation. Test for geographic variation through cluster analysis. (2B) Compare geographic variation of ADRD cumulative incidence rates pre- and post- Medicare AWV implementation. Determine if Medicare AWV participation is associated with increased ADRD diagnosis and reduced geographic variation.

Hypotheses: Significant variation exists in ADRD diagnosis rates across DELMARVA+PA counties. Higher county-level Medicare AWV implementation rates increases ADRD diagnosis rates and reduces geographic variation in county-level ADRD diagnosis rates.

3. Evaluate the impact of Medicare AWV implementations on health outcomes in an ADRD population.

Approach: Compare health care utilization (HCU) among individuals with ADRD with a history of a Medicare AWV participation prior to diagnosis versus those without.

Hypotheses: Individuals who received an AWV prior to diagnosis will have fewer ED visits and hospitalizations; however, outpatient visits may increase.

1.2 Rationale and Significance

Recognizing the growing burden of Alzheimer's disease and related dementias (ADRD) on patients, families, and the United States (US) health care system, President Obama signed the National Alzheimer's Project Act (NAPA) into law in 2011(Khachaturian et al., 2012). One goal of NAPA is to improve the ability of the federal government to track the monetary costs incurred by individuals and public programs, such as Medicare and Medicaid that result from ADRD. Additionally, the National Institute on Aging has been involved in identifying research priorities under this law. One priority is to better understand the barriers and facilitators of early diagnosis of dementia in primary care settings and to document disparities in diagnosis and treatment among vulnerable elders, to include ethnicity (Khachaturian et al., 2012; Zuckerman et al., 2008).

Early detection of cognitive impairment is a step toward timely and accurate diagnosis of ADRD; however, cognitive impairment remains severely under-detected by primary care providers (Camicioli et al., 2000; Chodosh et al., 2004; Valcour et al., 2000). It is

estimated that less than half of persons with dementia (PWD) receive a formal medical diagnosis even though they may be receiving care for their disease (Boustani et al., 2005). As a result, diagnosis can occur relatively late in the disease course, if at all. Care experts believe that lack of routine assessment to detect cognitive impairment in primary care settings is one of the most important barriers to dementia diagnosis (Fortinsky & Simmons, 2017). Without a timely, accurate diagnosis, people with ADRD and their caregivers are unlikely to benefit from appropriate care, effective drug therapy, and services, such as community-based education, support, and long-term care planning. In order to promote increased detection of ADRD in the primary care setting, the Annual Wellness Visit (AWV) requiring a cognitive assessment was added as a benefit for Medicare beneficiaries under the Affordable Care Act in 2011 (Bartels et al., 2015). The *central hypothesis* is that routine assessment for cognitive impairment, measured by use of the Medicare AWV, will lead to timely and increased detection and diagnosis of ADRD; however, geographical variation in assessment and diagnosis practices may modify this impact. Additionally, geographic variation in ADRD diagnosis may lead to variation in health outcomes. The Medicare AWV could improve assessment and decrease variation in cognitive impairment detection and ADRD diagnosis.

This study examined if and where geographic variation exists in the assessment and diagnosis of ADRD. Geographic variation, as well as factors such as access to health care resources, have a direct impact on burden of illness and may indicate socio-environmental contributions to ADRD detection, diagnosis, treatment, and outcomes. This study is the first of its kind to determine whether cognitive impairment assessments

through the Medicare AWV reduces ADRD diagnosis variation. This study further examined whether Medicare AWVs lead to improved health outcomes among PWD. In the short term, study results will provide insights that allow for improved detection of ADRD; which could directly improve quality of care and promote more desirable health outcomes. In the long term, this project hopes to inform the development of future policy around timely detection of ADRD through routine cognitive assessment. Understanding where and why geographic variation exists in ADRD diagnosis, will allow for more tailored interventions to improve quality of care, reduce costs, and improve outcomes.

2. BACKGROUND

2.1 Alzheimer's disease and Related Dementias

Alzheimer's disease (AD) is a degenerative brain disease and is the most common type of Alzheimer's disease and related dementias (ADRD), accounting for 60 to 80 percent of cases (Alzheimer's Association, 2019; Wilson et al., 2012). In the US, AD is the fifth leading cause of death among individuals age 65 years and older and the sixth leading cause of death among all ages (Barker et al., 2002). The population of those living with AD in the US is predominately female, non-Hispanic White, and more likely than those without AD to have other chronic conditions (Barker et al., 2002). Other dementia types include vascular dementia, dementia with Lewy-bodies, mixed dementia, frontotemporal dementia, and other types that are rarer. An estimated 5.8 million Americans are living with AD in 2019 (Alzheimer's Association, 2019). It is projected that the number of individuals age 65 years and older with ADRD in the United States (US) will surpass 7.2 million by 2030, an estimated 40 percent increase from the 5.1 million individuals affected in 2015 (Alzheimer's Association, 2019). One in ten people age 65 and older (10 percent) has Alzheimer's disease, one-third of people age 85 and older (32 percent) have Alzheimer's disease, and of those with Alzheimer's disease, the vast majority (82 percent) are age 75 or older (Prince et al., 2013).

Although symptoms vary by individual, ADRD are commonly characterized by a decline in memory, language, problem-solving, and other cognitive skills which affect a person's ability to perform everyday activities. As the disease progresses, cognitive and functional abilities decline. In the more advanced stages, people need help with basic activities of

daily living such as bathing, dressing, eating, and using the bathroom. Eventually, they may lose their ability to communicate, recognize familiar objects and people, and rely on 24-hour care (Barker et al., 2002).

2.2 Detection and Diagnosis

Detection and diagnosis of ADRD has evolved over the past two decades, but there are still many challenges. At this time, there is no single accepted tool to assess cognitive impairment (Plassman et al., 2007). Use of available, objective assessment tools, including the Mini-Cog (Brodaty et al., 2006), Memory Impairment Screen (MIS) (Borson et al., 2003), and General Practitioner assessment of Cognition (GPCOG) (Buschke et al., 1999), have improved detection capabilities over observation alone. Clinical diagnosis of ADRD; however, lacks standardized criteria and involves a challenging evaluation process that requires ruling out other potential causes of dementia (Brodaty et al., 2002).

2.3 Strategies for Detection of Cognitive Impairment

A workgroup of the Erotological Society of America (GSA) developed a flow diagram (Figure 2.1) from the perspective of Medicare beneficiaries and their families, which illustrates the aspirational process for achieving increased detection of cognitive impairment in a primary care setting. It shows how increased detection leads to earlier and optimal diagnostic evaluation, referral to post diagnosis support and educational services in the community, and ultimately, to improved health related outcomes and well-

being for Medicare beneficiaries with diagnosed dementia and their families (Boustani et al., 2005).

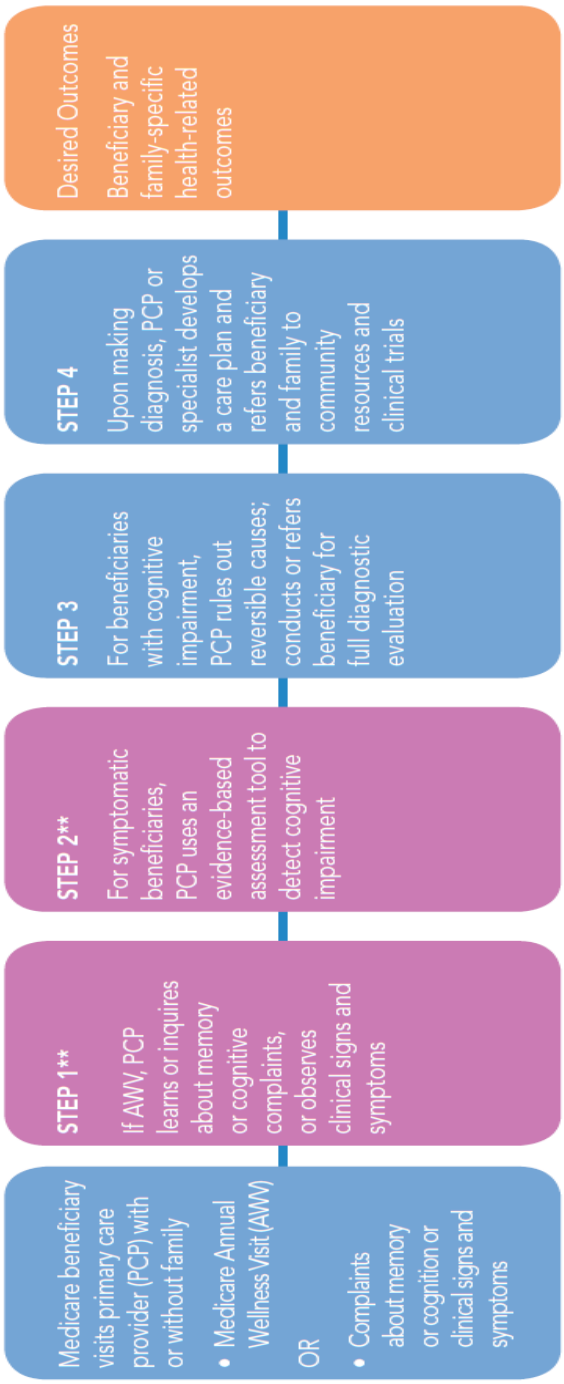


Figure 2.1 GSA's Four-step Process to Increased Detection of Cognitive Impairment in a Primary Care Setting

Early detection of cognitive impairment is a step toward timely and accurate diagnosis of ADRD; however, cognitive impairment is severely under-detected by primary care providers. In the primary care setting, cognitive impairment is unrecognized in 27%-81% of individuals (Callahan et al., 1995; Camicioli et al., 2000; Chodosh et al., 2004; Valcour et al., 2000). As a result, ADRD diagnosis can occur relatively late in the disease course, if at all. The Medicare AWV could be a first step in reducing missed or delayed dementia diagnosis, thus allowing for better health care management and more favorable outcomes for affected patients and their families and caregivers (Boustani et al., 2005).

2.4 Guidelines for Diagnosis

In 2011, the diagnostic criteria for Alzheimer's disease were revised by the National Institutes of Health and the Alzheimer's Association. The update identified three stages of AD: 1) the earliest preclinical stages of the disease, 2) mild cognitive impairment, and 3) dementia due to Alzheimer's pathology (Albert et al., 2011; Cordell et al., 2013; Sperling et al., 2011). They are described as:

1) Preclinical – This only applies in the research setting and describes a phase in which brain changes, including amyloid buildup and other early nerve cell changes, may already be in process. At this point, significant clinical symptoms are not yet evident. In some people, amyloid buildup can be detected with positron emission tomography (PET) scans and cerebrospinal fluid (CSF) analysis, but it is unknown what the risk for progression to Alzheimer's dementia is for these individuals. Use of these imaging and

biomarker tests at this stage are recommended only for research. These biomarkers are still being developed and standardized and are not ready for use by clinicians in general practice.

2) Mild Cognitive Impairment (MCI) – Again this largely applies to research, although the NIH clarified existing guidelines for MCI for use in a clinical setting. The MCI stage is marked by symptoms of memory problems, enough to be noticed and measured, but not compromising a person's independence. People with MCI may or may not progress to Alzheimer's dementia. Researchers will particularly focus on standardizing biomarkers for amyloid and for other possible signs of injury to the brain. Currently, biomarkers include elevated levels of tau or decreased levels of beta-amyloid in the CSF, reduced glucose uptake in the brain as determined by PET, and atrophy of certain areas of the brain as seen with structural magnetic resonance imaging (MRI). These tests are used primarily by researchers, but may be applied in specialized clinical settings to supplement standard clinical tests to help determine possible causes of MCI symptoms.

3) Alzheimer's Dementia – These criteria apply to the final stage of the disease and are most relevant for doctors and patients. The NIH outlined ways clinicians should approach evaluating causes and progression of cognitive decline. The guidelines also expand the concept of Alzheimer's dementia beyond memory loss as its most central characteristic. A decline in other aspects of cognition, such as word-finding, vision/spatial issues, and impaired

reasoning or judgment may be the first symptom to be noticed. At this stage, biomarker test results may be used in some cases to increase or decrease the level of certainty about a diagnosis of Alzheimer's dementia and to distinguish Alzheimer's dementia from other dementias, even as the validity of such tests is still under study for application and value in everyday clinical practice.

While there is more work required to validate tests used to detect these stages with high certainty, when an individual is aware of their diagnosis at earlier stages of AD, they and their caregivers have the advantage of being involved in decision making about treatment and health care (McKann et al., 2011). There is also an opportunity to begin accessing services to improve quality of life.

2.5 Treatment

Four drugs are currently approved by the FDA for use in the ADRD population, including three cholinesterase inhibitors (CIs): donepezil, rivistigmine, galantimine and one N-methyl-D-aspartate (NMDA) receptor antagonist, memantine. Tacrine, another cholinesterase inhibitor, was discontinued in the US in 2013 due to safety concerns. These drugs are palliative rather than curative or disease-modifying therapies, and they do not alter the prognosis of AD. There have been many observational studies outside the US to characterize utilization trends of anti-dementia drugs; however, evidence on US utilization is limited and variable (Hoffman et al., 2010; Taipale et al., 2014). A study conducted by Theodorou et al. in 2010 examined utilization patterns of current anti-

dementia therapies in a large prescription claims database of a pharmacy benefit manager and found that drug use significantly increased with age. On average, about 45 percent of individuals ages 65 and over with AD were using one of the four anti-dementia treatments in 2008 (Theodorou et al., 2010). A similar study looked at prescription claims in a Medicare Advantage (MA) ADRD population from 2004 to 2007 and observed 5.3 percent utilization of anti-dementia drugs in 2007 (Fowler et al., 2013). A pilot study conducted by the University of Maryland School of Pharmacy using a 2013 AD cohort of Medicare Advantage and privately insured individuals, showed that 29 percent of newly diagnosed AD cases filled a prescription for an AD drug; 71 percent remained untreated by drugs within 1.5 years of diagnosis (Hanna et al., 2015). There is a growing need to generate data on current US-based AD therapy trends among ADRD populations.

2.6 Medicare Annual Wellness Visit

The Medicare Annual Wellness Visit (AWV) became a medical benefit for Medicare beneficiaries under the 2010 Affordable Care Act (ACA) (Patient Protection and Affordable Care Act, 42 U.S.C. § 18001, 2010). The Medicare AWV has 100% coverage under Medicare Part B if performed by a physician, qualified non physician practitioner, or a Medicare professional (including a health educator, registered dietitian, nutrition professional, or other licensed practitioner), or a team of medical professionals who are directly supervised by a physician (CMS, 2011). Medicare beneficiaries who have been on Medicare Part B coverage for more than 12 months are eligible for the Medicare AWV. Beneficiaries who are within the first 12 months of the effective date of coverage are eligible for the Initial Preventative Physical Examination (IPPE) or “Welcome to

Medicare" exam. The Medicare AWV is different from an annual physical or IPPE because it is more heavily focused on prevention. The Medicare AWV can be characterized by three components, a health risk assessment, provider consultation, and personalized prevention plan. Within the three components of the Medicare AWV, several features can be found (Figure 2.2), including detection of any cognitive impairment, defined as "assessment of an individual's cognitive function by direct observation, with due consideration of information obtained by way of patient report, concerns raised by family members, friends, caretakers, or others" (Fortinsky & Simmons, 2017).

Figure 2.2 Annual Wellness Visit versus Preventative Physical Exam. Reference: Life Line Community Healthcare

The Alzheimer's Association published recommendations for operationalizing the detection of cognitive impairment during the AWV in the primary care setting. The resulting Alzheimer's Association Medicare Annual Wellness Visit Algorithm for Assessment of Cognition includes review of patient health risk assessment (HRA) information, patient observation, unstructured queries during the AWV, and use of structured cognitive assessment tools for both patients and informants. By assessing and documenting cognitive status on an annual basis during the AWV, clinicians can more easily determine gradual cognitive decline over time in an individual patient—a key criterion for diagnosing dementia due to Alzheimer's disease and other progressive conditions affecting cognition (Brodaty et al., 2006).

Per the algorithm (Figure 2.3), patients with assessments that indicate cognitive impairment during the AWV should be further evaluated to determine appropriate diagnosis (e.g., Mild Cognitive Impairment (MCI), Alzheimer's disease, etc.) or to identify other causes. As reflected in the algorithm, initiation of a full dementia evaluation is outside the scope of the AWV, but can occur in a separate visit either on the same day, during a newly scheduled visit, or through referral to a specialist (Cordell et al., 2013). Specialists who have expertise in diagnosing dementia include geriatricians, geriatric psychiatrists, neurologists, and neuropsychologists. The two-visit approach has been cited as a time-effective process to evaluate suspected dementia in primary care and is consistent with the two-step approach widely used in epidemiologic research on dementia. Regardless of the timing and setting, clinicians are encouraged to counsel patients to include an informant in the diagnostic process.

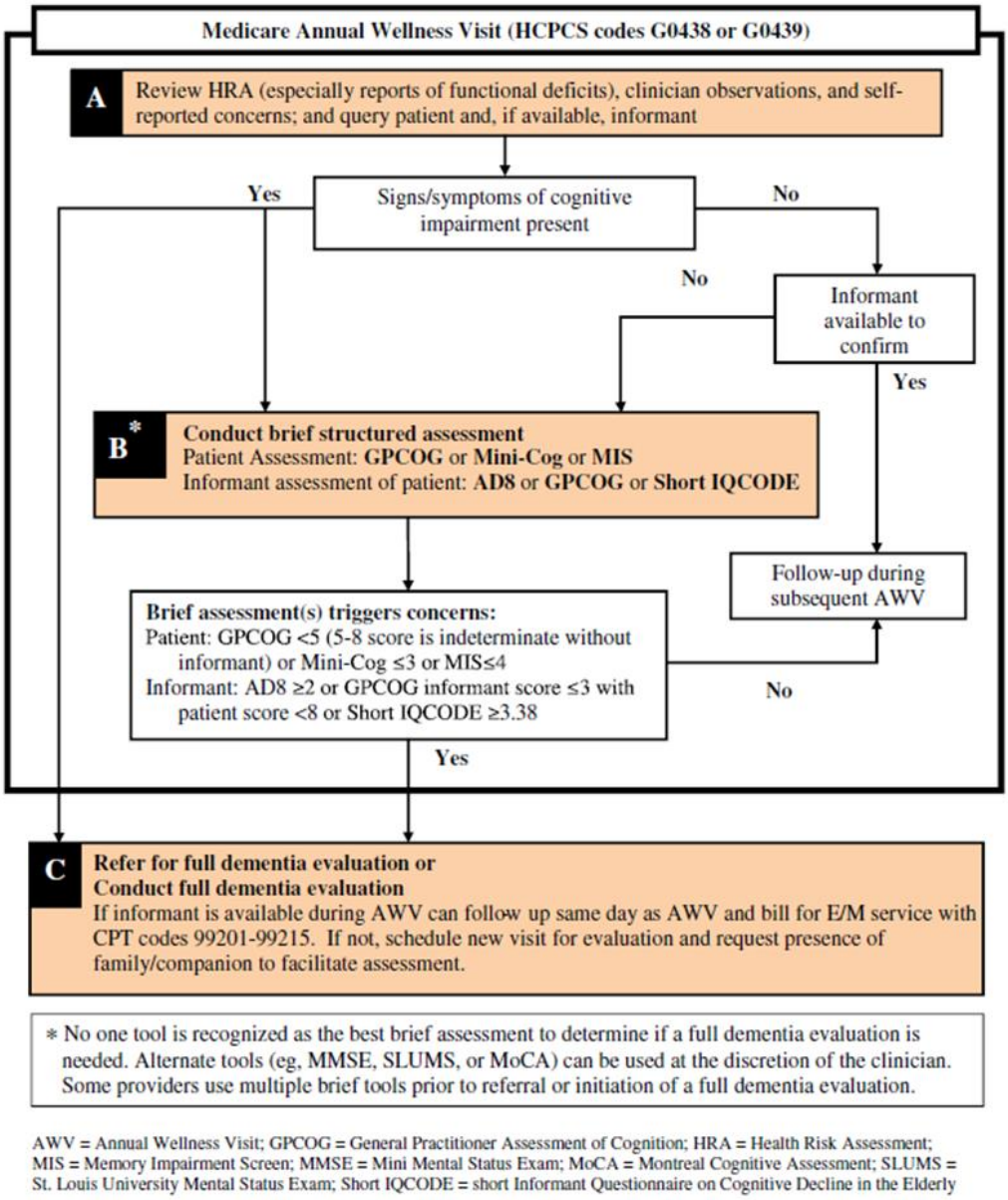


Figure 2.3 Alzheimer's Association Medical AWV Algorithm for Assessment of Cognition

In its first year of implementation, Medicare AWV participation reached over 2 million Medicare beneficiaries (Centers for Medicare & Medicaid Services, 2011). Ganguli et al. reported on national trends of AWV use from 2011 to 2014 (Chung et al., 2015; Ganguli et al., 2017). They found that AWV use increased from 7.5 percent to 15.6 percent

between 2011 and 2014. Regional AWV rates in 2014 varied from 3.0% (95% CI, 2.5%-3.5%) in San Angelo, Texas, to 34.3% (95% CI, 33.0%-35.8%) in Appleton, Wisconsin. White urban residents and those from higher-income areas were more likely to receive an AWV, as were patients who received an AWV in the previous year, or belonged to an Accountable Care Organization, a group of providers who collaborate to provide coordinated care for Medicare patients (Ganguli et al., 2017). In 2015, participation in the AWV among Medicare beneficiaries reached 9 million (16.4 %) since implementation (Chung et al., 2015). Despite slow uptake, the Erotological Society of America Workgroup deems the AWV as a 'springboard' to detection of cognitive impairment, diagnosis, and post- diagnosis support (Fortinsky & Simmons, 2017).

2.7 Geographic Variation

Experts believe that lack of routine assessment to detect cognitive impairment in primary care settings is one of the most important reasons for variation in dementia diagnosis (Fortinsky & Simmons, 2017). Geographic variation in medical care has been documented since the early 1970s (Wennburg & Gittelsohn, 1973). Studies of small areas support the notion that there is a lack of conformity of practice styles among large regional communities of physicians. Each state and region has many hospital-service areas, and local practice patterns vary substantially among them (Wennburg, 1999). Understanding where geographic variation exists in health care delivery, use, and outcomes has a substantial impact on how health care policies are designed to improve the overall quality of health care and the overall well-being of individuals. Identifying areas of the US where care for health conditions differs may also tackle the issue of racial

health disparities because it is known that racial and ethnic minorities tend to live in different areas from white populations (Baicker et al., 2005).

Similarly, it is expected that geographic variation in assessment for and diagnosing ADRD exists because of varying health care practices and availability of essential health care resources. These factors have a direct impact on burden of illness and may indicate socio-environmental contributions to ADRD detection, diagnosis, treatment, and outcomes. Geographic variation in dementia prevalence and death has been documented worldwide (Russ et al., 2012). However, US geographic variation in cognitive impairment assessment and ADRD diagnosis is not well documented. In the wake of the Medicare AWV implementation, there is an opportunity to track routine cognitive impairment assessments in older adults on a national scale to better understand geographic variation and the impact of the AWV. The AWV provides an unprecedented opportunity to overcome current barriers and initiate discussions about cognitive function among the Medicare population who are most at risk for ADRD (Cordell et al., 2013).

2.8 Variation in Care and Outcomes

Individuals with ADRD require significant amounts of health care and long-term services in a variety of settings. These services include, but are not limited, to home visits, skilled nursing facilities, nursing home care and support services. In addition, individuals with ADRD are affected by unwanted outcomes such as emergency room (ER) visits, hospitalizations, long-term nursing care, and shorter survival. Maslow et al. found that those with dementia are hospitalized 2-3 times as often as people the same age who do

not have the disease (Maslow, 2006). Another study by Zhu et al. that examined quarterly Medicare utilization and expenditures 2 years before and after diagnosis of dementia found significantly increased odds of hospitalizations, home health and skilled nursing care, and use of durable medical equipment post diagnosis in participants with dementia compared to non-demented controls (Zhu et al., 2015).

Questions remain about factors leading to this variation in care, which in turn result in adverse outcomes in the ADRD population. Some researchers have hypothesized that dementia symptoms go unnoticed by clinicians, thus creating lags in diagnosis (Knopman, 1998; Knopman et al., 2000); while others think that clinicians may feel there is nothing they can do, so opt to not treat the symptoms or prescribe support services such as therapy or counseling. The Alzheimer's Association conducted a survey to understand interactions between caregivers of a loved one or family member with AD and primary care physicians (PCPs) in efforts to help provide effective treatment and care to people with AD. They found that among 376 caregivers and 500 PCPs, 80 percent of PCPs believed that the disease could be stabilized for a period of time, if treated early, but only 32 percent of caregivers reported the doctor communicating this possibility (Alzheimer's Association, 2001). Caregivers were more likely to say the doctor told them the condition could not be helped much, if at all, even with treatment, and that the condition was just part of the aging process.

Another hypothesis is, that PCPs may lack training in ADRD management, resulting in variation of ADRD care practices. In a survey conducted by Fortinsky et al. exploring

PCPs self-reported approaches and barriers to management of patients with dementia in Connecticut (CT) and Maine (ME), researchers found that CT PCPs were more likely to prescribe additional AD and non-AD medications than their ME counterparts. Additionally, a greater proportion of CT PCPs reported barriers to optimal dementia care, including time constraints (54% vs. 31% of Maine PCPs), unfamiliarity with community resources (46% vs. 30%), and reimbursement constraints (45% vs. 23%) (Fortinsky et al., 2010).

There is some evidence that treatment with anti-dementia drugs may modify health outcomes in the ADRD population. Treatment with cholinesterase inhibitors (CI) have been associated with fewer hospitalizations, falls/fractures, and delayed admission into long-term nursing home care. One study of New Jersey Medicaid AD recipients between 1997 to 2009 examining the implications of early treatment found that the initiation of CIs at earliest symptomatic onset of dementia resulted in a 91-day delay to nursing home admission compared to non-treated persons (Geldmacher et al., 2014). In addition, cognitive impairment associated with ADRD seems to complicate the treatment of coexisting comorbid conditions, resulting in higher overall resource utilization (Gutterman et al., 1999).

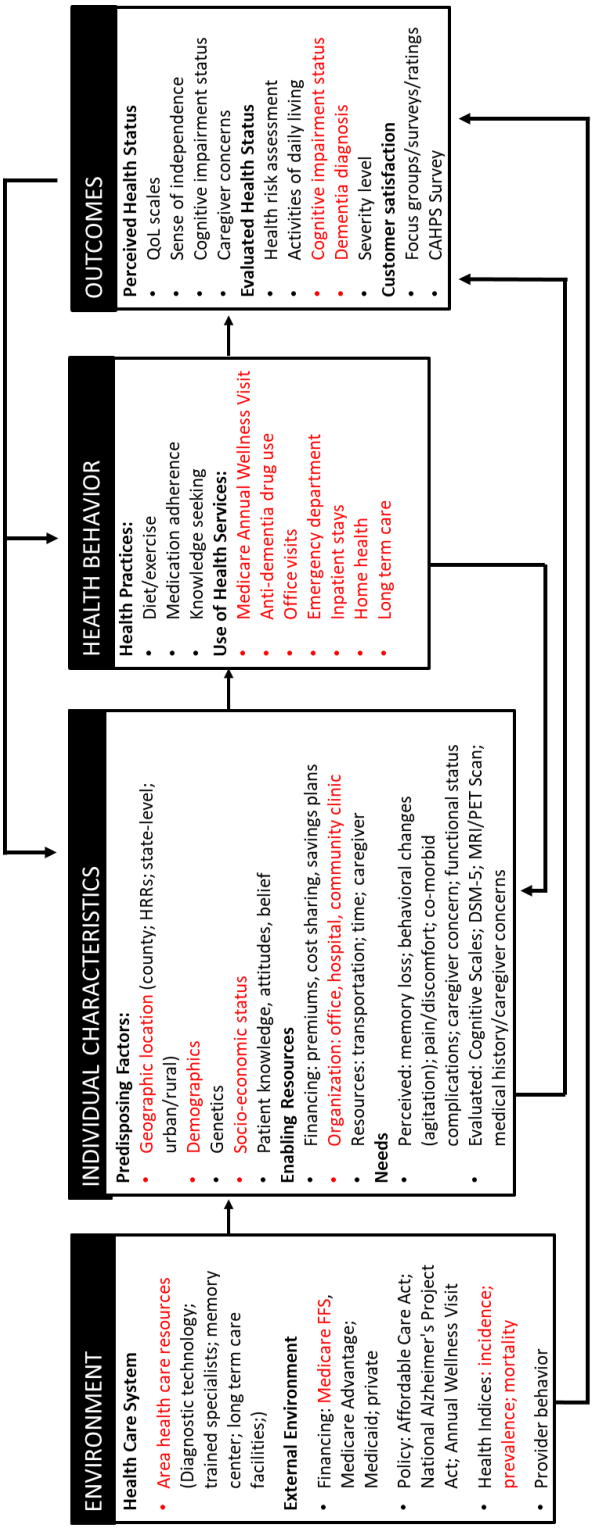
Variation in care and outcomes has also been observed between men and women, as well as between race/ethnicity groups. It has been documented that women have different outcomes than men upon being diagnosed with ADRD. Because women tend to live longer on average, they also tend to utilize more health care and experience co-morbid

complications at later ages (Seshadri et al., 2006). Gender and race-specific health care utilization patterns are not as well known. Although non-Hispanic Whites comprise the majority of the total US ADRD population, Blacks and Hispanics are disproportionately affected by ADRD. Compared to non-Hispanic Whites, Blacks are about twice as likely to have ADRD and Hispanics are about one and one-half times as likely to have ADRD as non-Hispanic Whites (Alzheimer's Association, 2019). However, these studies do not stratify by dementia-type and do not focus on variation in health care resource utilization as it is related to diagnosis.

Opportunities remain to investigate the source of variation in care and outcomes by first examining variation at diagnosis. Additionally, understanding how policies, such as the Medicare AWV, impact geographic variation in ADRD diagnosis and outcomes is needed to improve understanding of where disparities exist in the ADRD population.

3. THEORETICAL FRAMEWORK

The conceptual model shown below (Figure 3.1) illustrates the hypothesized sources of county-level variation in the assessment and detection of ADRD in a Medicare population. This framework is adapted from Anderson's Behavioral Model of Health Services Utilization (Andersen, 1995). It portrays the multiple influences (contextual and individual) on variation in health services use and subsequently, on health status. Environmental characteristics include availability of health care resources and population health indices. This model also includes provider behavior in knowledge and attitudes about diagnosing ADRD due to competing demands during a routine visit, and perceived lack of effective treatments, which may be associated with county-level variation. Individual characteristics include predisposing factors such as geographic location, demographics, and socioeconomic status while enabling resources include access to local health care organizations. Under individual-level needs, the perception of whether signs and symptoms of cognitive impairment and/or memory loss constitute seeking evaluation from a healthcare provider could also affect ADRD diagnosis. The feedback loops suggest reciprocal relationships between outcomes and the use of the Medicare AWV to detect ADRD, influenced by geographic variation of environmental and individual characteristics. The contents of the framework highlighted in red indicate factors that will be assessed and measured throughout the research aims.



Adapted from Anderson's Behavioral Model of Health Services. Red denotes variables, which will be measured in this dissertation.

Figure 3.1 Conceptual Model: Geographic Variation in the assessment and Diagnosis of ADRD in a Medicare population

4. PATHWAY TO DIAGNOSIS: PERSONS-WITH-DEMENTIA AND CAREGIVER EXPERIENCES REACHING A DIAGNOSIS

4.1 Abstract

Background: Most persons-with-dementia (PWD) are diagnosed late in disease progression, experience misdiagnosis, or go undiagnosed. Yet, the PWD diagnosis experience is largely unstudied and may vary by geographic location. The objective was to investigate pathways to dementia among PWD and caregivers and the effects of geographical factors on pathway experience.

Methods: Caregivers and PWD were recruited from counties representing three distinct rural and urban regions of Maryland: western, central, and eastern. PWD were required to be over 65 years of age, English speaking, and diagnosed within the last 5 years. Caregivers could participate alone or in a caregiver-PWD dyad. Semi-structured interviews were conducted to understand steps taken to reach a dementia diagnosis, perceptions on diagnosis experience, and ability to obtain resources based on where participants lived. Pathways to a dementia diagnosis were diagrammed for each PWD. Themes were identified by interpretive phenomenological analysis using NVIVO software. Results were then analyzed to see if pathways differed by region.

Results: Twelve interviews were conducted with 5 caregiver-PWD dyads and 12 caregivers. PWD were predominately white females, mean age 75 years, whose caregiver was their spouse (100%). Overall, the pathway to diagnosis (i.e., time from signs/symptoms recognition to diagnosis) ranged from 2 to 15 years. The most common

signs/symptoms reported were forgetfulness, disorientation, and frustration/agitation. Average time from the first doctor visit concerning signs/symptoms to dementia diagnosis was 3.3, 2, and 5.3 years for western, central, and eastern regions, respectively. Participants from western and eastern regions visited multiple specialists prior to diagnosis compared to central region (up to 3 versus 1). Negative/unsatisfactory experiences during a doctor's visit leading to finding a new provider were reported by 40% of cases. Upon diagnosis, most participants felt unsure about next steps and were not prompted to be involved in care planning.

Conclusion: Understanding the dementia diagnosis experience from PWD and caregiver perspectives is a critical step toward improving diagnosis and practice. This small study is suggestive of geographic variations that require further study. Participants from rural regions of Maryland experienced longer journeys to dementia diagnosis involving multiple specialists. Providers serving in these areas may require more dementia-related education and support to ensure timely dementia diagnosis. Improving patient-provider encounters and care coordination throughout the diagnostic process appears to be needed.

4.2 Introduction

The number of individuals age 65 years and older with Alzheimer's disease and related dementias (ADRD) in the United States (US) is estimated to surpass 7.1 million by 2030; with health care costs projected to rise dramatically as a result (Alzheimer's Association, 2019). Recognizing the growing burden of ADRD on patients, families, as well as the health care system, President Obama signed the National Alzheimer's Project Act (NAPA) into law in 2011 (Khachaturian, Khachaturian, & Thies, 2012; Patient Protection and Affordable Care Act, 42 U.S.C. § 18001, 2010). NAPA established a national plan to address Alzheimer's disease, which includes the goal of enhancing care quality and efficiency by ensuring timely and accurate diagnosis of ADRD.

A timely diagnosis of ADRD can positively affect care and outcomes of Persons with Dementia (PWD). At earlier stages of the disease, PWD are more likely to benefit from current anti-dementia drug therapy and novel treatments under development. An earlier diagnosis can also help PWD and caregivers become better equipped to deal with the disease and arrange financial, legal, and clinical matters, as well as prepare for social system support. Earlier diagnosis and treatment may provide the additional benefit that the PWD can live at home longer, which may improve quality of life and decrease long-term care costs for families (Connolly et al., 2011; Fortinsky & Simmons, 2017). The journey to an ADRD diagnosis; however, is often prolonged and variable. Literature has estimated a diagnosis could take 6 months to 10 years depending on an individual's experience (Chrisp et al., 2011; Krull, 2005; Rogers et al., 2017; Speechly et al., 2008; Teel & Carson, 2003). This variation in the diagnosis process is problematic because it

could result in years of uncertainty and stress for persons-with-dementia (PWD) and their caregivers. Planning for the future, such as for finances and a will often do not start until a provider relays an ADRD diagnosis.

It is unknown if and where variations in screening for and diagnosing ADRD exist across the United States (US). Differences in the characteristics of where someone lives may affect their pathway to an ADRD diagnosis. Many studies have focused on the incidence of ADRD and outcomes in PWD, but few have focused on experiences leading up to a diagnosis and how those experiences may set the course for future care (Rogers et al., 2017).

Recent studies on dementia incidence have focused on small populations specific to a single geographic location. We hypothesize that geographic variations, as well as factors such as access to health care resources, have a direct impact on burden of illness and may indicate socio-environmental contributions to dementia detection, diagnosis, and outcomes (Fortinsky & Simmons, 2017; Russ et al., 2012). Furthermore, experiences of PWD and caregivers have not been studied to understand their journey toward an ADRD diagnosis from a socio-environmental perspective. A few studies have observed variations in rural versus urban participants in PWD and caregiver diagnosis experiences (Prorok et al., 2013; Speechly et al., 2008). They found that rural participant comments were more positive toward their primary care provider and diagnosis experience. Urban participants had less challenges with home care and long term care post diagnosis.

However, these variations were not formally analyzed and studying geographical differences was not established *a priori*.

Geographic differences in ADRD awareness efforts, access to providers who are confident in making the diagnosis, medical practice norms toward identification, or availability of resources could affect PWD and caregiver diagnosis experiences. They may also contribute to variations in timely and accurate diagnosis of ADRD. As consumers of health care services, PWD and caregivers provide unique insights toward understanding how health systems can become more dementia-capable (Tilly et al., 2014; Valcour et al., 2000). The objective of this study was to investigate pathways to dementia diagnosis among PWD and caregivers and assess how rural versus urban geographical location affects the pathway experience. This study also investigated whether differences exist in PWD and caregiver perceptions of their diagnosis experience, ability to seek services and support for cognitive impairment concerns, as well as, health care decisions, based on where they live.

4.3 Methods

Advisory Committee

An advisory committee for the study was formed and comprised three PWD and their caregivers, a caregiver/patient advocate, a nurse practitioner, the program director of the Greater Maryland Chapter of Alzheimer's Association, and the director of Integrace Institute. The advisory committee was engaged early in the planning of the study to obtain insights on the pathway to diagnosis, understand the sensitive nature of the topic,

and validate the appropriateness of interview questions. The advisory committee also met with researchers at the culmination of the study to aid in the interpretation and dissemination of results back to the dementia community and those who serve them.

Recruitment

This study involved interviews across three regions of Maryland to understand PWD and caregiver experiences with obtaining an ADRD diagnosis. From a policy perspective, Maryland has become a model state for developing strategic goals to reduce the burden of ADRD. With a strong advocacy presence, Maryland has exhibited legislative momentum toward the prevention and early identification of ADRD which mirrors the priorities set forth by the National Alzheimer's Project Act (Khachaturian et al., 2012). Piloting this study in Maryland opens up future opportunities to conduct the same research on a national level in partnership with the national and local Alzheimer's Association chapters across the US. From a geographic perspective, the eastern, central, and western regions of Maryland have communities of differing age, race, social norms, and income distributions, with varying access to care. Maryland, a neighbor to Virginia, Pennsylvania, and D.C.; exhibits characteristics of both Northern and Southern regions of the United States. Thus, the intent was to capture both PWD and caregivers perspectives about the pathway to reaching a dementia diagnosis across these three, diverse geographic Maryland regions.

Participants were recruited from the western region of MD (Garrett to Frederick county), central region (Carroll to St. Mary's county), and the eastern region (Cecil to Worcester

county) with the help of the Greater Maryland Chapter of the Alzheimer's Association and Integrace Institute. Caregivers were defined as adults who had a family member diagnosed with ADRD within the last five years. Five years from diagnosis was used as a cut-off so that PWD and caregivers could adequately recall the years of experiences leading up to diagnosis. PWD were defined as individuals over the age of 65 diagnosed with early-stage dementia, Alzheimer's disease, vascular dementia, Lewy-body dementia, or frontotemporal dementia within the last five years. PWD at an early stage could interview with their care partner as a dyad, while caregivers could interview alone to represent a PWD not comfortable discussing the topic or with more advanced disease. Interested participants were screened to ensure residence in one of the three Maryland regions, age of the PWD, ADRD diagnosis year of the PWD, and that the caregiver was present during the ADRD diagnostic process. Individuals were not able to participate in the study if the PWD or caregiver were unable to give informed consent, non-English speaking, the PWD resided in a long-term care facility at diagnosis, and if the caregiver was not present with the PWD during the ADRD diagnosis journey.

Ethics

The interview study received approval from a University of Maryland Baltimore (UMB) institutional review board (IRB) in Baltimore, MD, USA (IRB number: HP-00077152). A waiver of documentation of consent was approved for this study. All participants provided verbal informed consent prior to each interview.

Interview Process

In-person, semi-structured interviews were conducted and audio-recorded. The Pathway to Diagnosis interview guide was divided into 3 major sections: (1) Journey to Diagnosis, (2) Detection, Work up, Diagnosis, and (3) Living with the Diagnosis (see Appendix). *Journey to Diagnosis* involved the caregiver's account of signs and symptoms observed in their loved one leading up to their initial encounters with a health care provider. This included family history as well as behavioral and lifestyle changes. Questions about the Medicare Annual Wellness Visit, a benefit that came out of the Affordable Care Act were asked to tie participation and knowledge of the benefit to the diagnosis journey. *Detection, Work up, and Diagnosis* involved describing doctors' visits and went further in detail about the conversations, cognitive impairment assessments and procedures conducted during the visits. This section also focused on the timeframe in which the ADRD diagnosis was communicated to the caregiver and PWD. Participants were asked to describe any treatment and/or resources provided by the doctor as a result of the diagnosis. Resources included clinical trials, support groups, social services, long-term care advice, etc. Participants were also asked if they felt where they lived affected their journey to an ADRD diagnosis. This was meant to understand whether their experiences were tied their access to care in their region. *Living with the diagnosis* covered understanding the current use of support services, the impact of where participants lived upon accessing those services, unmet needs of caring for the PWD, and ranking desirability of select health outcomes while living with dementia.

Data Coding and Analysis

Individual pathways to an ADRD diagnosis were diagrammed chronologically for PWD and compared to determine regional differences. In order to extract all ideas, perceptions, thoughts, opinions and information regarding PWD and caregiver experiences around ADRD diagnosis, interview transcripts underwent interpretive phenomenological analysis(Giorgi et al., 2019) by two reviewers (MH and RL) using NVIVO Version 12.2.0. Phenomenological analysis allowed individual and region-specific themes to emerge from interviews. MH read the full transcripts to develop the initial coding structure, followed by RL who coded transcripts based on the coding structure. Codes were grouped into themes through multiple consensus building activities among the reviewers (Campbell et al., 2013).

4.4 Results

Study Participants

Twelve in-person interviews were conducted: four in the western region, five in the central region, and three in the eastern region of Maryland (Table 4.1). Overall, five caregiver-PWD dyad interviews and 7 caregiver-only interviews were conducted totaling 17 participants. All caregiver participants had a spousal relationship with the PWD. Overall, PWD were majority white, females with a mean age of 75. The PWD had a mean(standard deviation) age of 75(6), 76(6), and 74(6) for western, central, and eastern regions, respectively. The racial breakdown was 100% White, 60% White and 40% Black, and 100% White for western, central, and eastern regions respectively. A family history of dementia was reported in 42% of PWD.

Table 4.1 Person-with-Dementia (PWD) Characteristics by Maryland Region

	Western N=4 Interviews	**Central N=5 Interviews**	**Eastern N=3 Interviews**
Age of PWD, mean(sd)	75(6)	76(6)	74(6)
Sex of PWD, n(%) Male Female	 1(25) 3(75)	 2(40) 3(60)	 2(66) 1(33)
Race of PWD, n(%) White Black	 4(100) -	 3(60) 2(40)	 3(100) -
Family history of Dementia, n(%)	1(25)	3(60)	1(33)
Clinical trial participation during workup, n(%)	3(75)	3(60)	2(66)
Medicare Annual Wellness Visit participation	1(25)	0(0)	1(33)
Drug therapy at diagnosis, n(%)	3(75)	3(60)	2(66)

Based on the caregivers report, three PWD were diagnosed as general dementia, four with early-stage Alzheimer's disease, four with Alzheimer's disease, and one with vascular dementia. One PWD was diagnosed with vascular dementia and it was later changed to Alzheimer's disease based on the results of a PET scan. No participants reported a MCI diagnosis prior to a dementia diagnosis. The majority of the work ups were conducted by a specialist; however, the results were sent back to the PWD's primary care physician. Thus, the dementia diagnosis was most often delivered in the primary care setting. Two participants reported they participated in a Medicare Annual Wellness visit prior to diagnosis. Treatment with anti-dementia medication at diagnosis was reported by two-thirds of the cases.

Journey to Diagnosis

Overall, the pathway to diagnosis (i.e., time from initial recognition of signs/symptoms to a dementia diagnosis) ranged from 2 to 15 years. The shortest pathway described spanned

2 years from the spouse noticing signs and symptoms of cognitive and behavioral changes to a formal diagnosis of dementia by a health care provider. This pathway involved a visit with a primary care provider who deemed the caregiver's concerns about their loved one 'due to old age'. As a result of persistent symptoms and behavioral changes, the caregiver proceeded to take their loved one to a neurologist for further evaluation. Upon a full evaluation and neuroimaging, the loved one was diagnosed with dementia. The longest pathway to diagnosis spanned 15 years with the majority of that time attributed to signs of memory loss that became more noticeable as time progressed. When the spouse expressed memory concerns to their loved one's primary provider, a CAT scan was conducted. This was at the point that a real awareness of cognitive impairment was convincingly communicated to the spouse. The loved one was referred to a neurologist who was affiliated with a clinical trial that provided a PET scan at no cost. Upon receiving the results of the PET scan, a dementia diagnosis was delivered.

The average time from an initial doctor's visit concerning signs/symptoms to a dementia diagnosis was 3.5 years overall, with 3.3, 2, and 5.3 years for western, central, and eastern regions, respectively. Participants from eastern and western regions were more likely to visit multiple neurologists; up to 3 different specialists leading up to an ADRD diagnosis. Figure 4.1 depicts two examples of complex pathways to an ADRD diagnosis. The first pathway began with 3 years of noticeable changes observed in the loved one's behavior. These signs were followed by memory issues which led to the loved one not being able to work and carry out routine activities such as cooking and cleaning. Following four more years, the spouse takes the loved one to a primary care visit and

discusses memory and behavior concerns. The loved one is referred to a Neurologist. During the neurologist visit, there was a battery of tests, however, the spouse and loved one never received communication regarding the results. Later that year, the spouse took their loved one to a new neurologist where the love one had an MRI which led to a dementia diagnosis. A PET scan later confirmed the diagnosis. The second example was a female, aged 78 from western Maryland whose pathway ran 13 years. The pathway began with a long history of falls with evolving issues of distance and depth perception without any associated diagnoses. The first encounter with a primary care physician about cognitive concerns occurred approximately 10 years after the start of previous events and soon after memory symptoms became apparent to her spouse. During the visit, the primary care provider conducted an in-office cognitive assessment and concluded that the loved one was “okay”. The last few years leading to an ADRD diagnosis involved multiple visits to multiple specialists until the loved one was enrolled into a clinical trial and diagnosed with early stage Alzheimer’s disease based on cognitive testing and a PET scan.

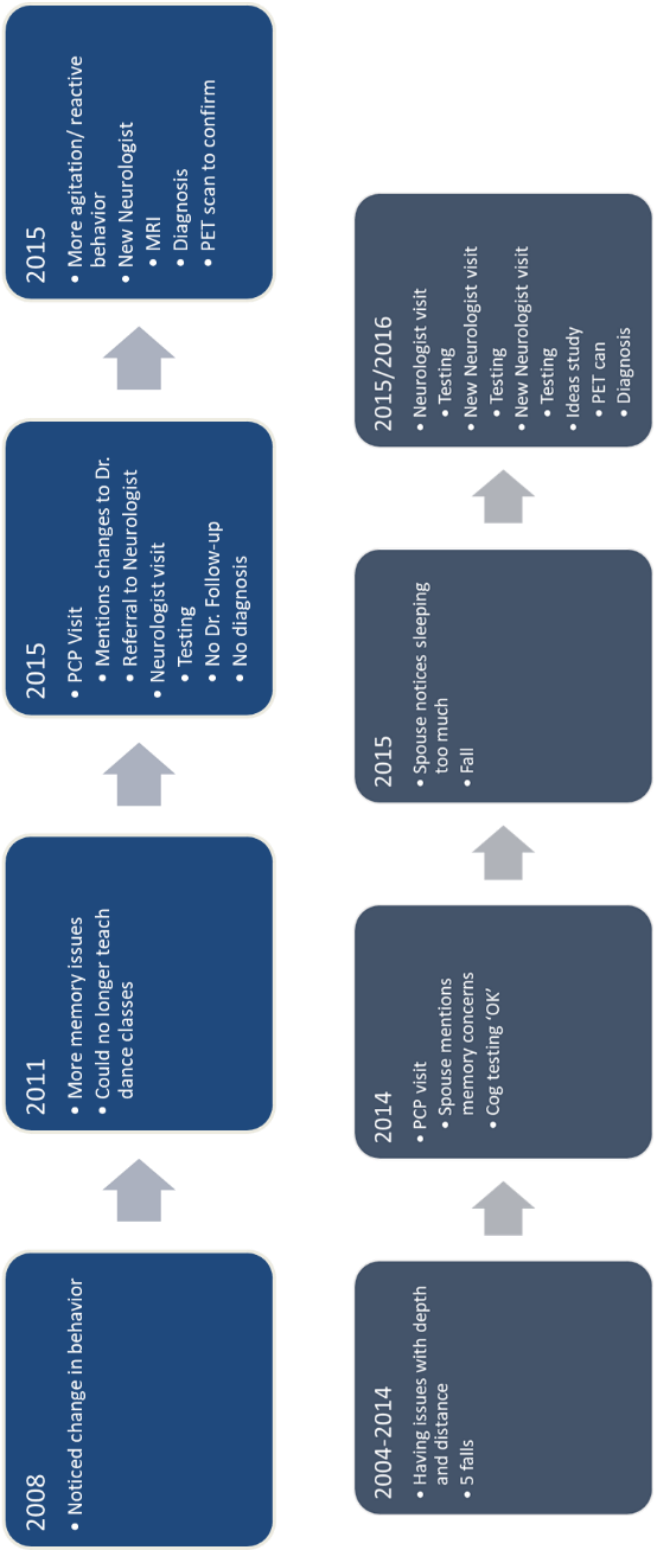


Figure 4.1 Complex Pathways to Diagnosis

Geographic Impact

Participants were asked if they felt where they lived affected their diagnosis journey. The majority of participants did not feel their geographic location affected their diagnosis journey and felt they resided in a resource-rich area for treating their condition.

> *Well we're between Baltimore and Washington. We're located in an area where there's a lot of medical research going on with the NIH. You have Baltimore, University of Maryland Medical Center, we got a lot going. (Dyad #2; Central region)*

> *I don't really see this where we live. We could live in western Maryland. I think it's about the person or the couple, in my case, and what we expect, what - you know, and so whether I'm in a low income area or a high income area, that's not going to stop me from seeking help that I think we need. (Caregiver #2; Western region)*

There were a few who thought that their experiences may have been impacted by their geographic location.

> *I think it was really a choice. You know, [of the] practitioner, you know, that sort of thing. Like, for example, we live in the area not far from Catonsville in Baltimore County. So, you know, that's what medical care [is there]- the doctor's office happens to be in Owings Mill. Neurologist office happens to be at a hospital*

in Baltimore City. So I think it's really more the - the practitioners. (Dyad #3; Central region)

Well I suspect had I lived, say, in Anne Arundel County, there may have been more options and may not have been a seven month wait... so geographically yes perhaps we would have been able to get in initially sooner. (Caregiver #2; Eastern region)

In general, participants cited income and distance as factors that would have contributed to a geographic impact on their diagnosis experience. Despite where participants lived in Maryland, they felt their local and distant resources were worth the drive for the best care. Given that check-ups are usually every 6 months, anything up to an hour drive was manageable. When asked how long, would be too long to travel, anything over an hour was too much.

"You know, we live in a good area. It's affluent and all that. So I think you tend to get maybe a little more help there than you would in a backstreet of a city somewhere." (Dyad #1; Eastern region)

"And if a person lives for example in an economically depressed area, what is your access? And if, you know, if it's not a clean area, well, you know, that certainly can have a negative effect as well." (Dyad #3; Central region)

Not everyone can afford to travel…or if it is public transportation, well, that you know, has - that takes a great deal, more time…So if I was, you know outside, of an hour's realm of seeking care or getting to the city, you know, maybe the terms of, you know, consistency of seeking care from a particular neurologist or something could be impacted. (Dyad #3; Central region)

If we lived up above Frederick or out in Hagerstown we wouldn't have been able to utilize a lot of those groups because we would have been too far away. (Dyad #2; Central region)

Participants in the eastern region of Maryland expressed how resources after diagnosis could be improved. They admitted that the lack of support groups in the area were due to the area being less populated, but felt they would participate more if they were closer.

But I do feel we're very blessed to have Integrace not too far from here. You know they're all about education and support so I really feel blessed in that regard. Sometimes I would like to see a support group closer to home, like maybe in Kent Island. Sure. Like particularly for evening sessions, I didn't always feel like making a drive to Easton. (Caregiver #2; Eastern region)

So support groups, yeah. It's probably not the best thing over here…meaning, it's not densely populated. (Caregiver #1; Eastern region)

Themes of ADRD Diagnosis Journey

Four themes emerged from the in-person interviews regarding PWD and caregiver experiences in getting to an ADRD diagnosis: making sense of signs and symptoms, health-care experience satisfaction, acceptance of diagnosis, and the impact/burden of ADRD (Figure 4.2).

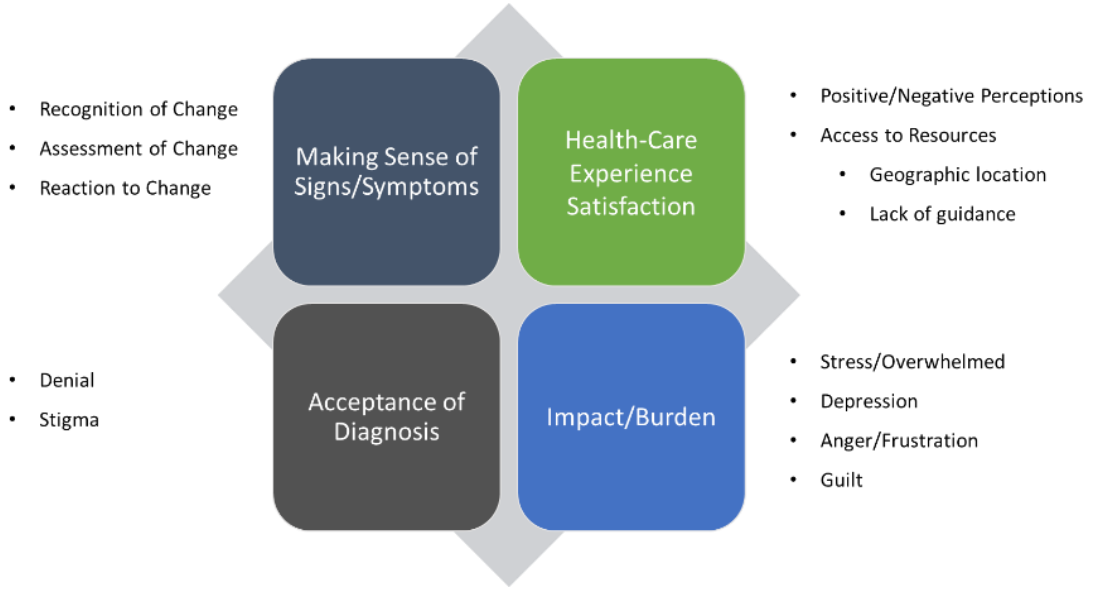


Figure 4.2 Themes from Qualitative Analysis of Pathway to Diagnosis Interviews

Making Sense of Signs and Symptoms

Making Sense of Signs and Symptoms was an iterative and prolonged process for those observing changes in their loved one during the pre-diagnostic phase of ADRD. This process involves recognition of changes, assessment of changes, reaction to changes and the influence of others (Rogers et al., 2017). The most common signs and symptoms reported by caregivers were memory issues/forgetfulness, difficulty finding words, disorientation, and frustration/agitation. Caregivers reported that knowledge of a close

friend or immediate family member with dementia made it easier to recognize signs and symptoms in their loved one. Signs and symptoms were applied to a framework adapted from the Loreck et al. Dementia Signs and Symptoms Scale (DSS) (Figure 4.3) (Loreck et al., 1994). Cognitive symptoms such as memory loss, comprehension, and word-finding difficulties were not part of the scale but are often the first signs reported by a caregiver. Signs and symptoms did not vary by geographic location, but were specific to the PWD.

*Source: Loreck, D.J., Bylsma, F.W., & Folstein, M.F. (1994). The Dementia Signs and Symptoms Scale: A new scale for comprehensive assessment of psychopathology in Alzheimer's disease. The American Journal of Geriatric Psychiatry, 2, 60-74.
^ Cognitive symptoms was not part of Loreck et al. DSS.

Figure 4.3 Reported Signs and Symptoms Prior to Dementia Diagnosis*

Signs that led to behavioral changes in PWD included: agitation and frustration with modern technology such as operating an iPod, responding to automated telephone prompts, and working a remote control. Examples of signs which led to lifestyle changes included: unable to conduct routine tasks at work or teach well-known material, paying bills at the wrong time or making a check out to the wrong recipient, forgetting directions to frequently visited places like home, church, or supermarket, and not remembering how to conduct daily routines like taking out the trash, retrieving the mail, and doing the laundry.

The caregiver taking concern about these signs/symptoms to a provider initiated the phase of detecting dementia or any cognitive impairment in their loved ones. None of the caregivers or PWD reported receiving a cognitive impairment assessment as a result of the provider's intuition or routine care; it was always prompted by the caregiver expressing their concerns. A few participants recalled ever receiving an in-office cognitive impairment assessment during a health care provider visit. The cognitive impairment assessments mentioned during interviews included the mini-cog, clock drawing test, the interlocking pentagon drawing test, counting backwards from 100 by 7, and naming the US presidents in descending order.

> *"And in my notes I put that I noticed that around the same time his memory loss manifested that he was having terrible, terrible sleep patterns and stomach problems." (Caregiver #1; Eastern region)*

"My wife has blown up a couple times, and we just couldn't figure out why." (Caregiver #1; Western region)

"I would say those two people noticed things before I actually did." (Caregiver #2; Eastern region)

"Well, she had a bad head injury and that's what started mine. I had a bad head injury." (Dyad #2; Central region)

"But there are times - I just stop talking. I can't think what to say or what to do or I - not what to do but - and it's so frustrating." (Dyad #1; Western region)

Health Care Experience Satisfaction

PWD and caregiver experiences leading to an ADRD diagnosis primarily involved doctor's visits. These encounters shaped their perceptions of their journey to diagnosis. Satisfaction with provider encounters were positive and negative.

"He has always ended his exam by looking at you and saying, do you have any questions? Is there anything else? …And he will take the time." (Dyad #2; Western region)

"I really do feel that where we're going and with the physician we have and the research has me, us better aware." (Dyad #1; Central region)

"You come here and it's not just - our first visit with this doctor was an hour-and-a-half, an hour, 45 minutes. Who does that? And this was so unheard of. And she or he had shown a lot of compassion, which is the one thing you don't see with doctors." (Dyad #1; Western region)

Forty percent of the study's cases had negative/unsatisfactory experiences during a doctor's visit. Negative experiences were associated with longer times to a diagnosis. Upon diagnosis, most participants felt unsure about next steps and were not prompted to be involved in care planning. This delay was often due to PWD and caregivers finding a new doctor to gain a second opinion or having a doctor they felt was better care for them during the diagnostic process.

"So it became a case of - we'll see you in six months or don't call us, we'll call you. You couldn't make an appointment." (Dyad #1; Western region)

"And I sat in his office ... I was in tears, you know…it was a level of, you know I was upset. But it's like I'm, you know, trying to tell you. But you're not hearing me. And this is… [our] primary care physician." (Dyad #3; Central region)

"..maybe I'm wrong about Dr. X - he didn't lead us to anything that was helpful as far as now what do you do. And I'm not sure if we had seen Dr. Y first, I would be

quite surprised since his wife is so involved here, if he wouldn't have pointed us here immediately, but I don't know… it was just pure luck that I saw that ad because if I hadn't we could have been floundering for a long time until I would find [resources]. (Dyad #2; Western region)

Acceptance of Diagnosis

Some PWD and caregivers at the time of the interview were still in denial of the dementia diagnosis and how the disease would progress in their loved one relative to others. These participants were less likely to participate in support groups due to their belief that their loved ones were not as severe as others who attended.

"So I really wasn't – [I] didn't want to accept that it's Alzheimer's. When I saw the words consistent with I said, well, that doesn't mean 100 percent. It just means it looks like, right?" (Dyad #2; Western region)

"I think my wife is very discreet in that she doesn't want anybody else to know. And just recently I've told her people. You know, you just can't cover it up." (Caregiver #1; Western region)

"And I know facts... But I will still deny or refuse to accept [her] health … I read [the book] to the end because I needed to have the information, but I kept saying no, no, no. This is not the life I am going to see. This will not happen. I refuse to let it happen. And I mean - and I let it go at that. I can't - you know, there's some

things - when you're young, you're immortal...But in [her] case I refuse to accept that this is going to progress any more than it already has and it's been a slow progression." (Dyad #2; Western region)

"It's got a stigma attached to it." (Dyad #2: PWD; Central region)

Other PWD and caregivers had a positive outlook on the diagnosis and living with the disease. Their source of optimism came from their spiritual life and the fact that they can't change the diagnosis.

"And if it comes up I'll tell you I have dementia and I'm taking it one day at a time and you can do it this way." (Dyad #2: PWD; Western region)

"So I'm still happy. I'm with people….I like to be around people. Some people crawl into a hole and I don't know." (Dyad #2: PWD; Central region)

"But it also was helpful for me - our spiritual life is very solid." (Caregiver #1; Central region)

"Several people have said they just have to be, you know, of good humor because there's nothing you can do about it at this point with the current medical." (Caregiver #1; Central region)

Impact and Burden

Feelings of blame, stress, anger/frustration, depression and being overwhelmed were reflected in caregiver narratives. Blame was directed towards the caregiver by the PWD and would involve blaming the caregiver for trying to help them with daily tasks or accusing caregivers of trying to send them away to a nursing facility. Stress was primarily based on finances due to living on a lower income because of early retirement or diminishing profits from a family business that the caregiver can no longer manage. The ability to afford long-term care services, home health, and respite care also posed a burden on caregivers. This often resulted in caregivers feeling depressed and overwhelmed about their new role. Anger and frustration were commonly expressed when caregivers talked about adjusting their reactions to the decreased cognitive and physical function in their loved ones. Having to change their plans to take care of their loved one, repeating things until their loved one comprehended, ensuring their loved one was safe from wandering, prevention of overmedicating, or injuring themselves were provided examples.

> *"You know, I think sometimes it's not really digested. You know, and you can become overwhelming. And I think it is - it's overwhelming that the person that gets to be very depressed. (Dyad #1; Central region)*

> *"That's why I say it comes and it goes and it sometimes goes and doesn't come back. So that's why the insidiousness, is there such a word, of it… because it's just - and it's maddening." (Dyad #2; Western region)*

"And I decided not to overdo the educational sessions because I know what I need to know and it really to me it's just depressing to dwell on it. Why do I need to hear over and over again what's going - that disease is going to progress? I know." *(Caregiver #2; Eastern region)*

PWD expressed frustration with dealing with the symptoms of ADRD. They also felt compassion for their care-partner and the toll it may be taking on them.

"I don't know what to - how to say the frustration I have that - not with - there is more to it… also with the doctors. And it's been a roller coaster. And it's frustrating. I am trying to keep memory going. And it's - and then it goes. And I talk and then it's gone. And a lot of things are - I don't even know what the (unintelligible) what I'm saying. And it's frustrating because I can't remember things. I lose things. But, yet, I'm doing great things. I'm doing things in the house. We had a business. And so we had a lot of work plus the kids that grew up thankfully. Well - and so my life - and just trying to say… now I'm already losing what I'm trying to say." (Dyad #1: PWD; Western region)

"Maybe like if he would like to go away for a day or something, someone to stay with me if there's any connection…But like something where he could get a day off from me." (Dyad #3: PWD; Central region)

4.5 Discussion

This study investigated pathways to dementia diagnosis from the perspective of PWD and caregivers. Additionally, it looked for geographical variation in those pathways across three regions in Maryland. The pathway to diagnosis (i.e., time from initial recognition of signs/symptoms to a dementia diagnosis) was variable with a range of 13 years. The average time from the first doctor visit concerning signs/symptoms to dementia diagnosis (3.3, 2, and 5.3 years for western, central, and eastern regions, respectively) fell in the middle of previously reported results. Findings were similar to studies conducted by Speechly and Chrisp who found average times to a diagnosis to be 3 years and 3.3 years, respectively (Chrisp et al., 2011; Speechly et al., 2008).

Despite the majority of PWD and caregivers' opinion that where they lived did not affect their journey to diagnosis, individual pathways revealed variations in time to diagnosis by Maryland region. Capturing the literal pathways to diagnosis in diagrams that described participants' actions taken from recognition of signs/symptoms to a formal diagnosis of dementia by a health care provider revealed these variations. On average, participants from the more rural eastern and western regions took 1-2 years longer from the first doctor visit about memory concerns to ADRD diagnosis compared to the central region. This inconsistency between PWD and caregiver perspectives and study findings may be expected since participants often focused on their own journey had no other experiences to compare.

The rural versus urban context of the three Maryland regions may have led to the variations by region due to possible variations of access to care. Access to care is described as the availability of doctors skilled in diagnosing and treating ADRD and access to specialists such as neurologists who are skilled to use advanced technologies to confirm a diagnosis. It is also possible that doctors fail to diagnose dementia because they do not know what resources or therapy options to offer PWD. Variations in pathway to diagnosis may also be due to patient and caregiver care-seeking behaviors rather than provider behavior. It is possible that an individual is suffering from cognitive/memory issues, but does not desire to know whether it is cognitive or early signs of dementia due to stigma, fear of losing their job and/or lack of effective treatments. On the other hand, some individuals will seek care for their cognitive/memory concerns until there is a diagnosis of some form (i.e. stress, mild cognitive impairment, ADRD, etc.)

Related to this issue is the Medicare Annual Wellness Visit, which was authorized under the Affordable Care Act (Bartels et al., 2015; Colburn & Nothelle, 2018). This free visit was designed to be a springboard for detecting cognitive impairment in the primary care setting. Only two (17%) participants reported knowing if the PWD received a Medicare Annual Wellness visit prior to diagnosis. This is consistent with the reported national average for participation in the Medicare Annual Wellness Visit by Medicare beneficiaries and validates the continued need to raise more awareness of this free benefit (Ganguli et al., 2017). The remaining participants were unsure whether they or their loved one had received an AWV primarily because the word ‘wellness’ is often associated with the physical and both services occur annually. Even when the distinction

between the two types of visits were described, participants were still unsure of their experience having a Medicare AWV. A caregiver who participated in the Medicare AWV was disappointed that even though Medicare will cover the Medicare AWV, when problems were discovered, Medicare did not cover some of the additional services needed. It also begs the question of who is responsible for ensuring participation in the Medicare AWV, the health care provider or the beneficiary.

There also is uncertainty about whether or not a cognitive impairment assessment is actually conducted during AWVs. This may lead to varying conclusions on whether the Medicare AWV has an impact on cognitive impairment detection and a subsequent ADRD diagnosis. In 2017, CMS developed and recognized a cognitive assessment code (HCPCS code, G0505) to be used by physicians and non-physician practitioners to evaluate a patient with cognitive impairment, such as ADRD (CMS, 2017). In 2018 the HCPCS code was changed over to a new CPT code (99483) to cover cognitive assessment and care planning for a patient with cognitive impairment, "requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements" (CMS, 2017). These codes will hopefully aid in incentivizing physicians to conduct cognitive assessments where appropriate. This also improves the ability for researchers and healthcare decision-makers to track the pathway from detection of cognitive impairment to a formal ADRD diagnosis.

The first visit with a doctor regarding memory concerns leading to a diagnosis was often preceded by years of signs and behavior changes in the PWD. This is consistent with a

study by Chrisp et al. that reported a 3-year gap between the time from thinking that something may be amiss to beginning the formal process of diagnosis with a health care provider (Chrisp et al., 2011). Making sense of signs and symptoms was a major theme that came out of this study. Shifting from recognizing changes in their loved one to seeking professional help for those changes could be a long process. Possible variation in PWD and caregiver making sense of signs/symptoms may have led to differences in care seeking (Teel & Carson, 2003). This supported the decision to measure time to ADRD diagnosis from the point of the first health care encounter to allow for a comparable baseline for the diagnostic process. Early on, caregivers of Alzheimer's patients may normalize these behaviors in their loved ones. These normalizations allow caregivers to continue living as though their loved ones were healthy, by understanding the behavior as a result of emotional trauma or stress or as part of the normal aging process (Krull, 2005). These normalizations come to an end as a result of a pivotal event, the influence of an outsider, or due to a family history of the disease (Krull, 2005). Factors in addition to the misattribution of symptoms by caregivers contributing to this gap in time may include: denial by the PWD and/or caregiver and the refusal to seek medical advice, lack of confirmation from the social context, lack of responsiveness of the general practitioner", and misdiagnosis of PWD leading to inadequate advice/help (van Vliet et al., 2011).

Positive and negative encounters with health care providers were correlated with time to diagnosis. Positive encounters resulted in shorter and less complex pathways to diagnosis while negative or unsatisfactory encounters resulted in longer and more complex pathways to an ADRD diagnosis. Participants from eastern and western regions were

more likely to visit multiple neurologists; up to three different specialists leading up to an ADRD diagnosis. Forty percent of the cases reported that negative/unsatisfactory experiences during a doctor's visit led to finding a new provider. These experiences included the provider deeming everything as okay, the concern that the provider was not taking a patient-centered approach towards the visit, and the provider left the PWD and caregiver without guidance on next steps. Findings from this study are similar to findings observed in Teel et al.'s study which investigated caregiver experiences with dementia diagnosis in Kansas. The study found that caregivers reported consulting with multiple PCPs and specialists in the diagnostic search, which often took several years before a diagnosis was obtained (Teel & Carson, 2003). Caregivers had to be extremely diligent in their quest and often ended up feeling mistrustful about the information they received from the physician (Teel & Carson, 2003). Prorock et al. conducted a study of health care experience with PWD and caregivers. They found similar challenges including time to diagnosis prolonged paths to accessing necessary services and supports, and difficulty navigating the health care system and services. They proposed a model for health care experience, which outlined components of care that appeared common across positive health care experiences. The components are informed patient and caregiver, supported patient and caregiver, strong provider - patient/caregiver relationship, communication by provider, knowledgeable provider, and accessible provider (Prorok et al., 2013). The first three components have been categorized as patient and caregiver factors, while the latter three have been grouped as provider-related factors (Prorok et al., 2013).

The latter two themes focused on the ADRD diagnosis and the disease's impact on PWD and their caregiver. What was apparent from the interviews was that participants were at difference stages of accepting the diagnosis. Other studies have also observed related features of the journey. When a diagnosis of dementia is made and disclosed, the person and family member receiving the diagnosis may experience a range of different emotions including shock, anger, fear, frustration, anxiety, loss, guilt or sadness (Robinson et al., 2005). Different coping mechanisms may be adopted such as disguising any symptoms, distancing oneself from the illness, normalizing or denying the symptoms, or merely focusing on one's physical health (van Vliet et al., 2011). In some cases, the person affected may feel relieved since the diagnosis explains why these changes are occurring. In this study, caregivers were more concerned about how the disease would progress in their loved one and whether the diagnosis was accurate. Meanwhile, PWD were more concerned about the stigma around the diagnosis and how others, especially relatives and friends, would treat them differently. Privacy was key for these couples. On the other hand, a number of participants accepted the diagnosis with a positive outlook. They tended to be more active in support groups and social gatherings. Caregivers were more likely to participate in educational activities and use social networks as a way make caring for a PWD more manageable. Some PWD and caregiver attributed their positive outlook of the ADRD diagnosis to having a strong support system and spiritual foundation.

Throughout the 12 interviews with PWD and caregivers, the impact the ADRD diagnosis has had on their lives could not be ignored. Caregivers expressed blame, stress,

anger/frustration, depression and feeling overwhelmed. These feelings were manifested through managing symptoms and behavioral changes in their loved one, changes in finances and employment, coping with emotions about the disease, and lifestyle changes. Depression was often a consequence of the other attributes. The above findings are consistent with other studies. A meta-analysis found overall prevalence rates of 34 and 44%, respectively, of elevated depressive and anxiety symptoms in caregivers of PWD (Sallim et al., 2015). The burden of ADRD on caregivers has raised concern about their own mental and overall health (Cheng, 2017). PWD shared in feeling frustrated and depressed when experiencing the symptoms of cognitive decline (Aminzadeh et al., 2007). PWD who are younger with early stage ADRD, often struggle the most with manifestations of the disease (van Vliet et al., 2011).

This study had strengths and limitations. This is the first study to publish ADRD diagnosis experiences by geographic location. Findings support the notion that individuals may experience differences in their journey to an ADRD diagnosis based on where they live. It is also among the few articles based on a population of individuals in the United States that sampled participants from both rural and urban areas. Due to the small sample size, we were able to conduct in-depth interviews with PWD and caregivers, which enhanced the results. The inclusion of both the caregiver and PWD in the same interview session was also a unique feature of the study. The account of the diagnostic journey for a PWD really depended on the caregiver's voice, while experiences living with the disease resonated from the PWD voice. One limitation on the sample selection is that all the relationships between the caregiver and PWD was a

spousal relationship. These findings may not be representative of other family members or friends who may take on the role of caregiver.

A small sample size in a targeted location, Maryland, could also be considered a limitation. Findings from this study cannot be generalized to all PWD and caregivers. Study participants were more affluent, educated and involved in their care than the general population. Sixty-seven percent of PWD participated in a clinical trial during the work-up phase. This was to be expected as the primary recruiting site, Integrace Institute, was one of 26 Maryland physician referral sites for the nationwide Imaging Dementia - Evidence for Amyloid Scanning (IDEAS) study. PWD and caregivers outside of this population may have unique experiences on their pathway to diagnosis not fully-captured in this study. Also, studies conducted outside the US may contain individuals with varying access to care and under a different health care structure, such as universal healthcare may result in different findings. However, study findings could be useful for hypothesis generation and the improvement of interventions, such as the Medicare Annual Wellness Visit focused on timely and accurate ADRD diagnosis. Another limitation in this study and similar studies about ADRD diagnosis is that severity is unknown. A standard metric to identify “timely” diagnosis does not exist and clinical observations of disease severity could vary by healthcare provider.

5. IMPACT OF THE MEDICARE ANNUAL WELLNESS VISIT ON GEOGRAPHIC VARIATION IN DEMENTIA DIAGNOSIS

5.1 Abstract

Introduction: The Medicare Annual Wellness Visit was developed from the Affordable Care Act to support early detection and diagnosis of Alzheimer's disease and related dementias (ADRD). The objective of this study was to evaluate the impact of the Medicare AWV implementation on geographic variation in ADRD diagnosis rates in Delaware, Maryland, Virginia, and Pennsylvania (DELMARVA + PA).

Methods: An ecological study investigating county-level ADRD cumulative incidence in DELMARVA+PA before and after the implementation of the Medicare AWV. Five-year ADRD cumulative incidence was measured from 2006-2010 (pre-policy) and 2011-2015 (post-policy). Generalized linear models and geographically-weighted models were used to estimate the association between geographic variation in ADRD cumulative incidence and implementation of the Medicare AWV controlling for demographic, geographic, and access to care measures.

Results: In the DELMARVA+PA region, there were 18,126 Medicare beneficiaries with a new ADRD diagnosis from 2006-2010 (pre-policy) and 18,918 from 2011 and 2015 (post-policy). Average Medicare AWV participation was 5.7 percent. There was wide variation in 5-year ADRD cumulative incidence rates and AWV uptake across counties in the study area. Controlling for the number of general practitioners, percent Black, median household income, and percent urban, Medicare AWV participation was not associated

with increased in 5-year ADRD cumulative incidence (rate ratio [RR]: 0.998; p-value=0.67). There was increased clustering of predicted incident rates of ADRD in more urban areas of DELMARVA+PA where there tended to be higher levels of Medicare AWV participation.

Conclusions: The Medicare AWV did not reduce geographic variation in 5-year ADRD cumulative incidence in DELMARVA+PA. Low and variable participation of the Medicare AWV may be the cause. Health plans and service providers could use these findings to promote participation in the Medicare AWV in more rural areas that could benefit from increased ADRD detection and diagnosis.

5.2 Introduction

The number of individuals age 65 years and older with Alzheimer's disease and related dementias (ADRD) in the United States (US) is estimated to surpass 7.1 million by 2030, with health care costs projected to rise dramatically as a result ("2019 Alzheimer's disease facts and figures," 2019). In the primary care setting; however, cognitive impairment is under-detected by 27%-81% (Callahan et al., 1995; Camicioli et al., 2000; Chodosh et al., 2004; Valcour et al., 2000). It is estimated that less than half of persons with dementia (PWD) receive a formal medical diagnosis even though they may be receiving care for their disease (Boustani et al., 2005). As a result, diagnosis can occur relatively late in the disease course, if at all. Care experts believe that lack of routine assessment to detect cognitive impairment in primary care settings is one of the most important barriers to dementia diagnosis (Fortinsky & Simmons, 2017). Without a timely, accurate diagnosis, people with ADRD and their caregivers are unlikely to benefit from appropriate care, effective drug therapy, and services, such as community-based education, support, and long-term care planning.

Variations exist in ADRD diagnosis due to system-, provider-, and patient/caregiver-level factors (Bradford et al., 2009). One important patient/caregiver-level factor is limitations due to access to diagnostic care. These limitations are attributable but not limited to financial barriers, lack of provider availability, and geographic location. Geographic variations in medical care have been documented since the early 1970s (J Wennburg & Gittelsohn, 1973). Prior studies of small areas support the notion that there is a lack of conformity of practice styles among large regional communities of

physicians. Each state and region has many hospital-service areas, and local practice patterns vary substantially among them (Wennburg, 1999). Research shows where a patient lives can have a large impact on the level and quality of health care the patient receives (Baicker et al., 2005; Russ et al., 2012). Understanding where geographic variation exists in health care delivery, use, and outcomes for health conditions, such as ADRD will have a substantial impact on how healthcare policies are designed and implemented to improve the quality of health care and the well-being of individuals.

Similarly, it is expected that geographic variation in assessment for and diagnosis of ADRD exists because of varying health-care practices and availability of essential health-care resources. These factors have a direct impact on burden of illness and may indicate socio-environmental contributions to ADRD detection, diagnosis, treatment, and outcomes. Geographic variation in dementia prevalence and death have been documented worldwide (Russ et al., 2012). However, geographic variation in ADRD incidence is not well documented.

In the wake of the Medicare Annual Wellness Visit (AWV), there is an opportunity to (1) understand geographic variation in ADRD diagnosis and (2) the impact of the Medicare AWV on geographic variation in ADRD diagnosis. The Medicare AWV, requiring a cognitive assessment, was added as a benefit fully-covered under Medicare Part B in 2011 through the Affordable Care Act (Patient Protection and Affordable Care Act, 42 U.S.C. § 18001, 2010). It was implemented to promote increased detection of ADRD in the primary-care setting. The Medicare AWV is different from a routine physical exam or

Initial Prevention Physical Exam (i.e. the "Welcome to Medicare" visit) because it the Medicare AWV is more heavily focused on prevention. The purpose of the Medicare AWV is to annually update the patient's medical history, screen for common problems such as risk for falls, depression and cognitive impairment, and discuss prevention recommendations (Colburn & Nothelle, 2018).

The Medicare AWV provides an unprecedented opportunity to overcome current barriers and initiate discussions about cognitive function among the Medicare population, who are most at risk for ADRD due to age (Cordell et al., 2013). The objective of this study was to evaluate the impact of the Medicare AWV implementation on geographic variation in ADRD diagnosis rates in Delaware, Maryland, Virginia, and Pennsylvania (DELMARVA + PA). Given the urban/rural variation observed in the prior study (Aim 1), we hypothesized that significant geographic variation exists in DELMARVA + PA ADRD diagnosis rates and Medicare AWV implementation would increase ADRD diagnosis rates in counties with higher participation and reduce geographic variation in ADRD diagnosis rates overall.

5.3 Methods

Approach

This was an ecological study investigating differences in ADRD cumulative incidence in DELMARVA+PA counties before and after the implementation of the Medicare AWV.

Study Area

Maryland, Delaware, Virginia (DELMARVA), and Pennsylvania (PA) were chosen as the study area. For continuity, District of Colombia (D.C.) was included in the study area as it is located between Maryland and Virginia. The previous study (Aim 1) focused on comparing ADRD diagnosis journeys among western, central and eastern regions in Maryland. To build upon that work, we wanted to focus this study on Maryland and surrounding states in the mid-Atlantic region of the US. Since Maryland only has 24 counties, expanding the study area to DELMARVA and PA also increased the study's sample size.

DELMARVA is an acronym for the peninsula consisting of the shoreline counties of the three states: Maryland, Delaware, and Virginia. For this study, we defined DELMARVA. In addition, we included Pennsylvania, which is contiguous to Maryland and refer to the region as DELMARVA+PA. This yielded over 4 million Medicare beneficiaries represented in the 228 counties of DELMARVA + PA. From a geographic perspective, Maryland, Delaware, Virginia, and Pennsylvania, exhibit characteristics of both Northern and Southern regions of the United States. While the northern portion of DELMARVA, such as the Wilmington, Delaware metro area, is similar to the urban regions of Philadelphia, the Maryland and Virginia Delmarva counties (as well as the southern two counties in Delaware) are more conservative than their "mainland" counties (Wikipedia contributors, 2019). In this geographic area, there are a combination of highly populated urban areas, suburban areas, and rural areas that are mountainous, as well as flat plains and coastal areas (*The Rural Maryland Council*, 2019). Pennsylvania is among the most

rural states, with the population of nearly 12.8 million people stretched across 19 urban and 48 rural counties, anchored by two major metropolitan areas in Philadelphia and Pittsburgh. Rurality contributes to a rich diversity among Pennsylvanians but also presents challenges with regard to providing appropriate care and support for individuals with ADRD and their families (*County Profiles—The Center for Rural PA*, 2019). Residents of these areas are, on average, older, poorer, and possess greater health care needs than those in urban areas, yet have less access to fewer primary care providers, nursing homes, and home and community-based services (*County Profiles—The Center for Rural PA*, 2019).

From a policy perspective, Maryland has become a model state for developing strategic goals to reduce the burden of ADRD. With a strong advocacy presence, Maryland has exhibited legislative momentum toward the prevention and early identification of ADRD which mirrors the priorities set forth by the National Alzheimer's Project Act (Khachaturian et al., 2012). Delaware, Pennsylvania, and Virginia have comprehensive state plans to address ADRD which includes priorities such as, awareness, increased health care delivery and workforce training, improved detection, caregiver support, and research initiatives.

Data sources

Chronic Condition Data Warehouse

This study used a 5% sample of de-identified Medicare administrative and claims data from the Centers for Medicare and Medicaid Services (CMS) Chronic Condition Data

Warehouse (CCW) for years 2006-2015 (Centers for Medicare and Medicaid, 2010). Its administrative files include beneficiary personal information regarding demographic characteristics, original reason for Medicare entitlement (age, disability and/or ESRD), plan type, enrollment status, and billing geography. Administrative claims data from Medicare Fee-for-Service Parts A, B, and D provide long-term follow-up of beneficiary interactions with the health care system among geographically and socioeconomically diverse populations. At an annual summary level, the administrative files provide chronic condition flags for 27 select chronic conditions, including ADRD, using claims-based algorithms that recognize service use patterns as a proxy for treatment of the condition (Centers for Medicare and Medicaid, 2010).

Area Health Resources Files

The Area Health Resources Files (AHRF), provided by the Health Resources and Services Administration, is a public use database that contains over 6,000 variables in files for each of the US's county, state, and national levels in eight broad areas: Health Care Professions, Health Facilities, Population Characteristics, Economics, Health Professions Training, Hospital Utilization, Hospital Expenditures, and Environment (HRSA, 2019). Data sources contributing to AHRF include the US Census bureau, the HRSA data warehouse, the American Medical Association physician master files, the American Hospital Association facilities database, the American Community Survey, and CMS Enrollment data. AHRF also contains geographic codes and descriptors, which enable linkage to other data sources.

Cartographic Boundary Files

County shapefiles of DELMARVA+PA were obtained from the Census Bureau's Master Address File/Topologically Integrated Geographic Encoding and Referencing (MAF/TIGER) database. The geodatabases include feature class layers of information for the fifty states, the District of Columbia, Puerto Rico, and the Island areas (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the United States Virgin Islands) (U.S. Census Bureau, 2019).

Explanatory Variables

Demographic Information

The total number of general practitioners, percentage of Whites/Caucasians and Blacks/African Americans, Median household income, and Medicare enrollment total (including age and disabled eligibility) were obtained from the AHRF files and summarize across counties for the pre- and post- policy period (Table 5.1).

Table 5.1 Explanatory Variables

Demographic factors:	**Geographic factors**	**Access to health care factors**
• Percent White/Caucasian • Percent Black/African American • Median Household Income • Medicare Enrollment, Aged & Disabled	• Percent Urban Population	• Medicare Annual Wellness Visit • Total General Practitioners • Health Professional Shortage Area-Primary Care • Total Number Hospitals • Total Number Nursing Facilities

ADRD Cumulative Incidence Rates

CCW contains flags for 27 chronic conditions, including Alzheimer's disease and related dementias. The CCW Flag for ADRD includes the following International Classification

of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes: 331.0, 331.11, 331.19, 331.2, 331.7, 290.0, 290.10, 290.11, 290.12, 290.13, 290.20, 290.21, 290.3, 90.40, 290.41, 290.42, 290.43, 294.0, 294.10, 294.11, 294.20, 294.21, 294.8, and 797. ADRD beneficiaries were flagged as an incident case if they had at least one inpatient, Skilled Nursing Facility, Home Health Agency, Part B institutional, or Part B non-institutional (carrier) claim with a related code in any position during a 3-year reference period as defined by CCW's algorithm (Taylor et al., 2002). Individuals with a new ADRD diagnosis between 2006 and 2015 were eligible for the study. Five-year cumulative incidence rates for ADRD were calculated per county for the pre- and post-policy periods: 2006 to 2010 and 2011 to 2015, respectively. Cumulative incidence was defined as:

$$\boldsymbol{CI_i}: \frac{Number\ of\ new\ ADRD\ diagnoses\ during\ period}{total\ population\ at\ risk} \text{ for a given US county, } i.$$

Counties in the pre-policy period with 5- year incidence rates lower than 11 per 1,000 people were excluded from analyses. Counties with extremely low incidence were thought to bias the results and produce artificial geographic variation in the data. The exclusions were also applied to the post-policy period and comprised of approximately 15 percent counties in each policy period.

Medicare Annual Wellness Visit

Medicare AWV participation was defined as the percent of Medicare beneficiaries diagnosed with a new diagnosis of ADRD with a Medicare AWV in the same year for a

given county. County-level AWV participation was averaged over post-policy period (2011-2015) since access to the Medicare AWV was only available after 2010, upon the implementation of the Affordable Care Act. Medicare AWV participation was obtained among the ADRD population identified from the 5% sample of Medicare beneficiaries.

Geographic Measures

Percent urban population was obtained from the AHRF (Table 5.1). Percent urban was defined as the percent of "densely developed residential, commercial and other nonresidential areas" within a county. Urbanized Areas are quantified as territories (i.e a set of adjacent census tracts and/or census blocks) having 50,000 or more people (U.S. Census Bureau, 2012).

Access to Care Measures

The Institute of Medicine defined access to health care as "the timely use of personal health services to achieve the best health outcomes" (Institute of Medicine (US) Committee on Monitoring Access to Personal Health Care Service, 1993). It was further defined by Healthy People 2020 into four components: coverage, services, timeliness, and workforce (Healthy People 2020, 2010). Variables relevant to points of service and access to services necessary to obtain an ADRD diagnosis were identified in the AHRF. The measures included total number of general practitioners (including primary care, family, and general medicine physicians), hospitals, nursing facilities, and number of primary care provider shortage areas (HPSA) (Table 5.1). The HPSA variable was designated by HRSA's Bureau of Health Workforce as an area having shortages of

primary care providers. This variable was used to designate areas within counties that may lack of access to providers in primary-care settings where cognitive impairment or ADRD should be detected.

Statistical Analysis

Mapping and Cluster Analysis

For each policy period, choropleth maps were created to visualize the geographic distribution of 5-year cumulative incidence rates of ADRD at the county-level. Choropleth maps use different shading and coloring to display aggregated data in defined geographic areas (GISGeography, 2019).

Descriptive Analyses

All explanatory variables were characterized by policy period. The Shapiro-Wilk test was used to evaluate the normality of continuous variables (Mecklin, 2020). If normally distributed, continuous variables were summarized by a mean and standard deviation. Otherwise, a median and interquartile range was reported. Frequency counts (percentage) of observed levels were reported for all categorical measures.

Cluster Analysis

In order to determine evidence of geographic variation in ADRD cumulative incidence rates in DELMARVA + PA, clustering methods were employed (ESRI, 2015; Griffith, 1987; Mitchell, 2005). A Moran's I (Index ranging from 0 to 1) statistic was used to test if there was a significant amount of spatial autocorrelation or dependency in the data

(Anselin, 1995). If the statistic was positive and statistically significant at the 5% significance level, spatial autocorrelation existed at a global level. Thus, this result would justify using a geographically weighted regression (GWR) model to understand the effects of the predictor variables at the local level.

Global Moran statistic, I is defined as:

$$I = \frac{n \sum_i \sum_j W_{ij} (Z_i - \bar{Z})(Z_j - \bar{Z})}{(\sum_i \sum_j W_{ij}) \sum_k (Z_k - \bar{Z})^2},$$

where Z_i could be the residuals ($O_i - E_i$) or standardized incidence of an area, and W_{ij} is a measure of the closeness of areas i and j

The null hypothesis was that the distribution of ADRD incidence across DELMARVA+PA was due to random chance (i.e., no clustering). If the null hypothesis was rejected, there was evidence of clustering, i.e. spatial autocorrelation and geographic variation was confirmed.

Hot Spot Analysis (Getis-Ord Gi Statistic)*

Upon testing for global spatial autocorrelation, Getis-Ord Gi* statistics were computed to determine where significant patterns of spatial autocorrelation (i.e., clusters of ADRD incidence) existed across DELMARVA+PA by calculating the Gi* statistic for each area. A Z-score and p-value were computed to determine the statistical significance of clustering. If the Z-score was between -1.96 and 1.96, the null hypothesis could not be rejected and the pattern exhibited could be due to random spatial processes. If the Z-score fell out of the range, a statistically significant spatial autocorrelation i.e., clustering in the data was evident. A high Gi* indicated a “hotspot” of high ADRD cumulative incidences

whereas low Gi* meant a "cold" spot of low ADRD cumulative incidences (Anselin & Getis, 1992).

Generalized Linear Model

A correlation matrix of the regression variables was constructed to assess and prevent any collinearity between explanatory variables. Spearman's rank correlation, variance inflator factor (VIF) and scatterplots were also used to examine correlation. The VIF cut-off was 5 for probable multicollinearity of a variable. A generalized linear model (GLM) was used to fit the model for each policy period that best explained 5-year ADRD cumulative incidence rates controlling for county-level factors. A Poisson distribution was selected for these data because the outcome of interest was cumulative incidence rate of ADRD with a low frequency of occurrence. The model was denoted as:

$$\ln(\hat{\mu}) = \beta_0 + \sum \beta_p X_p,$$

where $\hat{\mu}$= the p redicted rate of ADRD incidence; β_0 = the intercept; X_p= (1 to p) where p is the number of predictor variables, and β the regression coefficient. The model implies that the logarithm of the function is a linear function of the parameters.

The GLM was reduced to achieve the most parsimonious model using the Akaike's information criterion (AICc) to assess model performance. A lower AICc value provided a better fit of the observed data. When the best model was achieved, a joint F- statistic was conducted to measure overall model statistical significance at alpha=0.05. The null hypothesis was that all variables are equal to zero; the explanatory variables in the model are not effective. The null was rejected if at least one variable estimate was not equal to zero reflected by a p-value greater than or equal to 0.05. The percent deviance explained,

also known as the *pseudo* R^2, is the proportion of the dependent variable variance accounted for by the explanatory variable.

Geographically Weighted Generalized Linear Model

A geographically weighted generalized linear model (GWGLM) with a Poisson distribution was conducted for each policy period on 5-year ADRD cumulative incidence rates using the explanatory variables from the best-fit GLM. (Nakaya et al., 2005) GWGLMs add a level of modeling sophistication by allowing the relationships between the outcome and explanatory variables to vary by a geographic unit such as a county. This model was used to account for any clustering of 5-year ADRD cumulative incidences as a result of the Moran's I test for spatial autocorrelation.

The GWGLM was denoted as:

$$\ln(\hat{\mu}_i) = \beta_0(u_i, v_i) + \sum \beta_k (u_i, v_i) X_{i,k},$$

where $\hat{\mu}_i$ = the predicted rate of ADRD incidence in the i^{th} county; (u_i, v_i) = x, y coordinates; $\beta_0(u_i, v_i)$ = the intercept; $X_{i,k}$ = set of observations for k^{th} predictor variable and the i^{th} county, and $\beta_k (u_i, v_i)$ = the regression coefficient.

The AICc from the GWGLM was compared to the GLM AICc to assess the benefits of moving from a global model (GLM) to a local regression model (GWGLM). If the AICc values for two models differed by more than 3, the model with the lower AICc value is held to be better. This study used SAS® 9.4 (Cary, NC) for data management and descriptive statistics; and ArcGIS Pro™ 2.4.1 (ESRI, Redlands, CA) for mapping and statistical analyses. All analyses were conducted separately for pre- and post- Medicare AWV implementation periods. The pre- and post- policy models were compared using a

Moran's I test to determine if there was a reduction of spatial autocorrelation or clustering of the predicted values of 5-year ADRD cumulative incidence adjusting for Medicare AWV participation (in the post-policy period) and other county-level factors.

5.4 Results

The study population consisted of 18,126 individuals with a new ADRD diagnosis from 2006-2010 (pre-policy) and 18,918 individuals with a new ADRD diagnosis from 2011 and 2015 (post-policy) (Figure 5.1). With counties as the unit of analysis, in the post-policy period, the average Medicare AWV participation was 5.7 percent with standard deviation of 4.3 percent. The percent of Medicare AWV participation ranged from zero to 26.7. On average, whites and blacks represented 80.3 and 15.4 percent of the population, respectively (Table 5.2)

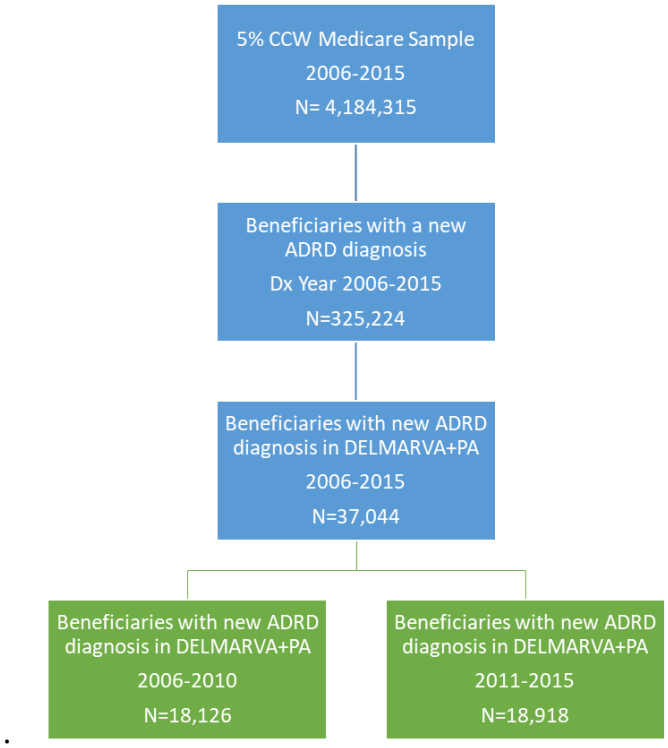


Figure 5.1 Creation of Study Population

The mean(standard deviation) of total Medicare beneficiaries across DELMARVA+ PA counties was 17,921(30,239) and 18,410(28,323) for the pre- and post- policy periods, respectively. The average percent urban population was 54.3(35.4) and 52.7(36.3) percent for the pre- and post- policy periods, respectively. In terms of access to care measures, the median number of general practitioners across counties was 13 with an interquartile range of 33 in the pre-policy and 37 in the post-policy period. The average total of hospitals and nursing homes where 2.1(3.7) and 0.2(0.6), respectively for both policy periods. Eighty-seven percent of counties were considered either a whole or partial health provider shortage area.

Table 5.2 County-Level Population Characteristics by Policy Period (Pre versus Post)

Characteristic, Mean(Stdev)	Pre- Medicare AWV Implementation (2006-2010)	Post- Medicare AWV Implementation (2011-2015)
Medicare AWV Participation	-	5.7(4.3)
Percent White Population	81.1 (17.1)	78.1(17.5)
Percent Black/African Am	15.1(16.3)	15.9(16.2)
Median Household Income	45,804.8(14,492)	51,445(17,273)
Percent Urban Population	54.3(35.4)	52.7(36.3)
Medicare Enrollmnt, Aged & Disabled Total	17,921(30,239)	18,410(28,323)
Total General Practitioners	13(33)^	13(37)^
Health Provider Shortage Area- Primary Care	167(87.0)*	167(87.0)*
Number of Hospitals	2.1(3.7)	2.1(3.7)
Number of Nursing Facilities	0.2(0.6)	0.2(0.6)

^Median and interquartile range reported
*N and percentage reported

Mapping

Figure 5.2 depicts 5-year ADRD cumulative-incidence rates per 1,000 people during the pre- and post- policy periods. Average 5-year ADRD cumulative incidence estimates were 18.7 and 17.8 for pre- and post- policy periods, respectively. Based on the choropleth map of the pre-policy period, the darker shading of green reflecting high

ADRD cumulative incidence per 1,000 Medicare beneficiaries was observed in central and eastern regions of Maryland, all of Delaware as well as northeastern Virginia. The lighter green shading reflected low ADRD cumulative incidence per 1,000 Medicare beneficiaries observed in northern Pennsylvania and western Virginia. In the post policy period, there was an overall decrease in 5-year cumulative incidence of ADRD in Pennsylvania, whereas Virginia and Maryland had pockets of increased 5-year cumulative incidence of ADRD (Figure 5.2).

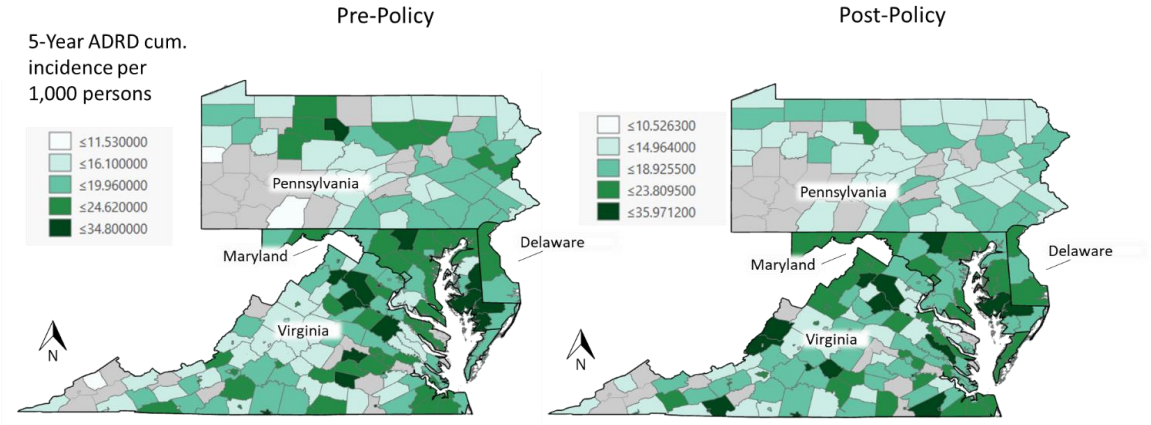


Figure 5.2 County-level 5- Year ADRD Cumulative Incidence Rates by Policy Period

Among the counties with the largest increases in ADRD cumulative incidence, Medicare AWV participation varied (Figure 5.3). Higher participation rates of the Medicare AWV, shaded in dark purple, were concentrated in the same counties with high ADRD cumulative incidence (eastern Virginia, Maryland, and Delaware). However, high Medicare AWV participation rates were also observed in middle and northeast Pennsylvania where there was low ADRD cumulative incidence rates. Only half of the top-ten counties with the highest-percent increase in 5-year cumulative incidence had Medicare AWV participation over the DELMARVA + PA average of 5.7%.

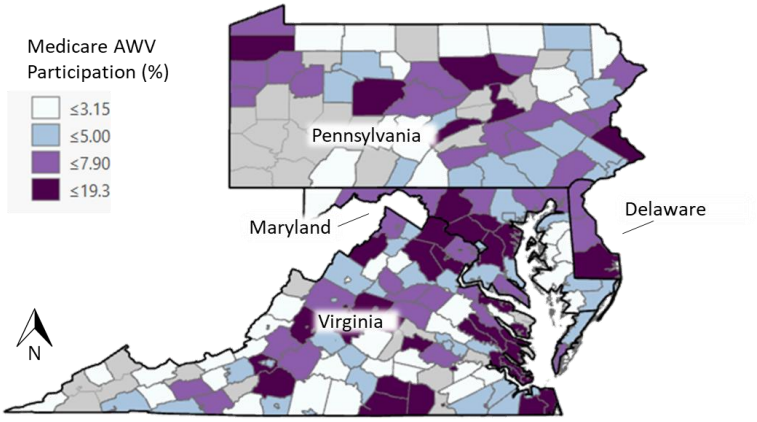


Figure 5.3 Medicare Annual Wellness Visit Participation by County (Post-policy Period)

Cluster Analysis

In the pre-policy period, the Moran's I statistic was 0.17 (Figure 5.4). Given the z-score of 4.9 and p-value <0.001, there was less than a one-percent likelihood that the clustered pattern of ADRD cumulative-incidence rates were a result of random chance. Thus, there was strong evidence of clustering of 5-year cumulative incidence of ADRD. In the post-policy period, the Moran's I statistic was 0.10 with a z-score of 2.94 and p-value of 0.003. There was less than a one-percent likelihood that the clustered pattern of ADRD cumulative-incidence rates were a result of random chance. In both policy periods, we concluded there was significant spatial clustering.

Hot spot analysis using Getis-Ord Gi* statistics confirmed the location of the existing clusters observed in the raw incidence data. Significant hotspots were observed around central/eastern Maryland, northeastern Virginia and Delaware denoted in orange/red (Figure 5.4). Significant "cold" spots were observed in central and eastern Pennsylvania as well as western Virginia denoted in green/blue. Comparing pre and post policy

periods, there is a distinct disappearance of the significant hotspots among counties in central/eastern Maryland and northeastern Virginia.

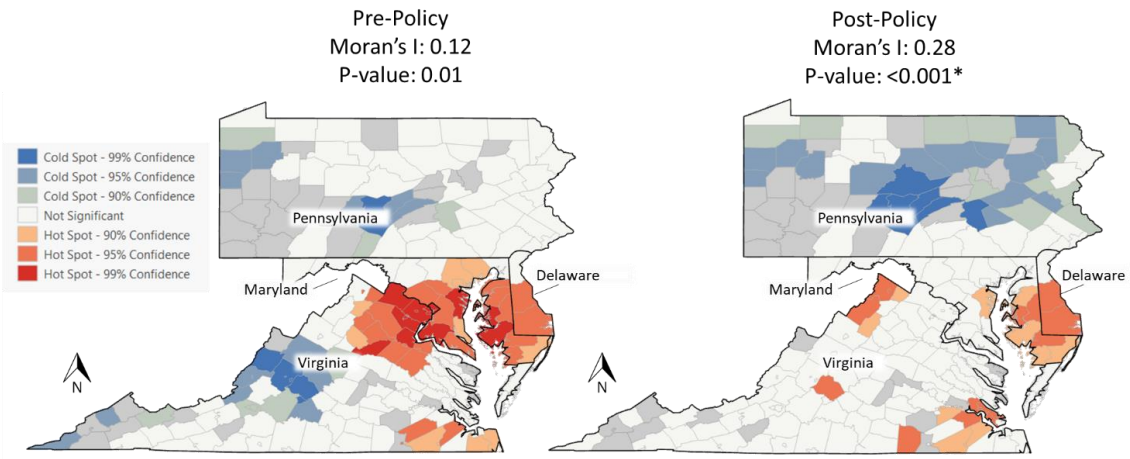


Figure 5.4 Local Cluster Hotspot Analysis Results

Model results

Table 5.3 contains GLM results for pre- (Model 1) and post- policy period (Model 2). The final Model 1 for the pre-policy period included the following parameters: Number of General Practitioners, Percent Black/African American, Median Household Income, and Percent Urban. Holding all other parameters constant, the cumulative incidence for ADRD tended to be higher in counties that had higher proportions of Blacks. For a given county a 1 percent increase in the proportion of blacks resulted in an estimated 0.004 percent increase in 5-year ADRD cumulative incidence per 1,000 people. Having more general practitioners, however, resulted in lower ADRD cumulative incidence. Counties that had higher Median Household Income had higher ADRD cumulative incidence. Higher cumulative incidence ADRD was also associated with counties that had a higher percent of urban areas. Model 2 included the above parameters plus the Medicare AWV

parameter. In Model 2, results for number of General Practitioners, Percent Black/African American, and percent Urban were similar. While all four effects were statistically significant in Model 1 at the .05 level, for Model 2 median household income became statistically insignificant. Participation in the Medicare AWV was not significantly associated with an increase in county-level ADRD incidence in the post-policy model (Table 5.3).

Table 5.3 Generalized Linear Model (GLM) and Geographically-weighted Generalized Linear Model (GWGLM) Results

	GLM Model Results		**GWR Model Results**	
Model 1: Pre- policy	Coefficient	P-Value	Coefficient Minimum	Coefficent Maximum
Intercept	14.654	<0.001*	14.59	15.28
General Practitioners	0.9996	0.01*	1.00	1.00
Black/African Am (%)	1.004	<0.001*	1.003	1.004
Median Household Income	1.00	0.03*	1.00	1.000
Urban (%)	1.002	0.002*	1.001	1.002
Model 2: Post-policy	Coefficient	P-Value	Coefficient Minimum	Coefficent Maximum
Intercept	15.717	<0.001*	13.46	18.64
General Practitioners	1.000	0.01*	1.00	1.000
Medicare AWV	0.998	0.67	0.99	1.001
Black/African Am (%)	1.004	<0.001*	1.00	1.006
Median Household Income	1.000	0.54	1.00	1.000
Urban (%)	1.001	0.01*	1.001	1.003

*P-value < 0.05

GWGLM models produced ranges of county-specific coefficient estimates for Models 1 & 2 parameters. The ranges demonstrated the variability of coefficient estimates across DELMARVA+PA (Table 5.3). The range of coefficients themselves did not demonstrate whether they were randomly distributed across the geographic area; however, the choropleth maps of each parameter's county-level coefficients were mapped to observe any spatial patterns. Although there was a lack of statistical significance in Model 2,

Medicare AWV participation had the strongest association with increased ADRD cumulative incidence in eastern Pennsylvania, Delaware, eastern Maryland, and eastern Virginia, denoted in dark blue (Figure 5.5). In these areas, a one-percent increase in Medicare AWV participation was associated with up to a 0.10 percent increase (range -0.01 to 0.01 percent) in 5-year ADRD cumulative incidence (Table 5.3).

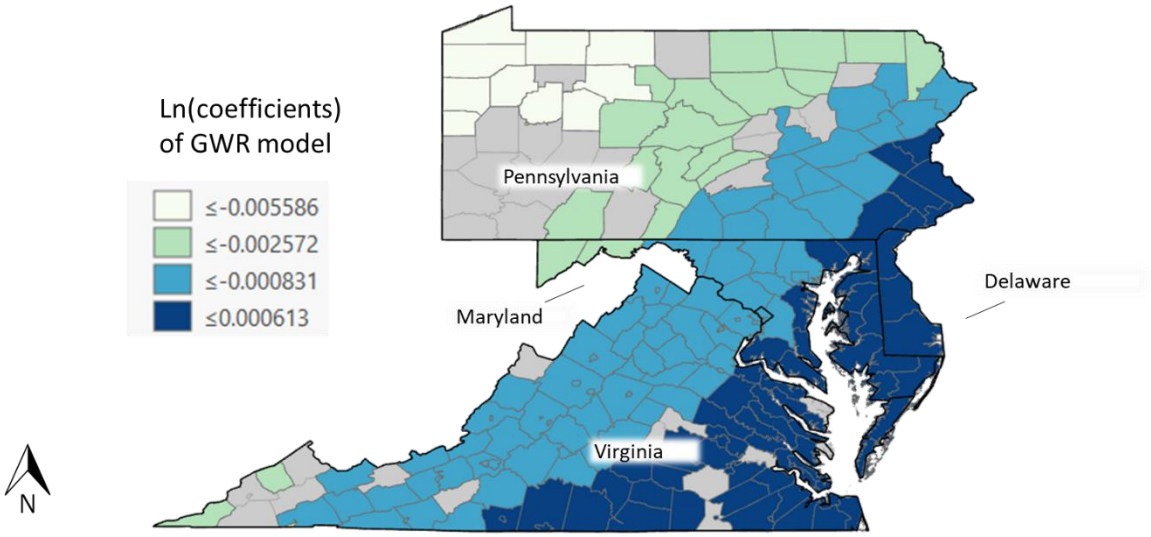


Figure 5.5 Spatially Non-stationary Associations between ADRD Cumulative Incidence and Medicare AWV Participation

Model comparison: Pre-policy versus Post-policy

Choropleth maps of GWGLM predicted values of 5-year ADRD cumulative incidence are depicted in Figure 5.6 for both policy periods. Instead of reducing clustering, adjusting for county-level factor and the Medicare AWV in the post-policy period strengthened the clustering of high rates of 5-year ADRD cumulative incidence. Higher rates of 5-year ADRD cumulative incidence could be observed in counties located in regions of eastern Virginia, Maryland, and Delaware. In the pre-policy period, the Moran's I statistic was 0.46 with a z-score of 15.4 and p-value <0.001. In the post-policy

period, the Moran's I statistic was 0.51 with a z-score of 17.3 and p-value <0.001 (Figure 5.6). The Moron's I test for spatial autocorrelation results confirmed the clustering of predicted values with similar magnitudes observed for both policy periods.

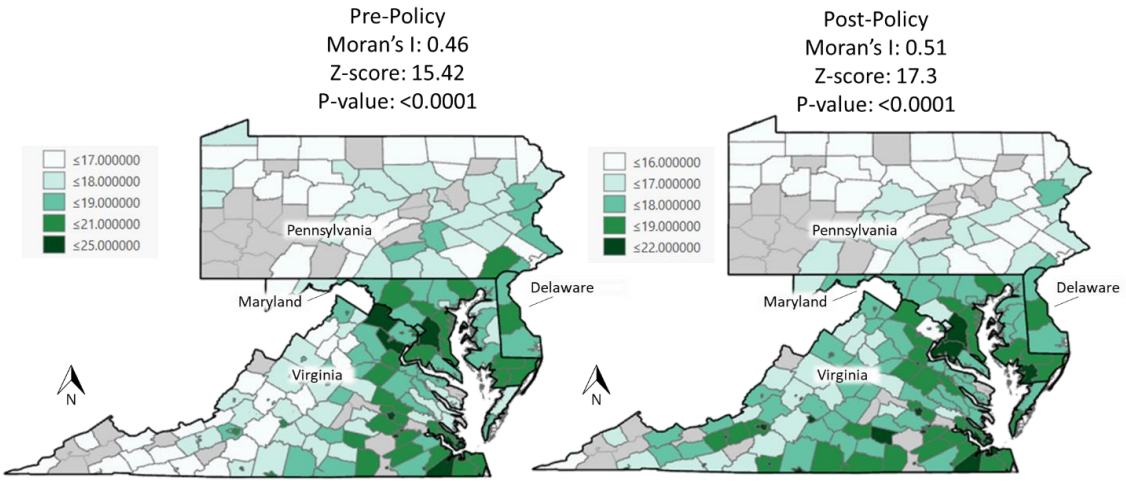


Figure 5.6 County-level Predicted 5- Year ADRD Cumulative Incidence Rates by Policy Period Adjusted for County-Level Factors

5.5 Discussion

Incidence of ADRD in DELMARVA+PA

While the number of adults living with ADRD in the US and other countries is expected to grow exponentially by 2030 due to increased life expectancy, recent studies suggest that age-specific risk (i.e., the risk of dementia at a specific age) has declined over the past 30 years in some high-income countries, including the United States, England, and the Netherlands (Hudomiet et al., 2018; Langa et al., 2017; Matthews et al., 2019; Satizabal et al., 2016; Schrijvers et al., 2012). A study by Langa et al. found that the number of new cases of dementia in adults 65 years and older in the United States fell by 24% in a 12-year period; from 11.6% in 2000 to 8.8% in 2012 (Langa et al., 2017).

Another decrease in the number of adults 65 and older living with dementia in the United States (from 12.0% in 2000 to 10.5% in 2012) was reported in a study by Hudomiet et al. (Hudomiet et al., 2018). Both studies suspected that the trends observed may in part be due to higher education levels, better access to health care, and improvements in cardiovascular treatments.

Average incidence estimates in this study were 18.7 and 17.8 for pre- and post- policy periods, respectively. These estimates are higher than previously reported national estimates. This may be due to the specific 5-year time period that incidence was measure and unique to the geographic area, DELMARVA+PA, from which the incidence was estimated. The DELMARVA+ PA region has a number of research institutions containing special Alzheimer research units and memory clinics aimed at providing specialized care, which may lead to more detection and diagnosis of ADRD. Governing bodies that fund Alzheimer's research are also in close proximity such as the National Institutes of Health. DELMARVA+ PA also have extensive state plans to address efforts to raise awareness, identify ADRD earlier, and develop a workforce that is trained and skilled to diagnose ADRD and provide high-quality care. Comparisons of these factors in other regions of the country would be needed to investigate whether the above projected reasons for higher DELMARVA+PA incidence are correct.

Small Area Variation in ADRD Incidence

Although incidence rates are higher than the national average, choropleth maps and the Global Moran's I test demonstrated significant spatial clustering of ADRD diagnoses in

DELMARVA+PA both pre and post Medicare AWV implementation. The cluster locations reflected distinct urban and rural areas of the states. High cumulative incidence rates were clustered around central Maryland and eastern Virginia, which are urban areas. Clusters of low cumulative incidence rates were located in Pennsylvania and the western part of Virginia; primarily rural areas.

Rural counties in DELMARVA+ PA face a host of difficult challenges relating to persistent unemployment and poverty, changing technological and economic conditions, an aging population, inadequate access to quality housing, health care and other services, and deteriorating or inadequate transportation, communications, sanitation, and economic development infrastructure. Variations in ADRD diagnosis in these counties compared to urban counties may be due to those challenges (Koller & Bynum, 2014). Variations may be due to differences in clinical practice and training which may impact the detection and documentation of ADRD in health care settings (Connolly et al., 2011).

It is not feasible to measure all the probable factors contributing to geographic variations in ADRD diagnosis using administrative claims data. Access to county-level factors through HRSA made it possible to use measures of socio-economic, geographic and access to health care in health services research. GLM Model results revealed that number of general practitioners, percent Black/African American, median household income, percent urban, and Medicare AWV participation were contributors to explaining variation in ADRD cumulative incidence. However, there is still 80 percent of variance in 5-year ADRD cumulative incidence unexplained by these county-level attributes.

Individual-level factors such as, socioeconomic status, education, genetics, co-morbid burden, family support, and cultural acceptance of mental health may further explain the variation of ADRD incidence. However, these measures are at a different unit of analysis and are often difficult to obtain in administrative claims and public use files.

GWGLMs greatly improved the model fit of pre- and post- AWV implementation (1092.0 versus 174.7 (Model 1) and 1097.0 versus 180.4 (Model 2). The GWGLMs also improved the percent deviation (or variance) explained in pre and post- policy models (1.5% and 8.3%, respectively) (Table 5.4). The spatial patterns observed for each model parameter imply that the strength of associations between ADRD cumulative incidence and each parameter vary depending on spatial location. Thus, assuming a causal relationship, the effects of the parameters are not constant across the study area but are heavily dependent on the geographic location. This geographic variability makes it challenging to draw plausible conclusions about how these factors work together to get an individual to an ADRD diagnosis.

Table 5.4 Generalized Linear Model (GLM) and Geographically-weighted Generalized Linear Model (GWGLM) Comparisons

	Model 1: Pre-AWV Implementation	Model 2: Post-AWV Implementation
% Deviance explained by the global (GLM) model (non-spatial):	15.2	10.7
% Deviance explained by the local (GWR) model:	**16.5**	**18.2**
Difference in % deviance explained (global versus local):	1.5	8.3

Medicare AWV Impact on Geographic Variation

The average county-level participation for Medicare AWV was 5.7 with a standard deviation of 4.3. This is below the reported national average of 17 percent for participation in the Medicare Annual Wellness Visit by CMS and validates the continued need to raise more awareness of this free benefit (Ganguli et al., 2017). Controlling for county-level factors, our study showed no significant association between Medicare AWV participation and 5-year ADRD cumulative incidence. However, based on the GWGLM the strongest associations between Medicare AWV and 5-year ADRD cumulative incidence were observed in eastern Virginia, Maryland, and Delaware, which are made up of mostly urban areas and urban areas surrounded by rural areas (Figure 5.5). This implies that there are areas of DELMARVA+PA that benefited from Medicare AWV participation while others did not. The lack of significance in these findings may be due to outlier effects of some counties. For example, Bland, VA, which had a 277 percent increase in ADRD cumulative incidence had no Medicare AWV participation based on the sampled population, while Forest, PA, with a 144 percent increase in cumulative incidence had a 26.7 percent Medicare AWV participation in the post-policy period. Thirty counties had no Medicare AWV participation in the study period. Those counties were largely rural while counties with higher participation rates of Medicare AWV were urban with higher median household income (Figure 5.3). Medicare AWV participation in these counties were more consistent with the national average.

Study findings are not consistent with our initial hypothesis that Medicare AWV would reduce geographical variability. In fact, the Medicare AWV was associated with

increased clustering of incident cases of ADRD in more urban areas of DELMARVA+PA where there tended to be higher levels of Medicare AWV participation. Controlling for demographics, health care access and urbanization alone contributed to clustering of predicted 5-year ADRD cumulative incidence in the pre- and post- policy periods (Figure 5.6). A prior study characterizing participants of the Medicare AWV found that White individuals, urban residents, and those from higher-income areas, belonging to an accountable care organization (ACO) and with 1 or 2 comorbidities were more likely to receive a Medicare AWV (Ganguli et al., 2017). These findings are consistent with the greater diversity of urban areas, a higher median income, and centralized health care systems in metropolitan areas, observed in this study.

Increased Medicare AWV participation is needed as well as efforts to evaluate AWV utilization and effectiveness, especially among low socioeconomic status ethnoracial minorities, with targeted interventions and incentives in more rural areas. Lind et al. found that Medicare AWV utilization varied by ethnoracial group, with disparities largely explained by differences in income and education (Lind et al., 2018). They also found that having a usual place of care and a non-rural residence were strong predictors of utilization (Lind et al., 2018). This study similarly found that a county with a high percentage of urban areas was significantly associated with increased Medicare AWV participation (Table 5.3).

There has been debate about whether the incentives for providers are good enough to encourage uptake of the Medicare AWV, especially when a ‘routine physical’ may result

in higher reimbursements; ($175 for the Medicare AWV versus up to $400 for a routine physical) which Medicare does not cover (Beckman et al., 2019). There are also concerns that the Medicare AWV is too time consuming and limits discussion about cognitive impairment with unknown returns of improved health outcomes. From the patient perspective, the majority of beneficiaries do not know about the Medicare AWV or cannot distinguish it from other 'wellness' visits (Aim 1). They are also concerned that the benefit is not 100 percent covered because referrals, tests, and procedures associated with the visit may be costly. To encourage more awareness and uptake, a rebranding of the Medicare AWV could be warranted with more transparency around actual out-of-pocket costs for beneficiaries while including incentives to match a provider's likelihood of administering this preventative visit.

Strengths and Limitations

This is the first study to investigate the impact of Medicare AWV implementation on geographic variations in ADRD diagnosis. Other studies have focused increased detection of cognitive impairment and found that although there were differences in utilization of health care services tied to cognitive care, there were no significant differences in ADRD incidence between Medicare AWV and no Medicare AWV groups (Fowler et al., 2018). This study focuses on the geographic variability of ADRD diagnoses. The Medicare AWV was designed to be a 'springboard' for detecting cognitive impairment in the primary-care setting, meaning there may be areas in which the Medicare AWV led to increased ADRD incidence relative to others. This study set out to reveal and characterize those areas in DELMARVA+ PA.

This study was an ecological study having inherent limitations. The findings should not be used to make inferences at the individual-level. A change in the unit of analysis, i.e., to zip-code level or to state level could have altered the study findings. This is also known as the modifiable-area-unit problem (Openshaw, 1983). Using county-level rather than individual demographics may have introduced ecological bias because there may exist individual-level factors such as socioeconomic status, education, genetics, co-morbid burden, family support, and cultural acceptance of mental health that further explain the variation of ADRD incidence (Beale et al., 2008). There may also exist external factors such as physician knowledge and beliefs around detecting and diagnosing ADRD.

The issue of under detection also still poses a problem in ADRD diagnosis. Studies, such as Aim 1 above, show evidence of variable and often poor diagnostic sensitivity, affected by several factors including disease type and severity, behavioral symptoms, and rate of contact between provider and the person with probable ADRD (Bradford et al., 2009). Given the outcome of ADRD diagnosis was captured only from administrative claims, the estimates of cumulative incidence may be low. This underestimate may be due to ADRD being undetected by a provider or by the ADRD diagnosis not being documented. It is unclear what percentage of the underestimation of ADRD is due to each source.

GWGLM models had better statistical fit (lower AIC's) than the global GLM models. The percent of deviation explained doubled in both the pre and post models with

GWGLM. These findings are similar to other studies that have compared local geographically weighted regression models to global regression models investigating the associations between disease and risk factors(Cheng, 2017; Comber, Brunsdon, & Radburn, 2011; Liu et al., 2011; Vona-Davis & Rose, 2009).

However, some caveats to the GWGLM should be noted. These models are meant to complement GLMs and should not be used alone. Local models such as GWGLMs aid in the analysis of the spatial variation in relationships between disease outcomes and risk factors. Thus, they should be used only as exploratory tools to investigate spatial non-stationarity due to the issues of probable multicollinearity of the regression variables (Páez et al., 2011; Wheeler & Tiefelsdorf, 2005). Despite these caveats, the use of GWGLM helped improve our understanding of how difference determinants may influence special patterns of disease occurrence, which cannot be determined with traditional GLMs (Odoi & Busingye, 2014). The modest explanatory power of GWGLMs in this study suggests that either a key component of population level access or resources is missing from the analysis or the included access and resource variables may perform differently in rural versus urban areas.

6. IMPACT OF THE MEDICARE ANNUAL WELLNESS VISIT ON HEALTH OUTCOMES IN A DEMENTIA POPULATION

6.1 Abstract

Introduction: The Medicare Annual Wellness Visit (AWV), established under the Affordable Care Act (ACA), includes cognitive-impairment assessment. As an annual opportunity to facilitate the detection and diagnosis of Alzheimer's disease and related dementias (ADRD), it is imperative to understand if the Medicare AWV improves health outcomes in the ADRD population. The objective of this study was to evaluate the impact of the Medicare AWV on health outcomes in an ADRD population.

Methods: This was a retrospective cohort study investigating health care utilization (HCU) comprised of Emergency Department (ED) visits, hospitalizations, and outpatient visits among Medicare beneficiaries newly diagnosed with ADRD who had a Medicare AWV prior to diagnosis compared to those who did not. HCU was measured for the twelve months before and after the diagnosis. Medicare beneficiaries with a new diagnosis of ADRD between January 1, 2012 and December 31, 2014 were eligible for the study. Twelve months of continuous Part A and Part B were required before and after the date of their ADRD diagnosis. Difference-in-Difference models were used to understand the change in health outcomes before and after ADRD diagnosis among Medicare AWV exposure groups controlling for demographics and comorbidities. Data for individual beneficiaries were obtained from de-identified Medicare administrative and claims data from the Centers for Medicare and Medicaid Services (CMS) Chronic Condition Data Warehouse (CCW) for years 2011 to 2015. Community level data were

obtained from Area Health Resources Files (AHRF), provided by the Health Resources and Services Administration.

Results: Receiving a Medicare AWV in the six months prior to ADRD diagnosis was associated with a significant increase in each of the components of HCU [ED visits (rate ratio [RR]: 1.20, 95% confidence interval (CI): 1.11, 1.30), hospitalizations (RR: 1.26, 95% CI: 1.13, 1.40), and outpatient visits (RR: 1.08, 95% CI: 1.04, 1.12)]. Sensitivity analyses for individuals who had a Medicare AWV 7 to 12 months prior to diagnosis revealed a significant increase in ED visits (RR: 1.12, 95% CI: 1.03, 1.22); however, hospitalizations (RR: 1.03, 95% CI: 0.91, 1.16), and outpatient visits (RR: 1.02, 95% CI: 0.97, 1.07) estimates were not statistically significant.

Conclusions: Results suggest the Medicare AWV appears to be facilitating more follow-up care and uptake of preventative services for ADRD, which is reflected by increased HCU rates for beneficiaries who have had the Medicare AWV prior to ADRD diagnosis. It may take longer than one year to see improved outcomes that result in fewer hospitalizations or ED visits as a result of the follow-up and/or preventive services. As participation and awareness of the Medicare AWV continue to increase, studying the impact on short and long-term health outcomes and costs will be critical.

6.2 Introduction

The Medicare Annual Wellness Visit (AWV) became a medical benefit for eligible beneficiaries under the 2010 Affordable Care Act (ACA) (Patient Protection and Affordable Care Act, 42 U.S.C. § 18001, 2010). The Medicare AWV is fully covered under Medicare Part B (CMS, 2011) and can be characterized by three components: a health risk assessment, provider consultation, and personalized prevention plan. Within the three components of the AWV, there are several features intended to detect cognitive impairment, including direct observation, patient report, and concerns raised by family members or others (R.H. Fortinsky & Simmons, 2017). A full dementia evaluation is outside the scope of the Medicare AWV, but can occur in a separate visit either on the same day, during a newly scheduled visit, or through referral to a specialist (Cordell et al., 2013). The Erotological Society of America deems the Medicare AWV a 'springboard' to detection of cognitive impairment, Alzheimer's disease and related dementias (ADRD) diagnosis, and post- diagnosis support (R.H. Fortinsky & Simmons, 2017).

In its first year of implementation, Medicare AWV participation reached over 2 million Medicare beneficiaries (Centers for Medicare & Medicaid Services, 2011). Reports on national trends found Medicare AWV participation increased from 7.5 percent to 16.4 percent from 2011 to 2015 (Chung et al., 2015; Ganguli et al., 2017). White urban residents and those from higher-income areas were more likely to receive a Medicare AWV. Receiving a priori Medicare AWV or belonging to an Accountable Care Organization (ACO) were also characteristics of individuals who were more likely to

obtain a Medicare AWV (Ganguli et al., 2017). Utilization of the Medicare AWV is slowing rising; however, its benefits for improving patient outcomes and controlling healthcare costs continue to be debated (Bluestein et al., 2017; Mehrotra & Prochazka, 2015; Rothberg, 2014).

Prior studies have reported that the AWV was associated with reduced healthcare utilization and increased use of recommended preventative services (Beckman et al., 2019; Jiang et al., 2018). Jiang et al. found that the Medicare AWV was associated with significantly higher odds of receiving preventive services and a reduction of total healthcare costs. Given the importance of the Medicare AWV as an opportunity to facilitate detection and diagnosis of ADRD, it is imperative to understand if the Medicare AWV could improve health outcomes in this population. The objective of this study was to evaluate the impact of the Medicare AWV on healthcare utilization (HCU) in an ADRD population on the pathway to a diagnosis. Based on findings of above noted studies we hypothesized that ED visits and hospitalizations would decrease and outpatient visits would increase compared to individuals who did not have a Medicare AWV leading up to an ADRD diagnosis.

6.3 Methods

Approach

This study was a retrospective cohort study investigating the impact of the Medicare AWV on HCU in a population of Medicare beneficiaries newly diagnosed with ADRD. Annual HCU was compared between individuals who had a Medicare AWV prior to

ADRD diagnosis and those who did not have a Medicare AWV prior to ADRD diagnosis.

Data sources

Chronic Condition Data Warehouse

This study used a 5% sample of de-identified Medicare administrative and claims data from the Centers for Medicare and Medicaid Services (CMS) Chronic Condition Data Warehouse (CCW) for years 2011 to 2015. Its administrative files include beneficiary personal information regarding demographic characteristics, original reason for Medicare entitlement (age, disability and/or ESRD), plan type, enrollment status, and billing geography. Administrative claims data from Medicare Fee-for-Service Parts A, B, and D provide long-term follow-up of beneficiary interactions with the health care system among geographically and socioeconomically diverse populations. At an annual summary level, the administrative files provide chronic condition flags for 27 select chronic conditions, including ADRD, using claims-based algorithms that recognize service use patterns as a proxy for treatment of the condition (Chronic Conditions Data Warehouse: Condition Categories, 2019).

Area Health Resource Files

The Area Health Resources Files (AHRF), provided by the Health Resources and Services Administration, is a public use database that contains over 6,000 variables for each files of the US's county, state, and national levels in eight broad areas: Health Care Professions, Health Facilities, Population Characteristics, Economics, Health Professions

Training, Hospital Utilization, Hospital Expenditures, and Environment (HRSA, 2019). Data sources contributing to AHRF include the US Census bureau, the HRSA data warehouse, the American Medical Association physician master files, the American Hospital Association facilities database, the American Community Survey, and CMS Enrollment data. AHRF also contains geographic codes and descriptors, which enable linkage to other data sources.

Study Population

Medicare beneficiaries with a new diagnosis of ADRD between January 1, 2012 and December 31, 2014 were eligible for the study. We used the CCW flag to define ADRD diagnosis. The CCW Flag for ADRD includes the following International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes: 331.0, 331.11, 331.19, 331.2, 331.7, 290.0, 290.10, 290.11, 290.12, 290.13, 290.20, 290.21, 290.3, 90.40, 290.41, 290.42, 290.43, 294.0, 294.10, 294.11, 294.20, 294.21, 294.8, and 797. ADRD beneficiaries were flagged as an ADRD incident case if they had at least one inpatient, Skilled Nursing Facility, Home Health Agency, Part B institutional, or Part B non-institutional (carrier) claim with a related code in any position during a 3-year reference period as defined by CCW's algorithm (Taylor et al., 2002). Individuals were required to have 12 months of continuous Part A and Part B coverage, without coverage from a Medicare Advantage plan (Part C), before and after their first ADRD diagnosis. Beneficiaries were excluded if they had incomplete demographic information or incomplete Medicare coverage 12-months before and after their index diagnosis.

The exposure group had a Medicare AWV in the six months prior to their diagnosis, as determined by a Medicare AWV in their Part B claims. A 6-month timeframe was selected to maximize the chance that exposure to the Medicare AWV could truly impact the pathway to an ADRD diagnosis and subsequent health outcomes. Individuals were excluded from the exposure group if they (1) had a Medicare AWV more than 6 months prior to their ADRD diagnosis or (2) any time after their diagnosis during the 12-month follow-up. The comparison group had no record of Medicare AWV participation 12 months pre- and post- ADRD diagnosis.

Healthcare Utilization

The primary HCU outcomes were counts of 12-month ED visits, hospitalizations, and outpatient visits after a new ADRD diagnosis. ED visits were captured in carrier, outpatient, and inpatient files. The Yale definition, which built upon current existing definitions and used expert consensus to reflect the current organization and delivery of acute care, was used to count ED visits (Venkatesh et al., 2017). Hospitalizations visits were captured in inpatient files, while outpatient visits were captured in carrier and outpatient files. Algorithms from the Research and Data Assistance Center (ResDAC) were used to count hospitalizations and outpatient visits for each beneficiary (CMS, 2017). To facilitate our statistical approach, we also captured counts of HCU during the 12 months before ADRD diagnosis.

Explanatory Variables

Medicare Annual Wellness Visit

Participation in a Medicare AWV was obtained in the carrier file of CCW claims by searching for Healthcare Common Procedure Coding System (HCPCS) codes G0438 and G0439. Beneficiaries were identified to be in the exposure group as having a Medicare AWV within 6 months prior to ADRD diagnosis. The unexposed group had no exposure to the Medicare AWV during the 24-month observation period.

Demographic Information

Beneficiary information for age, sex, and race (White, Black, Asian, and Hispanic) was obtained from the demographic file of CCW in the year of ADRD diagnosis. Metropolitan status was derived from the rural-urban continuum variable in the AHRF and coded as a dichotomous variable where 1 denoted counties in metro areas of fewer than 250,000 to one million population or more; 0 denoted an urban population of less than 2,500 to 20,000 or more, both adjacent and not adjacent to a metro area ("USDA ERS - Documentation," 2013).

Comorbidity Index

The enhanced Deyo ICD-9-CM coding algorithm for Charlson comorbidities was used to define the burden of comorbidities for each beneficiary (Quan et al., 2005). The Charlson comorbidity index scores included 17 comorbidities, including ADRD. Deyo et al. adapted the Charlson algorithm for research relying primarily on ICD-9-CM diagnosis and procedural codes and Quan et al. enhanced the algorithm to align with nuances of the

ICD-10-CM codes (Deyo et al., 1992; Quan et al., 2005). Comorbidities were obtained from CCW to compute the comorbidity index.

Statistical Analysis

Descriptive Analyses

All explanatory variables were characterized by Medicare AWV exposure (none and in the 6 months prior to ADRD diagnosis). Frequency counts (percentage) of observed levels were reported for all categorical measures in Table 6.1 along with Chi-squared ($\chi 2$) compared explanatory variables across Medicare AWV exposure groups.

Generalized Linear Model

The impact of Medicare AWVs on ED visits, hospitalizations, and outpatient visits 12 months pre- and post- ADRD diagnosis between exposed and unexposed groups was investigated by a difference-in-difference (DID) Poisson regression model (Cataife & Pagano, 2017; Warton et al., 2016). The DID study assessed the changes in subsequent 12-month ED visits, hospitalizations, and outpatient visits between beneficiaries who did and did not receive a Medicare AWV prior to ADRD diagnosis. Assuming that health care utilization is different in the 12-month exposure groups, the DID model allowed for each beneficiary to serve as their own control, thus eliminating the known and unknown individual factors associated with the outcomes of interest (Warton et al., 2016). In summary, DID generates a causal estimate of the change in an outcome associated with the initiation of the exposure of interest while controlling for biases due to secular trends and confounding. Parallel trends assumptions were visually checked by monthly plots of

ED visits, hospitalizations, and outpatient visits in the 12 months before and after ADRD diagnosis (12-months pre/post).

The DID Poisson model was defined as:

$$\ln(\hat{\mu}) = \beta_0 + \beta_1\, AWV\ Exposure_1 + \beta_2\, Post\ Period_2 + \beta_3\, (AWV * Post)_3 + \sum \beta_p\, X_{p,}$$

where $\hat{\mu}$= the predicted number of either ED visits, or hospitalizations; β_0 = the intercept; $\beta_1$is the regression coefficient for AWV Exposure; $\beta_2$is the regression coefficient for 12-month period post ADRD diagnosis; $\beta_3$is the DID regression coefficient for the interaction between AWV Exposure and time period; X_p= (1 to p) where p is the number of explanatory variables, and β_p =(1 to P) the regression coefficient for the explanatory variables. The model implies that the logarithm of the function is a linear function of the parameters.

A joint F- statistic was conducted to measure the overall statistical significance of that model at alpha=0.05. The null hypothesis was rejected if at least one variable estimate was not equal to zero reflected by a p-value greater than or equal to 0.05. This study used SAS® 9.4 (Cary, NC) for data management and quantitative statistical analysis.

Upon checking for violation of the parallel trends assumption in HCU measures, it was observed that there was an exponential spike in HCU in the 2 months leading up to an ADRD diagnosis (Figure 6.2). This is consistent with other studies that have characterized HCU leading to an ADRD diagnosis; however, the spike seemed to violate the parallel trends assumption making a DID model inappropriate for this data. Consequently, we decided to remove the 2 months prior to ADRD diagnosis and to match that time frame only follow-up for 10 months post diagnosis. Thus, the DID results reflect the impact of the Medicare AWV on HCU by comparing a ten month period, starting two months before ADRD diagnosis with the immediate ten months after ADRD diagnosis.

Sensitivity Analysis

Based on previous work (Aim 1), it is very unlikely that an individual would obtain a Medicare AWV, detect cognitive impairment and then immediately seek care to obtain a formal ADRD diagnosis. On average there is a three year lag between the time an individual first sees a doctor about memory concerns to an ADRD diagnosis; this lag is longer in rural areas (AIM 1). To account for this potential lag, we examined the association between the Medicare AWV and HCU in a group of individuals that had a Medicare AWV 7 to 12 months prior to ADRD diagnosis. DID models were run for each HCU measure and compared to the DID models of the original exposure group.

6.4 Results

The study population consisted of 69,660 individuals with a new ADRD diagnosis between 2012 and 2014 (Figure 6.1). Applying the inclusion criteria, 21.5 percent of individuals were excluded leaving 54,724 individuals. Of those, 93 percent of beneficiaries had no Medicare AWV before or after an ADRD diagnosis. Cases with a Medicare AWV within 6 months prior to an ADRD diagnosis represented N=3,709 individuals. On average, Whites and Blacks represented 85 and 10 percent of the population, respectively, and the majority of beneficiaries were between 75 and 84 years old. Fifteen percent of individuals who received a Medicare AWV resided in a metropolitan area compared to 13 percent in the comparison group (Table 6.1). Beneficiaries who received a Medicare AWV prior to diagnosis had less comorbidities on average compared to those who did not receive a Medicare AWV. Hyperlipidemia was

more prevalent in the group who received a Medicare AWV prior to diagnosis (80 versus 74 percent) while stroke and hypertension were slightly more prevalent in the non-Medicare AWV group (20 versus 18 percent; 88 versus 87 percent, respectively). These three comorbidities were included to capture conditions that are often measured and highly prevalent in the ADRD population. The group with a Medicare AWV from 7 to 12 months prior to diagnosis has similar characteristics with an N=1,937 (Table 6.2).

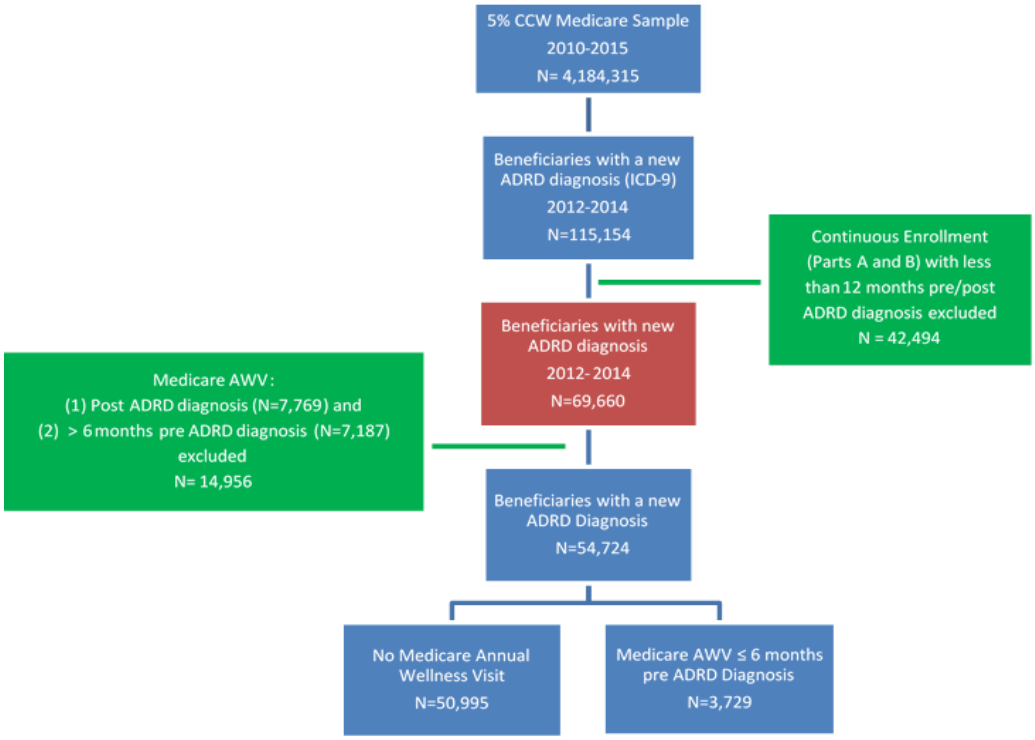


Figure 6.1 Study Population

Figure 6.2 depicts monthly counts of ED visits, hospitalizations, and outpatient visits 12 months before (removing the immediately prior two months to accommodate the DID analysis) and after ADRD diagnosis for the non-AWV group and two AWV exposure groups. For all three groups, HCU increased leading up to ADRD diagnosis. Then, post-

diagnosis, the plot lines dropped back pre-diagnosis, which are set at the point of the first health care encounter prior to ADRD diagnosis (with the two-month adjustment discussed above). Those who participated in a Medicare AWV within six months prior to a diagnosis had on average lower health care utilization compared to those who did not. The data used for the plots are unadjusted for demographic characteristics, which may explain the differences. Lower counts of ED visits, hospitalizations, and outpatient visits were observed up to 12 months prior to ADRD diagnosis and the difference in health care utilization between the two Medicare AWV exposure groups was greatest from during the six months prior to ADRD diagnosis. Those who participated in a Medicare AWV within 7 to 12 months prior to a diagnosis had counts of ED visits and hospitalizations that fell right between 6-month and the no Medicare AWV group. Outpatient visits; however, were the highest among the 7- to 12- month Medicare AWV exposure group.

Table 6.1 Study Population Characteristics by Medicare AVW Exposure Group (≤ 6 Months prior to Diagnosis)

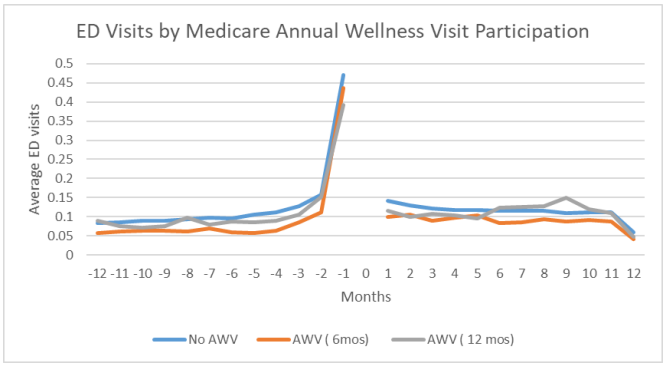
Characteristics	**Non- Medicare AWV N=50,995**	**Medicare AWV* N=3,709**	**Total N=54,704**	**Chi-square p-value**
Male, n(%)	18,325(35.9)	1,313 (35.4)	19,638 (35.9)	0.512
Age, n(%)				<0.001
Less than 65 65-74 75-84 Great than 84	3,635(7.1) 10,215(20.3) 19,275(37.8) 17,870(35.0)	203(5.5) 823(22.2) 1,520(41.0) 1,163(31.4)	3,838(7.1) 11,038(20.2) 20,795(38.1) 19,033(34.8)	
Race, n(%)				<0.001
White Black Asian Hispanic Other	43,548(85.4) 4,853(9.5) 745(1.5) 928(1.8) 1,246(1.7)	3,174(85.6) 315(8.5) 77(2.1) 56(1.5) 167(1.6)	46,722(85.4) 5,168(9.5) 822(1.5) 984(1.8) 226(1.6)	
Metropolitan, n(%)	6,648(13.0)	546(14.7)	7,194(13.2)	0.003
Charlson Index, n(%)				<0.001
None 1-2 3-4 5+	4,304(8.4) 13,694(26.9) 13,127(25.7) 19,844(38.9)	404(10.9) 1,102(29.7) 921(24.8) 1,282(34.6)	4,708(8.6) 14,796(27.1) 14,048(25.7) 21,126(38.6)	
Stroke, n(%)	10,727(21.4)	654(17.6)	11,381(20.8)	<0.001
Hyperlipidemia, n(%)	37,860(74.2)	2,963(79.9)	40,823(74.6)	<0.001
Hypertension, n(%)	45,037(88.3)	3,219(86.8)	48,256(88.2)	0.005

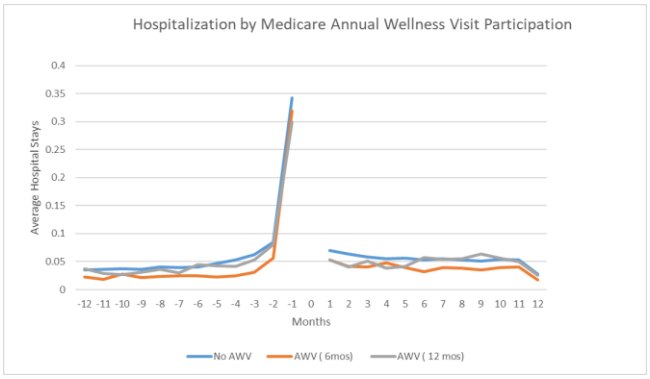
*Medicare AWV ≤ 6 months prior to ADRD diagnosis
**Chi-square p-value significant at 0.05

Table 6.2 Study Population Characteristics by Medicare AVW Exposure Group (7-12 Months Prior to ADRD Diagnosis)

Characteristics	**Non- Medicare AWV N=50,995**	**Medicare AWV* N=1,937**	**Total N=52,932**	**Chi-square p-value**
Male, n(%)	18,325(35.9)	700 (36.4)	19,025 (35.9)	0.855
Age, n(%)				<0.001
Less than 65 65-74 75-84 Great than 84	3,635(7.1) 10,215(20.3) 19,275(37.8) 17,870(35.0)	129(6.7) 468(24.2) 770(39.7) 570(29.4)	3,764(7.1) 10,683(20.2) 20,045(37.9) 18,440(34.8)	
Race, n(%)				<0.001
White Black Asian Hispanic Other	43,548(85.4) 4,853(9.5) 745(1.5) 921(1.8) 928(1.8)	1,632(84.3) 168(8.7) 52(2.7) 50(1.5) 35(1.8)	45,180(85.4) 5,021(9.5) 797(1.5) 971(1.8) 963(1.8)	
Metropolitan, n(%)	6,648(13.0)	306(15.8)	6954(13.1)	0.0004
Charlson Index, n(%)				<0.001
None 1-2 3-4 5+	4,304(8.4) 13,694(26.9) 13,127(25.7) 19,844(38.9)	186(9.6) 520(26.9) 513(26.5) 718(37.1)	4,490(8.5) 14,214(26.9) 13,640(25.8) 20,562(38.9)	
Stroke, n(%)	10,727(21.4)	360(18.6)	11,087(21.0)	0.009
Hyperlipidemia, n(%)	37,860(74.2)	1,537(79.4)	39,397(74.4)	<0.001
Hypertension, n(%)	45,037(88.3)	1,690(87.3)	46,727(88.3)	0.15

*Medicare AWV 7-12 months prior to ADRD diagnosis
**Chi-square p-value significant at 0.05





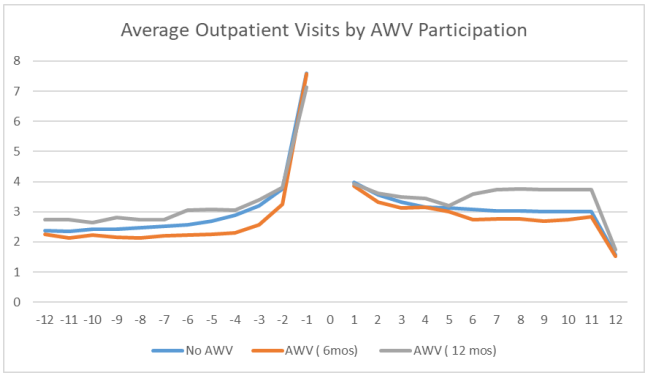


Figure 6.2 Monthly Counts of ED visits, Hospitalizations and Outpatient Visits by Medicare AWV Exposure Group

Model results

Table 6.3 contains DID coefficient estimates for ED visits, hospitalizations, and outpatient visits. A Medicare AWV within 6 months prior to ADRD diagnosis was associated with a significant increase in HCU [ED visits (Rate ratio [RR]: 1.20, 95% confidence interval (CI): 1.11, 1.30), hospitalizations (RR: 1.26, 95% CI: 1.13, 1.40), and outpatient visits (RR: 1.08, 95% CI: 1.04, 1.12)]. Table 6.4 displays DID results for the exposure group that had a Medicare AWV during 7 to 12 months prior to an ADRD diagnosis. Exposure to a Medicare AWV during this timeframe was associated with a significant increase in ED visits (RR: 1.12, 95% CI: 1.03, 1.22); however, hospitalizations: (RR: 1.03, 95% CI: 0.91, 1.16), and outpatient visits (RR: 1.02, 95% CI: 0.97, 1.07) were not statistically significant.

Table 6.3 Unadjusted and Adjusted Associations (Rate Ratio, 95% Confidence intervals) from Difference-in-Difference (DID) Models Estimating Effect of the Medicare Annual Wellness Visit (AWV)1 on Healthcare Utilization (N=54,704)

	ED Visits	**Hospitalizations**	**Outpatient Visits**
Unadjusted			
AWV vs. Non-AWV cohort	0.66 (0.61, 0.71)*	0.57 (0.52, 0.62)*	0.86 (0.83, 0.89)*
Post vs. Pre-AWV in Non-AWV cohort	1.22 (1.20, 1.25)*	1.34 (1.31, 1.36)*	1.23 (1.21, 1.24)*
Post-AWV in AWV cohort (DID)	1.20 (1.11, 1.30)*	1.26 (1.13, 1.40)*	1.08 (1.04, 1.12)*
Adjusted[2]			
AWV vs. Non-AWV cohort	0.70 (0.65, 0.75)*	0.61 (0.56, 0.70)*	0.90 (0.87, 0.93)*
Post vs. Pre-AWV in Non-AWV cohort	1.22 (1.20, 1.24)*	1.34 (1.31, 1.37)*	1.22 (1.21, 1.24)*
Post-AWV in AWV cohort (DID)	1.20 (1.11, 1.30)*	1.26 (1.13, 1.40)*	1.08 (1.04, 1.12)*

[1]Medicare AWV ≤ 6 months prior to ADRD diagnosis
[2]Adusted for Male, Age, Race, Metropolitan Status, and Charlson Comorbidity Index
*Rate Ratio statistically significant with p-value <0.05

Table 6.4 Unadjusted and Adjusted Associations (Rate Ratio, 95% Confidence intervals) from Difference-in-Difference (DID) Models Estimating Effect of the Medicare Annual Wellness Visit (AWV) on Healthcare Utilization (N=52,923)

	ED Visits	**Hospitalizations**	**Outpatient Visits**
Unadjusted			
AWV vs. Non-AWV cohort	0.87 (0.80, 0.95)*	0.87 (0.78, 0.97)*	1.06 (1.01, 1.12)*
Post vs. Pre-AWV in Non-AWV cohort	1.22 (1.20, 1.24)*	1.34 (1.31, 1.37)*	1.22 (1.21, 1.24)*
Post-AWV in AWV cohort (DID)	1.12 (1.03, 1.22)*	1.03 (0.91, 1.16)	1.02 (0.97, 1.07)
Adjusted[2]			
AWV vs. Non-AWV cohort	0.90 (0.82, 0.97)*	0.89 (0.80, 0.99)*	1.07 (1.03, 1.12)*
Post vs. Pre-AWV in Non-AWV cohort	1.22 (1.20, 1.24)*	1.34 (1.31, 1.37)*	1.22 (1.21, 1.24)*
Post-AWV in AWV cohort (DID)	1.12 (1.03, 1.22)*	1.03 (0.91, 1.16)	1.02 (0.97, 1.07)

[1]Medicare AWV 7-12 months prior to ADRD diagnosis
[2]Adusted for Male, Age, Race, Metropolitan Status, and Charlson Comorbidity Index
*Rate Ratio statistically significant with p-value <0.05

6.5 Discussion

The objective of this study was to understand if having a Medicare AWV leading up to an ADRD diagnosis can change the trajectory of health outcomes in a population that is vulnerable and often dealing with multiple comorbidities. Among beneficiaries who were diagnosed with ADRD, study results found significant increases in all three components of HCU over the ten months following diagnosis for those who had an AWV within six months prior to the diagnosis compared to those who did not. However, for those who had a Medicare AWV 7 to12 months prior to their diagnosis there was increased use of outpatient services, but no difference in ED or hospitalization compared those who never had a Medicare AWV.

Plots of counts (unadjusted for demographics) of HCU showed trends that were lower in the AWV exposed group 10 months before ADRD diagnosis. However, the HCU rose at a faster rate in the period after ADRD diagnosis for the AWV exposed group. More in-depth analysis of the primary reasons for the ED visits and hospitalizations may be needed to understand these increases. Perhaps these individuals delayed seeking care for memory concerns and were diagnosed at a more severe stage of ADRD leading to increased ED visits and hospitalizations. With similar increases in HCU but smaller in magnitude, the group who had a Medicare AWV 7 to 12 months prior to an ADRD diagnosis had HCU that fell between the non-exposed group and the 6-month Medicare AWV group.

Outpatient visits were significantly increased in the Medicare AWV exposed group, suggesting that the Medicare Annual Wellness visit may have facilitated more follow-up care such as referrals to specialists and diagnostic testing. Beckman et al.'s DID study observed a cost reduction in outpatient services. Costs were not measured in the present study; however, depending on the types of services utilized, costs could be higher or lower. For example, the majority of preventative services are fully covered under Medicare with no copays, whereas specialist visits would require out of pocket payment. Exposure to the AWV may have made the patient aware of covered preventive services. Beckman et al. and Jiang et al. both observed higher use of preventative services among those with a Medicare AWV compared to those who did not have the service. The Medicare AWV's focus on wellness and prevention could support those findings. Future

research should investigate the impact of the Medicare AWV on the uptake of preventative services in the ADRD population (Beckman et al., 2019; Jiang et al., 2018).

Strengths and Limitations

This is the first study to study the impact of the Medicare AWV on health outcomes in a newly diagnosed ADRD population. Due to the Medicare AWV being early in implementation and the study population limited to newly diagnosed ADRD beneficiaries in a 3-year timeframe, the small sample size in the exposed group was expected. The study sample was also restricted to Medicare fee-for-service beneficiaries with continuous enrollment over the study period. Therefore, the findings cannot be generalized to those enrolled in Medicare managed care plans, those uninsured or younger patients.

One advantage of using a DID design in a fixed cohort is that each individual serves as his or her own control, eliminating both measured and unmeasured confounding. The case-mix differences between the exposed and reference groups poses a threat to internal validity if group characteristics are so dissimilar that changes in the reference group over time are not representative of secular trends in the absence of the exposure (Warton et al., 2016). There may be bias due to patients' self-selection into undergoing a Medicare AWV as those receiving it tended to be White, urban residents from higher-income areas.

Another potential limitation is that this study may suffer from classification bias. Under detection poses a problem in ADRD diagnosis (Connolly et al., 2011). Studies show

evidence of variable and often poor diagnostic sensitivity, which is affected by several factors including disease type and severity, behavioral symptoms, and rate of contact between provider and the person with probable ADRD (Bradford et al., 2009). Given that ADRD diagnosis was captured only from administrative claims, the estimates of newly diagnosed ADRD may be underestimated. This may be due to ADRD being undetected by a provider or because the ADRD diagnosis was not documented.

Measurement bias may also play into understanding the impact of the Medicare AWV. It is known that variation in provider behavior can impact quality of care and health outcomes. The Medicare AWV takes a lot of time to conduct with few financial incentives for the provider. Given the high volume of patients that come through the primary care setting, it is not possible to know whether individuals who received a Medicare AWV knew about receiving it or received all the components of the visit, in particular the cognitive assessment especially keyed to detect ADRD. This variability in administering the Medicare AWV could attenuate the visit's impact on health outcomes and health care utilization while biasing estimates towards the null. Obtaining more information regarding the Medicare AWV and how it is conducted across providers in different health care settings is needed.

7. CONCLUSIONS AND IMPLICATIONS FOR FUTURE RESEARCH

The overall objective of this dissertation was to investigate the impact of the Medicare AWV on differential rates of ADRD diagnosis and subsequent health care utilization with attention to geographic and ecological variation in ADRD diagnosis. The central hypothesis was that the Medicare AWV, with its cognitive assessment component, would lead to increased detection and diagnosis of ADRD; however, geographical variation in assessment and diagnostic practices may modify this impact. By minimizing the geographic variation in ADRD diagnosis, the Medicare AWV could increase detection/diagnosis and subsequently improve health outcomes. The objective was carried out over three related studies.

The first was a qualitative study in Maryland to understand geographic variations in the pathway to an ADRD diagnosis from the PWD and caregiver perspective while capturing the steps taken from a health service use perspective. The second study aimed to formally test for geographic variation in ADRD diagnosis rates across five Middle-Atlantic states (DELMARVA+PA) and investigate how variation in the delivery of the Medicare AWV impacts geographic variation in ADRD diagnosis. The final study examined whether the Medicare AWV could be tied to health outcomes in a national sample of Medicare beneficiaries who received a Medicare AWV on the pathway to an ADRD diagnosis compared to those who did not.

Main Findings

In the first study, findings revealed that the journey to an ADRD diagnosis can vary in length of time and complexity. Average time to ADRD diagnosis was longer among individuals from regions that were more rural versus urban. Delays in ADRD detection and diagnosis stemmed from the variations in cognitive impairment assessment, specialist referrals, and symptom severity. This study also found that in the study area diagnosis confirmation most often occurred through participation in a clinical trial and was rarely detected in the primary care setting through a service such as the Medicare AWV. This condition is likely unique to Maryland, the venue for the study, so further research in other regions of the US is needed. Themes from the qualitative analysis suggest opportunities may exist to improve the pathway to diagnosis for PWD and caregiver in the primary care setting. Providers from more rural areas may require more education and support to increase detection, improve the timeliness and accuracy of diagnosis, develop a more patient-centered approach to disease management.

The second study demonstrated evidence of differences in county-level ADRD cumulative incidence between rural and urban settings of DELMARVA+PA; with higher ADRD diagnosis rates correlated with higher Medicare AWV participation among urban counties. These findings align with our Aim 1 findings and our hypothesis. When controlling for geographic variation due to demographics, urban status, and other access to care factors, the association between Medicare AWV participation and ADRD diagnosis was not statistically significantly. However, mapping and cluster analysis of model estimates revealed patterns of higher rates of Medicare AWV participation with

increased ADRD incidence in eastern Virginia, Maryland, and Delaware counties of the DELMARVA+PA study region, which tend to be more urban. Relative to the pre-policy period, these clustered patterns were not reduced in the post-policy period; contrary to our hypothesis. Findings suggest that Medicare AWV participation is still concentrated in urban, more affluent, and resource-rich areas which may already have more ADRD diagnoses due to other enabling factors. In the long-term, targeting participation to more rural areas with limited resources and lower socio-economic status may result in more substantial conclusions on the importance of the Medicare AWV in detecting cognitive impairment in the primary care setting; and ultimately minimizing urban/rural differences in ADRD diagnosis and outcomes.

The final study demonstrated that receiving a Medicare AWV on the pathway to an ADRD diagnosis was associated with increased HCU compared to those diagnosed with ADRD who did not receive a Medicare AWV. Findings were consistent for individuals who had a Medicare AWV within 6 months prior to an ADRD diagnosis and those receiving a Medicare AWV up to a year prior to diagnosis. Ideally, this impact would have yielded less HCU of ED and hospitalizations and more of outpatient services by the ADRD population. Based on that preferred outcome and prior research, this study hypothesized that ED visits and hospitalizations of people diagnosed with ADRD would decrease and outpatient visits would increase for those who had a Medicare AWV in the six months prior to the diagnosis compared to individuals who had not. It turned out that there was an increase in all three components of HCU in the year following diagnosis of ADRD by those who had a Medicare AWV compared to those who did not. Thus, results

remain inconclusive on the true impact of the Medicare AWV on HCU and health outcomes in the ADRD population and the broader Medicare population. The Medicare AWV may be facilitating more follow-up care and uptake of preventative services, which is reflected as more outpatient visits by individuals who had a Medicare AWV prior to an ADRD diagnosis. It may take a longer follow-up period to observe improved outcomes that result in the hypothesized fewer ED visits and/or hospitalizations, likely due to more follow-up, use of preventive services, awareness, and availability.

Implications for Future Research

Study findings could inform future ADRD research by improving the general understanding of dementia screening and diagnostic process from the PWD/caregiver perspective and how it aligns with what is observed in real-world data. Researchers and policymakers could further use study findings to identify areas of unmet need across PWD and caregiver communities while considering varying levels of access to care due to geographic location. Interventions and allocations of resources for timely and accurate ADRD diagnosis may be more impactful in areas of need versus a "one size fits all" approach. Finally, future assessment of the Medicare AWV could inform health care payers about whether the financial incentives for detection and diagnosis of ADRD are at the right threshold to result in the health care benefits it was intended for in the Affordable Care Act.

In conclusion, these studies are the first, to our knowledge to investigate the impact of the Medicare AWV on geographic variation in ADRD diagnosis. Despite an inconclusive

assessment of the impact of the Medicare AWV, early implementation findings and existing literature demonstrate its potential to increase ADRD detection, facilitate timely diagnosis, and improve health outcomes. The Medicare AWV may also mitigate the geographic variations observed in dementia diagnosis and subsequent health outcomes; however, it remains under-utilized especially in geographic areas and health care settings that may benefit from it the most. As participation and awareness of the Medicare AWV continue to increase, there will be more opportunities to study the potential long-term impact of the Medicare AWV on reducing geographic variation in ADRD diagnosis and subsequent health outcomes.

8. APPENDICES

8.1 Appendix 1

Aim 1 Manuscript Interview guide
Pathway to Diagnosis: persons with dementia and caregiver experiences on reaching a dementia diagnosis

Hello, my name is Maya Hanna and I am a graduate student at the University of Maryland School of Pharmacy. I would like to thank you for agreeing to speak with me today. I'd like to learn from your experiences with obtaining a dementia diagnosis. Your opinion is valuable and you will help me learn more about the things that may be improved or maintained during the diagnostic process and the care following a diagnosis. I want to begin by providing you with some background information about this project. This work is funded by the University of Maryland's PATIENTs program in partnership with the Agency for Research and Healthcare Quality, which is a program to involve patients in research as experts on their health condition.

The information you give me is completely confidential. I will not associate your name with anything you say during this interview.

You can decide not to answer a question. That is fine. If at any time you want to stop the interview, please just let me know and we will stop.

I will not identify you by name, but will use the information you provide to help better understand experiences with obtaining a dementia diagnosis.

This interview is being recorded so that my research team does not get anything wrong when we write our research report. Your identity will remain anonymous, meaning we will not use your name in any written documents and we will not link your name to any comments in the report. In order to protect your privacy, please don't mention any persons with dementia or healthcare providers by name.

I am going to read the informed consent document aloud and have provided a copy to you by email. Once we have gone through the consent document, I will need you to either agree or disagree to participate aloud. If you agree to participate, we will continue to the interview. (Informed consent here – see Appendix 1)

Do you have any questions?
I am going to start the tape recorder and would like you to state that you are a person with dementia or caregiver of a person with dementia and that you agree to participate in this

interview. **START TAPE RECORDER - HAVE PARTICIPANT STATE THEIR AGREEMENT. PROCEED WITH THE INTERVIEW:**

If there are no further questions, I would like to begin the interview.

Domain 1 – Journey to Diagnosis/ Detection	
PD1	Can you describe what happened or what steps you went through to get to a diagnosis? What was your experience? Begin when you first recognized signs or symptoms until the time when you first saw a doctor who diagnosed you with dementia. • Probe: What was the first thing you did? Then from there? • How long did it take to get a diagnosis from when you first recognized signs or symptoms?
Domain 2 – Detection, Work up and Diagnosis	
DX1	Would you describe for me how you (or your family member) first understood that you might have dementia? • Probe: What made you go to a doctor or provider to seek medical advice? Or did your doctor initiate the conversation? • Did you voice any concerns or issues? What were they? • Did you seek a second opinion?
DX2	In what health care setting were you (or your family member) diagnosed? • Probe: Was this a regular office visit or did you go to the doctor or provider specifically for this diagnosis? • Was this an annual wellness visit? • Have you ever had an AWV? If so, did your loved one have a cognitive impairment assessment?
DX3	How did your doctor explain dementia to you? Did you leave fully understanding dementia and options for next steps? • If not, do you have suggestions for how this could be improved?
DG5	Did you undergo any additional procedures to confirm your diagnosis? • Probe: Did you have to see a specialist? • Did you have to obtain an MRI or PET scan?
DG6	Did you receive an option for drug therapy?
DG7	Were there any community or medical resources you were told about or used when you got your diagnosis? Can you describe them please?
DG8	Do you think that where you live affected your experience in getting to a diagnosis? If so, how?
Domain 3 – Living with the Diagnosis	
LD1	Do you currently use support services or would you if made available? If so, please describe where you go and how far you do drive to get support or resources (such as doctors' appointments, support groups, family members who help take care of their loved ones, social gatherings).
LD2	Do you think that where you live affects your access health care resources or support services? If so, how?

LD3	Are there any concerns living with dementia or caring for your family member with dementia? • Probe: If you're concerned about your dementia, who would you trust to talk to? • Could you describe for me your network of support? How does your network help with your (or your family member's) care?
LD4	Has your loved one experience any of these events since being diagnosed? ER Visit Hospitalization Nursing Home placement Could you rank the following outcomes in terms of least desirable (1- meaning the most undesirable outcome) : ER Visit Hospitalization Nursing Home placement
Domain 4 – Additional Topics	
OT1	What advice you would give to someone else living in this area or currently going through this experience of a dementia diagnosis or is recognizing early signs of memory loss in their loved one?
OT2	Is there anything you would like to add about your diagnosis experience? Anything you think I should have asked that I didn't ask?

Thank you again for participating in this interview and providing insights into your experiences. It has been very helpful. Once I've concluded this project, would you like for me to send a copy of the results to you? Would it be okay for me to contact you about future studies?

If you have any questions or comments, please feel free to contact me by phone or email. Please accept this $50 gift card as an appreciation for your time.

8.2 Appendix 2

Study Notice

PATHWAY TO DIAGNOSIS STUDY
WHAT IS THE PURPOSE OF THIS STUDY?
To understand persons with dementia and family caregiver experiences with obtaining an Alzheimer's or related dementia diagnosis given where they live.

WHO IS ELIGIBLE?
Caregivers of a person with dementia OR individuals with early stage dementia and their care partners residing in Maryland.

WHAT DO THEY NEED TO DO?
1. Call the Integrace Institute at 410-552-3218 to determine full eligibility (5 minutes).
2. Attend a 1-hr interview and receive a $50 gift card for your participation.

WHO IS CONDUCTING THE STUDY
In partnership with the University of Maryland and Agency for Research and Healthcare Quality.
For further information, please contact:
Maya Hanna at mhanna@umaryland.edu or (410) 706-0908.

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